

# Guide to Public Health Laboratory Services

MDH- Laboratories Administration The J. Mehsen Joseph Public Health Laboratory 1770 Ashland Avenue, Baltimore MD 21205 Telephone: 443-681-3800 Fax: 443-681-4501 https://health.maryland.gov/laboratories/Pages/home.aspx

January 2024

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Wes Moore, Governor · Aruna Miller, Lt. Governor · Laura Herrera Scott, M.D., M.P.H., Secretary

Laboratories Administration Robert A. Myers, Ph.D., Director 1770 Ashland Avenue Baltimore, Maryland 21205

January 16, 2024

Dear Health Professionals:

This reference guide lists public health laboratory services available to health officers, physicians, and other health professionals to assist in the prevention, diagnosis, and control of human diseases. The listing of laboratory services is arranged alphabetically by test and includes contact information for the laboratory that performs the test.

Specimens and samples submitted to the central and regional laboratories should be collected and submitted in special kits provided by the Laboratories Administration. These kits may also be obtained from the regional laboratories or county health departments. Use of these kits assures collection of the proper type of specimen, preservation of specimen integrity, proper demographic/epidemiological information, and prompt distribution for examination when received in the laboratory.

Records of patient information and test results are treated as confidential information and will be released only to the submitting physician or other legally authorized individual.

Public Health professionals and physicians using the Administration's services are invited to visit the central laboratory in Baltimore or their regional laboratory. A few minutes spent in the laboratory can often result in clarification of points regarding types of tests performed, specimen kits available, and many other points' important to effective use of laboratory services. This personal contact not only improves services but also can be informative to the physician and stimulating to the laboratorian in supporting the practice of modern scientific medicine.

The most up-to-date version of this guide is available for downloading and printing off the internet at: <u>https://health.maryland.gov/laboratories/Pages/home.aspx</u>

Robert A- m

Robert A. Myers, Ph.D. Director

#### GENERAL ORGANIZATION OF THE LABORATORIES ADMINISTRATION

GENERAL ORGANIZATION OF THE LABORATORIES ADMINISTRATION	
REGISTRATION & LABORATORY REPORTS	
SPECIMEN ACCESSIONING LABORATORY	•
SPECIMEN KIT PREPARATION UNIT	443-681-3777
DFFICE OF FISCAL ADMINISTRATION: Fax# 443-681-4503	
BILLING OFFICE	
PROCUREMENT OFFICE	443-681-3813
OFFICES OF LABORATORY QUALITY ASSURANCE, SAFETY, and TRAINING: Fax#	
QUALITY ASSURANCE OFFICER	
TRAINING COORDINATOR	
OFFICE OF SAFETY AND SECURITY	443-681-3792
DIVISION OF PUBLIC HEALTH MICROBIOLOGY: Fax# 443-681-4506	
DIVISION CHIEF	
ACUTE BACTERIAL CORE (ABC) SURVEILLANCE LABORATORY	
BIOTERRORISM LABORATORY	•
CLINICAL MICROBIOLOGY	•
ENTERIC BACTERIOLOGY	
GC	•
MYCOBACTERIOLOGY (TB)	
MYCOLOGY	
PARASITOLOGY	
DIVISION CHIEF CORE SEQUENCING LABORATORY	
MOLECULAR DIAGNOSTICS LABORATORY	
MOLECULAR EPIDEMIOLOGY LABORATORY	
RETROVIROLOGY LABORATORY	
VIRAL DISEASE ASSESSMENT LABORATORY	
DIVISION OF NEWBORN AND CHILDHOOD LABORATORY SCREENING: Fax# 443 DIVISION CHIEF	
DIVISION MANAGER	
NEWBORN SCREENING:	
BIOCHEMICALS	443-681-3901f
ENDOCRINOLOGY	
HEMOGLOBINOPATHIES	
SEVERE COMBINED IMMUNODEFICIENCY DISEASE (SCID)	443-681-3913 443-681-3913/443-681-3912
TANDEM MASS SPECTROMETRY	
DIVISION OF VIROLOGY and IMMUNOLOGY: Fax # 443-681-3844 DIVISION CHIEF	
DIVISION OF VIROLOGY and IMMUNOLOGY: Fax # 443-681-3844	
DIVISION OF VIROLOGY and IMMUNOLOGY: Fax # 443-681-3844 DIVISION CHIEF ARBOVIRUS SEROLOGY	
DIVISION OF VIROLOGY and IMMUNOLOGY: Fax # 443-681-3844 DIVISION CHIEF ARBOVIRUS SEROLOGY CHLAMYDIA	
DIVISION OF VIROLOGY and IMMUNOLOGY: Fax # 443-681-3844 DIVISION CHIEF ARBOVIRUS SEROLOGY CHLAMYDIA HEPATITIS	
DIVISION OF VIROLOGY and IMMUNOLOGY: Fax # 443-681-3844 DIVISION CHIEF ARBOVIRUS SEROLOGY CHLAMYDIA HEPATITIS MICROBIAL SEROLOGY	

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BIOLOGICAL AGENTS REGISTRY (BAR) PROGRAM 443-681-37	89
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#### DIVISION OF ENVIRONMENTAL SCIENCES: Fax# 443-681-4507

[Refer to "Guide to Environmental Laboratory Services" for info	rmation on environmental testing in this division]
DIVISION CHIEF	
CHEMICAL EMERGENCY PREPAREDNESS AND RESPONSE	443-681-3857

MD Department of Health-Laboratories Administration The J. Mehsen Joseph Public Health Laboratory ih St Dallas St Ve adway St N Castle St E Chase St N Durham St ase St NGOY t E Eager S 2 N Bond St **Rutland Ave** E Eager St N Washington St Z Broadway Barnes St N Castle St N Wolfe St MD Department of Health Laboratories Administration Ashland Ave Ashland Ave and Ave N Durham St N Chapel St N Broadway N Bond St Miller St EN N Washington St E Madison St Rutland Ave-Metro-Johns Hopkins Hosp North E Monument St N Wolfe St Metro-Johns Hopkins Hosp South Johns Hopkins Hospital Johns Hopkins Hospital bing Z Z © 2016 Microsoft Corporation © 2016 HERE

MD Department of Health-Laboratories Administration

#### A. GENERAL INFORMATION

# A.1. CENTRAL LABORATORY

Hours: Monday thru Friday 8:00 a.m. – 4:30 p.m. Saturday 7:30 a.m. – 12:00 p.m. Sunday Closed Location: 1770 Ashland Avenue Baltimore, MD 21205 Mailing Address: Laboratories Administration P.O. Box 2355 Baltimore, MD 21203-2355

### **NON-EMERGENCY NUMBERS:**

DIRECTOR'S OFFICE	443-681-3800
CENTRAL LABORATORY FAX	443-681-4501
REGISTRATION and LABORATORY REPORTS	443-681-3820
SPECIMEN ACCESSIONING LABORATORY	

## 24-HOUR EMERGENCY NUMBERS:

#### **ANIMAL RABIES EMERGENCY EXAMINATION REQUESTS (See page 16)**

# NON-RABIES CASES

IN-RABIES CASES	
BORATORY EMERGENCY PREPAREDNESS	
AND RESPONSE CELL PHONE:	410-925-3121
RECTOR'S EMERGENCY CELL PHONE:	
DR. ROBERT MYERS	443-928-0925
2. REGIONAL PUBLIC HEALTH LABORATORIES HOURS AND LOCATIONS	
2.a. EASTERN SHORE REGIONAL LABORATORY (ESRL-Salisbury):	
urs: Monday thru Friday 8:00 a.m. – 4:30 p.m.	
urday/Sunday Closed	
curday/Sunday Closed cation: 926 Snow Hill Road-Cottage 500	
cation: 926 Snow Hill Road-Cottage 500	443-928-0925

ESRL FAX	410-749-1173
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# 24-HOUR EMERGENCY NUMBER: 443-523-5056 (cell-Primary) 443-928-0925 (cell-Backup)

# A.2.b. WESTERN MARYLAND REGIONAL LABORATORY (WMRL – Cumberland):

Hours: Monday thru Friday 8:00 a.m. – 4:30 p.m.	
Saturday/Sunday Closed	
Location: 12503 Willowbrook Road	
The Brook Building, Entrance #6	
Cumberland, MD 21502	
Director, Robert A. Myers, Ph.D	. 443-928-0925
WMRL Office	301-759-5115
WMRL FAX	301-777-2021

#### 24-HOUR EMERGENCY NUMBER: 301-268-4468 (cell)

#### **A.3. COURIER SERVICE**

The Laboratories Administration contracts to provide specimen courier service for many local health departments. Problems concerning the courier service should be reported immediately by calling 443-681-3820.

### A.4. SPECIMEN REJECTION POLICY

The Laboratories Administration's "Specimen/Sample Acceptance and Rejection Criteria" policy helps to assure the accuracy, reliability, and timeliness of laboratory test results by eliminating the testing of unacceptable specimens. When the laboratory determines that a specimen is unacceptable for testing, the laboratory, whenever feasible, notifies the submitter immediately by telephone, confirms the notification in writing, and temporarily retains the specimen for possible future testing (e.g., in cases where additional information provided by the submitter would make the specimen acceptable for testing).

#### A.5. BILLING

Questions concerning client billing, laboratory billing, and laboratory reimbursement by the Maryland Medical Assistance Program or other third party payer should be directed to the Head of the Laboratory Administration's Billing Unit by telephoning 443-681-3810.

#### **B. SPECIMEN SUPPLIES, PACKAGING, TRANSPORT, AND DELIVERY**

#### **B.1. PACKAGING FOR TRANSPORT:**

Care must be taken to ensure a proper transport environment for specimens. Collect recommended quantities of test specimen and follow all directions for recording date and, where appropriate, time of specimen collection. Also make every effort to see that specimens are transported at required temperatures and in appropriate collection containers. Collection containers and other specimen supplies are available from the Laboratory's Supply Unit (443-681-3777). In addition, always separate glass tubes by using either protective material or separate biohazard bags to prevent breakage and cross-contamination during transport (see Basic Triple Packaging on page 10). A submitter using a courier service should take similar precautions by submitting individual tubes and requisition slips in separate, sealable plastic biohazard bags protected in an appropriate shipping container.

# TEST COLLECTION COMPONENTS AND OTHER LABORATORY SUPPLIES:

The Laboratories Administration provides test request forms and specimen collection components (e.g., tubes, bags, etc.). Questions about supplies should be directed to the nearest Regional Laboratory or the Central Laboratory Supplies Unit at 443-681-3777 or email <u>mdhlabs.outfits@maryland.gov</u>. To obtain the electronic fillable "Testing Supplies Order Form" visit our website at:

# https://health.maryland.gov/laboratories/docs/Outfit%20Suppy%202023.pdf

Fax the completed "Testing Supplies Order Form" to 443-681-3850 or email mdhlabs.outfits@maryland.gov.

For newborn screening collection devices call 443-681-3900 or email mdphl.nbs@maryland.gov.

For newborn screening collection cards visit our website: <u>https://health.maryland.gov/laboratories/Pages/Newborn-</u> <u>Screening.aspx</u>.

Note that various tests and specimens require different types of collection devices, transport media, and transport containers. Using the incorrect kit, collection component, or container will often render a test specimen unacceptable for analysis. If you have a question regarding the acceptable collection container contact the testing laboratory.

# **B.1.a. VIA STATE CONTRACTED COURIER**

Counties using the state contracted courier service must pack specimens and/or samples according to the temperature storage requirements. Specimens requiring freezing should be frozen and packed with adequate cooling (dry ice) material to maintain their proper temperature for up to 36 hours. Coolers are required to transport all specimens and/or samples through the state contracted courier. Therefore, it is essential that all coolers be properly labeled. Each cooler should specify the conditions for storage on all visible outer surfaces – "ROOM TEMPERATURE", "REFRIGERATE", or "FREEZE". Each cooler for specific laboratories should be labeled on all visible outer surfaces for "ENVIRONMENTAL" or "RABIES". Both Environmental and Rabies coolers must only be used as labeled. **DO NOT use or re-use Environmental or Rabies coolers for any other types of specimens (samples, or add any other types of specimens to these coolers. A "RABIES" cooler must only be used for rabies samples, and an "ENVIRONMENTAL" cooler must only be used for environmental specimens. Specimens/samples that are received in an Environmental or Rabies cooler that are not intended for Environmental or Rabies testing will be rejected and discarded for safety reasons. (Please see Rabies Section on page 15 for detailed information on animal rabies submissions).** 

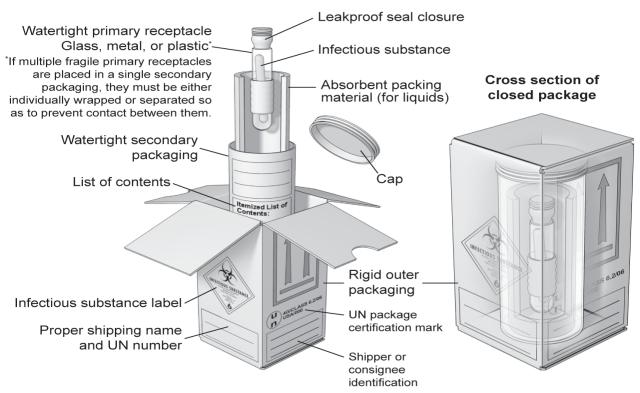
# B. 1. b. VIA U.S. MAIL OR OTHER CARRIER:

Due to regulations published by IATA (International Air Transportation Association), US DOT (United States Department of Transportation), and the USPS (United States Postal Service), the Laboratories Administration's specimen collection components may be used only when sending specimens via private or state-contracted courier. These containers are not approved or certified for use in the USPS system or other common carriers (e.g., FedEx, UPS, etc.). Infectious substances sent through the mail or by other common carriers must be packaged by individuals trained and certified in Infectious Substances shipping. **Certified packaging systems are not supplied by the Laboratories Administration.** 

Before using the USPS or other carrier, the shipper must refer to the current IATA, USPS and DOT regulations. IATA has divided infectious substances into two categories. IATA "Category A Infectious Substance" includes substances that are "transported in a form that, when exposure to it occurs, is capable of causing permanent disability, life-threatening or fatal disease in otherwise healthy humans or animals." "Category A Infectious Substances" are subject to the more stringent packing requirements described in IATA Packing Instruction 602. An IATA "Category B Infectious Substance" is defined as "an infectious substance that does not meet the criteria for inclusion in Category A." The proper shipping name of UN 3373 is Biological substance Category B. This includes human or animal material transported for research, diagnosis, disease treatment, etc., and diagnostic or clinical cultures. These specimens must be mailed and transported in packaging that meets IATA Packing Instruction 650.

# BASIC TRIPLE PACKAGING (Refer to tests for specific details)

Basic triple packaging systems include a primary receptacle such as a tube with adhesive tape around the screw cap or a plate with parafilm around the edges. The primary (1°) receptacle, along with required absorbent and cushioning material, is placed inside a secondary (2°) container. The 2° container for diagnostic specimens should be a sealed biohazard or Ziploc bag. The 2° container is then securely placed within an outer shipping container (tertiary (3°) container), generally a corrugated cardboard box with cushioning material inside to surround the 2° container. This outermost container bears the name, address, and telephone number of shipper, name of person responsible with 24/7 telephone number, and the complete name, shipping address, and telephone number of the recipient, plus all the required markings. Include an itemized list of contents in a sealed plastic bag, placed between the 3° and 2° containers. Specific instructions for various tests can be found in the test list section of this guide.



Example of a correctly prepared and labeled triple package for Biological specimen, Category B (UN 3373) (previously known as Clinical specimen and Diagnostic Specimen. A Category B infectious substance is one that does not meet the criteria for inclusion in Category A. A Category B infectious substance does not cause permanent disability or life-threatening or fatal disease to humans or animals when exposure to it occurs. The proper shipping name for a Category B infectious substance, "Biological specimen, Category B," is assigned to identification number "UN 3373." The proper shipping names "Diagnostic specimen" and "Clinical specimen" may no longer be used (as of January 1, 2007). (Modified from Biosafety in Microbiological and Biomedical Laboratories [BMBL], 5th edition)

# **BASIC TRIPLE PACKAGING:**

1) A watertight primary receptacle.

- 2) A watertight secondary receptacle.
- 3) An outer packaging of adequate strength for its capacity, mass and intended use.

Note: For a liquid specimen, absorbent material must be placed between the primary and secondary containers and be capable of absorbing the entire contents of the primary receptacle(s).

Certified packaging systems are designed to withstand specific pressure changes and drop tests. Packaging systems that meet the packing instruction standards are currently available from vendors specializing in products certified to meet the IATA, USPS, and other carriers' requirements. Packaging systems using fiberboard or aluminum canisters, zip-lock bags, or other uncertified components may not be in compliance.

# IT IS THE RESPONSIBILITY OF THE SHIPPER TO COMPLY WITH ALL LAWS AND REGULATIONS REGARDING THE SHIPPING OF INFECTIOUS SUBSTANCES.

Questions may be referred to the MD Department of Health Laboratories Administration's Quality Assurance Officer, Heather Peters, by calling 443-681-3791 or by email <u>heather.peters@maryland.gov</u>.

Resources: http://www.cdc.gov/biosafety/publications/bmbl5/ http://www.usps.com/

# **B.2. DELIVERY/DROP-OFF TO CENTRAL LABORATORY**

Specimens intended for the Central Laboratory should be directed to 1770 Ashland Avenue Baltimore, MD 21205. The Laboratory facility is located at the corner of Ashland and Rutland Avenues. All specimen and sample deliveries to the laboratory must be delivered to the loading dock located on Rutland Avenue. Temporary parking is available at the loading dock. Couriers delivering specimens are required to sign a loading dock security log sheet upon arrival.

# **B.2.a. Specimen/Sample Deliveries Accepted**

#### Clinical

Monday-Friday 8:00am-6:00pm Saturday: 7:30am-12:00pm

#### **Newborn Screening**

Monday-Friday 8:00am-6:30pm Saturday: 7:30am-2:00pm

Rabies specimens and testing: Contact Rabies on-call staff (see page 15).

#### B.2.b. HOLIDAYS

A detailed holiday schedule can be found on the Laboratories Administration website at <a href="https://health.maryland.gov/laboratories/docs/Rev.%202023%20HOLIDAY%20SCHEDULE.pdf">https://health.maryland.gov/laboratories/docs/Rev.%202023%20HOLIDAY%20SCHEDULE.pdf</a>

# B.2.c. OTHER EMERGENCY REQUESTS INVOLVING DROP OFF OR LABORATORY SERVICES

Emergency on-call numbers:

(1.) Biological, chemical or radiological terrorism:	
Amy Armitage/Emergency On Call Phone	410-925-3121 (cell)
Robert Myers	443-928-0925 (cell)
(2.) Microbiology emergency:	
Robert Myers	443-928-0925 (cell)
(3.) Environmental Sciences emergency:	
Sinisa Urban	410-598-7355 (cell)

For unknown powders and environmental samples for bioterrorism/chemical terrorism see the Laboratories Administration website at <u>https://health.maryland.gov/laboratories/Pages/home.aspx</u> or call a phone number under B.2.c.(1.), above.

#### C. SPECIMEN COLLECTION, PREPARATION, AND HANDLING

# C.1. GENERAL

Specimen quality is a product of the nature of the specimen itself, how well it was collected, and the manner in which it is or was transported to the laboratory. A laboratory can provide accurate and clinically relevant test results only if it receives good test specimens. Before attempting to collect a specimen, look up the desired test(s) in this reference guide. Check to see if there are specific requirements for:

- 1. Specimen type or volume;
- 2. Collecting procedures;
- 3. Collecting devices or containers.

Use the correct test request form and properly and legibly complete this form to ensure accurate and efficient laboratory service. Use a soft pencil or black ballpoint to print the information. Be sure to include proper identifying information on the test request form and the specimen itself.

Please note the clinic's full mailing address, test request authorized by personnel, and telephone number to assure proper return of test results. Then see that the test request form accompanies the specimen. The following sections provide practical guidelines to physicians, nurses, and other non-laboratory health personnel who must routinely collect and submit clinical specimens to one of the State's public health laboratories (i.e., MD Department of Health Laboratories Administration).

#### **C.1.a. PATIENT PREPARATION**

Prior to the time scheduled to collect a patient's specimen the patient should receive appropriate instructions concerning fasting, diet, and medication restriction. For example, a patient about to submit a specimen for a microbiology culture should have specimen(s) collected before starting antimicrobial therapy.

# C.1.b. SPECIMEN HANDLING BY SUBMITTER

The most common specimen handling errors include failing to:

- 1. Tighten specimen container lids or caps;
- 2. Label a specimen correctly; and
- 3. Provide all pertinent clinical information.

Properly identifying specimens is extremely important. Legibly label each specimen container or tube with the patient's full name, and date of specimen collection, just as they appear on the test request form. Information on specimens should be checked against information on the test request form for agreement before the specimen is sent to the laboratory.

#### C.2. PROCUREMENT AND SUBMISSION REQUIREMENTS, PRECAUTIONS, AND PROBLEMS BY SPECIMEN TYPE

#### C.2.a. BLOOD/SERUM

#### C.2.a.(1.) HEMOLYSIS

In general, grossly or even moderately hemolyzed blood specimens may not be acceptable for testing. Hemolyzed serum is pink or red, rather than the normal clear straw color. Most cases of hemolysis can be avoided by observing the steps below.

1. Use a needle no smaller than 20- or 21- gauge. (On occasion, however, it may be necessary to use a 22- or 23- gauge needle for patients from elderly and pediatric populations with small or difficult veins.) Hemolysis can be avoided by not placing small gauge Butterfly needles into Vacutainer tubes. Carefully and safely remove Butterfly and replace with a 16-gauge needle before penetrating Vacutainer tube.

2. If there is air leakage around the needle or loss of vacuum in the tube, replace the vacuum tube.

3. Collect blood in room temperature containers unless the specimen requirement specifies otherwise.

4. When a vacuum tube fills too slowly due to an incomplete venipuncture, damage to the red blood cells may result. Correct by deeper vein entry or select another puncture site and collect a second specimen.

5. Do not remove the needle from the vein until the vacuum tube is completely filled or the tube is pulled back from holder to release pressure. Premature removal causes a rush of air to enter the tube, with resultant damage to the red cells.

#### C.2.a.(2.) PAIRED SERA/PARALLEL TESTING

Both acute and convalescent sera are required to determine recent infection. Acute sera may be tested immediately and then stored until the convalescent sera are submitted. When both sera are available parallel testing under identical testing conditions will be performed to ensure an accurate comparison of acute and convalescent antibody titers. See Submission of Specimen for requested serological test.

#### C.2.a.(3.) VACUUM TUBES CONTAINING ANTICOAGULANTS

When using vacuum tubes containing anticoagulants and preservatives:

1. Tap the tube gently at a point just below the stopper to release any additive adhering to the tube or stopper.

2. Permit the tube to fill completely to ensure the proper ratio of blood to additive.

3. To ensure adequate mixing of blood with the anticoagulant or preservative, use a slow rolling wrist motion to invert the tube gently five or six times. Rapid wrist motion or vigorous shaking contributes either to small clot formation or hemolysis and fails to initiate proper mixing action.

4. Check to see that all the preservative or anticoagulant is dissolved. If any preservative powder is visible, continue inverting the tube slowly until the powder is dissolved.

#### C.2.a.(4.) VACUUM TUBES WITHOUT ANTICOAGULANTS

When using vacuum tubes containing no anticoagulants or preservatives, or SST serum Separator Tubes:

1. Permit the tube to fill completely.

2. Let the specimen stand for a minimum of 30 minutes and not longer than 45 minutes prior to centrifugation. This allows time for the clot to form. If the specimen is allowed to stand longer than 45 minutes, chemical activity and degeneration of the cells within the tube will take place, and test results will be altered as a consequence.

3. Centrifuge the specimen at the end of the 30 to 45 minute period in strict accordance with manufacturer's instructions for speed and duration of centrifugation.

#### C.2.a.(5.) QUANTITY NOT SUFFICIENT (QNS)

One of the most common errors in specimen collection is the submission of an insufficient quantity of specimen for testing. To ensure an adequate amount of specimen:

1. Always draw whole blood in an amount 2 ½ times the required volume of serum needed for a particular test. For example, if 4mL serum are required, draw at least 10mL whole blood.

2. For most profile testing submit one full tube of serum (8-10mL).

#### C.2.b. ENTOMOLOGICAL SPECIMENS

Identification of insects and other ectoparasites of medical importance (e.g., ticks, bed bugs, etc.) can be provided as a referral service. Please call the Microbiology Division (443-681-3943/443-681-3952) prior to submitting insect specimens.

**C.2.c.** RABIES SPECIMENS

# C.2.c.(1.) HOURS OF OPERATION

The MD Department of Health Laboratories Administration Rabies Laboratory operates from 8:00 AM to 4:30 PM weekdays (Monday through Friday except on holidays. On-call laboratory scientists are available for requests that require test results as soon as possible so that a medical determination on rabies post-exposure prophylaxis (PEP) can be made.

Specimens must be received at the MD Department of Health Laboratories Administration by 12:00 PM on Fridays to have the test results reported by Friday 4:30 PM. Specimens received on Fridays after 12:00 PM will have the results ready the next regular workday.

Specimens received on evenings from Monday through Friday, Fridays from 12:00 PM to 4:30 PM, on a weekend, or on a State holiday will be processed on the next regular workday, except for situations that require test results as soon as possible so that a medical determination about rabies PEP can be made (emergency examination). In these situations, prior approval by epidemiology staff in the MD Department of Health Office of Infectious Disease Epidemiology and Outbreak Response (IDEOR) is necessary before testing will be initiated by on-call laboratory scientists. (For details, please see the Emergency Examination Requests section below).

# C.2.c.(2.) DELIVERY PROCEDURES

Delivery of specimens must be from Monday through Friday 7:30AM to 6:00PM (regular workdays) to the MD Department of Health Laboratories Administration Loading Dock at 1770 Ashland Ave Baltimore, Maryland 21205. All animal submission of specimen must be routed through the local health department and sent via courier service. <u>Do not use</u> the U.S. Postal Service or other public transportation service to send specimens. (For emergency examination situations, please see the Emergency Examination Requests section below).

# C.2.c.(3.) ORDERING TESTS

For routine testing Monday through Friday, all local health departments must use the **MD Department of Health** Laboratories Administration's MyLIMS (Laboratory Information Management Systems)

<u>https://starlims3.health.maryland.gov/starlims11.MDlabs.prod/</u> for submission of specimens. The updated rabies submission form (DHMH 1188 08/17) will print out automatically when the animal rabies test is ordered through the MyLIMS system, and must be included in the cooler and attached to the specimen being submitted. One Rabies Submission Form should accompany each animal submitted. Specimens approved for emergency testing must be accompanied by a fully completed handwritten Rabies Submission Form if access to MyLIMS is not possible. An emergency contact name and phone number must be listed on the Rabies Submission Form. The updated rabies submission form (DHMH 1188 08/17) can be downloaded from our website at.

# https://health.maryland.gov/laboratories/Pages/Rabies.aspx

# C.2.c.(4.) CRITERIA FOR ANIMAL SUBMISSION

Live animals will **NOT** be accepted in the laboratory. Terrestrial animals acceptable for submission to the MD Department of Health are rabies vector species (e.g., raccoons, foxes, skunks, etc.) that expose humans, livestock, or pets. Exposure is defined as a bite that breaks the skin or contact of mucous membranes or broken skin with either animal saliva or nervous tissue. Birds, fish, reptiles and amphibians will not be accepted for rabies testing under any circumstances. Small rodents, including squirrels, chipmunks, gerbils, guinea pigs, hamsters, rabbits, mice, rats, voles, shrews and moles, will not be accepted for testing unless (1) the animal has bitten a human and (2) prior approval for testing has been authorized by the MD Department of Health IDEOR epidemiology staff. Most recent human cases of rabies in the U.S. have been associated with bats, and bat bites may be difficult to recognize. Bats should be submitted for testing in all cases of direct human contact with a bat or when bite or mucous membrane contact cannot be ruled out. Live animals will **NOT** be accepted in the laboratory.

**Please Note:** Large animal heads (e.g. horse and cow) should be submitted to the Maryland Department of Agriculture for brain tissue extraction.

# C.2.c.(5.) EMERGENCY EXAMINATION REQUESTS

Some situations that occur after regular business hours may require rabies test results as soon as possible so that a medical determination about rabies PEP can be made. In these Situations, on-call laboratory scientists are available; and specimens may be examined Fridays from 12:00 PM to 4:30 PM, on a weekend, or on a State holiday, with prior approval of the MD Department of Health PHPA (Prevention and Health Promotion Administration) epidemiology staff. To reach the epidemiology staff during regular business hours, contact the MD Department of Health PHPA for Zoonotic and Vector-borne Diseases (CZVBD) at 410-767-5649 (main); 410-767-6703 (MD Department of Health State Public Health Veterinarian); or 410-767-6618 (CZVBD) Rabies Chief). After hours, use the MD Department of Health IDEORB (Infectious Disease Epidemiology and Outbreak Response Bureau) Epidemiologist-On-Call pager at 410-716-8194 or call the SYSCOM operator at 410-795-7365 and ask to be directed to the Epidemiologist-on-Call for all rabies consultations.

After receiving approval for an emergency examination request, contact one of the following MD Department of Health Laboratories Administration staff **(in the order listed below)** to arrange for testing and appropriate submission. (NOTE In addition to the rabies submission form, the specimen should be accompanied by the submitter's after-hours contact information to receive results).

- 1) Rabies Lab On-Call No: 443-735-1291
- 2) Rabies Lab Supervisor (Kenneth Okogi): 443-799-9490
- 3) OLEPR Chief (Amy Armitage): 410-925-3121
- 4) Laboratory Director, Dr. Robert Myers: 443-928-0925

# C.2.c.(6.) SPECIMEN COLLECTION

Live animals will <u>NOT</u> be accepted in the laboratory. Animals should be euthanized in a manner that will not destroy the brain tissues to be examined in the diagnosis of rabies. When possible, only the animal's head should be submitted for diagnostic purposes. For animals weighing more than 20 pounds, particularly large dogs, only the head may be submitted for testing. If an animal is being submitted to MD Department of Health Labs from an animal pathology or diagnostic laboratory, and the animal has already been prepared for necropsy, the submitter should submit all or a cross section of the brainstem and half of the cerebrum.

**Please Note:** Large animal heads (e.g. horse and cow) should be submitted to the Maryland Department of Agriculture for brain tissue extraction.

# C.2.c.(7.) PACKAGING AND SHIPPING

•All rabies specimens must be placed into coolers that are clearly marked as rabies coolers. No other non-rabies clinical samples may be placed into rabies coolers or these samples will be rejected.

- •Rabies coolers must fully close and must be waterproof.
- •Each specimen must be individually packaged in a leak-proof bag and clearly labeled.
- •Each specimen must be accompanied by a Rabies Submission Form for proper identification.
- •All Rabies Submission Forms must be filled out correctly and legibly including exposure type.
- •Coolers may be shipped with ice or ice packs but the ice should not occupy more than 1/3 of the cooler.
- Live animals will **NOT** be accepted in the laboratory.
- •Submitters should avoid freezing specimens. If frozen specimens are received, testing will be delayed.
- Trash **MUST** not be sent in rabies coolers.

•Animal rabies packaging and training video available at <a href="https://health.maryland.gov/laboratories/Pages/Rabies-Animal-DFA.aspx">https://health.maryland.gov/laboratories/Pages/Rabies-Animal-DFA.aspx</a>

# D. GUIDE TO PUBLIC HEALTH LABORATORY TESTS:

TEST:	ABCs (previously BIDS) includes Neisseria meningitidis, Haemophilus influenzae, Group A
	streptococcus, Group B Streptococcus, and Streptococcus pneumoniae. Listeria monocytogenes is
	handled as an ABCs isolate and evaluated by the National Antimicrobial Resistance Monitoring Systems
	(NARMS) Program.
Synonym:	Active Bacterial Core Surveillance (Bacterial Invasive Disease Surveillance)
Laboratory/Phone:	Microbiology / 443-681-3952
Turnaround Time:	N/A
Specimen Required:	Pure culture on agar slant in screw cap tube.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen
	type/source, and the date and time of collection. The specimen/sample must be properly labeled and
	match the test requisition or electronic test order.
Specimen Volume (Optimum):	Bacterial isolate
Specimen Volume (Minimum):	N/A
Collect:	N/A
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Indicate ABCs # and organism identification on test request form.
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of
	transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing
	guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at Room/Ambient Temperature (2-30°C) - DO NOT REFRIGERATE ISOLATE - DO NOT FREEZE.
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid
	misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new
	specimen will provide appropriate materials and clinically relevant information to support good patient
	care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
	<ul> <li>Specimen frozen</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	N/A
Reference Range:	N/A
Additional Information:	SUBCULTURE TO AGAR SLANT BEFORE TRANSPORTING. DO NOT SEND CULTURE PLATES.
Purpose of Test:	Active Bacterial Core Surveillance (ABCs) is a core component of the CDC's Emerging Infections Programs
-	Network (EIP).
Method:	Isolate is subcultured and identified prior to submission to CDC.
Interfering Substances/Limitations	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
5	1770 Ashland Avenue, Baltimore, Maryland 21205
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# MD Department of Health-Laboratories Administration

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Active Bacterial Core Surveillance (ABCs) is a core component of the CDC's Emerging Infections Programs Network (EIP), collaboration between CDC, state health departments,
and universities. ABCs is an active laboratory and population-based surveillance system for invasive bacterial pathogens of public health importance. For each case of invasive
disease in the surveillance population, a case report with basic demographic information
is completed and bacterial isolates are sent to CDC and other reference laboratories for additional laboratory evaluation.
ABCs was initially established in four (4) states in 1995. It currently operates among ten
(10) EIP sites across the United States, representing a population of over 38 million persons. At this time, ABCs conducts surveillance for six (6) pathogens: Group A and
Group B streptococcus (GAS, GBS), Haemophilus influenzae, Neisseria meningitidis,
<i>Streptococcus pneumoniae,</i> and Listeria monocytogenes. The MD Department of Health is an EIP site with partner Johns Hopkins Bloomberg School of Public Health.

TEST:	Adenovirus, Viral Culture
Synonym:	Adenovirus: Virus Culture, Virus isolation: Refer to instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934
Turnaround Time:	3-28 days

TEST:	AFB/Acid-fast Bacilli culture ( <i>Mycobacterium tuberculosis</i> identification)
Synonym:	AFB/Acid Fast Bacteria Identification (Acid Fast Bacilli); M. Tuberculosis culture: Refer to
	instructions for Mycobacterium tuberculosis culture.
Laboratory/Phone:	Mycobacteriology / 443-681-3942

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TEST:	Amoebiasis (Ova and Parasites Microscopic Examination)
Synonym:	Amoebiasis; Amebiasis: Refer to instructions for Ova and Parasites Microscopic
	Examination.
Laboratory/Phone:	Microbiology / 443-681-3952

TEST:	Anthrax, Cutaneous
Synonym:	Bacillus anthracis, Woolsorters' disease
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952
Turnaround Time:	2-7 days [from specimen receipt in the Laboratory]
Specimen Required:	1. Vesicular Stage: Vesicular fluid
	2. Eschar Stage: Eschar material
	3. Isolate
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must
	be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	N/A
Specimen Volume (Minimum):	N/A
Collect:	1. Vesicular Stage: Collect vesicular fluid on sterile swab from previously unopened vesicles.
	2. Eschar Stage: Collect eschar material by carefully lifting the eschar's outer edge,
	insert sterile swab, then slowly rotate for 2-3 seconds beneath the edge of the eschar without removing it.
	3. Isolate: Pure culture, 24 hours old, growing on sheep blood agar plate.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on the form.
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Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	1. Swabs: Transport directly to laboratory at room/ambient temperature (2-30 °C)
	when transport time is <1 hour. For transport time > 1 hour, transport at 2-8°C on cold packs.
	<ol> <li>Isolate: Transport the specimen at room/ambient temperature (2-30 °C) on a sealed sheep blood agar plate.</li> </ol>
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate
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	inappropriate therapy. A request for a new specimen will provide appropriate materials
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
Availability:	24 hours/day, 7 days/week
Results and Interpretation:	Bacillus anthracis isolated/detected.
	Bacillus anthracis not found.
Additional Information:	Call 410-925-3121 before sending specimen to the Laboratory.
Purpose of Test:	To confirm diagnosis of cutaneous anthrax.
Method:	LRN Methods
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
-	1770 Ashland Avenue, Baltimore, Maryland
Comment:	Call 410-925-3121 before sending to the Laboratory.

TEST:	Anthrax, Gastrointestinal
Synonym:	Bacillus anthracis, Woolsorters' disease
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952
Turnaround Time:	2-7 days [from specimen receipt in the Laboratory]
Specimen Required:	1. Blood Cultures
	2. Stool
	3. Rectal swab (for patients unable to pass a specimen)
	4. Isolate
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	N/A
Specimen Volume (Minimum):	N/A
Collect:	1. Blood Cultures: Collect appropriate blood volume and number of sets per routine
	laboratory protocol.
	2. Stool: Transfer ≥ 5g of stool directly into a clean, dry, sterile, wide-mouth, leak-proof
	container.
	3. Rectal swab: Insert a sterile swab one (1) inch beyond the anal sphincter.
	4. Isolate: Pure culture, 24 hours old, growing on a sheep blood agar plate.
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Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form
	may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on the form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<ol> <li>Blood Cultures: Transport directly to the laboratory at room/ambient temperature (2-30 °C).</li> <li>Stool: Transport unpreserved stool to laboratory within one (1) hour at room/ambient temperature (2-30 °C). For transport time &gt; 1 hour, transport at 2-8°C on cold packs. Cary-Blair or equivalent transport media is acceptable.</li> <li>Rectal Swab: Transport swab(s) directly to laboratory at room/ambient temperature (2-30 °C). For transport at 2-8°C on cold packs.</li> <li>Isolate: Transport the specimen at room/ambient temperature (2-30 °C) on a sealed sheep blood plate.</li> </ol>
Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Broken specimen/sample container</li> <li>The wrong specimen for test request</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> </ul>
Availability:	24 hours/day, 7 days/week
Results and Interpretation:	Bacillus anthracis is isolated/detected. Bacillus anthracis not found.
Additional Information:	Call 410-925-3121 before sending specimen to the Laboratory.
Purpose of Test:	To confirm diagnosis of gastrointestinal anthrax.
Method:	LRN Methods
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Call 410-925-3121 before sending specimen to the Laboratory.

TEST: Anthrax, Inhalational Synonym: Bacillus anthracis, Woolsorters' disease Laboratory/Phone: Office of Laboratory Emergency Preparedness and Response: 410-925-3121 (24/7 emergency contact number) Select Agents Microbiology Laboratory: 443-681-3954 Division of Microbiology Laboratory: 443-681-3952 **Turnaround Time:** 2-7 days [from specimen receipt in the Laboratory] Specimen Required: 1. **Blood Cultures** 2. Sputum 3. Isolate Specimen should be labeled with patient's last and first name, patient's address, DOB, Specimen Identification: specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order. Specimen Volume (Optimum): N/A Specimen Volume (Minimum): N/A Blood Cultures: Collect appropriate blood volume and number of sets per routine 1. Collect: laboratory protocol. Sputum: Collect >1 ml of a lower respiratory specimen into a sterile container. Isolate: Pure culture, 24 hours old, growing on a sheep blood agar plate. 2. 3. Continued Next Page>

Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on the form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<ol> <li>Blood Cultures: Transport directly to the laboratory at room/ambient temperature (2-30 °C).</li> </ol>
	2. Sputum: Transport in sterile, screw-capped container at room/ambient
	temperature (2-30 °C) when transport time is <1 hour. For transport time > 1 hour, transport at 2-8°C on cold packs.
	3. Isolates: Transport at room/ambient temperature (2-30 °C) on a sealed sheep blood agar plate.
Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> <li>Broken specimen for test request</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> </ul>
Availability:	24 hours/day, 7 days/week
Results and Interpretation:	Bacillus anthracis isolated/detected; Bacillus anthracis not found.
Additional Information:	Call 410-925-3121 before sending specimen to the Laboratory.
Purpose of Test:	To confirm diagnosis of Inhalational Anthrax.
Method:	LRN Methods
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
-	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Call 410-925-3121 before sending to the Laboratory.

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TEST:	Antimicrobial Susceptibility Test
Synonym:	Disk Diffusion Susceptibility Testing, E-test, Susceptibility Testing or Microbroth Dilution
	Susceptibility Testing
Laboratory/Phone:	Microbiology / 443-681-3952
Turnaround Time:	48-72 hrs. [from specimen receipt in the Laboratory]
Specimen Required:	Original specimen or pure isolate of rapidly growing non-fastidious aerobic bacteria.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Viable pure isolate on an appropriate slant.
Specimen Volume (Minimum):	N/A
Collect:	N/A
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at Room/Ambient Temperature (2-30°C) or specimens in cryovials transport frozen on dry ice (-2°C or colder).
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate
	results and to avoid misleading information that might lead to misdiagnosis and
	inappropriate therapy. A request for a new specimen will provide appropriate materials
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
	<ul> <li>Non-viable organism</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Results are reported as S-I-R, following Clinical Laboratory Standards Institute (CLSI)
	criteria for organism/source combination.
Reference Range:	CSLI guidelines
Additional Information:	If original specimen is submitted, pathogenic bacteria should be isolated from it.
Purpose of Test:	To assist the physician in choosing an appropriate antimicrobial agent(s) for therapy.
Method:	Disk Diffusion
Interfering Substances:	Administration of antimicrobial agents before specimen collection.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	The antibiotics tested and reported will follow the latest CLSI recommendations
	appropriate for the bacterial species submitted for testing; the methodology used will
	also follow CLSI recommendations.

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TEST:	Antimicrobial Susceptibility Test, Minimum Inhibitory Concentration (MIC),
	Aerobic Bacteria
Synonym:	N/A
Laboratory/Phone:	Microbiology 443-681-3952
Turnaround Time:	48-72 hrs. [from specimen receipt in the Laboratory]
Specimen Required:	Original specimen or a pure isolate of aerobic bacteria.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must
	be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Viable pure isolate on an appropriate slant.
Specimen Volume (Minimum):	N/A
Collect:	N/A
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at Room/Ambient Temperature (2-30°C) or specimen in cryovial transport
	frozen on dry ice (-2°C or colder).
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate
	results and to avoid misleading information that might lead to misdiagnosis and
	inappropriate therapy. A request for a new specimen will provide appropriate materials
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Results are reported as S-I-R following Clinical Laboratory Standard Institute (CLSI)
	criteria for organism/source combination.
Reference Range:	CSLI guidelines
Additional Information:	Test is performed on aerobic possible pathogens.
Purpose of Test:	To assist the physician in choosing an appropriate drug therapy, monitoring emerging
	resistance, monitoring percentage susceptibility trend.
Method:	E-Test, Microbroth Dilution, or Vitek
Interfering Substances:	Administration of antimicrobial before specimen collection.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
0	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

TEST: **Arbovirus Endemic IgM Panel** Panel includes WNV, SLE, EEEV, JCV Synonym: Arthropod-borne virus: WNV (West Nile Virus), EEEV (Eastern Equine Encephalitis Virus), SLEV (St. Louis Encephalitis Virus), Jamestown Canyon Virus (JCV) Laboratory/Phone: Virology: 443-681-3931/3936 **Turnaround Time:** 5-10 business days during Arbovirus Season (excluding PRNT Testing) Specimen Required: Serum (blood); CSF Specimen identification: The specimen/sample must be properly labeled and include the patient's name or unique patient/sample identifier matching the test requisition or electronic test order. Specimen Volume (Optimum): 2 ml serum; 2ml CSF Specimen Volume (Minimum): 1 ml serum; 0.5 ml CSF Collect: Red top vacuum tube, transfer serum to sterile tube: CSF in sterile container with leakproof cap. MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be Form: downloaded from MDH Laboratory website). For testing to be initiated, the following information MUST be provided: date of onset, and date specimen collected. Also, please provide patient's date of birth, diagnosis, symptoms, fatality, travel history, immunizations, and whether patient is immunocompromised. Packaging and Shipping\*: Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). \*Refer to current Federal regulations for specific shipping requirements. **Transport Conditions:** Per CDC Assay Packet Insert: Store and transport at 2-8°C on cold packs in a cooler. If shipping is delayed beyond 48 hours, CSF must be transported at -20°C or colder and shipped on dry ice. Grossly hemolyzed specimens, unlabeled specimen, leaking container, mismatch Specimen Rejection Criteria: between labeling of specimen and test request form, and CSF specimen collected > 48 hours prior to arrival without being frozen. Monday through Friday. Availability: Continued Next Page>

Results and Interpretation:	(EIA) IgM: Negative, High Background, Equivocal, Positive
	(MIA) IgM: Positive, Negative, Nonspecific
	Serum and CSF that tests positive for IgM is consistent with acute infection.
Additional Information:	For more information, see the CDC link at:
	https://www.cdc.gov/ncezid/dvbd/
	The MDH Laboratories Administration routinely tests for IgM antibody to WNV, SLEV, JCV, and EEEV, which are endemic to this area. Confirmatory testing by PRNT (plaque reduction neutralization test) may be necessary on positive samples. A convalescent serum sample (collected > 10 days after onset date) is needed for PRNT testing. Please contact the Arbovirus Serology laboratory with any questions regarding PRNT. Lacrosse IgM serology testing is available based on patient's travel history.
Purpose of Test:	For the presumptive detection of WNV, SLEV, EEEV, JCV, and LAC IgM antibodies. Confirmatory testing by PRNT may be required.
Method:	EIA, MIA (Microimmunoassay), PRNT
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Serology testing for WN/SLE will be performed on all serum specimens. If sample volume
	permits, EEE IgM and JCV serology testing will also be performed.
	Paired specimens are NOT required. NOTE: Jamestown Canyon virus testing is for
	EPIDEMIOLOGICAL purposes and a result report will not be issued.

TEST:	Arbovirus Endemic Panel – Molecular Detection (qPCR)
	Panel includes: West Nile Virus, Eastern Equine Encephalitis Virus, St. Louis Encephalitis
	Virus, Enterovirus, and La Crosse Virus
Synonym:	Arthropod-borne virus: West Nile Virus (WNV), Eastern Equine Encephalitis Virus (EEEV),
	St. Louis Encephalitis Virus (SLEV), Enterovirus (Entero), and La Crosse Virus
Laboratory/Phone:	Molecular Diagnostics: 443-681-3924
Turnaround Time:	5-10 business days
Specimen Required:	Serum Aliquot from Red/Tiger/Gold/Orange Top Vacutainer®
	OR
	CSF Aliquot
	*Leak proof caps/lids should be used*
Specimen Identification:	The specimen must be properly labeled with at least two unique identifiers. The patient's
	full name or unique patient/specimen identifier, along with the specimen collection
	date/time must be included. Label on the specimen tube must match the laboratory test
	requisition (MDH Form #4676 Infectious Agents: Culture/Detection) or electronic test
	order that is submitted.
	For testing to be initiated, the following information MUST also be provided: date of
	onset, patient's date of birth, diagnosis, symptoms, fatality, travel history, immunizations,
	and whether the patient is immunocompromised.
Specimen Volume (Optimum):	Serum Aliguot from Red/Tiger/Gold/Orange Top Vacutainer®: 2mL
specificit volume (optimum).	OR
	CSF Aliguot: 2mL
Specimen Volume (Minimum):	Serum Aliquot from Red/Tiger/Gold/Orange Top Vacutainer®: 1mL
	OR
	CSF Aliquot: 0.6mL
	Continued Next Page>

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Collect:	Serum Aliquot from Red/Tiger/Gold/Orange Top Vacutainer® /
	CSF Aliquot:
	1) Label specimen tube according to the "Specimen Identification" section above to meet
	requirements for clinical testing; set forth by the Clinical Laboratory Improvements Act of
	1988 (CLIA).
	2) Collect the appropriate serum or CSF specimen.
	-Aliquot serum into a sterile tube.
	3) Cap specimen tube.
	<ol> <li>Confirm that the cap is not cross threaded.</li> </ol>
	5) Parafilm cap and tube together.
	6) Store specimens appropriately until shipping.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection - (Order Forms: 443-681-3777). An
	electronic copy can be found by clicking the link above or on the Maryland Department of
	Health: Laboratories Administration home page:
	https://health.maryland.gov/laboratories/Pages/home.aspx
	https://neath.maryianu.gov/iaboratones/Pages/nome.aspx
	*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the
	*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.
	*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form. Specimens must be triple packaged to ensure proper transport (they cannot break, be
Packaging and Shipping*:	*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.
Packaging and Shipping*:	<ul> <li>*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.</li> <li>Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 &amp; 10 for</li> </ul>
Packaging and Shipping*:	*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form. Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 & 10 for triple packing guidance).
Packaging and Shipping*: Transport Conditions:	<ul> <li>*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.</li> <li>Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 &amp; 10 for triple packing guidance).</li> <li>*For specific shipping requirements refer to current regulations put forth by Federal,</li> </ul>
	<ul> <li>*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.</li> <li>Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 &amp; 10 for triple packing guidance).</li> <li>*For specific shipping requirements refer to current regulations put forth by Federal, State, Local governments and other governing agencies.</li> </ul>
	<ul> <li>*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.</li> <li>Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 &amp; 10 for triple packing guidance).</li> <li>*For specific shipping requirements refer to current regulations put forth by Federal, State, Local governments and other governing agencies.</li> <li>Specimen to be received &lt;48 hours from time of collection:</li> </ul>
	<ul> <li>*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.</li> <li>Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 &amp; 10 for triple packing guidance).</li> <li>*For specific shipping requirements refer to current regulations put forth by Federal, State, Local governments and other governing agencies.</li> <li>Specimen to be received &lt;48 hours from time of collection: Refrigerate specimens at 2-8°C. Transport overnight on cold packs (2-8°C).</li> </ul>
	<ul> <li>*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.</li> <li>Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 &amp; 10 for triple packing guidance).</li> <li>*For specific shipping requirements refer to current regulations put forth by Federal, State, Local governments and other governing agencies.</li> <li>Specimen to be received &lt;48 hours from time of collection: Refrigerate specimens at 2-8°C. Transport overnight on cold packs (2-8°C). OR Freeze specimens at ≤-70°C. Transport overnight on dry ice (-2°C or colder).</li> <li>Specimen to be received ≥48 hours from time of collection (MUST BE FROZEN):</li> </ul>
	<ul> <li>*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.</li> <li>Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 &amp; 10 for triple packing guidance).</li> <li>*For specific shipping requirements refer to current regulations put forth by Federal, State, Local governments and other governing agencies.</li> <li>Specimen to be received &lt;48 hours from time of collection: Refrigerate specimens at 2-8°C. Transport overnight on cold packs (2-8°C). OR Freeze specimens at ≤-70°C. Transport overnight on dry ice (-2°C or colder).</li> </ul>

AD Department of Health-Laboratories	Administration The J. Mehsen Joseph Public Health Laboratory
Availability: Results and Interpretation:	Attentional of the second of the se
	• La crosse Encephantis virus fina was not berecteb by RT-qFCR – specimen
	negative for La Crosse Encephalitis Virus.
Reference Range:	negative for La Crosse Encephalitis Virus. N/A
Reference Range: Additional Information:	negative for La Crosse Encephalitis Virus.         N/A         The term "Arbovirus" has no taxonomic significance, but is a shortened name given to viruses that are transmitted by blood feeding arthropods (mosquitoes, ticks, etc.).         Arboviruses that cause human encephalitis are members of three virus families: The Togaviridae (genus Alphavirus), Flaviviridae, and Bunyaviridae. For more information, see the CDC link at:
	negative for La Crosse Encephalitis Virus.           N/A           The term "Arbovirus" has no taxonomic significance, but is a shortened name given to viruses that are transmitted by blood feeding arthropods (mosquitoes, ticks, etc.).           Arboviruses that cause human encephalitis are members of three virus families: The Togaviridae (genus Alphavirus), Flaviviridae, and Bunyaviridae. For more information, see

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Method:	Real-Time PCR
Interfering Substances:	PCR inhibitors: DNases/RNases, Sodium hypochlorite (Bleach), Ethanol, etc.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	**All CSF specimens will be tested by PCR & serology. PCR testing will only be
	performed on serum specimens collected in the acute phase (<10 days between onset
	date and collection date). PCR testing will be performed on all immunocompromised
	patient samples**

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TEST:	Arbovirus Travel-Associated IgM Panel
	Panel includes Chikungunya, Dengue, Zika
Synonym:	Arthropod-borne virus: Chikungunya, Dengue fever, Zika
Laboratory/Phone:	Virology: 443-681-3931/3936
Turnaround Time:	5-10 business days during Arbovirus Season (excluding PRNT Testing)
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include the patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml serum
Specimen Volume (Minimum):	3 ml serum
Collect:	Red top vacutainer tube, transfer serum to sterile tube.
Form:	MDH Form# 4677 Serological Testing (Order Forms: 443-681-3777)
	For testing to be initiated, the following information MUST be provided: date of onset,
	and date specimen collected. Also please provide: patient's date of birth, diagnosis,
	symptoms, fatality, travel history, immunizations, and whether patient is
	immunocompromised.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured, or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA IgM Assay Packet Insert: For up to 7 days after collection transport separated
	serum at 2-8°C on cold packs. If shipping is delayed beyond 7 days, serum must be
	transported at -20°C or colder and shipped on dry ice.
	transported at 20 e of colder and shipped of dry ide.
Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, and mismatch
	between labeling of specimen and test request form, specimen collected > 7 days prior to
	arrival without being frozen, and does not meet epidemiological criteria required for
	testing (e.g. travel history, symptoms, etc.)
Availability:	Monday through Friday.
Results and Interpretation:	Zika IgM: Negative, Presumptive Positive, "Other Flavivirus Presumptive Positive"
	Dengue & Chikungunya IgM: Positive, Negative, Equivocal
	Non-Negative results may be confirmed by PRNT.
Additional Information:	
Purpose of Test:	For the presumptive detection of Chikungunya, Dengue & Zika virus IgM antibodies.
	Confirmatory testing by PRNT may be required.
Method:	ELISA, PRNT
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland
	Avenue, Baltimore, Maryland 21205
Comment:	Serology testing for Dengue/Zika/Chikungunya will be performed on all serum specimens
	that meet epidemiological criteria. Convalescent specimen for additional PRNT testing
	may be required.
	For additional information: <u>https://phpa.health.maryland.gov/pages/zika.aspx</u>

TEST:	Arbovirus Travel Panel – Molecular Detection (qPCR)
	Panel includes: Zika Virus, Chikungunya Virus, and Dengue Virus
Synonym:	Arthropod-borne virus: Zika Virus (ZIKV), Chikungunya Virus (CHIKV), and Dengue Virus (DENV)
Laboratory/Phone:	Molecular Diagnostics: 443-681-3924
Turnaround Time:	5-10 business days
Specimen Required:	Serum Aliquot from Red/Tiger/Gold/Orange Top Vacutainer® -Serum
	<b>**OPTIONAL</b> (will be rejected without an accompanying serum specimen)**
	Whole Blood in Lavender/Purple Top Vacutainer® with EDTA: -Whole Blood
	Urine in specimen collection container. -Urine (Tested for Zika Only)
	*Leak proof caps/lids should be used*
Specimen identification:	The specimen must be properly labeled with at least <b>two unique identifiers</b> . <b>The patient's full name or unique patient/specimen identifier, along with the specimen collection date/time</b> must be included. Label on the specimen tube must match the laboratory test requisition ( <u>MDH Form #4676 Infectious Agents: Culture/Detection</u> ) or electronic test order that is submitted.
	For testing to be initiated, the following information MUST also be provided: date of onset, patient's date of birth, diagnosis, symptoms, fatality, travel history, immunizations, and whether the patient is immunocompromised.
Specimen Volume (Optimum):	Serum Aliquot from Red/Tiger/Gold/Orange Top Vacutainer®: 5mL AND Whole Blood in Lavender/Purple Top Vacutainer® with EDTA: 5mL OR
	Urine in specimen collection container: 10mL
Specimen Volume (Minimum):	Serum Aliquot from Red/Tiger/Gold/Orange Top Vacutainer®: 3mL AND
	Whole Blood in Lavender/Purple Top Vacutainer® with EDTA: 4mL OR Urine in specimen collection container: 5mL
Collect:	Serum Aliquot from Red/Tiger/Gold/Orange Top Vacutainer®/ Whole Blood in
concet.	Lavender/Purple Top Vacutainer® with EDTA / Urine in specimen collection container:
	1) Label specimen tube according to the "Specimen Identification" section above to meet
	requirements for clinical testing; set forth by the Clinical Laboratory Improvements Act of
	1988 (CLIA).
	2) Collect the appropriate specimen(s). SERUM IS REQUIRED.
	-Aliquot serum into a sterile tube.
	3) Cap specimen tube.
	4) Confirm that the cap is not cross threaded.
	5) Parafilm cap and tube together.
	<ul><li>6) Store specimens appropriately until shipping.</li><li>7) Store specimens appropriately until shipping</li></ul>

Form:	MDH Form #4676 Infectious Agents: Culture/Detection - (Order Forms: 443-681-3777). Ar
	electronic copy can be found by clicking the link above or on the Maryland Department of Health: Laboratories Administration home page:
	https://health.maryland.gov/laboratories/Pages/home.aspx
	*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be triple packaged to ensure proper transport (they cannot break, be punctured, or leak their contents) under normal conditions of (Refer to pages 9 & 10 for triple packing guidance).
	*For specific shipping requirements refer to current regulations put forth by Federal, State, Local governments and other governing agencies.
Transport Conditions:	Serum and Urine (FREEZING PREFERRED)
	Specimen to be received <7 days from time of collection:
	Refrigerate specimens at 2-8°C. Transport overnight on cold packs (2-8°C) OR dry ice (-2°C or colder). OR
	Freeze specimens at ≤-20°C. Transport overnight on cold packs (2-8°C) OR dry ice (-2°C or colder).
	Specimen to be received ≥7 days from time of collection (MUST BE FROZEN): Freeze specimens at ≤-20°C. Transport overnight on cold packs (2-8°C) OR dry ice (-2°C or colder).
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.
	<ul> <li>Specimen(s) received outside temperature range(s) below:</li> </ul>
	• Refrigerated (Cold Packs)/Frozen (Dry Ice): 8°C or colder.
	• Whole blood specimen: 2-8°C.
	<ul> <li>Specimen(s) collected &gt;14 days from onset to collection date.</li> </ul>
	• Specimen(s) received after prolonged delay (>48 hours) unless frozen.
	Inappropriate specimen transport conditions.
	Unlabeled or improperly labeled specimens.
	Non-sterile or leaking container.
	Broken specimen/sample container.
	Illegible, or no submitter information on the request form.
	• Mismatched form and specimen.
	• The wrong specimen source for the test requested.
	<ul> <li>Inappropriate outfit (specimen collection kit) for requested test.</li> </ul>
	Incorrect transport media.
	Rapid Test Lysis Buffer     Incorrect swab.
	Cotton swabs.     Calcium alginate swabs
	<ul> <li>Calcium alginate swabs.</li> <li>Illegible or no patient information on the specimen.</li> </ul>
	Expired transport media.
	<ul> <li>No specimen received.</li> <li>Quaptity not sufficient for testing</li> </ul>
	Quantity not sufficient for testing.
Availability:	Monday - Friday
,	Continued Next Page>

Results and Interpretation:	Trioplex - CHIKV, DENV, and ZIKV
	• No Zika, dengue, or chikungunya RNA detected by rRT-PCR – Negative.
	<ul> <li>Specimen inconclusive for the presence of Zika, dengue, and chikungunya RNA by rRTPCR. An inconclusive result may occur in the case of an inadequate specimen – Inconclusive.</li> </ul>
	<ul> <li>Dengue RNA detected by rRTPCR. No Zika or chikungunya RNA detected – Positive for DENV, but negative for ZIKV and CHIKV.</li> </ul>
	• Chikungunya RNA detected by rRT-PCR. No dengue or Zika RNA detected – Positive for CHIKV, but negative for ZIKV and DENV.
	• Zika RNA detected by rRTPCR. No dengue or chikungunya RNA detected – Positive for ZIKV, but negative for DENV and CHIKV.
	• Dengue and chikungunya RNA detected by rRT-PCR. No Zika RNA detected – Positive for DENV and CHIKV, but negative for ZIKV.
	• Zika and dengue RNA detected by rRT-PCR. No chikungunya RNA detected – Positive for ZIKV and DENV, but negative for CHIKV.
	<ul> <li>Zika and chikungunya RNA detected by rRT-PCR. No dengue RNA detected – Positive for ZIKV and CHIKV, but negative for DENV.</li> </ul>
	<b>Zika, dengue, and chikungunya RNA detected by rRT-PCR</b> – Positive for ZIKV, DENV, and CHIKV
Additional Information:	The term "Arbovirus" has no taxonomic significance, but is a shortened name given to viruses that are transmitted by blood feeding arthropods (mosquitoes, ticks, etc.). Arboviruses that cause human encephalitis are members of three virus families: The Togaviridae (genus Alphavirus), Flaviviridae, and Bunyaviridae. For more information, see the CDC link at:
	https://www.cdc.gov/ncezid/dvbd/
	For information specific to Zika please see MDH link below:
	https://health.maryland.gov/phpa/pages/zika.aspx
Purpose of Test:	To provide <b>qualitative</b> results for the detection of ZIKV, CHIKV, and DENV RNA in specimens.
Method:	Real-Time PCR
Interfering Substances:	PCR inhibitors: DNases/RNases, Sodium hypochlorite (Bleach), Ethanol, etc.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	**PCR testing will only be performed on specimens that meet current epidemiological criteria. A serum specimen must accompany urine or whole blood specimens or testing will not be performed**
	-Patient must have symptoms. -Patient must have traveled (outside the continental U.S.) to a country endemic to Zika virus. Please see CDC link with map below (countries in dark purple or red): https://wwwnc.cdc.gov/travel/page/zika-travel-information

TEST:	Arthropod Identification
Synonym:	Tick identification/Ectoparasite
Laboratory/Phone:	Microbiology/ 443-681-3952
Turnaround Time:	48-72 hrs. [from specimen receipt in the Laboratory]
Specimen Required:	Whole parasite
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
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Specimen Volume (Optimum):	Whole parasite
Specimen Volume (Minimum):	N/A
Collect:	Collect the whole parasite; put it in a clean container with a tight-fitting lid with
	alcohol.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at Room/Ambient Temperature (2-30°C).
Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> <li>Broken specimen for test request</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> <li>Received only partial parasite</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Genus/species
Reference Range:	N/A
Additional Information:	N/A
Purpose of Test:	Identify disease carrying arthropods
Method:	Macroscopic examination
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
-	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

TEST: Aspergillus fumigatus Azole Resistance Susceptibility Synonym: Aspergillus fumigatus AFST, Aspergillus fumigatus Susceptibility Screen, ARLN Aspergillus Testing Laboratory/Phone: Microbiology/ARLN 443-681-4569 **Turnaround Time:** 20 business days Specimen Required: Isolate subcultures on sabouraud dextrose agar slant with a leak-proof screw top lid. Specimen Identification: Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order. Specimen Volume (Optimum): N/A Specimen Volume (Minimum): N/A Collect: N/A Form: MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate "ARLN Aspergillus fumigatus Azole Resistance" on the form. Indicate specimen type using the "Specimen Code" on form Specimens must be packaged in a triple packaging system to ensure that under normal Packaging and Shipping\*: conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). \*Refer to current Federal regulations for specific shipping requirements. Continued Next Page>

Transport Conditions:	Store and ship at 2-8°C on cold packs or ambient temperature (2-30°C)
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials         and clinically relevant information to support good patient care.         Unlabeled or improperly labeled specimen         Non-sterile or leaking container         Inappropriate specimen transport conditions         Illegible, or no submitter information on the request form         Broken specimen/sample container         The wrong specimen for test request         Inappropriate outfit for requested test         Illegible or no patient information on the specimen         Expired transport media         Specimen received after prolonged delay (usually more than 72 hours)
Availability:	Monday through Friday
Results and Interpretation:	Confirmation of submitted isolate identification as <i>Aspergillus fumigatus</i> and antifungal susceptibility testing (AFST) if applicable
Reference Range:	CLSI Guidelines and epidemiological cutoff values
Additional Information:	N/A
Purpose of Test:	Antifungal susceptibilities of potentially pathogenic organisms
Method:	Microscopic ID, microbroth dilution for AFST
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

TEST:	Aspergillus serology
Synonym:	Aspergillosis antibody test
Laboratory/Phone:	Virology: 443-681-3938/3931
Turnaround Time:	5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include the patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer tube
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to Page 9 & 10). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport whole blood or separated serum at 2-8°C on cold packs for up to 72 hours after collection. For > 72 hours after collection transport -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN
Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, insufficient volume, mismatch between labeling of specimen and test request form, specimen collected > 3 days prior to arrival without being frozen.
Availability:	Monday through Friday
Results and Interpretation:	POSITIVE- Antibodies against (A. fumigatus, A. flavus, A. niger) detected. NEGATIVE- Antibodies against (A. fumigatus, A. flavus, A. niger) not detected.
Additional Information:	
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Purpose of Test:	For the detection of antibody to A. fumigatus, A. flavus, A. niger
Method:	Immunodiffusion
Interfering Substances:	Hemolysis
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required. False negatives can occur with specimens from patients receiving long term antifungal or corticosteroid therapy.

TEST:	Babesia Serology
	(Tick-borne Disease Panel)
Synonym:	Babesia microti, babesiosis,
Synonym.	Refer to instructions in Tick-Borne Disease Panel
Laboratory/Phone:	443-681-3938/3931
Specimen Required:	Serum (acute and convalescent preferred)
	≥1:64: Reflect infection at an undetermined time by Babesia microti
Results and Interpretation:	<1:64: Babesia antibody not detected. Another specimen should be drawn if
	the original was taken soon after onset
Additional Information:	http://www.cdc.gov/parasites/babesiosis/
Purpose of Test:	For the detection IgG antibodies which may be due to a Babesia microti
Methods:	Immunofluorescence Assay (IFA)
	Cross reaction with Plasmodium spp. has been documented. Cross reactivity
Comment:	with Babesia divergens also occurs which causes a more severe infection in
	European patients is possible.
	A four-fold increase in titer between acute and convalescent serum specimens
	supports the diagnosis of recent infection. Acute phase sera should be
	collected within the first week after onset of illness, and convalescent phase
	sera, 2-4 weeks after onset.

TEST:	Bacillus anthracis Culture
Synonym:	For Bacillus anthracis culturing: Refer to Anthrax, Cutaneous, Anthrax, Gastrointestinal,
	or Anthrax, Inhalational, for specific instructions as required.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Bacillus cereus Culture
Synonym:	Bacillus cereus Culture: For specific instructions refer to Foodborne Pathogens (Bacillus
	cereus, Clostridium perfringens, Staph aureus).
Laboratory/Phone:	Microbiology / 443-681-3952

TEST:	Bacterial Culture, Routine
Synonym:	Aerobic culture, routine culture, eye culture, ear culture, genital culture, nose culture,
	respiratory culture, throat culture, urine culture, wound culture, sterile fluid culture.
Laboratory/Phone:	Microbiology / 443-681-3952
Turnaround Time:	Varies depending on culture site and organisms isolated, usually 2-4 days (or longer if
	fastidious organism isolate) [from specimen receipt in the Laboratory].
Specimen Required:	Swab from site in transport media (Amies, Stuarts, culturette)
	Aseptically aspirated pus or tissue
	Clean-catch urine
	Fluid in sterile container with leak-proof lid
	Do not send a syringe with needle attached. (Specimen will be rejected)
Specimen identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must
	be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Swab or 0.5 ml fluid
Specimen Volume (Minimum):	N/A
Collect:	Most sites: Use swab to collect and place in transport media (Amies or Stuarts).
	Urine: fresh, clean-catch urine in screw cap jar, refrigerate, must reach lab within 24
	hours, ship promptly on cold packs.
	Wound: Disinfect contiguous areas of skin or mucous membrane containing resident
	normal flora prior to culture collection. Collect exudates from the interior of productive
	lesions.
	Keep tissue samples moist.
	A thin, air-dried smear for Gram stain obtained from the same site as the culture is
	recommended.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport Room/Ambient temperature (2-30°C): abscesses, burn swabs, dental cultures,
	ear (inner ear), eye specimens, sterile body fluids, genital, Intra Uterine Device (IUD),
	spore testing, tissues, wound swabs, nasopharynx, upper respiratory cultures, blood
	culture bottles, bone marrow, and cerebrospinal fluid (CSF).
	Transport at (2-8°C) on cold packs if kept > 2 hours after collection: catheters, ear
	(external ear) sputum, urine – all types, and autopsy tissue.
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate
	results and to avoid misleading information that might lead to misdiagnosis and
	inappropriate therapy. A request for a new specimen will provide appropriate materials
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
	<ul> <li>Specimen received after prolonged delay (usually more than 72 hours)</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Identification of potentially pathogenic organisms and antimicrobial susceptibilities, if
	clinically appropriate.
Reference Range:	No growth, routine/normal skin flora, routine/normal "body site" flora.

#### MD Department of Health-Laboratories Administration

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Additional Information:	N/A
Purpose of Test:	Isolation, identification and if clinically appropriate, antimicrobial susceptibilities of potentially pathogenic organisms.
Method:	Culture, staining, biochemical testing, antimicrobial susceptibility testing.
Interfering Substances/Limitations:	Only rapid-growing, no fastidious aerobic organisms can be recovered and identified by routine culture methods. "Bacterial culture, routine" will not detect anaerobic bacteria, chlamydia, viruses, fungi, or mycobacteria.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

TEST:	Bacterial Referred Isolate for ID
Synonym:	Isolate for Identification; referred culture
Laboratory/Phone:	Microbiology / 443-681-3952
Turnaround Time:	Varies depending on organisms submitted.
Specimen Required:	Isolate subcultured on agar slant with a leak-proof screw top lid.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must
	be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	N/A
Specimen Volume (Minimum):	N/A
Collect:	N/A
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport Room/Ambient temperature (2-30°C) or specime in cryovial transport at -2°
Transport Conditions:	or colder on dry ice.
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate
	results and to avoid misleading information that might lead to misdiagnosis and
	inappropriate therapy. A request for a new specimen will provide appropriate material
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
	<ul> <li>Specimen received after prolonged delay (usually more than 72 hours)</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Identification of submitted isolate.
Reference Range:	N/A
Additional Information:	N/A
Purpose of Test:	Identification and if clinically appropriate, antimicrobial susceptibilities of potentially
	pathogenic organisms.
Method:	Culture, staining, biochemical testing, and MALDI-TOF.
Interfering Substances/Limitations:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

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TEST:	Bang's Disease (Brucella serology and Brucella species culture)
Synonym:	Bang's Disease, Undulant fever, Malta Fever, and Rock of Gibraltar Fever: Refer to
	instructions for Brucella serology or Brucella species, culture.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

TEST:	Blood Culture (limited to Medical Examiner and special requests only)	
Synonym:	N/A	
Laboratory/Phone:	Microbiology 443-681-3952	
Turnaround Time:	Seven (7) days [from specimen receipt in the Laboratory]	
Specimen Required:	Blood collected in B-D blood culture bottle	
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,	
	specimen type/source, and the date and time of collection. The specimen/sample must	
	be properly labeled and match the test requisition or electronic test order.	
Specimen Volume (Optimum):	10 ml of right-heart blood	
Specimen Volume (Minimum):	N/A	
Collect:	Best collected before body is handled too much or opened. Decontaminate skin or seal	
	surface of heart or other organ before inserting needle.	
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or	
	form may be downloaded from MDH Laboratory website).	
	Indicate specimen type using the "Specimen Code" on form.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal	
· · · · · · · · · · · · · · · · · · ·	conditions of transport they cannot break, be punctured or leak their contents (Refer to	
	pages 9 & 10 for triple packing guidance).	
	*Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	Transport Room/Ambient temperature (2-30°C).	
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate	
	results and to avoid misleading information that might lead to misdiagnosis and	
	inappropriate therapy. A request for a new specimen will provide appropriate materials	
	and clinically relevant information to support good patient care.	
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>	
	<ul> <li>Non-sterile or leaking container</li> </ul>	
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>	
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>	
	<ul> <li>Mismatched form and specimen</li> </ul>	
	<ul> <li>Broken specimen/sample container</li> </ul>	
	<ul> <li>The wrong specimen for test request</li> </ul>	
	<ul> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> </ul>	
	- megible of no patient mormation on the specimen	
Availability:	Expired transport media	
Availability:	Monday through Friday	
Results and Interpretation:	If $\leq$ 3 organisms then Genus/species.	
Deference Dange	If $\geq$ 3 organisms – no identification (hold organism for 10 days).	
Reference Range: Additional Information:	No growth after seven (7) days incubation.	
Purpose of Test:	Assist Medical Examiner to establish the cause of death.	
Method:		
	Culture, biochemical, and MALDI-TOF.	
Interfering Substances:	Antibiotic therapy	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory	
<u> </u>	1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	N/A	

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TEST:	Bordetella Pertussis Culture
Synonym:	Pertussis, Whooping cough; B. pertussis culture, PCR
Laboratory/Phone:	Microbiology: 443-681-3952
Turnaround Time:	7-10 days [from receipt in the Laboratory], preliminary as soon as positive is detected.
Specimen Required:	Nasopharyngeal aspirates or nasopharyngeal swabs are both acceptable. Throat swabs are less suitable since <i>B. pertussis</i> exhibits tropism for ciliated respiratory epithelium, which is not found in the pharynx. However, throat swabs may be suitable for PCR diagnosis. Dacron <sup>™</sup> swabs are to be used for both culture and PCR. Cotton-tipped swabs are to be avoided since they contain fatty acids that are toxic and may inhibit the growth of <i>B. pertussis</i> .
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Culture: Nasopharyngeal specimen on Dacron™ swab inserted in Regan-Lowe transport media. PCR: Nasopharyngeal specimen on Dacron™ swab, submitted in Regan-Lowe transport media.
Specimen Volume (Minimum):	N/A
Collect:	<ul> <li>Collect according to kit instructions. To order Pertussis culture kit, call 443-681-3777. Use Dacron<sup>™</sup>-tipped swabs only.</li> <li>Remove swabs from sterile package.</li> <li>Infants and young children should be supine. The infant/child's head must be held immobile by an assistant.</li> <li>Pass two (2) swabs simultaneously through one nostril and gently along the floor of the nasopharyngeal cavity until it reaches the posterior nares. NOTE: Do not force swabs. Obstructions may be due to septal deviation.</li> <li>Gently rotate both swabs together and leave in nasopharynx for 15 to 30 seconds to absorb mucus.</li> <li>Repeat procedure through other nostril using the same two (2) swabs.</li> <li>Place each swab into a separate tube of transport media, run the swab (streak) up the agar and then put the swab into the media.</li> <li>Label both transport tubes with patient's name and place each tube back into the Ziploc bag.</li> </ul>
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport specimen at room/ambient temperature (2-30°C) the same day specimen is collected. If delays are expected (not transported the same day), place inoculated tubes into an incubator at 35-37°C. Cooled transport of the specimen significantly decreases the number of bacteria.
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate	
	results and to avoid misleading information that might lead to misdiagnosis and	
	inappropriate therapy. A request for a new specimen will provide appropriate materials	
	and clinically relevant information to support good patient care.	
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>	
	<ul> <li>Non-sterile or leaking container</li> </ul>	
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>	
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>	
	<ul> <li>Mismatched form and specimen</li> </ul>	
	<ul> <li>Broken specimen/sample container</li> </ul>	
	<ul> <li>The wrong specimen for test request</li> </ul>	
	<ul> <li>Inappropriate outfit for requested test</li> </ul>	
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>	
	<ul> <li>Expired transport media</li> </ul>	
	<ul> <li>Regan-Lowe media not used</li> </ul>	
	<ul> <li>Media expired</li> </ul>	
	<ul> <li>Specimen frozen</li> </ul>	
	<ul> <li>Unlabeled specimen or name discrepancy between specimen and request label</li> </ul>	
	<ul> <li>Prolonged delay in transport (usually more than 72 hours)</li> </ul>	
Availability:	Monday through Friday	
Results and Interpretation:	N/A	
Reference Range:	No Bordetella pertussis cultured or detected.	
Additional Information:	The best yield is obtained when culture and PCR are used to diagnose this infection.	
Purpose of Test:	Culture: Isolate and identify B. pertussis and B. parapertussis; establish diagnosis of	
	whooping cough.	
	PCR: Detect the presence of <i>B. pertussis</i> nucleic acid (DNA).	
	Culture: isolation and identification using culture	
Method:	Maldi-Tof	
	PCR: Polymerase chain reaction, real-time	
Interfering Substances:	N/A	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory	
	1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	N/A	

TEST:	Bordetella pertussis, parapertussis, holmesii – Molecular Detection (qPCR) **PCR cannot be ordered independently of culture (See Bordetella pertussis culture). Both assays are performed in parallel**
Synonym:	B. pertussis, BP, pertussis, and Whooping cough
Laboratory/Phone:	Molecular Diagnostics: 443-681-3924
Turnaround Time:	2-3 business days
Specimen Required:	Nasopharyngeal swab (must be a synthetic swab – i.e. Dacron™) in Regan-Lowe
	transport media.
	-Nasopharyngeal.
Specimen Identification:	The specimen must be properly labeled with at least two unique identifiers. The
	patient's full name or unique patient/specimen identifier, along with the specimen
	collection date/time must be included. Label on the specimen tube must match the
	laboratory test requisition (MDH Form #4676 Infectious Agents: Culture/Detection) or
	electronic test order that is submitted.
Specimen Volume (Optimum):	Nasopharyngeal swab in Regan-Lowe transport media
Specimen Volume (Minimum):	Nasopharyngeal swab in Regan-Lowe transport media
	Continued Next Page>

Collect:	Nasopharyngeal swab in Regan-Lowe transport media:
conect.	1) Label specimen tubes according to the "Specimen Identification" section above to
	meet requirements for clinical testing; set forth by the Clinical Laboratory Improvements
	Act of 1988 (CLIA).
	2) Infants and young children should be supine. The infant/child's head must be held
	immobile by an assistant.
	3) Gently pass two (2) swabs ( <b>SYNTHETIC</b> ) simultaneously through one nostril, along the floor of the nasopharyngeal cavity, until it reaches the posterior nares. <b>NOTE: Do not</b>
	force swabs. Obstructions may be due to septal deviation.
	4) Gently rotate both swabs together and leave in nasopharynx for 15 to 30 seconds to absorb mucus.
	5) Using the same two (2) swabs repeat the procedure through the other nostril.
	6) Place each swab into a separate tube of transport media (2). Run each swab (streak)
	up their individual media (Regan-Lowe) tubes: <b>leave swabs in their respective tubes</b> .
	7) Cap media tubes.
	8) Confirm that the cap is not cross threaded and that the swabs are not spring loaded
	underneath them.
	9) Place both tubes into the specimen bag.
-	10) Store specimens appropriately until shipping.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection - (Order Forms: 443-681-3777).
	An electronic copy can be found by clicking the link above or on the Maryland
	Department of Health: Laboratories Administration home page:
	https://health.maryland.gov/laboratories/Pages/home.aspx
	*All test requests must be made by an ordering physician (MD, NP, etc.) with their
	name in the appropriate section of the form. Indicate specimen source type next to the
	requested test using the "Specimen Code" on form.
	Specimens must be triple packaged to ensure proper transport (they cannot break, be
Packaging and Shipping*:	punctured, or leak their contents) under normal conditions of (Refer to pages 9 & 10 for
	triple packing guidance).
	*For specific shipping requirements refer to current regulations put forth by Federal,
	State, Local governments and other governing agencies.
Transport Conditions:	Specimens to be received <24 hours from time of collection:
	-Transport specimens at ambient/room temperature (2-30°C) on the day of collection.
	Specimens to be received ≥24<72 hours from time of collection (IF delays are
	expected):
	Incubate specimens at 35-37°C. Transport overnight at ambient/room temperature (2-
	30°C).
	*Cooled transport of specimens may significantly decrease the number of bacteria.
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Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Specimen(s) received outside temperature range(s) below: <ul> <li>Ambient/room temperature: 2-30°C.</li> </ul> </li> <li>Specimen(s) received after prolonged delay (&gt;72 hours).</li> <li>Inappropriate specimen transport conditions.</li> <li>Unlabeled or improperly labeled specimens.</li> <li>Non-sterile or leaking container.</li> <li>Broken specimen/sample container.</li> <li>Illegible, or no submitter information on the request form.</li> <li>Mismatched form and specimen.</li> <li>The wrong specimen source for the test requested.</li> <li>Inappropriate outfit (specimen collection kit) for requested test.</li> <li>Incorrect transport Media</li> <li>Rapid Test Lysis Buffer</li> <li>Viral Transport Media</li> <li>Cotton swabs.</li> <li>Cotton swabs.</li> <li>Calcium alginate swabs.</li> <li>Illegible or no patient information on the specimen.</li> </ul>
Availability: Results and Interpretation:	<ul> <li>Quantity not sufficient for testing.</li> <li>Monday - Friday</li> <li>B. pertussis DNA DETECTED – Specimen positive for B. pertussis.</li> <li>B. parapertussis DNA DETECTED – Specimen positive for B. parapertussis.</li> <li>B. holmesii DNA DETECTED – Specimen positive for B. holmesii.</li> <li>B. pertussis, B. parapertussis, and B. holmesii DNA NOT DETECTED – Specimen negative for Bordetella.</li> <li>INVALID - RP UNSATISFACTORY – Indicates insufficient quantity of human nucleic acid present in specimen(s). Please recollect and submit an additional</li> </ul>
Reference Range:	<ul> <li>specimen(s) for follow-up testing.</li> <li>INDETERMINATE – Requires confirmation by other means (culture, serology, or epi linkage).</li> <li>N/A</li> </ul>
Additional Information:	Cotton-tipped swabs are to be avoided since they contain fatty acids that are toxic and may inhibit the growth of <i>B. pertussis</i> , and cotton may contain PCR inhibitors.
Purpose of Test:	To provide qualitative results for the detection of BP DNA in specimens.
Method:	Real-Time PCR
Interfering Substances:	PCR inhibitors: DNases/RNases, Sodium hypochlorite (Bleach), Ethanol, etc.
	MD Department of Health Laboratories Administration, Central Laboratory
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Testing Site:	
Testing Site:	1770 Ashland Avenue, Baltimore, Maryland 21205

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TEST:	Bordetella Pertussis Toxin IgG Antibody	
Synonym:	Anti-pertussis toxin IgG, Anti-PT IgG	
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889	
Turnaround Time:	2-5 business days	
Specimen Required:	Serum	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique	
	patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum)	
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum)	
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer	
Form:	For outbreak investigation use only. Prior approval by MDH Epidemiology (410-767-6628) required. Specific specimen criteria applies, for details call 443-681-3889	
Transport Conditions:	Transport whole blood or separated serum at 2-8°C on cold packs. Specimen must be tested within 14 days of collection.	
Packaging and Shipping:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Specimen Rejection Criteria:	Specimen from patients vaccinated against B. pertussis in <6 months or patients <11 years of age cannot be tested. Discrepancy between name on tube and name on form, unlabeled specimen, insufficient volume, hemolysis, gross bacterial contamination. Specimens collected > 14 days prior to arrival.	
Availability:	Monday through Friday	
Results and Interpretation:	Results can be used for investigational use only         Pertussis antitoxin IgG level:         Positive: ≥ 100IU/mI         Negative: <40 IU/mI	
Additional Information:	For more information, see the CDC link at: <u>https://www.cdc.gov/pertussis/</u>	
Purpose of Test:	Test is for detecting elevated antibody titers. This is designed to be used in adult and adolescent populations for epidemiological studies and outbreak response as these patients may not seek medical attention when the isolation of <i>Bordetella pertussis</i> by culture or PCR would be likely. At this time, the serologic test results should not be relied for case confirmation of pertussis infection. This assay should not be used to and assess susceptibility/immunity to pertussis or for clinical diagnosis. It is limited to <u>surveillance</u> purposes only.	
Method:	ELISA	
Interfering Substances:	Cannot test specimen from patients vaccinated against B. pertussis toxin within the last 6	
Testing Site:	months or from patients <11 years of age.	
Comment:	This test is used for surveillance purpose only.	

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TEST:	Borrelia burgdorferi Serology
1251.	(Tick-borne Disease Panel)
Synonym:	Borrelia burgdorferi IgG/IgM Antibody, Lyme Disease Refer to instructions in Tick-Borne Disease Panel
Laboratory (Dhana)	
Laboratory/Phone:	443-681-3938/3931
Specimen Required:	Serum
Results and Interpretation:	<ul> <li>NON-REACTIVE. Indicates no detectable antibodies to Borrelia burgdorferi. A negative result does not exclude a Lyme disease infection. Patients with early stages of infection or who have undergone antibiotic therapy may not produce measurable IgG/IgM antibodies. Additional specimens should be submitted in 2-4 weeks if Borrelia burgdorferi exposure has not been ruled out.</li> <li>REACTIVE. Antibodies to Borrelia burgdorferi have been detected. Sera from individuals with other pathogenic spirochetal diseases, bacterial and viral infections, and individuals with connective tissue autoimmune diseases or anti-nuclear antibody may also have antibodies which cross-react with B. burgdorferi.</li> <li>EQUIVOCAL—Immunological status cannot be determined, please re-draw patient in 2-4 weeks</li> </ul>
Additional Information:	http://www.cdc.gov/lyme/
Purpose of Test:	For the detection IgG/IgM antibodies to Borrelia burgdorferi
Methods:	CLIA—Chemiluminescent Immunoassay, Western Blot
Comment:	Your health care provider has ordered a laboratory test for the presence of Lyme Disease for you. Current Laboratory testing for Lyme Disease can be problematic and standard laboratory tests often result in false negative and false positive results, and if done too early, you may not have produced enough antibodies to be considered positive because your immune response requires time to develop antibodies. If you are tested for Lyme Disease and the results are negative, this does not necessarily mean you do not have Lyme Disease. If you continue to experience unexplained symptoms, you should contact your health care provider and inquire about the appropriateness of retesting or initial or additional treatment. The Western blot test will be used to confirm the presence of <i>B. burgdorferi</i> specific antibodies detected by the CLIA screening test on all Positive & Equivocal specimens.

TEST:	Botulism (Clostridium botulinum–Adult and Clostridium botulinum–Infant)
	Must have consent of the State Epidemiologist before sending specimen to the
	Laboratory (410-767-6685).
Synonym:	Botulism; Clostridium botulinum: Refer to instructions for Clostridium botulinum-Adult
	and <i>Clostridium botulinum</i> –Infant.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Brucella serology (CDC Referral)	
Synonym:	Bang's Disease, Undulant fever, Malta Fever	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	2 weeks (CDC Referral)	
Specimen Required:	Serum	
Specimen identification:	Label tube with patients first and last name. The specimen/sample must be properly labeled and match the test requisition or electronic test order.	
Specimen Volume (Optimum):	2 ml. (Whole Blood)	
Specimen Volume (Minimum):	1 ml. (Whole Blood)	
Collect:	Red-top vacutainer	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	Transport whole blood or separated serum at 2-8°C on cold packs. Serum can also be transported at -20°C or colder and shipped on dry ice. WHOLE BLOOD CANNOT BE FROZEN	
Specimen Rejection Criteria:	Hemolysis; insufficient volume	
Availability:	Monday through Friday	
Results and Interpretation:	Given on CDC report	
Additional Information:	http://www.cdc.gov/brucellosis/index.html	
Purpose of Test:	Detect antibody to Brucella	
Method:	Brucella microagglutination test (BMAT)	
Interfering Substances:	No serology available for B. canis or RB51. May have poor sensitivity for chronic or complicated brucellosis.	
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	Contact the MD Department of Health Epidemiologist at (410)767-6700 for prior approval of specimen submission. Required supplemental information: Exposure and travel history, include other relevant risk factors; clinical symptoms, treatment and relevant lab results.	

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TEST:	Brucella species, culture
Synonym:	Bang's Disease, Undulant fever, Malta Fever, and Rock of Gibraltar Fever
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952
Turnaround Time:	5 - 30 days [from specimen receipt in the Laboratory]
Specimen Required:	1. Blood or bone marrow
	2. Spleen, liver or abscess
	3. Serum-acute and convalescent-phases
	4. Isolate
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must
	be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	N/A
Specimen Volume (Minimum):	N/A
	Continued Next Page>

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Collect:	<ol> <li>Blood: Collect appropriate blood volume and number of sets per routine laboratory protocol. Specimens should be inoculated into appropriate culture media within two (2) hours of collection.</li> </ol>
	2. Biopsied Tissue: Collect per laboratory protocol. Tissues must be kept moist; add several drops of sterile saline if necessary.
	3. Serum: At least 1 ml of serum. Follow standard laboratory protocol. Preferably serum refrigerated.
	4. Isolate: Pure culture, 24 hours old, growing on a sheep blood agar plate or slant.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	1. Blood Cultures: Transport at room/ambient temperature (2-30 °C). DO NOT
	REFRIGERATE.
	2. Tissue: Transport at room/ambient temperature (2-30 °C) within 1 hour of
	collection, adding several drops of sterile normal saline to keep tissues moist for
	immediate processing. For transport time > 1 hour, transport at 2-8°C on cold pack
	3. Serum: Transport at 2-8°C on cold packs.
	4. Isolates: Transport at room/ambient temperature (2-30 °C) on a sealed sheep bloo
	agar plate or slant.
Specimen Rejection Criteria	The following rejection criteria are designed to prevent the reporting of inaccurate
	results and to avoid misleading information that might lead to misdiagnosis and
	inappropriate therapy. A request for a new specimen will provide appropriate materials
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> </ul>
Availability:	24 hours/day, 7days/week
Results and Interpretation:	Brucella species isolated/detected
nesates and interpretation.	Brucella species not found
Additional Information:	Call 410-925-3121 before sending specimen to the Laboratory.
Purpose of Test:	To confirm the diagnosis of Brucella species.
Method:	LRN protocols
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
<u> </u>	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Brucella species are highly infectious. PLEASE use a biological safety cabinet when
	working with specimens suspected of being Brucella species.
	Call 410-925-3121 before sending to the laboratory.

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TEST:	Burkholderia mallei and Burkholderia pseudomallei
Synonym:	B. mallei is the causative agent of Glanders; and
	B. pseudomallei is the causative agent of Melioidosis
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952
Turnaround Time:	4 - 8 days [from specimen receipt in the Laboratory]
Specimen Required:	1. Blood: Collect blood specimens before antibiotics are administered.
	2. Urine
	3. Abscesses, tissue aspirates, body fluids: Collect tissues and fluids rather than swabs,
	when possible.
	4. Isolate
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must
	be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	1. Blood: Collect appropriate volume and number of sets per laboratory protocol.
	2. Urine: 5 ml.
	<ol> <li>Abscesses, tissues and body fluids: Collect per routine laboratory protocol.</li> </ol>
Specimen Volume (Minimum):	N/A
Collect:	1. Blood: Collect appropriate blood volume and number of sets as per routine
	laboratory protocol.
	<ol> <li>Urine: Collect 5 ml. of midstream clean-catch specimen or a cauterization specimen.</li> </ol>
	3. Abscesses, tissues aspirates, body fluids: Collect tissues and body fluids rather than
	swabs.
	4. Isolate: Pure culture, 24 hours old, growing on a sheep blood agar plate or slant.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
Torm.	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	1. Blood Cultures: Transport at room/ambient temperature (2-30 °C). DO NOT
	REFRIGERATE.
	<ol> <li>Urine: Transport in a sterile, well-sealed container at 2-8°C on cold packs.</li> </ol>
	<ol> <li>Abscesses, tissues, and fluids: Transport at room/ambient temperature (2-30 °C)</li> </ol>
	within 1 hour of collection. For transport time $> 1$ hour, transport at 2-8°C on cold
	packs.
	4. Isolate: Transport the specimen at room/ambient temperature (2-30 °C) on a sealed
	sheep blood agar plate or slant.
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate
specificit rejection citteria.	results and to avoid misleading information that might lead to misdiagnosis and
	inappropriate therapy. A request for a new specimen will provide appropriate materials
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> <li>Declar specimen (complex specimen)</li> </ul>
	<ul> <li>Broken specimen/sample container</li> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
	24 hours/day, 7 days/week
Availability:	
Availability: Results and Interpretation:	B. mallel/B. pseudomallel isolated/detected.
Availability: Results and Interpretation:	<i>B. mallei/B. pseudomallei</i> isolated/detected.
Results and Interpretation:	B. mallei/B. pseudomallei not found.
Results and Interpretation: Additional Information:	B. mallei/B. pseudomallei not found.Call 410-925-3121 before sending specimen to the Laboratory.
Results and Interpretation:	B. mallei/B. pseudomallei not found.

Comment:	Call 410-925-3121 before sending to the Laboratory.
	1770 Ashland Avenue, Baltimore, Maryland 21205
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
Interfering Substances:	N/A

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TEST:	C. difficile Toxin (A and B)
Synonym:	Clostridium difficile toxin, C. diff
Laboratory/Phone:	Microbiology: 443-681-3952
Turnaround Time:	Two (2) days [from specimen receipt in the Laboratory]
Specimen Required:	Fresh, unpreserved stool specimen
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must
	be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Two (2) grams
Specimen Volume (Minimum):	N/A
Collect:	Stool in a clean screw cap specimen collection cup without preservatives
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured, or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: Store and transport at 2-8°C on cold packs within 72 hours
Transport conditions.	of collection. If >72 hours after collection store and transport at -20C or colder on dry ice.
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate
specimen Rejection chiena.	results and to avoid misleading information that might lead to misdiagnosis and
	inappropriate therapy. A request for a new specimen will provide appropriate materials
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
	<ul> <li>Expired transport media</li> <li>Formed stool</li> </ul>
	<ul> <li>Stool preserved in 10% formalin, SAF, or PVA</li> </ul>
Availability:	
Availability:	Monday through Friday
Results and Interpretation:	Positive (Toxin A and/or Toxin B present) or Negative (No Toxin A or Toxin B detected)
Reference Range:	Negative
Additional Information:	<i>Clostridium difficile</i> can be grown and isolated on a stool culture, but its presence does
	not indicate whether the strain present is a toxin producer. It also does not distinguish
	between <i>C. difficile</i> colonization and overgrowth/infection.
Purpose of Test:	The <i>Clostridium difficile</i> toxin test is used to diagnose antibiotic-associated diarrhea and
	pseudomembranous colitis that is caused by <i>C. difficile</i> . It may also be ordered to detect
	recurrent disease.
Method:	EIA (Enzyme Immunoassay)
Interfering Substances:	N/A
Testing Site:	Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	This test does not differentiate between Toxin A and Toxin B.



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TEST:	<i>Campylobacter</i> Culture Enteric Culture, Routine ( <i>Salmonella, Shigella, Campylobacter</i> , and Shiga toxins– producing <i>E. coli</i> )
Synonym:	Stool culture for enteric pathogens; enteric pathogens; stool culture and sensitivity; feces culture: Refer to instructions for Enteric Culture, Routine (Salmonella, Shigella, Campylobacter, and Shiga toxins–producing <i>E. coli</i> ).
Laboratory/Phone:	Microbiology-Enterics: 443-681-4570

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TEST: Candida spp. Identification & Susceptibility Synonym: Candida identification, Candida speciation, Candida reference culture/ID, ARLN Candida speciation, ARLN Candida testing Laboratory/Phone: Microbiology/ARLN 443-681-4569 **Turnaround Time:** 14 business days Specimen Required: Isolate subcultures on sabouraud dextrose agar slant with a leak-proof screw top lid. Specimen Identification: Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order. Specimen Volume (Optimum): N/A Specimen Volume (Minimum): N/A Collect: N/A MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or Form: form may be downloaded from MDH Laboratory website). Indicate "ARLN Candida identification" on the form. Indicate specimen type using the "Specimen Code" on form Specimens must be packaged in a triple packaging system to ensure that under normal Packaging and Shipping\*: conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). \*Refer to current Federal regulations for specific shipping requirements. **Transport Conditions:** Store and transport isolate at room/ambient temperature (2-30°C). Specimen Rejection Criteria: The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care. Unlabeled or improperly labeled specimen Non-sterile or leaking container . Inappropriate specimen transport conditions Illegible, or no submitter information on the request form Mismatched form and specimen . Broken specimen/sample container . The wrong specimen for test request Inappropriate outfit for requested test Illegible or no patient information on the specimen . Expired transport media Specimen received after prolonged delay (usually more than 72 hours) . Grossly contaminated specimens Availability: Monday through Friday **Results and Interpretation:** Identification of submitted isolate and antifungal susceptibility testing (AFST) if applicable **Reference Range:** CLSI Guidelines and epidemiological cutoff values Additional Information: N/A Purpose of Test: Identification and if appropriate, antifungal susceptibilities of potentially pathogenic organisms Method: MALDI-TOF for ID, microbroth dilution for AFST **Interfering Substances:** N/A MD Department of Health Laboratories Administration, Central Laboratory Testing Site: 1770 Ashland Avenue, Baltimore, Maryland 21205 Comment: N/A

TEST:	Carbapenem Resistance reference testing
Synonym:	CRE reference testing, carbapenem resistance testing, ARLN CRE testing
Laboratory/Phone:	Microbiology/ARLN 443-681-4569
Turnaround Time:	10 business days
Specimen Required:	Isolate subcultured on agar slant with a leak-proof screw top lid. Isolate submitted should be a pure culture of an Enterobacterales, Pseudomonas aeruginosa, or Acinetobacter baumannii complex that displays characteristics of a carbapenem resistant organism (Intermediate or Resistant to one or multiple of the carbapenems, positive for carbapenemase production, or carries a detected carbapenemase gene).
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	N/A
Specimen Volume (Minimum):	N/A
Collect:	N/A
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate "CRE Testing" on the form.         Indicate specimen type using the "Specimen Code" on form.         Specimens must be packaged in a triple packaging system to ensure that under normal
Packaging and Shipping*:	conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Store and transport isolate at room/ambient temperature (2-30°C).
Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> <li>Broken specimen/sample container</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> <li>Specimen received after prolonged delay (usually more than 72 hours)</li> <li>Specimen grossly contaminated</li> <li>Submitter organism ID does not match MDPHL organism ID</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Identification of submitted isolate and antibiotic susceptibility reported with Minimum inhibitory concentrations with S-I-R interpretations following the Clinical Laboratory Standards Institute (CLSI) criteria for organism. A comprehensive PCR panel of carbapenemase genes and mCIM testing is also performed if applicable.
Reference Range:	CLSI guidelines
Additional Information:	N/A
Purpose of Test:	Identification of carbapenemase-producing carbapenem resistant Enterobacterales, Pseudomonas aeruginosa, or Acinetobacter baumannii complex. This data is used for epidemiological purposes
Method:	MALDI-ToF for ID, Microbroth dilution for AST
Interfering Substances:	Administration of antimicrobial agents before specimen collection
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	

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TEST:	CDC Referrals (Serology)
Synonym:	CDC's Infectious Diseases Laboratories provides an online Test Directory that allows you
	to identify the right test for your needs.
	http://www.cdc.gov/laboratory/specimen-submission/list.html#B
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	Refer to CDC Test Directory
	http://www.cdc.gov/laboratory/specimen-submission/list.html#B
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	See CDC specific transport requirements.
Specimen Rejection Criteria:	Hemolysis; insufficient volume
Availability:	Monday through Friday
Results and Interpretation:	Given on CDC report
Additional Information:	Call 443-681-3938/3931 before sending specimen to State lab.
Purpose of Test:	Detect antibodies which may be due to a particular infectious agent
Methods:	Varies
Interfering Substances:	Icteric, hemolyzed, lipemic specimen
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Contact the MD Department of Health Epidemiologist at (410)767-6700 for prior
	approval of specimen submission. Required supplemental information: Exposure and
	travel history, include other relevant risk factors; clinical symptoms, treatment and
	relevant lab results.

TEST:	Chagas disease Serology
Synonym:	Trypanosoma cruzi
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer tube
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected
	MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Transport whole blood or separated serum at 2-8°C on cold packs. If shipping is delayed beyond 7 days after collection serum must be transported at -20°C or colder and shipped on dry ice. WHOLE BLOOD CANNOT BE FROZEN
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Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, insufficient volume, mismatch between labeling of specimen and test request form, specimen collected > 5 days prior to arrival without being frozen.
Availability:	Monday through Friday
Results and Interpretation:	<ul> <li>NEGATIVE: Antibodies to T. cruzi have not been detected and there is a high probability of non-infection or an early infection with low level of antibody present.</li> <li>EQUIVOCAL: The presence or absence of antibody to T. cruzi cannot be established.</li> <li>POSITIVE: Antibodies to T. cruzi, the causative agent of Chagas' disease were detected.</li> </ul>
Additional Information:	http://www.cdc.gov/parasites/chagas/
Purpose of Test:	Detect antibodies which may be due to Trypanosoma cruzi
Methods:	EIA
Interfering Substances:	Hemolysis
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, MD 21205
Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required. Positive and Equivocal results will be forwarded to CDC for confirmation.

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TEST:	Chancroid Culture (Hemophilus ducreyi)
Synonym:	Haemophilus ducreyi culture: Refer to instructions for Hemophilus ducreyi Culture.
Laboratory/Phone:	Microbiology: 443-681-4570

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TEST:	Chikungunya IgM Serology
	(Arbovirus Travel-Associated Panel)
	Test available based on patient's travel history.
Synonym:	Arthropod-borne virus: Chikungunya Virus
	Refer to instructions in Arbovirus Travel-Associated Panel
Laboratory/Phone:	443-681-3931/3936
Results and Interpretation:	Negative:         No detectable IgM antibody, The result does not rule out Chikungunya virus infection. An additional sample should be tested within 7-14 days if early infection is suspected.           Equivocal:         Chikungunya virus IgM antibody cannot be determined, further testing by PRNT (plaque reduction neutralization test) is required.           Positive:         Presence of detectable IgM antibody, presumptive infection with Chikungunya virus. Confirmatory testing by PRNT (plaque reduction neutralization test) is required. A positive IgM result may not indicate a recent infection because IgM may persist for several months after infection.
Additional Information:	https://www.cdc.gov/chikungunya/
Purpose of Test:	For the presumptive detection of IgM antibody to Chikungunya Virus. Confirmatory testing by PRNT may be required.
Method:	EIA (Screening) & PRNT (Plaque Reduction Neutralization Test) referral to the Centers for Disease Control and Prevention (CDC) for confirmatory testing.
Comment:	Results are for epidemiological purposes only. Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required.

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TEST:	Chlamydia Cell Culture
Synonym:	
Laboratory/Phone:	443-681-3937
Turnaround Time:	10 business days
Specimen Required:	Swab: endocervix, urethra, conjunctiva, nasopharynx, throat, rectum, vagina. For other
	sources, call lab to discuss.
	Place swab in FlexTrans <sup>™</sup> transport tube. (Check expiration date of transport media.)
Specimen Identification:	The specimen/sample must be properly labeled and include:
	1. The patient's name or unique patient/sample identifier matching the test
	requisition or electronic test order,
	2. If appropriate, the date and time of specimen/sample collection, and
	3. Any additional information relevant and necessary for the test.
Specimen Volume (Optimum):	3ml of media already in transport tube
Specimen Volume (Minimum):	3ml of media already in transport tube
Collect:	Swab placed in FlexTrans™ transport media, or other commercial media stating it is
	appropriate for Chlamydia
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order forms at: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Chlamydia trachomatis is located under Virus/Chlamydia heading. Indicate specimen
	type next to test requested using the "Specimen Code' on form.
Packaging and Shipping*:	Place tube in a sealed, biohazard transport bag with form in outer pocket
Transport Conditions:	Per FDA Packet Insert: Prior to use, store FlexTrans <sup>™</sup> transport media at room
	temperature, 2-8°C or -70°C. After collection, store specimen tubes at 2-8°C for up to 48
	hours. All collected specimens are to be transported on cold packs at 2-8°C to the
	laboratory immediately after collection. Must reach the lab within 2 days of collection. If
	the specimen cannot be processed within 2 days, freeze and transport at -70°C or colder
	on dry ice; however, freezing should be avoided if possible.
Specimen Rejection Criteria:	Too old, No patient ID on specimen, leaked, quantity not sufficient, no swab, expired
specifien Rejection Chiena.	transport, out of temp. range, no specimen received, broken, improper swab or
	collection kit, improper collection site, thick mucus, gross contamination, illegible ID,
	missing or incomplete lab slip (no site, date, gender, patient info., submitter info.),
	mismatched patient ID.
Availability:	Monday-Friday
Results and Interpretation:	Chlamydia spp. Isolated in cell culture.
Results and interpretation.	Chlamydia trachomatis not Isolated in cell culture.
	Chlamydia trachomatis toxic in cell culture. Resubmit.
Reference Range:	Not applicable.
Additional Information:	This test is limited to medico-legal specimens: cervical, rectal, male urethral; and non-
Additional mormation.	cervical, non-rectal, and non-male urethral specimens.
Purpose of Test:	Diagnostic, qualitative detection of Chlamydia
Method:	Cell culture
Interfering Substances:	A negative result does not exclude the possibility of infection. Interpret results in
	conjunction with other information.
	Do not use FlexTrans™ if leakage, evaporation, contamination, or pH changes are
	apparent.
	Prior to use, store FlexTrans™ transport media at room temperature, 2-8°C or -70°C.
	This culture confirmation kit will yield positive results with all <i>Chlamydia trachomatis</i>
	types as well as other Chlamydial species but will not differentiate between them.
Tosting Sito:	MDH Laboratories Administration, Central Laboratory
Testing Site:	1770 Ashland Avenue Baltimore, MD 21205
Commont:	
Comment:	

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TEST:	Chlamydia Serology
Synonym:	Chlamydia Group antigen antibody (IgG) EIA
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer tube
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form. Date specimen collected
	MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured, or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: For up to 2 days after collection, transport whole blood or
	separated serum at 2-8°C on cold packs. If >2 days after collection, transport serum at -
	20°C or colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN
Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, insufficient
	volume, mismatch between labeling of specimen and test request form, specimen
	collected > 2 days prior to arrival without being frozen.
Availability:	Monday through Friday
Results and Interpretation:	POSITIVE—Detectable IgG Chlamydial antibodies. Suggest immunological exposure to
	one or more chlamydial species.
	NEGATIVE—No detectable IgG Chlamydial antibodies. Suggest no prior immunological
	exposure to chlamydial species. Does not rule out recent exposure and collection of
	sample prior to development of IgG antibodies.
	EQUIVOCAL—Immunological exposure cannot be assessed.
Additional Information:	This test is not intended to replace culture
Purpose of Test:	For the detection of antibody to Chlamydia group antigen
Method:	EIA
Interfering Substances:	Hemolysis
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	This test does not differentiate between different species of Chlamydia. Serologic results
	should not be used as a sole means for diagnosis, treatment, or for the assessment of a
	patient's health. Clinical correlation is required

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TEST: Chlamydia trachomatis and Neisseria gonorrhoeae **Nucleic Acid Amplification Test (NAAT)** Synonym: Hologic Panther<sup>®</sup> Aptima<sup>®</sup> Combo 2 Assay Laboratory/Phone: Chlamydia Laboratory / 443-681-3937 Turnaround Time: Within 7 business days Specimen Required: Endocervical specimen with unisex swab Male urethral specimen with unisex swab Rectal specimen with multitest swab Vaginal self-collected specimen with multitest swab Vaginal clinician-collected specimen with multitest swab Pharyngeal specimen with multitest swab Male and female urine (first of the void) Label specimen with the full name exactly matching test requisition and date of Specimen identification: collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order. Continued Next Page>

Swab: Tube, Prefilled with 2.9 ml of preservation media. Urine: Optimal quality specimen is 20-30 ml of "first of the void" urine collected in a plastic collection cup. Swirl to mix. Using a sterile transfer pipette, transfer 2 ml from cup into labeled Hologic urine transport tube, prefilled with 2.0 ml of preservation media so volume falls between the two fill lines on the tube. Do not surpass the fill line. Swab: Tube, Prefilled with 2.9 ml of preservation media. Urine: Collect a minimum of 4ml (20-30 best) in a plastic collection cup. Using a sterile transfer pipette, transfer 2 ml from cup into labeled HOLOGIC urine tube prefilled with 2.0 ml of preservation media so volume falls between the two fill lines on the tube. Volume must be above the lower fill line. Swab: HOLOGIC Unisex Collection Kit or Vaginal collection kit for HOLOGIC Aptima 2 Urine: Sterile, preservative-free, leakproof, plastic specimen collection. Collect 20-30 ml of "first of the void urine." Transfer 2ml of swirled neat urine into the HOLOGIC collection tube between the two fill lines. Replace cap tightly.
Swab: Tube, Prefilled with 2.9 ml of preservation media. Urine: Collect a minimum of 4ml (20-30 best) in a plastic collection cup. Using a sterile transfer pipette, transfer 2 ml from cup into labeled HOLOGIC urine tube prefilled with 2.0 ml of preservation media so volume falls between the two fill lines on the tube. Volume must be above the lower fill line. Swab: HOLOGIC Unisex Collection Kit or Vaginal collection kit for HOLOGIC Aptima 2 Urine: Sterile, preservative-free, leakproof, plastic specimen collection cup. <b>The patient should not have urinated for at least 1 hour prior to specimen collection.</b> Collect 20-30 ml of "first of the void urine." Transfer 2ml of swirled neat urine into the HOLOGIC
Urine: Sterile, preservative-free, leakproof, plastic specimen collection cup. <b>The patient</b> <b>should not have urinated for at least 1 hour prior to specimen collection.</b> Collect 20-30 ml of "first of the void urine." Transfer 2ml of swirled neat urine into the HOLOGIC
MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777) Indicate specimen type next to test requested using the "Specimen Code" on form.
Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Per FDA Assay Packet Insert: Urogenital (cervical and urethral) swab specimens: Transport and store the swab in the swab specimen transport tube at 2°C to 30°C until tested. Specimens must be assayed within 60 days of collection. If longer storage is needed, freeze urogenital specimens in the swab specimen transport tube within 7 days of collection and transport at -20°C to -70°C on dry ice. Extragenital (throat and rectal) swab specimens: Transport and store the swab in the swab specimen transport tube between 2°C to 30°C, or if longer storage is needed -20°C to -70°C and transport on dry ice until tested. Specimens must be assayed within 60 days of collection. Urine specimens: Maintain urine specimen at 2°C to 30°C after collection and transfer to the Aptima urine specimen transport tube within 24 hours of collection (this is considered a processed sample). Transport to the lab in the primary collection container or preferably, the transport tube at 2°C to 30°C. Store at 2°C to 30°C and test the processed urine specimens within 30 days of collection. If longer storage is needed, freeze urine specimens in the Aptima Urine Specimen Transport Tube within 7 days of collection at -20°C to -70°C and transport dry ice. Swabs: 2-30°C. Must test within 60 days of collection.
Too old, No patient ID on specimen, >30 ml of collected urine, leaked, quantity not sufficient, no swab, two swabs, expired transport, out of temp. range, no specimen received, broken, improper swab or collection kit, improper collection site, thick mucus, illegible ID, missing or incomplete lab slip (no site, date, gender, patient info., submitter info.), mismatched patient ID.
<ul> <li>Monday-Friday</li> <li>Chlamydia trachomatis RNA was detected by Nucleic Acid Amplification using the Transcription Mediated Amplification (TMA) method.</li> <li>Chlamydia trachomatis RNA was not detected by Nucleic Acid Amplification using the Transcription Mediated Amplification (TMA) method.</li> <li>The specimen was Equivocal for Chlamydia trachomatis by Nucleic Acid Amplification using the Transcription Mediated Amplification (TMA) method.</li> <li>The specimen was Equivocal for Chlamydia trachomatis by Nucleic Acid Amplification using the Transcription Mediated Amplification (TMA) method. Specimen recollection is required for accurate determination.</li> <li>Neisseria gonorrhoeae was detected by Nucleic Acid Amplification using the Transcription Mediated Amplification (TMA) method.</li> <li>Neisseria gonorrhoeae was not detected by Nucleic Acid Amplification using the Transcription Mediated Amplification (TMA) method.</li> </ul>
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Reference Range:	Not applicable.
Additional Information:	Restricted testing (preapproved submitters only, call 443-681-3937)
Purpose of Test:	Direct, qualitative detection of Chlamydia trachomatis and Neisseria gonorrhoeae RNA .
Method:	Transcription Mediated Amplification (TMA)
Interfering Substances/Limitations:	Interfering substances:
	None
	Limitations:
	Assay cannot determine specimen adequacy. Proper collection is imperative.
	A negative test result does not exclude the possibility of infection. Interpret result in conjunction with other information.
	Therapeutic failure or success cannot be determined with the Aptima Combo 2 Assay
	since nucleic acid may persist following appropriate antimicrobial therapy.
	Only cell culture isolation should be used when testing for the evaluation of suggested sexual abuse or other medico-legal purposes.
	The Aptima Combo 2 Assay provides qualitative results. Therefore, a correlation cannot be drawn between the magnitude of a positive assay signal and the number of organisms in a specimen.
	Performance of this assay has not been evaluated for patients less than 14 years old. Vaginal self-collected specimens are not approved for home use or outside clinical setting.
	The presence of mucus inhibits the proper sampling of columnar epithelial cells in endocervical specimens.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Rectal and pharyngeal specimens are not an FDA approved specimen type for the
	Hologic <sup>®</sup> Aptima <sup>®</sup> Combo 2 Assay. Performance characteristics of the assay using rectal and pharyngeal specimens were validated by the MDH Laboratories.

TEST:	Clostridium botulinum-Adult
	MUST HAVE CONSENT OF THE STATE EPIDEMIOLOGIST BEFORE SENDING
	SPECIMEN TO THE LABORATORY (410-767-6685).
Synonym:	Botulism
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952
Turnaround Time:	3-7 days [from specimen receipt in the Laboratory]
Specimen Required:	Suspected foodborne botulism cases:
	Suitable specimens for examination are: serum, feces, vomitus, gastric contents.
	Suspected wound botulism cases:
	Suitable specimens for examination are: serum, tissue, feces.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must
	be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Serum: At least 10 ml (obtained from using at least 20 ml of whole blood).
Specimen Volume (Minimum):	N/A
Collect:	Serum: Collect using routine laboratory protocol using the red top or separator type
	tube (NO anticoagulants).
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Serum: Transport to the laboratory at 2-8°C on cold packs.
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate
	results and to avoid misleading information that might lead to misdiagnosis and
	inappropriate therapy. A request for a new specimen will provide appropriate materials
	and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
Availability:	24 hours/day, 7 days/week
Results and Interpretation:	Clostridium botulinum toxin detected/not detected.
Additional Information:	To request botulism testing for a suspect case, contact the MDH Infectious Disease
	Bureau at 410-767-6700 during business hours and after hours call the MDH
	Emergency Call Center at 410-795-7365 to arrange for an initial infectious disease
	consultation.
Purpose of Test:	To confirm the presence of <i>Clostridium botulinum</i> toxins
Method:	LRN Methods
Interfering Substances:	If the patient has been taking any medication that might interfere with toxin assays or
	culturing of the stool, the Laboratory should be notified. For example, it has been
	demonstrated that anticholinesterase drugs given orally to patients for myasthenia gravis
	can interfere with mouse botulinum toxin assays of stool extracts.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
C C	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	PHYSICIAN MUST CALL FOR A CONSULT BEFORE SENDING SPECIMEN. SPECIMENS ARE NOT
	PROCESSED UNTIL THE CASE IS APPROVED FOR TESTING. Contact the MDH Infectious
	Disease Bureau at 410-767-6700 during business hours and after hours call the MDH
	Emergency Call Center at 410-795-7365 to arrange for an initial infectious disease
	consultation.

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TEST:	Clostridium botulinum–Infant
	MUST HAVE CONSENT OF THE STATE EPIDEMIOLOGIST BEFORE SENDING
	SPECIMEN TO THE LABORATORY (410-767-6685).
Synonym:	Botulism
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952
Turnaround Time:	3-30 days [from specimen receipt in the Laboratory]
Specimen Required:	Suspected infant botulism cases:
	Suitable specimens: Stool, rectal swabs (not necessary to collect serum.)
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Stool: 10-50 grams (English walnut size)
Specimen Volume (Minimum):	N/A
Collect:	Stool: Collect in a sterile, well-sealed, unbreakable container. Ship on cold packs. If
	delayed, freeze stool specimen and ship frozen.
	Enema (if needed): Use minimal amount of sterile water or non-bacteriostatic water,
	place 20 ml of liquid into a sterile, well-sealed, unbreakable container.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
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Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
Packaging and Shipping *:	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Stool: Transport to the laboratory at 2-8°C on cold packs.
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results
	and to avoid misleading information that might lead to misdiagnosis and inappropriate
	therapy. A request for a new specimen will provide appropriate materials and clinically
	relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
Availability:	24 hours/day, 7 days/week
Results and Interpretation:	Clostridium botulinum toxin detected/not detected.
Additional Information:	To request botulism testing for a suspect case, contact the MDH Infectious Disease Bureau at 410-767-6700 during business hours and after hours call the MDH
	Emergency Call Center at 410-795-7365 to arrange for an initial infectious disease consultation.
Purpose of Test:	To confirm the presence of Clostridium botulinum toxin in the specimen.
Method:	LRN Methods
Interfering Substances:	Glycerin Enema will interfere with the recovery of Clostridium botulinum toxin.
	If the patient has been taking any medication that might interfere with toxin assays or
	culturing of the stool, the Laboratory should be notified. For example, it has been
	demonstrated that anticholinesterase drugs given orally to patients for myasthenia gravis
	can interfere with mouse botulinum toxin assays of stool extracts.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	PHYSICIAN MUST CALL FOR A CONSULT BEFORE SENDING SPECIMEN. SPECIMENS ARE NOT
comment.	PROCESSED UNTIL THE CASE IS APPROVED FOR TESTING. Contact the MDH Infectious
	Disease Bureau at 410-767-6700 during business hours and after hours call the MDH
	Emergency Call Center at 410-795-7365 to arrange for an initial infectious disease consultation.

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TEST:	Clostridioides difficile toxin
Synonym:	C. diff, C. difficile Toxin (A and B): refer to instructions for C. diff Toxin
Laboratory/Phone:	Microbiology 443-681-3952

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TEST:	Clostridium perfringens Culture
Synonym:	Clostridium perfringens Culture: Refer to instructions for Foodborne Pathogens (Bacillus
	cereus, Clostridium perfringens, Staph aureus).
Laboratory/Phone:	Microbiology 443-681-3952

TEST:	Corynebacterium diphtheriae culture (Diphtheria)
Synonym:	Corynebacterium diphtheriae culture: Refer to instructions for Diphtheria Culture.
Laboratory/Phone:	Microbiology / 443-681-3952

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TEST:	Coxiella Serology	
Synonym:	Coxiella burnetii, Q fever	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	5 business days	
Specimen Required:	Serum	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	2 ml. (Whole Blood)	
Specimen Volume (Minimum):	1 ml. (Whole Blood)	
Collect:	Red-top vacutainer tube	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	Per FDA Assay Packet Insert: For up to 5 days after collection, transport whole blood or	
	separated serum at 2-8°C on cold packs. If > 5 days after collection, transport serum at	
	-20°C or colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN.	
Specimen Rejection Criteria:	Hemolysis; insufficient volume, specimen collected > 5 days prior to arrival without being frozen	
Availability:	Monday through Friday	
Results and Interpretation:	Titer ≥ 1:16 in both Phase I and Phase II antigen suggests a C. burnetii infection. Phase I antibody titers of greater than or equal to Phase II antibody titers are consistent with a chronic infection or convalescent phase Q fever.	
	Titers < 1:16 in Phase I with titers >1:256 in Phase II antigen suggests a C. burnetii infection.	
	Titer < 1:16 in both Phase I and Phase II antigen. No antibody detected. This result is seen in persons with either no C. burnetii infection or with an early infection. If Q fever is suspected, collect a second specimen in 2-3 weeks.	
	A 4-fold IgG antibody endpoint titer increase is considered supportive evidence of current or recent acute infection.	
Additional Information:	http://www.cdc.gov/qfever/	
Purpose of Test:	Detect IgG antibodies which may be due to Coxiella burnetii infections	
Methods:	Hemolysis, lipemia	
Interfering Substances:	Icteric, hemolyzed, lipemic specimen	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, MD 21205	
Comment:	Serologic responses are time dependent. Specimens obtained too early in the infection may not contain detectable antibody levels. If Q fever is suspected obtain a second specimen 2-3 weeks later.	

TEST:	Coxsackie Virus, Virus Culture
Synonym:	Coxsackie Virus: Refer to instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934

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TEST:	Cryptococcal antigen	
Synonym:	Cryptococcus neoformans antigen	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	5 business days	
Specimen Required:	Serum or cerebrospinal fluid (CSF)	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	2 ml. (Whole Blood & CSF)	
Specimen Volume (Minimum):	1 ml. (Whole Blood & CSF)	
Collect:	Red Top vacutainer tube (Whole blood); CSF (Sterile container)	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Transport whole blood, separated serum, or CSF at 2-8°C on cold packs. Serum and CSF can also be transported at -20°C or colder and shipped on dry ice. WHOLE BLOOD CANNOT BE FROZEN	
Specimen Rejection Criteria:	Hemolysis; insufficient volume	
Availability:	Monday through Friday	
Results and Interpretation:	<ul> <li>POSITIVECryptococcus neoformans antigen detected. Additional follow-up and culture strongly recommended.</li> <li>NEGATIVE—Cryptococcus neoformans antigen not detected. If status of patient suggests a cryptococcal infection, subsequent specimens and culture strongly recommended.</li> </ul>	
Additional Information:		
Purpose of Test:	For the detection of <i>Cryptococcus neoformans</i> capsular polysaccharide antigens in serum or CSF	
Method:	Latex agglutination	
Interfering Substances:	Macroglobulins (e.g. Rheumatoid factors), hemolysis, lipemic	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required.	

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TEST: Cysticercosis serology (CDC Referral)		
Synonym:	Neurocysticercosis, Taenia solium, cysitcercus	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	18 business days (CDC Referral)	
Specimen Required:	Serum, CSF	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order	
Specimen Volume (Optimum):	2 ml. (Whole Blood & CSF)	
Specimen Volume (Minimum):	0.5 ml. (Whole Blood & CSF)	
Collect:	Red-top vacutainer tube (serum); lavender- top vacutainer tube (plasma); sterile container (CSF)	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal	
	conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance).	
	*Refer to current Federal regulations for specific shipping requirements.	

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Transport Conditions:	Per CDC guidelines: For up to 7 days after collection: transport whole blood, separated
	serum, and CSF at 2-8°C on cold packs. If > 7 days after collection, transport serum and CSF
	at -20°C or colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Availability:	Monday through Friday
Results and Interpretation:	Given on CDC report
Additional Information:	http://www.cdc.gov/parasites/cysticercosis/
Purpose of Test:	For the detection of an antibody response to cysticerci lesions.
Method:	Immunoblot, Western blot, Antibody detection
Interfering Substances:	Substance known to interfere with immunoassays include: bilirubin, lipids, and
	hemoglobin
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, MD 21205
Comment:	Contact the MD Department of Health Epidemiologist at (410)767-6700 for prior
	approval of specimen submission. Required supplemental information: Exposure and
	travel history, include other relevant risk factors; clinical symptoms, treatment and
	relevant lab results.

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TEST:Cytomegalovirus (CMV) CultureSynonym:Cytomegalovirus (CMV): Refer to instructions for Virus Culture.Laboratory/Phone:Virology: 443-681-3934

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TEST:	Cytomegalovirus Serology	
Synonym:	CMV, Cytomegalovirus IgG antibody	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	5 business days	
Specimen Required:	Serum	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique	
	patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	2 ml. (Whole Blood)	
Specimen Volume (Minimum):	1 ml. (Whole Blood)	
Collect:	Red-top vacutainer tube	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be	
	downloaded from MDH Laboratory website).	
	Indicate specimen type using the "Specimen Code" on form. Date specimen collected	
	MUST be provided.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal	
	conditions of transport they cannot break, be punctured or leak their contents (Refer to	
	pages 9 & 10 for triple packing guidance).	
	*Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	Per MDH Lab Specimen Stability Study: For up to 7 days after collection transport whole	
	blood or separated serum at 2-8°C on cold packs. If shipping is delayed beyond 7 days,	
	serum must be transported at -20°C or colder and shipped on dry ice. WHOLE BLOOD	
	CANNOT BE FROZEN.	
Specimen Rejection Criteria:	Grossly hemolyzed, icteric, or lipemic specimens, unlabeled specimens, leaking container,	
	insufficient volume, mismatch between labeling of specimen and test request form,	
	specimen collected > 7 days prior to arrival without being frozen.	
Availability:	Monday through Friday	
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Results and Interpretation:	POSITIVE Presence of detectable CMV IgG antibodies. A positive result generally
	indicates either recent or past exposure to CMV.
	NEGATIVE—Absence of detectable CMV IgG antibodies. A negative result generally
	indicates that immunity has not been acquired. If exposure to CMV is suspected
	despite a negative finding, a second sample should be collected and tested no less than one or two weeks later.
	EQUIVOCAL—Immunological status cannot be assessed. Please submit another sample in
	one to two weeks.
Additional Information:	
Purpose of Test:	For the detection of antibody to CMV
Method:	CLIA—Chemiluminescent Immunoassay
Interfering Substances:	Hemolysis, lipemia, icterus
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required.

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TEST:	Deerfly fever
Synonym:	Francisella tularensis; Pasteurella tularensis, tularemia, rabbit fever, deerfly fever, Ohara's
	disease, Francis disease: Refer to instructions for Francisella tularensis Culture.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Dengue Fever IgM Serology
	(Arbovirus Travel-Associated Panel)
	Test available based on patient's travel history.
Synonym:	Arthropod-borne virus: Dengue Fever
	Refer to instructions in Arbovirus Travel-Associated Panel
Laboratory/Phone:	443-681-3931/3936
Results and Interpretation:	Negative: No detectable IgM antibody, The result does not rule out Dengue virus
	infection. An additional sample should be tested within 7-14 days if early infection is
	suspected.
	Equivocal: Dengue virus IgM antibody cannot be determined, further testing by PRNT
	(plaque reduction neutralization test) is required.
	<b>Positive:</b> Presence of detectable IgM antibody, presumptive infection with Dengue virus.
	Confirmatory testing by PRNT (plaque reduction neutralization test) is required. A
	positive IgM result may not indicate a recent infection because IgM may persist for
	several months after infection.
Additional Information:	https://www.cdc.gov/dengue/
Purpose of Test:	For the presumptive detection of IgM antibody to Dengue Virus. Confirmatory testing by
	PRNT may be required.
Method:	ELISA (Screening). PRNT (Plaque Reduction Neutralization Test) referral to the Centers
	for Disease Control and Prevention (CDC) for confirmatory testing may be required.
Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the
	assessment of a patient's health. Clinical correlation is required. Results from
	immunocompromised patients must be interpreted with caution. Dengue virus IgM
	serological cross-reactivity with other flavivirus group including Japanese Encephalitis
	(JEV), West Nile Virus (WNV), Zika Virus (Zika), Saint Louis Encephalitis (SLE), and/or
	Yellow Fever (YFV) occurs. Any presumptive Dengue positive sera must be confirmed by
	Plaque Reduction Neutralization Test (PRNT).
	Yellow Fever (YFV) occurs. Any presumptive Dengue positive sera must be confirmed by

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TEST:	Diphtheria Culture
Synonym:	Corynebacterium diphtheriae culture
Laboratory/Phone:	Microbiology 443-681-3952
Turnaround Time:	48-72 hrs. [from specimen receipt in the Laboratory]
Specimen Required:	Respiratory illness: Throat and nasopharyngeal swabs.
	Cutaneous diphtheria: Skin, throat and nasopharynx.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	N/A
Specimen Volume (Minimum):	N/A
Collect:	Swab infected areas thoroughly, getting swab well into membranes or other lesions
	present. Inoculate Stuart Transport Media and break off stick where handled. Leave swab
Fermer	in the tube and tighten cap.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
Turner and Consultation of	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at room/ambient temperature (2-30°C).
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	Expired transport media
Availability:	Monday through Friday
Results and Interpretation:	Definitive identification of <i>Corynebacterium diphtheriae</i> . Toxigenicity testing will follow
	identification (Performed at the CDC).
Reference Range:	Corynebacterium diphtheriae <u>NOT</u> found.
Additional Information:	Take culture before starting antimicrobial therapy – if possible.
Purpose of Test:	Diagnosis of toxigenic strains of <i>Corynebacterium diphtheriae</i> and antibiotic treatment are essential in limiting spread of infection.
Method:	Culture and smear
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	When C. diphtheriae is isolated, the isolate is forwarded to the Centers for Disease Control
	and Prevention (CDC) for detection of the toxin.

 TEST:
 Disk Diffusion Susceptibility Testing

 Synonym:
 Disk Diffusion Susceptibility Testing: Refer to instructions for Antimicrobial Susceptibility Test

 Laboratory/Phone:
 Microbiology 443-681-3952

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TEST:	E. coli O157 typing
Synonym:	Isolate for E. coli O157 serotyping (referral isolate); and other than O157 serotypes.
Laboratory/Phone:	Microbiology-Enterics, 443-681-4570
Turnaround Time:	4 – 10 days [from specimen receipt in the Laboratory]
Specimen Required:	Pure isolate of <i>E. coli</i>
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Sorbitol negative <i>E. coli</i> from culture.
Specimen Volume (Minimum):	N/A
Collect:	N/A
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Store and transport isolate at room/ambient temperature (2-30°C). If specimen sent in
	Gram negative broth MUST be transported at (2-8°C) on cold packs.
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results
	and to avoid misleading information that might lead to misdiagnosis and inappropriate
	therapy. A request for a new specimen will provide appropriate materials and clinically
	relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	Expired transport media
Availability:	Monday through Friday
Results and Interpretation:	E. coli O157 identified and H7 antigens identified.
Reference Range:	No E. coli O157 detected
Additional Information:	Isolates submitted for <i>E. coli</i> O157 typing will be sub-cultured upon arrival and tested for
	shiga toxins, O157 antigen and biochemically identified as well as tested for H7 if needed.
Purpose of Test:	Detect the presence of <i>E. coli</i> O157
Method:	Culture and serotyping
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

TEST:	Eastern Equine Encephalitis Virus Serology (Arbovirus Endemic Panel)
Synonym:	Arthropod-borne virus: EEEV (Eastern Equine Encephalitis Virus)
	Refer to instructions for Arbovirus Endemic Panel.
Laboratory/Phone:	Virology: 443-681-3931/3936
Results and Interpretation:	<u>Megative</u> : No detectable IgM antibody, The result does not rule out Eastern Equine virus
	infection.
	Positive: Presence of detectable IgM antibody, presumptive infection with EEE virus.
	Confirmatory testing by PRNT (plaque reduction neutralization test) is required.

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TEST:	Echinococcus serology (CDC Referral)
Synonym:	Echinococcosis, Hydatitd Disease, Echinococcus granulosus, parasite
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	18 business days (CDC Referral)
Specimen Required:	Serum
Specimen Identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2ml. (Whole Blood)
Specimen Volume (Minimum):	0.5ml. (Whole Blood)
Collect:	Red-top vacutainer tube (serum) Lavendar-top vacutainer (plasma)
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<b>Per CDC Guidelines:</b> For up to 7 days after collection transport whole blood or separated serum at 2-8°C on cold packs. If shipping is delayed beyond 7 days, serum must be transported at -20°C or colder and shipped on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Hemolysis; insufficient volume
Availability:	Monday through Friday
Results and Interpretation:	Given on CDC report
Additional Information:	http://www.cdc.gov/parasites/echinococcosis/
Purpose of Test:	Detect antibodies which may be due Echinococcus parasite infections
Methods:	Immunoblot, Western blot, Antibody detection
Interfering Substances:	Substance known to interfere with immunoassays include: bilirubin, lipids, and hemoglobin
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, MD 21205
Comment:	Contact the MD Department of Health Epidemiologist at (410)767-6700 for prior
	approval of specimen submission. Required supplemental information: Exposure and travel history, include other relevant risk factors; clinical symptoms, treatment, and
	relevant lab results.

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TEST:	Echovirus Culture
Synonym:	Echovirus culture: Refer to instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934

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TEST:	Ehrlichia/Anaplasma Serology (Tick-borne Disease Panel)
Synonym:	Human Monocytic Ehrlichiosis (HME) or <i>Ehrlichia chaffeensis</i> Human Granulocytic Anaplasmosis (HGA) or <i>Anaplasma phagocytophilum</i> <b>Refer to instructions in Tick-Borne Disease Panel</b>
Laboratory/Phone:	443-681-3938/3931
Specimen Required:	Serum
Results and Interpretation:	NEGATIVE—Titer < 1:80 POSITIVE—Titer > 1:320 probable recent infection INDETERMINATE—Titer >1:80 but <1:320, possible early infection/past exposure with falling titers or cross-reactivity with related organism infections.
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The J. Mehsen Joseph Public Health Laboratory

Additional Information:	https://www.cdc.gov/ticks/tickbornediseases/anaplasmosis.html https://www.cdc.gov/ticks/tickbornediseases/ehrlichiosis.html
Purpose of Test:	For the detection of IgG antibodies to Ehrlichia chaffeensis and Anaplasma phagocytophilum
Method:	Immunofluorescence Assay (IFA)
Comment:	May not detect a recent infection, or infection in a person with a severely compromised immune system. A four-fold increase in titer between acute and convalescent serum specimens supports the diagnosis of recent infection. Acute phase sera should be collected within the first week after onset of illness, and convalescent phase sera, 2-4 weeks after onset. Cross reaction between <i>E. chaffeensis, E. canis</i> & <i>E. ewingii</i> infections can occur. Serology cannot differentiate the species.

TEST:	Enteric Culture, Routine
	(Salmonella, Shigella, Campylobacter, and Shiga toxins-producing <i>E. coli</i> )
Synonym:	Stool culture for enteric pathogens; enteric pathogens; stool culture and sensitivity; feces
	culture.
Laboratory/Phone:	Microbiology - Enterics 443-681-4570
Turnaround Time:	Usually four (4) days to several weeks [from specimen receipt in the Laboratory].
Specimen Required:	Stool in stool culture transport media (Para Pak for Enteric pathogens [orange cap]).
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	1-2 grams fresh stool; 5-10 ml if liquid
Specimen Volume (Minimum):	Rectal swab (less effective than stool specimen).
	NOTE: Campylobacter cannot be tested for on specimens submitted on a rectal swab.
Collect:	Fresh stool in Para Pak for enteric pathogens (Cary-Blair transport media), select portion of
	stool containing pus, blood or mucous; rectal swab inserted one (1) inch beyond anal
	sphincter, rotate carefully, withdraw and place in Cary-Blair transport medium.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website). Check Enteric Routine culture
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured, or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Para-Pak Transport Media packet insert: Orange top Para-Pak Transport Media:
	Store and transport at room/ambient temperature (2-30°C).
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Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> <li>Broken specimen/sample container</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> <li>Specimen received after prolonged delay (usually more than 96 hours)</li> <li>Dry specimen</li> <li>Specimen contaminated with urine or water</li> <li>Stool containing barium</li> <li>Insufficient quantity</li> <li>Specimen frozen</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Identification of pathogenic enteric organisms and determination of antimicrobial
	susceptibilities, if clinically appropriate.
Reference Range:	Normal stool flora
Additional Information:	Enteric culture screens routinely for Salmonella, Shigella, Campylobacter, and Shiga toxin – producing <i>E. coli</i> . Yersinia culture and Vibrio culture must be specifically indicated as they are not part of routine testing. Same transport media will support the growth and detection of these organisms. Collect specimens early in the course of enteric disease and prior to antimicrobial therapy. Collect 2 or 3 stools on separate days to increase the likelihood of isolating enteric pathogens. DO NOT COLLECT SPECIMEN FROM THE TOILET. AVOID CONTAMINATION WITH URINE.
Purpose of Test:	Isolation, identification and if clinically appropriate, antimicrobial susceptibilities of potentially pathogenic organisms.
Method:	Culture on selective media, staining, biochemical testing, antimicrobial susceptibility testing; EIA (Enzyme Immuno Assay) for <i>E. coli</i> O157.
Interfering	Administration of antibiotics, barium
Substances/Limitations:	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

TEST:	Enterohemorrhagic Escherichia coli (EHEC)
Synonym:	E. coli O157 typing; Isolate for E. coli O157 serotyping (referral isolate): Refer to
	instructions for <i>E. coli</i> O157 typing.
Laboratory/Phone:	Microbiology-Enterics 443-681-3952

TEST:	Enteroinvasive Escherichia coli (EIEC)
Synonym:	E. coli O157 typing; Isolate for E. coli O157 serotyping (referral isolate): Refer to
	instructions for <i>E. coli</i> O157 typing.
Laboratory/Phone:	Microbiology-Enterics 443-681-3952

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TEST:	Enterovirus Culture
Synonym:	Enterovirus (including Echovirus, Coxsackie, and Polio): Refer to instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934

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TEST:	Epstein Barr Virus Serology		
Synonym:	EBV, Epstein Barr Virus		
Laboratory/Phone:	443-681-3938/3931		
Turnaround Time:	5 business days		
Specimen Required:	Serum		
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique		
	patient/sample identifier matching the test requisition or electronic test order.		
Specimen Volume (Optimum):	2 ml. (Whole Blood)		
Specimen Volume (Minimum):	1 ml. (Whole Blood)		
Collect:	Red-top vacutainer tube		
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be		
	downloaded from MDH Laboratory website).		
	Indicate specimen type using the "Specimen Code" on form. Date specimen collected		
	MUST be provided.		
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal		
	conditions of transport they cannot break, be punctured, or leak their contents (Refer to		
	pages 9 & 10 for triple packing guidance).		
	*Refer to current Federal regulations for specific shipping requirements.		
Transport Conditions:	Per MDH Lab Specimen Stability Study: For up to 7 days after collection transport whole		
	blood or separated serum at 2-8°C on cold packs. If shipping is delayed beyond 7 days,		
	serum must be transported at -20°C or colder and shipped on dry ice. WHOLE BLOOD		
	CANNOT BE FROZEN.		
Specimen Rejection Criteria:	Grossly hemolyzed, icteric, or lipemic specimens, unlabeled specimens, leaking container,		
	insufficient volume, mismatch between labeling of specimen and test request form,		
A	specimen collected > 7 days prior to arrival without being frozen.		
Availability:	Monday through Friday		
Results and Interpretation:	<b>POSITIVE</b> —Antibodies detected (EBNA-1(Epstein Barr Nuclear Antigen) denotes previous		
	infection, VCA (Viral Capsid Antigen)-IgM denotes current or reactivated infection, VCA- IgG denotes current or previous infection, when EA (Early Antigen) & VCA-IgG positive may		
	denote chronic or recurrent illness.)		
	<b>NEGATIVE</b> —Antibodies not detected (EBNA-1, EA, VCA-IgG, presume susceptible to		
	primary infection, VCA IgM presume no active infection)		
	<b>EQUIVOCAL</b> —Immunological status cannot be determined. Please resubmit another		
	specimen in 1-3 weeks.		
Additional Information:			
Purpose of Test:	For the detection of antibodies to EBV		
Method:	CLIA—Chemiluminescent Immunoassay		
Interfering Substances:	Hemolysis, lipemia, icterus		
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory		
	1770 Ashland Avenue, Baltimore, Maryland 21205		
Comment:	This test aids in the diagnosis of Infectious mononucleosis.		
	Serologic results should not be used as a sole means for diagnosis, treatment, or for the		
	assessment of a patient's health. Clinical correlation is required.		

TEST:	Filariasis serology (CDC Referral)	
Synonym:	Wuchereria bancrofti, Brugia malayi, Bancroftian filariasis	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	18 business days (CDC Referral)	
Specimen Required:	Serum	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order	
Specimen Volume (Optimum):	2 ml. (Whole Blood)	
Specimen Volume (Minimum):	0.5 ml. (Whole Blood)	
Collect:	Red-top vacutainer (Serum) or Lavender-top vacutainer (Plasma)	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.	
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	travel history, include other relevant risk factors; clinical symptoms, treatment, and relevant lab results.	
Comment:	Contact the MD Department of Health Epidemiologist at (410)767-6700 for prior approval of specimen submission. Required supplemental information: Exposure and	
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, MD 21205	
Interfering Substances:	Icteric, hemolyzed, lipemic specimen	
Methods:	EIA, ELISA, Antibody Detection	
Additional Information: Purpose of Test:	Detect antibodies to filaria	
Results and Interpretation:	Given on CDC report	
Availability:	Monday through Friday	
Specimen Rejection Criteria:	Hemolysis; insufficient volume	
	colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN.	
Transport Conditions:	<b>Per CDC Guidelines:</b> For up to 7 days after collection, transport whole blood or separated serum at 2-8°C on cold packs. If > 7 days after collection, transport serum at -20°C or	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	

TEST:	Foodborne Pathogens (Bacillus cereus, Clostridium perfringens, Staph aureus)		
Synonym:	Foodborne Pathogenic Microorganisms, Stool Culture for Foodborne Pathogens		
Laboratory/Phone:	Microbiology 443-681-3952		
Turnaround Time:	3 - 5 days [from specimen receipt in the Laboratory]		
Specimen Required:	Stool, unpreserved in sterile specimen container		
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.		
Specimen Volume (Optimum):	4 gm		
Specimen Volume (Minimum):	N/A		
Collect:	Fresh, unpreserved stool in a sterile screw-top container. Submit within 48 hours.		
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.		
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.		
Transport Conditions:	Transport at room/ambient temperature (2-30°C).		
Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> <li>Broken specimen/sample container</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> <li>Stool in preservative</li> <li>Specimen received after prolonged delay (usually more than 72 hours)</li> </ul>		

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Results and Interpretation:	Staph. aureus: Any amount is significant and is reported as rare, few, moderate, or many.	
	Bacillus cereus and Clostridium perfringens: colony count of $\geq$ 100,000 CFU/ml is	
	considered significant.	
Reference Range:	(Staph aureus: Bacillus cereus: Clostridium perfringens) not found after 48 hours	
-	incubation.	
Additional Information:	<b>Bacillus cereus:</b> The symptoms of <i>B. cereus</i> diarrheal type food poisoning mimic those of <i>Clostridium perfringens</i> food poisoning. The onset of watery diarrhea, abdominal cramps, and pain occurs 6-15 hours after consumption of contaminated food. Nausea may accompany diarrhea, but vomiting (emesis) rarely occurs. Symptoms persist for 24 hours in most instances. The emetic type of food poisoning is characterized by nausea and vomiting within 0.5 to 6 hours after consumption of contaminated foods. Occasionally, abdominal cramps and/or diarrhea may also occur. Duration of symptoms is generally less than 24 hours.	
	<ul> <li>Clostridium perfringens: The common form of <i>C. perfringens</i> poisoning is characterized by intense abdominal cramps and diarrhea which begin 8-22 hours after consumption of foods containing large numbers of those <i>C. perfringens</i> bacteria capable of producing the food poisoning toxin. The illness is usually over within 24 hours but less severe symptoms may persist in some individuals for 1 or 2 weeks.</li> <li>Staph. aureus: The onset of symptoms in staphylococcal food poisoning is usually rapid and in many cases acute, depending on individual susceptibility to the toxin, the amount of contaminated food eaten, the amount of toxin in the food ingested, and the general health of the victim. The most common symptoms are nausea, vomiting, retching, abdominal cramping, and prostration. Some individuals may not always demonstrate all the symptoms associated with the illness. In more severe cases, headache, muscle cramping, and transient changes in blood pressure and pulse rate may occur. Recovery generally takes two (2) days; however, it is not unusual for complete recovery to take three (3) days and sometimes longer in severe cases.</li> </ul>	
Purpose of Test:	To detect the presence of bacteria that may be agents of food poisoning, since the presence of any amount of <i>Staph aureus</i> or the presence of large amounts (greater than 100,000 CFU/mI) of <i>Bacillus cereus</i> or <i>Clostridium perfringens</i> is consistent with a potential hazard to health.	
Method:	Culture, isolation and identification of <i>Bacillus cereus</i> , <i>Clostridium perfringens</i> or <i>Staph aureus</i> . Colony count performed on specimens for <i>Bacillus cereus</i> and <i>Clostridium perfringens</i> .	
Interfering Substances:	Stool preservative	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	N/A	

TEST:	Francis disease
Synonym:	Francisella tularensis; Pasteurella tularensis, tularemia, rabbit fever, deerfly fever, Ohara's
	disease, Francis disease: Refer to instructions for Francisella tularensis Culture.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Francisella tularensis Culture	
Synonym:	Pasteurella tularensis, tularemia, rabbit fever, deerfly fever, Ohara's disease, Francis	
	disease	
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:	
	410-925-3121 (24/7 emergency contact number)	
	Select Agents Microbiology Laboratory: 443-681-3954	
	Division of Microbiology Laboratory: 443-681-3952	
Turnaround Time:	2 -7 days [from specimen receipt in the Laboratory]	
Specimen Required:	1. Blood Cultures	
	2. Tissue samples	
	3. Tissue aspirates (Including lymph node and bone marrow)	
	4. Isolate	
	5. Respiratory Specimens: Sputum, BAL, or pleural fluid.	
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,	
	specimen type/source, and the date and time of collection.	
Specimen Volume (Optimum):	N/A	
Specimen Volume (Minimum):	N/A	
Collect:	1. Blood Culture: Collect appropriate blood volume and number of sets per routine laboratory protocol.	
	2. Tissues or scraping of an ulcer is preferable. A swab of the ulcer is an acceptable	
	alternative. Collect in a sterile container. For small amount tissue samples, add	
	several drops of sterile normal saline to keep the tissue moist.	
	3. Swabs: Collect a firm sample of the advancing margin of the lesion. If using a swab	
	transport carrier, the swab should be reinserted into the transport package and the	
	swab fabric moistened with the transport medium inside the packet.	
	4. Aspirate of involved tissue: Collect per routine laboratory protocol.	
	5. Isolate: Pick a pure culture to a chocolate agar plate or slant.	
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or	
	form may be downloaded from MDH Laboratory website).	
	Indicate specimen type using the "Specimen Code" on form.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal	
	conditions of transport they cannot break, be punctured or leak their contents (Refer to	
	pages 9 & 10 for triple packing guidance).	
	*Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	<ol> <li>Blood Cultures: Transport directly to the laboratory at room/ambient temperature (2-30 °C).</li> </ol>	
	2. Tissues: Transport in a sterile container. For a small sample, add several drops of	
	sterile saline to keep the tissue moist. Transport to the laboratory within 1 hour of	
	collection at room/ambient temperature (2-30 °C). For transport time > 1 hour,	
	transport at 2-8°C on cold packs.	
	3. Swabs: Transport to the laboratory 2-8°C on cold packs.	
	4. Aspirates: Transport to the laboratory within 1 hour of collection at room/ambient	
	temperature (2-30 °C). For transport time > 1 hour, transport at 2-8°C on cold packs.	
	5. Isolates: Transport the specimen at room/ambient temperature (2-30 °C) on a sealed	
	chocolate agar plate or slant.	
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results	
	and to avoid misleading information that might lead to misdiagnosis and inappropriate	
	therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.	
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>	
	<ul> <li>Non-sterile or leaking container</li> </ul>	
	<ul> <li>Inappropriate specimen transport conditions</li> <li>Illegible or no submitter information on the request form</li> </ul>	
	<ul> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> </ul>	
	<ul> <li>Broken specimen/sample container</li> </ul>	
	<ul> <li>The wrong specimen for test request</li> </ul>	
	<ul> <li>Inappropriate outfit for requested test</li> </ul>	
	<ul> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> </ul>	
Availability:	24 hrs./day, 7 days/week	
Results and Interpretation:	Francisella tularensis isolated/detected.	
nesures and interpretation.	Francisella tularensis isolated/detected.	
Additional Information:		
	Call 410-925-3121 before sending specimen to the Laboratory.	

Purpose of Test:	To confirm diagnosis of tularemia by culture.
Method:	LRN Protocols
Interfering Substances:	Isolate must be inoculated unto media that contains cystine (e.g., chocolate agar plate or slant).
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Francisella tularensis is highly infectious. <i>PLEASE</i> use a biological safety cabinet when working with specimens suspected of harboring <i>F. tularensis. Call</i> 410-925-3121 before sending to the Laboratory.

<b>N</b>	<b>A</b>		

TEST:	Francisella tularensis Serology (Tick-borne Disease Panel)		
Synonym:	Francisella tularensis, rabbit fever, deerfly fever, Ohara's disease, Francis disease Refer to instructions in Tick-Borne Disease Panel		
Laboratory/Phone:	443-681-3938/3931		
Specimen Required:	Serum (acute and convalescent preferred)		
Results and Interpretation:	Negative—No antibodies to <i>Francisella tularensis</i> were detected. Positive—Antibodies to <i>Francisella tularensis</i> were detected. (Titer provided)		
Additional Information:	https://www.cdc.gov/ticks/tickbornediseases/tularemia.html		
Purpose of Test:	For the detection of antibodies to Francisella tularensis		
Method:	Serum agglutination		
Comment: A known cross reaction exists between <i>Brucella abortus</i> . A four-fold increase in titer between acute and convalescent serum specimens supports the diagnosis of recent infection. Acute phase be collected within the first week after onset of illness, and convale phase sera, 2-4 weeks after onset.			

TEST:	Genital culture (Bacterial Culture, Routine)	
Synonym:	Aerobic culture, routine culture, genital culture: Refer to instructions for Bacterial	
	Culture, Routine.	
Laboratory/Phone:	Microbiology 443-681-3952	

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TEST:	Giardia (Ova and Parasites Microscopic Examination)	
Synonym:	Giardia, Parasitic identification: Refer to instructions for Ova and Parasites Microscopic	
	Examination.	
Laboratory/Phone:	Microbiology 443-681-3952 or 443-681-4570	

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TEST:	Glanders (Burkholderia mallei)
Synonym:	Glanders; Burkholderia (formerly Pseudomonas) mallei: Refer to instructions for
	Burkholderia mallei and Burkholderia pseudomallei.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Gonorrhea Culture
Synonym:	GC Culture, Neisseria gonorrhoeae Culture
Laboratory/Phone:	Microbiology 443-681-3952
Turnaround Time:	2-3 days – minimum [from specimen receipt in the Laboratory]
Specimen Required:	Cervical, rectal, throat, urethral, vaginal
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. Use permanent marker. Label bottom of plate (not lid). [Lot number and expiration date must remain visible on media.] The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	GC culture plate streaked with Dacron <sup>™</sup> swab immediately after collection.
Specimen Volume (Minimum):	N/A
Collect:	Materials*: GC culture plate, Dacron™ swab, CO₂ tablet, resealable plastic bag. Roll swab directly on the medium in a large "Z" (1a) (to provide adequate exposure of the swab to the medium for transfer of organisms.) Cross-streak immediately with a sterile loop (1b).         Image: Transfer of organisms.)       Cross-streak immediately with a sterile loop (1b).         Image: Transfer of organisms.)       Image: Transfer of organisms.)         Image: Transfer of organism
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on the form and number of hours
	incubated (if any).
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	When using the MTM (Modified Thayer Martin) agar plates transport at room/ambient
	<ul> <li>temperature 2-30°C in the resealable polyethylene bag that contains the CO<sub>2</sub> generating tablet.</li> <li>When using the BIOMED Diagnostics InTray GC culture and transport device: Transport at 18-25°C per FDA approved packet insert.</li> <li>DO NOT REFRIGERATE after specimen is collected. When packing plates for transport, keep them inverted and place in a suitable container that will protect them from extreme</li> </ul>
	heat or cold.
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Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> <li>Broken specimen/sample container</li> <li>The wrong specimen for test request</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Neisseria gonorrhea isolated and identified. Antibiotic susceptibilities reported.
Reference Range:	No Neisseria gonorrhea isolated
Additional Information:	Store unused plates under refrigeration upside down (media facing down). Discard any plate(s) with an expired expiration date or that exhibit growth prior to use (never use contaminated plates). Always allow plates to warm to room temperature before using (cold kills <i>Neisseria gonorrhea</i> ). Use Dacron <sup>™</sup> tipped swabs with plastic shafts (do not use cotton-tipped swabs, as they may contain fatty acids that can interfere with the survival of some organisms. Also do not use calcium alginate-tipped swabs. They can be toxic for some strains of <i>N. gonorrhoeae</i> .) Always allow the surface of plates to dry before using (a wet surface hampers isolated colony formation). DO NOT CRUSH OR ADD WATER TO THE CO <sub>2</sub> GENERATING TABLET (CAUSES LOSS OF CO <sub>2</sub> AND POSSIBLE CONTAMINATION BY WATER.) MOISTURE FROM THE MEDIUM WILL ACTIVATE THE CO <sub>2</sub> TABLET. Do not incubate inoculated plates in the clinic longer than 24 hours (over-incubation leads to more growth of contaminating normal flora). If incubated, indicate the number of hours on the test request form. If an incubator is not available, invert the inoculated plates and hold them at room temperature until picked up by the courier. Do not refrigerate after inoculating. When packing plates for transport, keep them inverted and place in a suitable container that will protect them from extreme heat or cold.
Purpose of Test:	Isolation, identification and antibiotic susceptibility testing for Neisseria gonorrhea.
Method:	Culture
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

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TEST:	Group A Strep Culture
Synonym:	Beta Strep culture, Streptococcus pyogenes culture, throat culture for Group A Strep
Lab/Phone:	Microbiology 443-681-3952
Turnaround Time:	1-2 days [from specimen receipt in the Laboratory]
Specimen Required:	Throat swab
Specimen identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	One (1) throat swab
Specimen Volume (Minimum):	N/A
Collect:	Culturette tube with transport medium
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at room/ambient temperature (2-30°C).
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care. Unlabeled or improperly labeled specimen Non-sterile or leaking container Inappropriate specimen transport conditions Illegible, or no submitter information on the request form Mismatched form and specimen Broken specimen/sample container The wrong specimen for test request Inappropriate outfit for requested test Illegible or no patient information on the specimen Expired transport media
Availability:	Monday through Friday
Results and Interpretation:	Group A Strep isolated and identified
Reference Range:	No Group A Strep detected
Additional Information:	N/A
Purpose of Test:	Detect the presence of Group A Strep
Method:	Culture
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

TEST:	Group A streptococcus (ABCs (previously BIDS))
Synonym:	Active Bacterial Core Surveillance (ABCs) (Bacterial Invasive Disease Surveillance) Group A
	streptococcus: Refer to instructions for ABCs (previously BIDS).
Lab/Phone:	Microbiology 443-681-3952

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TEST:	Group B Strep Screen
Synonym:	Prenatal screen for Group B Strep; Group B Strep culture; Genital Culture
Lab/Phone:	Microbiology 443-681-3952
Turnaround Time:	2-3 days [from specimen receipt in the Laboratory]
Specimen Required:	Vaginal/rectal swab
Specimen identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	One (1) vaginal/rectal swab
Specimen Volume (Minimum):	N/A
Collect:	Culturette tube with transport medium (Amies or Stuart's)
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at room/ambient temperature (2-30°C).
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results
	and to avoid misleading information that might lead to misdiagnosis and inappropriate
	therapy. A request for a new specimen will provide appropriate materials and clinically
	relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul><li>Illegible or no patient information on the specimen</li><li>Expired transport media</li></ul>
	<ul> <li>Specimen received after prolonged delay (usually more than 72 hours)</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Group B Strep isolated and identified
Reference Range:	No Group B Strep detected
Additional Information:	Prenatal screening for Group B Strep at 35-37 weeks gestation. If patient is allergic to
	penicillin, add note to this effect and request antimicrobial susceptibility testing to
	clindamycin and erythromycin.
	Gardnerella vaginalis isolation done on request for routine genital cultures.
Purpose of Test:	Detect the presence of Group B Strep
Method:	Culture
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

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TEST:	Group B Streptococcus (ABCs (previously BIDS))
Synonym:	Active Bacterial Core Surveillance (ABCs) (Bacterial Invasive Disease Surveillance) Group B
	Streptococcus: Refer to instructions for ABCs (previously BIDS).
Lab/Phone:	Microbiology 443-681-3952

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TEST:	Haemophilus ducreyi Detection (CDC Referral)
Synonym:	Chancroid Detection; Haemophilus ducreyi detection, Genital Ulcer Disease Molecular
	Detection Panel
Laboratory/Phone:	Microbiology 443-681-3952
Turnaround Time:	2 weeks [from specimen receipt in the Laboratory]:
Specimen Required:	Anogenital lesion swab
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	N/A
Specimen Volume (Minimum):	N/A
Collect:	Place anogenital lesion swabs immediately into tube containing nucleic acid amplification
	test (NAAT) transport medium and must be frozen (-20°C or lower) within 3 hours of
	collection; or stored refrigerated (2-8°C) for up to 48 hours and then frozen (-20°C or
	lower). Ship specimens frozen on dry ice within 14 days of collection.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured, or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport frozen at -2°C or colder on dry ice, as an etiologic agent.
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results
	and to avoid misleading information that might lead to misdiagnosis and inappropriate
	therapy. A request for a new specimen will provide appropriate materials and clinically
	relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate specimen collection device for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Positive Culture: Haemophilus ducreyi present. A positive culture indicates infection in a
	patient with an ulcerative lesion. Mixed infections with other agents known to cause
	ulcerative sexually transmitted diseases are not uncommon. The presence of
	Haemophilus ducreyi does not rule out these other infections which should be considered
	in the evaluation of the patient.
Reference Range:	Haemophilus ducreyi not found
Additional Information:	False-Negative cultures can result from prior antimicrobial therapy, strain growth
	variability, and sample and transport techniques
Purpose of Test:	Diagnosis of chancroids
Method:	CDC Genital Ulcer Disease Molecular Detection Panel - Real Time Multiplex PCR
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
-	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

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TEST:	Haemophilus influenzae (ABCs (previously BIDS))
Synonym:	Active Bacterial Core Surveillance (ABCs) (Bacterial Invasive Disease Surveillance)
	Haemophilus influenzae: Refer to instructions for ABCs (previously BIDS).
Laboratory/Phone:	Microbiology 443-681-3952

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TEST:	Hantavirus serology (CDC Referral)
Synonym:	Hanta, HPS, HFRS, Hantaan
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	10 business days (CDC Referral)
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
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# MD Department of Health-Laboratories Administration

Transport Conditions:	Per CDC Guidelines: For up to 7 days after collection transport whole blood or separated
	serum at 2-8°C on cold packs. If shipping is delayed beyond 7 days, serum must be
	transported at -20°C or colder and shipped on dry ice. WHOLE BLOOD CANNOT BE
	FROZEN.
Specimen Rejection Criteria:	Hemolysis; insufficient volume
Availability:	Monday through Friday
Results and Interpretation:	Given on CDC report
Additional Information:	http://www.cdc.gov/hantavirus/index.html
Purpose of Test:	Detect IgG & IgM antibody to the SNV
Method:	ELISA
Interfering Substances:	None
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Contact the MD Department of Health Epidemiologist at (410)767-6700 for prior
	approval of specimen submission. Required supplemental information: Exposure and
	travel history, include other relevant risk factors; clinical symptoms, treatment and
	relevant lab results. Required supplemental form at:
	http://www.cdc.gov/ncezid/dhcpp/vspb/pdf/specimen-submission.pdf

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TEST:	Helminths
Synonym:	Helminths are worm-like parasites that include the flukes (Trematodes); tapeworms (Cestodes); and roundworms (Nematodes): Refer to instructions for <b>Ova and Parasites Microscopic Examination</b> .
Lab/Phone:	Microbiology 443-681-3952

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TEST:	Hepatitis A IgM Antibody (Hepatitis A Screen)
Synonym:	Hepatitis A IgM Antibody, HAV IgM, HAVAB-M.
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum; plasma
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. Whole blood or 4 mL Serum
Specimen Volume (Minimum):	3 ml. Whole blood or 2 mL Serum
Collect:	Serum - Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer Plasma - Lavender-top (EDTA) vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form next to Hepatitis A Screen.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: Whole blood or separated serum/plasma transport within 3 days of collection at room temperature (21-30°C) or up to 7 days after collection transport at 2-8°C on cold packs. Separated Serum/Plasma only: For >7 days after collection transport -20°C or colder. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen, insufficient volume, hemolysis, gross bacterial contamination. Specimens collected > 7 days prior to arrival without being frozen.
Availability:	Monday to Friday. MUST call laboratory for prior approval.

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Results and Interpretation:	<ul> <li>Assay results should be interpreted only in the context of other clinical laboratory findings and the total clinical status of the individual. It has been shown that a viremic window exists with individuals infected with HAV, where the individual may be symptomatic for hepatitis but IgM anti-HAV nonreactive.</li> <li>Negative: IgM anti-HAV not detected. Does not exclude the possibility of exposure to or infection with HAV. Levels of IgM anti-HAV may be below the cut-off in early infection. Equivocal/Grayzone: HAV IgM antibody may or may not be present. Patients exhibiting grayzone test results should be closely monitored by redrawing and retesting approximately one week intervals. Monitoring the level of IgM anti-HAV by redrawing and retesting at approximately one week intervals will distinguish rapidly rising IgM anti-HAV levels often associated with late acute stage of HAV infection.</li> </ul>
	<b>Positive</b> : HAV IgM antibody detected. Presumptive evidence of HAV infection. A reactive IgM anti-HAV result does not rule out other hepatitis infections.
Additional Information:	For more information, see the CDC link at: <u>http://www.cdc.gov/hepatitis/index.htm</u>
Purpose of Test:	HAVAB-M assay is for the qualitative detection of IgM antibody to hepatitis A virus (IgM anti-HAV) in human serum or plasma. IgM anti-HAV is indicated for testing of specimens from individuals who have signs and symptoms consistent with acute hepatitis. Test results are used in conjunction with other laboratory results and clinical information as an aid in the diagnosis of acute or recent hepatitis A viral infection. During the acute phase of HAV infection, IgM anti-HAV appears in the patient's serum and is nearly always detectable at the onset of symptoms. In most cases, IgM anti-HAV response peaks within the first month of illness and can persist for up to six months. It is not intended for use in screening blood, plasma, or tissue donors.
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Interfering Substances:	Human anti-mouse antibodies (HAMA), found in patients who have received mouse monoclonal antibody treatments. Heterophilic antibodies in human serum, often found in patients routinely exposed to animals or animal serum products. Specimen with anti-E. coli, anti-CMV, or from hemodialysis patients. Heterophilic antibodies in human serum, often found in patients routinely exposed to animals or animal serum products. Specimen from individuals with Non-Hodgkin's Lymphoma may cross-react with this assay.
Testing Site:	MDH Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	<ul> <li>May not detect a recent infection, or infection in a person with severely compromised immune system.</li> <li>A reactive IgM anti-HAV result should be used and interpreted only in the context of the overall clinical picture. A negative test result does not exclude the possibility of exposure to hepatitis A virus. Levels of IgM anti-HAV may be below the cut-off in early infection and late acute infection.</li> </ul>

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TEST:	Hepatitis A IgG Antibody.	
Synonym:	HAV IgG, HAVAB-G	
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889	
Turnaround Time:	2-5 business days	
Specimen Required:	Serum	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique	
	patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	5 ml. Whole blood or 4 mL Serum	
Specimen Volume (Minimum):	3 ml. Whole blood or 2 mL Serum	
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be	
	downloaded from MDH Laboratory website).	
	Write "Hepatitis A IgG" on form. Indicate specimen type using the "Specimen Code".	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal	
	conditions of transport they cannot break, be punctured or leak their contents (Refer to	
	pages 9 & 10 for triple packing guidance).	
	*Refer to current Federal regulations for specific shipping requirements.	
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Transport Conditions:	Whole blood or separated serum transport within 4 days of collection at room temperature (2-30°C) or up to 8 days after collection transport at 2-8°C on cold packs per
	FDA assay packet insert. Separated Serum only: For >8 days after collection transport -
	20°C or colder per FDA packet insert. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen, insufficient
	volume, hemolysis, gross bacterial contamination. Specimens collected > 8 days prior to
	arrival without being frozen.
Availability:	Service available only to state and local health departments Monday to Friday.
Results and Interpretation:	Negative: No detectable IgG antibody to hepatitis A virus.
	Positive: Presence of detectable IgG antibody to HAV. It indicates past HAV infection or
	immunity by HAV vaccination.
Additional Information:	For more information, see the CDC link at: <u>http://www.cdc.gov/hepatitis/index.htm</u>
Purpose of Test:	HAVAB-G assay is for the qualitative detection of IgG antibody to hepatitis A virus (IgG
	anti-HAV) in human serum. Positive results suggest immunity to HAV infections.
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Interfering Substances:	Human anti-mouse antibodies (HAMA), found in patients who have received mouse
	monoclonal antibody treatments. Heterophilic antibodies in human serum, often found in
	patients routinely exposed to animals or animal serum products. Specimen with anti-E.
	coli, anti-CMV, or from hemodialysis patients. Heterophilic antibodies in human serum,
	often found in patients routinely exposed to animals or animal serum products.
Testing Site:	MDH Laboratories Administration, Central Laboratory
-	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	May not detect a recent infection, or infection in a person with severely compromised
	immune system.
	If HAVAB-G results are inconsistent with clinical evidence, additional testing is suggested
	to confirm the results.
	Specimens containing low antibody concentrations (near the cutoff) assayed after a
	freeze/thaw may exhibit elevated values that may be false positives.

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Hepatitis B Core Antibody IgM (Hepatitis B surface antigen Positive reflex test)	
HBc IgM Ab; anti-HBc IgM, CORE-M	
Vaccine Preventable Disease/443-681-3889	
2-5 business days	
Serum; plasma	
The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.	
5 ml. (Whole blood) or 4 ml. (Serum or Plasma)	
3 ml. (Whole blood) or 2 ml. (Serum or Plasma)	
Serum - Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer Plasma - Lavender-top (EDTA) vacutainer	
Test cannot be requested on MDH form # 4677, it is a reflex test for HBsAg positive specimens. Call the lab to request Core IgM testing.	
Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Per FDA Assay Packet Insert: Whole blood or separated serum/plasma transport within 3 days of collection at room temperature (24-30°C) or up to 7 days after collection transport at 2-8°C on cold packs. Separated Serum/Plasma only: For >7 days after collection transport -20°C or colder. WHOLE BLOOD CANNOT BE FROZEN.	
Discrepancy between name on tube and name on form, unlabeled specimen, insufficient volume, hemolysis, gross bacterial contamination. Specimens collected > 7 days prior to arrival without being frozen.	
Monday through Friday.	

Results and Interpretation:	Negative:IgM anti-HBc not detected. Does not exclude the possibility of exposure to or infection with HBV.Equivocal/Gray zone:IgM anti-HBc may or may not be present. Patients with specimens exhibiting gray zone test results should be retested at approximately one-week intervals. Monitoring the level of IgM anti-HBc by retesting at approximately one week intervals will distinguish rapidly rising IgM anti-HBc levels associated with early acute hepatitis B infection from gradually decreasing or unchanging IgM anti-HBc levels often associated with late acute stage of HBV infection, six to nine months from the appearance of HBsAg.Positive:Presumptive evidence of IgM anti-HBc antibodies.
Additional Information:	For more information, see the CDC link at: <u>http://www.cdc.gov/hepatitis/index.htm</u>
Purpose of Test:	The CORE-M assay is for the qualitative detection of IgM antibody to hepatitis B core antigen in human serum or plasma. A test for IgM anti-HBc is indicated as an aid in the diagnosis of acute or recent hepatitis B virus (HBV) infection in conjunction with other laboratory results and clinical information. It is not intended for use in screening blood, plasma, or tissue donors.
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Interfering Substances:	High levels of IgM (e.g. patients with multiple myeloma). Human anti-mouse antibodies (HAMA), found in patients who have received mouse monoclonal antibody treatments. Heterophilic antibodies in human serum, often found in patients routinely exposed to animals or animal serum products.
Testing Site:	MDH Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	May not detect a very recent infection, or infection in a person with severely compromised immune system. Current methods for the detection of IgM anti-HBc may not detect all infected individuals. A non-reactive test result does not exclude the possibility of exposure to or infection with HBV. CORE-M assay is limited to the detection of IgM anti-HBc in human serum or plasma. It can be used to determine whether a patient has, or has recently had, acute or subclinical hepatitis B infection. Supportive clinical information, including other hepatitis B markers, should also be evaluated. The test cannot determine a patient's immune status to hepatitis B.

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TEST:	Hepatitis B Core Antibody Total
Synonym:	CORE, anti-HBc lgG/lgM
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum; plasma
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum or Plasma)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum or Plasma)
Collect:	Serum - Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer
	Plasma - Lavender-top (EDTA) vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Write "Hepatitis B Core" on form. Indicate specimen type using the "Specimen Code".
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: Whole blood or separated serum/plasma transport within
	3 days of collection at room temperature (23-30°C) or up to 7 days after collection
	transport at 2-8°C on cold packs. Separated Serum/Plasma only: For >7 days after
	collection transport -20°C or colder. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic;
	gross bacterial contamination, and previously frozen specimens. Specimens collected > 7
	days prior to arrival without being frozen.
Availability:	Monday through Friday.
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Results and Interpretation:	Negative: Hepatitis B core antibodies not detected.
	Positive: Hepatitis B core antibodies were detected.
	The presence of anti-HBc antibodies does not differentiate between acute or chronic
	hepatitis B infections.
Additional Information:	For more information, see the CDC link at: <a href="http://www.cdc.gov/hepatitis/index.htm">http://www.cdc.gov/hepatitis/index.htm</a>
Purpose of Test:	The CORE assay is for the qualitative detection of antibodies to hepatitis B core antigen
	in human serum or plasma. It is intended as an aid in the diagnosis of acute, chronic, or
	resolved hepatitis B virus (HBV) infection in conjunction with other laboratory results and
	clinical information. It is not intended for use in screening blood, plasma, or tissue
	donors.
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Interfering Substances:	Human anti-mouse antibodies (HAMA), found in patients who have received mouse
	monoclonal antibody treatments. Heterophilic antibodies in human serum, often found
	in patients routinely exposed to animals or animal serum products.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	May not detect a recent infection, or infection in a person with severely compromised
	immune system.
	A nonreactive test result does not exclude the possibility of exposure to or infection with
	HBV.

TEST:	Hepatitis B Surface Antibody (Hepatitis B Panel, Hepatitis B post vaccine)
Synonym:	HBsAb, anti-HBs, AUSAB.
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum; plasma
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum or Plasma)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum or Plasma)
Collect:	Serum - Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer Plasma - Lavender-top (EDTA) vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form next to Hepatitis B post vaccine (HBsAb) or Hepatitis B Panel (HBsAg, HBsAb).
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: Serum/plasma transport within 3 days of collection at room temperature (21-22°C) or up to 7 days after collection transport at 2-8°C on cold packs. Separated Serum/Plasma only: For >7 days after collection transport -20°C or colder. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic; gross bacterial contamination. Specimens collected > 7 days prior to arrival without being frozen.
Availability:	Monday through Friday.
Results and Interpretation:	Negative: < 8.00 mIU/mL. Individual is considered not immune to HBV infection.
Reference Range	Patient's with a titer ≥12.00 mIU/mL is considered immune to Hepatitis B Virus infection.
Additional Information:	For more information, see the CDC link at: <u>http://www.cdc.gov/hepatitis/index.htm</u>
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# MD Department of Health-Laboratories Administration

Purpose of Test:	AUSAB assay is for the guantitative determination of antibody to hepatitis B surface
	antigen in human serum or plasma. It is intended for measurement of antibody response
	following hepatitis B virus (HBV) vaccination, determination of HBV immune status, and
	for the laboratory diagnosis of HBV disease associated with HBV test results and clinical
	information. It is not intended for use in screening blood, plasma, or tissue donors
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Interfering Substances:	Fibrin, often from patients receiving anticoagulant or thrombolytic therapy.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	May not detect a recent infection, or infection in a person with severely compromised
	immune system.
	For diagnostic purposes, results should be used in conjunction with patient history and
	other hepatitis markers for diagnosis of acute and chronic infection.
	A non-reactive test result does not exclude the possibility of exposure to hepatitis B
	virus. Results obtained with the AUSAB assay may not be used interchangeably with
	values obtained with different manufacturers' assay methods. Assay does not
	differentiate between vaccination and natural infection. Performance characteristics
	have not been established for therapeutic monitoring. A reactive anti-HBs result does
	not exclude coinfection by another hepatitis virus.

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TEST:	Hepatitis B Surface Antigen (Hepatitis B Panel; Hepatitis B Screen)
Synonym:	HBsAg, Hepatitis B surface Antigen Qualitative; HBsAg Qual.
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum; plasma
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum or Plasma)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum or Plasma)
Collect:	Serum - Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer
	Plasma - Lavender-top (EDTA) vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form next to Hepatitis B Screen
	(HBsAg) or Hepatitis B Panel (HBsAg, HBsAb).
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: Whole blood or separated serum/plasma transport within
	24 hours of collection at room temperature (15-30°C) or up to 6 days after collection
	transport at 2-8°C on cold packs. Separated Serum/Plasma only: For >6 days after
	collection transport -20°C or colder. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic;
	gross bacterial contamination. Specimens collected > 6 days prior to arrival without
	being frozen.
Availability:	Monday through Friday.
Results and Interpretation:	<b>NEGATIVE:</b> Specimen considered negative for HBsAg.
	POSITIVE: Specimen considered repeatedly reactive, see result for Hepatitis B Surface
	Antigen Confirmatory assay.
Additional Information:	For more information, see the CDC link at: <a href="http://www.cdc.gov/hepatitis/index.htm">http://www.cdc.gov/hepatitis/index.htm</a>
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Purpose of Test:	HBsAg Qualitative assay is for the qualitative detection of hepatitis B surface antigen in human serum or plasma. The assay may also be used to screen for HBV infection in
	pregnant women to identify neonates who are at risk for acquiring hepatitis B during the
	perinatal period. Assay results in conjunction with other laboratory results and clinical
	information, may be used to provide presumptive evidence of infection with HBV (state
	of infection or associated disease not determined) in persons with signs and symptoms
	of hepatitis and in persons at risk for hepatitis B infection. Not intended for use in
	screening blood, plasma, or tissue donors.
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Interfering Substances:	Human anti-mouse antibodies (HAMA), found in patients who have received mouse
	monoclonal antibody treatments. Heterophilic antibodies in human serum, often found
	in patients routinely exposed to animals or animal serum products.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	May not detect a recent infection, or infection in a person with severely compromised
	immune system.
	Assay performance characteristics have not been established when the HBsAg
	Qualitative assay is used in conjunction with other manufacturers' assays for specific HBV
	markers. Current methods for the detection of hepatitis B surface antigen may not
	detect all potentially infected individuals. A nonreactive test result does not exclude the
	possibility of exposure to or infection with hepatitis B virus. A nonreactive test result in
	individuals with prior exposure to hepatitis B may be due to antigen levels below the
	detection limit of this assay or lack of antigen reactivity to the antibodies in this assay. If
	the HBsAg Qualitative results are inconsistent with clinical evidence, additional testing is
	suggested to confirm the result for diagnostic purposes. Results should be used in
	conjunction with patient history and other hepatitis markers for diagnosis of acute and
	chronic infection. A reactive HBsAg result does not exclude co-infection by another
	hepatitis virus.

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TEST:	Hepatitis B Surface Antigen Confirmation (HBsAg Positive Reflex Test)
Synonym:	HBsAg Qualitative Confirmatory; HBsAg Qualitative Neutralization assay
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum; plasma
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum or Plasma)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum or Plasma)
Collect:	Serum - Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer Plasma - Lavender-top (EDTA) vacutainer
Form:	Test cannot be requested, it is a reflex test for HBsAg positive specimens.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Whole blood or separated serum/plasma transport within 24 hours of collection at room temperature (15-30°C) or up to 6 days after collection transport at 2-8°C on cold packs. <b>Separated Serum/Plasma only:</b> For >6 days after collection transport -20°C or colder. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic; gross bacterial contamination. Specimens collected > 6 days prior to arrival without being frozen.
Availability:	Monday through Friday.
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	Confirmed Dresses of UDs Antipos confirmed Confirmed application is in the
Results and Interpretation:	<ul> <li>Confirmed: Presence of HBs Antigen confirmed. Confirmed result may indicate acute or chronic HBV infection, depending on presence of other HBV serological markers.</li> <li>Not Confirmed: The presence of HBsAg cannot be confirmed via neutralization.</li> <li>The repeatedly reactive result obtained with the HBsAg Qualitative assay may be the result of a nonspecific reaction (false positive). As the presence of nonspecific binding may obscure low levels of HBsAg in the specimen due to early infection or early recovery, it is recommended that the patient be evaluated for other serologic markers of HBV infection (i.e., total anti-HBc or IgM antiHBc) and that the patient be retested for HBsAg in 4 to 6 weeks.</li> </ul>
Additional Information:	For more information, see the CDC link at: http://www.cdc.gov/hepatitis/index.htm
Purpose of Test:	The HBsAg Qualitative confirmation assay is for the qualitative confirmation of the presence of hepatitis B surface antigen (HBsAg) in human serum or plasma by specific antibody neutralization. Assay results, in conjunction with other laboratory results and clinical information, may be used to provide presumptive evidence of infection with HBV (state of infection or associated disease not determined) in persons with signs and symptoms of hepatitis and in persons at risk for hepatitis B infection. It is not intended for use in screening blood, plasma, or tissue donors.
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Interfering Substances:	Human anti-mouse antibodies (HAMA), found in patients who have received mouse monoclonal antibody treatments. Heterophilic antibodies in human serum, often found in patients routinely exposed to animals or animal serum products.
Testing Site:	MDH Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	May not detect a recent infection, or infection in a person with severely compromised immune system. Assay performance characteristics have not been established when HBsAg Qualitative Confirmatory assay is used in conjunction with other manufacturers' assays for specific HBV serological markers. If HBsAg Qualitative Confirmatory results are Inconsistent with clinical evidence, additional testing is suggested to confirm the result. For diagnostic purposes, results should be used in conjunction with patient history and other hepatitis markers for diagnosis of acute and chronic infection. Although there is an association between the presence of HBsAg infectivity and a reactive result, it is recognized that presently available methods for HBsAg confirmation may not detect all possible cases of HBV infection.

Hepatitis C Antibody (Hepatitis C Screen)
HCV Ab; anti-HCV; Hepatitis C Screen
Vaccine Preventable Disease/443-681-3889
2-5 business days
Serum; plasma
The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
5 ml. (Whole blood) or 4 ml. (Serum or Plasma)
3 ml. (Whole blood) or 2 ml. (Serum or Plasma)
Serum - Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer Plasma - Lavender-top (EDTA) vacutainer
MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form next to Hepatitis C Screen.
Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
<b>Per FDA Assay Packet Insert:</b> Whole blood or separated serum/plasma transport within 3 days of collection at room temperature (20-23°C) or up to 7 days after collection transport at 2-8°C on cold packs. <b>Separated Serum/Plasma only:</b> For >7 days after collection transport -20°C or colder. WHOLE BLOOD CANNOT BE FROZEN.

Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic gross bacterial contamination. Specimens collected > 7 days prior to arrival without bains factor.
	being frozen.
Availability:	Monday through Friday.
Results and Interpretation:	<b>Negative</b> : Antibodies to HCV not detected; does not exclude the possibility of exposure to HCV.
	<b>Equivocal/Grayzone</b> : Antibodies to HCV may or may not be present; another specimen should be obtained from the individual for further testing or follow CDC
	recommendations for supplemental testing. Follow up HCV RNA test is pending at the MDH Laboratories.
	Follow up HCV RNA test is pending at MDH Laboratories
	<b>Positive</b> : Presumptive evidence of antibodies to HCV; follow CDC recommendations for
	supplemental testing. Follow up HCV RNA test is pending at the MDH Laboratories.
Additional Information:	For more information, see the CDC link at: http://www.cdc.gov/hepatitis/index.htm
Purpose of Test:	Anti-HCV assay is for the qualitative detection of antibody to Hepatitis C Virus in human
Tupose of rest.	serum or plasma. Assay results, in conjunction with other laboratory results and clinical
	information, may be used to provide presumptive evidence of infection with HCV (state
	of infection or associated disease not determined) in persons with signs and symptoms
	of hepatitis and in persons at risk for hepatitis C infection. It is not intended for use in
N A a the a d	screening blood, plasma, or tissue donors
Method:	Chemiluminescent microparticle immunoassay (CMIA)
Interfering Substances:	Human anti-mouse antibodies (HAMA), found in patients who have received mouse
	monoclonal antibody treatments. Heterophilic antibodies in human serum, often found
	in patients routinely exposed to animals or animal serum products.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	May not detect a recent infection, or infection in a person with severely compromised immune system.
	A specimen positive or equivocal for Hepatitis C Antibody will be further tested fo HCV RNA at the MDH Public Health Laboratory if the specimen meets acceptability
	criteria.
	For diagnostic purposes, results should be used in conjunction with patient history and
	other hepatitis markers for diagnosis of acute and chronic infection. Current methods for
	the detection of antibodies to HCV may not detect all infected individuals. A nonreactive
	test result does not exclude the possibility of exposure to HCV. Nonreactive test results
	in individuals with prior exposure to HCV may be due to antibody levels being below the
	detection limit of this assay or to lack of antibody reactivity to the recombinant antigener used in this assay.
	Immunocompromised patients who have HCV may produce levels of antibody below the
	sensitivity of this assay and may not be detected as positive. The affinity or avidity differences of anti-human IgG/IgM for anti-HCV have not been determined with this
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	assay. Therefore, there may not be a demonstration of a significant increase in antibody
	level between acute and convalescent specimens for a patient in the late acute stage of
	infection when IgM antibodies are decreasing.
	Results obtained with Anti-HCV assay may not be used interchangeably with values
	obtained with different manufacturers' assay methods.
	Assay performance characteristics have not been established for newborns, infants,
	children, or populations of immunocompromised or immunosuppressed patients.
	A reactive anti-HCV result does not exclude co-infection by another hepatitis virus.
	The magnitude of an Anti-HCV assay result cannot be correlated to an end point titer.

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TEST:	Hepatitis C Virus (HCV) RNA (Preapproved Submitters or Reflex)
Synonym:	Hologic's Aptima <sup>®</sup> Hepatitis C Quant Dx Assay; HCV RNA
Laboratory/Phone:	Vaccine Preventable Diseases Section / 443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Plasma or Serum collected in plasma preparation tube (PPT, white or lavender top) or
	serum separator tube (SST, gold or tiger top)
Specimen identification:	Label specimen with the full name exactly matching form, date/time of collection and
	centrifugation. The specimen/sample must be properly labeled and match the test
	requisition or electronic test order.
Specimen Volume (Optimum):	5 ml of blood in plasma preparation tube (PPT) or serum separator tube (SST)
Specimen Volume (Minimum):	3 mL of blood in PPT or SST
Collect:	Preapproved submitters must call the Outfits Unit (443-681-3777) to order collection
	kit.
	All items required for specimen transport are provided in the specimen collection kit,
	including instructions. Tubes must be labeled with the patient's name or unique
	identifier. DO NOT uncap the patient specimen at any time. Aliquoted specimen will be
	rejected. Specimen must be centrifuged within 6 hours of collection. Collection and
	centrifugation date/time must be recorded on Serological Testing form. Failure to
	centrifuge will result in sample rejection.
	centinuge will result in sample rejection.
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website). Indicate specimen type "P" for plasma
	next to the CDC/Other Tests box and write "HCV RNA". Record the date/time of
	collection and centrifugation.
Packaging and Shipping*:	Follow submission guidelines, provided with each HCV RNA kit. Specimens must be
	packaged in a triple packaging system to ensure that under normal conditions of
	transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10
	for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: PPT or Specimen Aliquot Tube (SAT) transport at 2°C to
	25°C for up to 24 hours, PPT or SAT at 2°C to 8°C for up to 5 days, or PPT or SAT at -20°C
	for up to 60 days. SST or Specimen Aliquot Tube (SAT) at 2°C to 30°C for up to 24 hours,
	SST or SAT at 2°C to 8°C for up to 5 days, or SST or SAT at -20°C for up to 60 days.
	Each specimen must be clearly labeled, individually packaged in a leak-proof biobag, and
	accompanied with a completed MDH form #4677. Specimen in biobags should be placed
	in a cooler marked "HCV ONLY". Send specimen to MDH Laboratories Administration,
	1770 Ashland Avenue, Baltimore, MD via lab courier Monday-Thursday whenever
	possible, to avoid weekend deliveries.
Specimen Rejection Criteria:	Too old, patient ID on specimen is missing, illegible or does not match lab slip, quantity
speamen rejection entena.	not sufficient, expired collection tubes, improper transport temperature, broken or
	leaked in transit, improper collection tube type, specimen not centrifuged within 6 hours
	of collection, missing or incomplete lab slip (collection and centrifugation date and time,
	patient identifiers, submitter information).
Availability:	Monday-Friday
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Results and Interpretation:	Qualitative results reported as follows:
	HCV RNA Not Detected: No Current HCV Infection
	Follow-up testing is recommended as per national HCV guidelines for viral load
	assessment, and no further testing is recommended for diagnosis of HCV.
	As per the CDC HCV treatment guidelines, repeat HCV RNA testing is recommended after
	three months for patients exposed to HCV infection within 6 months or patients with clinical evidence of HCV infection.
	HCV RNA Detected: Follow-up testing is recommended as per national HCV guidelines
	for viral load assessment, and results must be interpreted within context of all
	relevant clinical and laboratory findings for diagnosis of HCV.
	Invalid: Error indicated in generation of the result. Specimen should be retested.
Additional Information:	Restricted test (preapproved submitters only, call 443-681-3889)
Purpose of Test:	Qualitative detection of HCV RNA or as reflex
Method:	Transcription-mediated amplification (TMA) and real-time transcription-mediated
	amplification (RT-TMA) using Hologic Panther® for the Aptima® HCV Quant Dx Assay.
Interfering Substances:	Rare, mutations within the highly conserved regions of the viral genome covered by the
	primers and/or probes in the Aptima HCV Quant Dx assay may results in failure to detect
	the virus.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Invalid result due to out of range value. Specimen should be resubmitted.

TEST:Herpes Simplex Virus (HSV Types 1 & 2)Synonym:Herpes Simplex Virus (HSV Types 1 & 2): Refer to instructions for Herpes Simplex<br/>Virus (HSV Types 1 & 2) – Molecular Detection (qPCR) and Virus Culture.Laboratory/Phone:Virology: 443-681-3934

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TEST:	Herpes Simplex Virus (HSV Types 1 & 2) – Molecular Detection (qPCR)
Synonym:	Herpes, HSV, and Genital herpes
Laboratory/Phone:	Molecular Diagnostics: 443-681-3924
Turnaround Time:	3-5 business days
Specimen Required:	Genital swab (must be a synthetic swab – i.e. Dacron™) in viral transport media (VTM). -Genital (bumps, blisters, ulcers, etc.) – Penis, vagina, etc.
Specimen Identification:	The specimen must be properly labeled with at least <b>two unique identifiers</b> . <b>The patient's full name or unique patient/specimen identifier, along with the specimen collection date/time</b> must be included. Label on the specimen tube must match the laboratory test requisition ( <u>MDH Form #4676 Infectious Agents: Culture/Detection</u> ) or electronic test order that is submitted.
Specimen Volume (Optimum):	Genital swab in VTM: 3mL
Specimen Volume (Minimum):	Genital swab in VTM: 1mL
Collect:	<ul> <li>Genital swab in VTM:</li> <li>1) Label specimen tube according to the "Specimen Identification" section above to meet requirements for clinical testing; set forth by the Clinical Laboratory Improvements Act of 1988 (CLIA).</li> <li>2) Collect the appropriate genital specimen with a SYNTHETIC swab.</li> <li>3) Place the swab into the VTM tube and break the swab handle off at the break point.</li> <li>4) Cap VTM tube.</li> <li>5) Confirm that the cap is not cross threaded and that the swabs are not spring loaded underneath them.</li> <li>6) Parafilm cap and tube together.</li> <li>7) Store specimens appropriately until shipping.</li> </ul>

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Form:	MDH Form #4676 Infectious Agents: Culture/Detection - (Order Forms: 443-681-3777). An
	electronic copy can be found by clicking the link above or on the Maryland Department of
	Health: Laboratories Administration home page:
	https://health.maryland.gov/laboratories/Pages/home.aspx
	*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in
	the appropriate section of the form. Indicate specimen source type next to the requested
	test using the "Specimen Code" on form.
	Specimens must be triple packaged to ensure proper transport (they cannot break, be
Packaging and Shipping*:	punctured, or leak their contents) under normal conditions of (Refer to pages 9 & 10 for triple
	packing guidance).
	*For specific shipping requirements refer to current regulations put forth by Federal, State, Local governments and other governing agencies.
Transport Conditions:	Specimen to be received <72 hours from time of collection:
ransport conditions.	Refrigerate specimens at 2-8°C. Transport overnight on cold packs (2-8°C).
	OR
	Freeze specimens at ≤-70°C. Transport overnight on dry ice (-2°C or colder).
	Specimen to be received ≥72 hours from time of collection (MUST BE FROZEN):
	Freeze specimens at ≤-70°C. Transport overnight on dry ice (-2°C or colder).
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results and
	to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A
	request for a new specimen will provide appropriate materials and clinically relevant
	information to support good patient care.
	<ul> <li>Specimen(s) received outside temperature range(s) below:</li> </ul>
	<ul> <li>Refrigerated (Cold Packs): 2-8°C.</li> </ul>
	<ul> <li>Frozen (Dry Ice): -2°C or colder.</li> </ul>
	<ul> <li>Specimen(s) received after prolonged delay (&gt;72 hours) unless frozen.</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions.</li> </ul>
	<ul> <li>Unlabeled or improperly labeled specimens.</li> </ul>
	Non-sterile or leaking container.
	Broken specimen/sample container.
	<ul> <li>Illegible, or no submitter information on the request form.</li> </ul>
	Mismatched form and specimen.
	• The wrong specimen source for the test requested.
	<ul> <li>Inappropriate outfit (specimen collection kit) for requested test.</li> </ul>
	<ul> <li>Incorrect transport media.</li> </ul>
	<ul> <li>Rapid Test Lysis Buffer</li> </ul>
	<ul> <li>Incorrect swab.</li> </ul>
	<ul> <li>Cotton swabs.</li> </ul>
	<ul> <li>Calcium alginate swabs.</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen.</li> </ul>
	Expired transport media.
	• No specimen received.
	Quantity not sufficient for testing.
	• Qualitity not sufficient for testing.

Results and Interpretation:	Screen
	Herpes simplex virus DNA DETECTED – Specimen positive for HSV.
	• Herpes simplex virus DNA NOT DETECTED – Specimen negative for HSV.
	<ul> <li>INVALID - RP UNSATISFACTORY – Indicates insufficient quantity of human nucleic acid present in specimen. Please recollect and submit an additional specimen for follow-up testing.</li> </ul>
	<ul> <li>EQUIVOCAL – An equivocal result may occur in the case of an inadequate specimen (low viral load). If patient diagnosis has not been determined, submit additional specimens for analysis.</li> </ul>
	Confirmation/Subtyping
	• Herpes simplex virus 1 DNA <b>DETECTED</b> – Specimen positive for HSV-1.
	<ul> <li>Herpes simplex virus 2 DNA DETECTED – Specimen positive for HSV-2.</li> </ul>
	<ul> <li>Herpes simplex virus 1 and 2 DNA DETECTED – Specimen positive for HSV-1 and HSV-2.</li> </ul>
Reference Range:	N/A
Additional Information:	All specimens are run on a screening PCR. Only specimens detected for HSV DNA are sent for confirmatory/subtyping (requires additional time).
Purpose of Test:	To provide qualitative results for the detection of HSV DNA in specimens
Method:	Real-Time PCR
Interfering Substances:	PCR inhibitors: DNases/RNases, Sodium hypochlorite (Bleach), Ethanol, etc.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

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TEST:	Herpes Simplex Virus Serology
Synonym:	Herpes simplex virus (HSV) type 1 & 2 IgG serology
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: For up to 7 days after collection, transport whole blood or separated serum at 2-8°C on cold packs. If > 5 days after collection, transport serum at -20°C or colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Grossly hemolyzed or lipemic specimens, unlabeled specimen, leaking container, insufficient volume, mismatch between labeling of specimen and test request form, specimen collected > 7 days prior to arrival without being frozen.
Availability:	Monday through Friday
Results and Interpretation:	POSITIVE—Presumptive evidence of IgG antibodies to HSV-1/HSV-2 NEGATIVE—No IgG antibodies to HSV-1/HSV-2 detected EQUIVOCAL—Immunological status cannot be determined, please re-draw patient in 4- 12 weeks.
Additional Information:	The performance of this assay has not been established for use in a pediatric population or for neonatal screening.
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# MD Department of Health-Laboratories Administration

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Purpose of Test:	Detect IgG antibodies to HSV I and HSV II
Method:	CLIA—Chemiluminescent Immunoassay
Interfering Substances:	Hemolysis, lipemia
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the
	assessment of a patient's health. Clinical correlation is required.

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TEST:	HIV-1 p24 Antigen and HIV-1/HIV-2 Antibody Combination Assay
Synonym:	HIV Ag/Ab Combo Assay
Laboratory/Phone:	443-681-3877
Turnaround Time:	3-7 working days
Specimen Required:	Serum from whole blood
Specimen identification:	Label container with patient's name, date of birth, and date of collection. (CTR# if applicable)
Specimen Volume (Optimum):	7 ml (Whole Blood)
Specimen Volume (Minimum):	5 ml (Whole Blood)
Collect:	Red-top vacutainer (Red-Top Serum Separator "Tiger Top" Tube is acceptable)
Form:	MDH 4677 Serological Testing (Order Forms: 443-681-3777) Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at 2-8°C on cold packs. DO NOT EXCEED STORAGE TIME LIMITATIONS SPECIFIED IN COMMENT SECTION BELOW.
Specimen Rejection Criteria:	Must comply with proper labeling, storage, and transport requirements.
Availability:	Testing is performed routinely
Results and Interpretation:	Non-reactive = HIV-1 p24 antigen and HIV-1/ HIV-2 antibodies not detected Reactive = Presumptive evidence of HIV-1 p24 antigen and/or HIV-1/ HIV-2 antibodies; perform confirmatory/ supplemental assays
Reference Range:	Signal to cutoff (S/CO) values $\geq$ 1.00 are presumptive reactive for HIV-1 p24 antigen or HIV-1/ HIV-2 antibodies.
Additional Information:	Confirmatory assays may be performed to confirm presence of HIV antibody or HIV-1 RNA; Supplemental assay may be performed to differentiate HIV-1 and HIV-2 infections.
Purpose of Test:	Aid in the diagnosis of HIV-1 / HIV-2 infection including primary or acute HIV-1 infection.
Method:	Chemiluminescence microparticle immunoassay (CMIA)
Interfering Substances:	Fibrin, red blood cells, or other particulate matter
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Store at room temperature no more than 3 days, or 7 days if stored 2-8°C following specimen collection. <b>Specimen must be received at the laboratory and tested within</b>
	7 days after collection.

TEST:	Infectious Mononucleosis (IM Serology)
Synonym:	Heterophile Antibody Assay
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	5 business days
Specimen Required:	Serum, plasma
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: For up to 72 hours after collection, transport whole blood
	separated serum, or plasma at 2-8°C on cold packs. If > 72 hours after collection,
	transport serum or plasma at -20°C or colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, insufficient volume, mismatch between labeling of specimen and test request form, specimen collected > 3 days prior to arrival without being frozen.
Availability:	Monday through Friday
Results and Interpretation:	POSITIVE: Infectious Mono heterophile antibody detected NEGATIVE: Infectious Mono heterophile antibody not detected
Additional Information:	Further EBV testing can aid in the clinical diagnosis
Purpose of Test:	Detect antibody in patients with infectious mononucleosis
Method:	Slide agglutination
Interfering Substances:	Hemolysis
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required.

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TEST:	Influenza Virus (Types A & B)
Synonym:	Influenza Virus (Types A & B): Refer to instructions for Virus Culture and Influenza &
	SARS-CoV2 – Molecular Detection (qPCR).
Laboratory/Phone:	Virology: 443-681-3934

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TEST:	Influenza & SARS-CoV2 – Molecular Detection (qPCR) **SARS-CoV 2 can be ordered independently of influenza**
Synonym:	Flu, INFA, INFB, Influenza A, Influenza B, SARS2, Coronavirus 2, COVID, and COVID-19
Laboratory/Phone:	Molecular Diagnostics: 443-681-3924
Turnaround Time:	2-5 business days
Specimen Required:	Respiratory swab (must be a synthetic swab – i.e. Dacron™) in viral transport media
Specifien Required.	(VTM). -Upper Respiratory – Nasopharyngeal, nasal, and oropharyngeal/throat.
	Aspirates/washings in specimen collection container. -Upper Respiratory – Nasopharyngeal wash/aspirate, or nasal aspirate. -Lower Respiratory – Sputum, lower respiratory tract aspirates, bronchoalveolar lavage, nasopharyngeal wash/aspirate, or nasal aspirate.
	**NASOPHARYNGEAL SWAB PREFERRED**
Specimen Identification:	The specimen must be properly labeled with at least two unique identifiers. The patient's full name or unique patient/specimen identifier, along with the specimen collection date/time must be included. Label on the specimen tube must match the laboratory test requisition (MDH Form #4676 Infectious Agents: Culture/Detection) or electronic test order that is submitted.
Specimen Volume (Optimum):	Respiratory swab in VTM: 3mL       OR
	Aspirates/washings in specimen collection container: 3mL
Specimen Volume (Minimum):	Respiratory swab in VTM: 1mL OR
Collect:	Aspirates/washings in specimen collection container: 0.6mL Respiratory swab in VTM:
	<ol> <li>Label specimen tube according to the "Specimen Identification" section above to meet requirements for clinical testing; set forth by the Clinical Laboratory Improvements Act of 1988 (CLIA).</li> <li>Collect the appropriate upper respiratory specimen with a SYNTHETIC swab.</li> <li>Place the swab into the VTM tube and break the swab handle off at the break point.</li> <li>Cap VTM tube.</li> <li>Confirm that the cap is not cross threaded and that the swabs are not spring loaded underneath them.</li> <li>Parafilm cap and tube together.</li> <li>Store specimens appropriately until shipping.</li> </ol>
	<ul> <li>Aspirates/washings in specimen collection container: <ol> <li>Label specimen collection container according to the "Specimen Identification" section above to meet requirements for clinical testing; set forth by the Clinical Laboratory Improvements Act of 1988 (CLIA).</li> <li>Collect the appropriate upper/lower respiratory specimen.</li> <li>Place the specimen into the specimen collection container.</li> <li>Cap specimen collection container.</li> <li>Confirm that the cap is not cross threaded.</li> <li>Parafilm cap and container together.</li> </ol> </li> </ul>
	7) Store specimens appropriately until shipping.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection - (Order Forms: 443-681-3777). An electronic copy can be found by clicking the link above or on the Maryland Department of Health: Laboratories Administration home page:
	https://health.maryland.gov/laboratories/Pages/home.aspx
	*All test requests must be made by an ordering physician (MD, NP, etc.) with their name in the appropriate section of the form. Indicate specimen source type next to the requested test using the "Specimen Code" on form.
	Continued Next Page>

	Specimens must be triple packaged to ensure proper transport (they cannot break, be
Packaging and Shipping*:	punctured, or leak their contents) under normal conditions of (Refer to pages 9 & 10 for
	triple packing guidance).
	*For specific shipping requirements refer to current regulations put forth by Federal,
	State, Local governments and other governing agencies.
Transport Conditions:	Specimen to be received <72 hours from time of collection:
	Refrigerate specimens at 2-8°C. Transport overnight on cold packs (2-8°C).
	OR
	Freeze specimens at ≤-70°C. Transport overnight on dry ice (-2°C or colder).
	Specimen to be received ≥72 hours from time of collection (MUST BE FROZEN):
	Freeze specimens at ≤-70°C. Transport overnight on dry ice (-2°C or colder).
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results
	and to avoid misleading information that might lead to misdiagnosis and inappropriate
	therapy. A request for a new specimen will provide appropriate materials and clinically
	relevant information to support good patient care.
	<ul> <li>Specimen(s) received outside temperature range(s) below:</li> </ul>
	• Refrigerated (Cold Packs): 2-8°C.
	• Frozen (Dry Ice): -2°C or colder.
	<ul> <li>Specimen(s) received after prolonged delay (&gt;72 hours) unless frozen.</li> </ul>
	Inappropriate specimen transport conditions.
	Unlabeled or improperly labeled specimens.
	Non-sterile or leaking container.
	Broken specimen/sample container.
	• Illegible, or no submitter information on the request form.
	Mismatched form and specimen.
	• The wrong specimen source for the test requested.
	<ul> <li>Inappropriate outfit (specimen collection kit) for requested test.</li> </ul>
	<ul> <li>Incorrect transport media.</li> </ul>
	<ul> <li>Rapid Test Lysis Buffer</li> </ul>
	<ul> <li>Incorrect swab.</li> </ul>
	<ul> <li>Cotton swabs.</li> </ul>
	<ul> <li>Calcium alginate swabs.</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen.</li> </ul>
	Expired transport media.
	No specimen received.
	<ul> <li>Quantity not sufficient for testing.</li> </ul>
Availability:	Monday - Friday
/ tranability.	Continued Next Page>

D Department of Health-Laboratorie	es Administration The J. Mensen Joseph Public Health Laboratory
Results and Interpretation:	Flu/SC2 Screen
	<ul> <li>Positive for Influenza A – Influenza A RNA detected in specimen.</li> </ul>
	<ul> <li>Positive for Influenza B – Influenza B RNA detected in specimen.</li> </ul>
	<ul> <li>Positive for COVID-19 – SC2 RNA detected in specimen.</li> </ul>
	<ul> <li>Positive for Influenza B and COVID-19 – Influenza B and SC2 RNA detected in specimen.</li> </ul>
	<ul> <li>Positive for Influenza A and Influenza B – Influenza A and Influenza B RNA detected in specimen.</li> </ul>
	<ul> <li>Positive for Influenza A and COVID-19 – Influenza A and SC2 RNA detected in specimen.</li> </ul>
	<ul> <li>Positive for Influenza A, Influenza B and COVID19 – Influenza A, Influenza B, and SC2 RNA detected in specimen.</li> </ul>
	<ul> <li>Negative – Influenza A, Influenza B, and SC2 RNA not detected in specimen.</li> </ul>
	<ul> <li>Invalid – Invalid result – May indicate insufficient quantity/quality of human nucleic acid OR presence of inhibitors in the specimen. Please recollect and submit an additional specimen for follow-up testing.</li> </ul>
	Influenza A Confirmation/Subtyping
	<ul> <li>Influenza A detected; Subtype: H3 detected – Specimen positive for Influenza A/H3.</li> </ul>
	<ul> <li>Influenza A detected; Subtype: H1pdm09 detected – Specimen positive for Influenza A/H1pdm09.</li> </ul>
	<ul> <li>Influenza A detected; Subtype: H3 detected; H1pdm09 detected – Specimen positive for Influenza A/H3 and A/H1pdm09.</li> </ul>
	<ul> <li>Influenza A detected; Presumptive positive for Influenza A(H3N2) variant virus Specimen positive for Influenza A(H3N2)v.</li> </ul>
	<ul> <li>Influenza A detected; Subtype undetectable – Specimen positive for Influenza A. Untypable.</li> </ul>
	<ul> <li>Influenza A NOT detected – Specimen negative for Influenza A.</li> </ul>
	<ul> <li>Inconclusive result – May indicate insufficient quantity/quality of human nucleic acid OR presence of inhibitors in the specimen. Please recollect and submit an additional specimen for follow-up testing.</li> </ul>
	Influenza B Confirmation/Subtyping
	<ul> <li>Influenza B detected; B/Victoria lineage detected – Specimen positive for Influenza B/Victoria.</li> </ul>
	<ul> <li>Influenza B detected; B/Yamagata lineage detected – Specimen positive for Influenza B/Yamagata.</li> </ul>
	<ul> <li>Influenza B detected; B/Victoria lineage detected; B/Yamagata lineage detected         <ul> <li>Specimen positive for Influenza B/Victoria and B/Yamagata.</li> </ul> </li> </ul>
	<ul> <li>Influenza B detected; Lineage undetectable – Specimen positive for Influenza B. Untypable.</li> </ul>
	<ul> <li>Influenza B NOT detected – Specimen negative for Influenza B.</li> </ul>
	Inconclusive result - May indicate insufficient quantity/quality of human nucleic
	acid OR presence of inhibitors in the specimen. Please recollect and submit an
	additional specimen for follow-up testing.
Reference Range:	N/A
Additional Information:	All specimens are run on a screening PCR. Only specimens with Influenza RNA detected are sent for confirmatory/subtyping (requires additional time).
Purpose of Test:	To provide qualitative results for the detection of Influenza virus RNA in specimens
Method:	Real-Time PCR
Interfering Substances:	PCR inhibitors: DNases/RNases, Sodium hypochlorite (Bleach), Ethanol, etc.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	**SARS-CoV 2 can be ordered independently of influenza**



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TEST:	Interferon-Gamma Release Assay (IGRA)
Synonym:	Refer to Instructions for QuantiFERON Plus
Laboratory/Phone:	(443) 681-3942

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TEST: Japanese Encephalitis (CDC Referral) CDC test available based on patient's travel history. Arthropod-borne virus: Japanese Encephalitis (JE) Synonym: Laboratory/Phone: Virology: 443-681-3936/3931 **Turnaround Time:** 3 weeks (CDC Referral) Specimen Required: Serum (blood), CSF Specimen identification: Label container with patient's last name, first name, DOB, specimen type, date and time of collection. Specimen Volume (Optimum): 2 ml serum Specimen Volume (Minimum): 1 ml serum Collect: Red-top vacutainer tube, transfer serum to sterile tube Form: MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Write "S" for serum in the "Other Tests Request" and indicate Japanese Encephalitis. For testing to be initiated, the following information MUST be provided: date of onset, date specimen collected, travel history, and flavivirus vaccination history. Also please provide patient's date of birth, diagnosis, symptoms, fatality, and whether patient is immunocompromised. Packaging and Shipping\*: Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). \*Refer to current Federal regulations for specific shipping requirements. **Transport Conditions:** Per CDC Guidelines: For up to 120 days after collection, transport whole blood, separated serum, or CSF at 2-8°C on cold packs. If > 120 days after collection, transport serum or CSF at -20°C or colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN. Specimen Rejection Criteria: Grossly hemolyzed specimen, unlabeled specimen, leaking container, mismatch between labeling of specimen and test request form/electronic test order, and does not meet epidemiological criteria required for testing (e.g., travel history, etc.) Availability: Specimens shipped to the CDC Monday-Wednesday. **Results and Interpretation:** Serum that tests positive for IgM and negative for IgG is consistent with acute Japanese Encephalitis infection. A positive Japanese Encephalitis EIA is confirmed by PRNT (plaque reduction neutralization). A positive IgG antibody and a negative IgM antibody are consistent with infection in the distant past and are not consistent with acute infection. Additional Information: The term "Arbovirus" has no taxonomic significance, but is a shortened name given to viruses that are transmitted by blood feeding arthropods (mosquitoes, ticks, etc.). Arboviruses that cause human encephalitis are members of three virus families: The Togaviridae (genus Alphavirus), Flaviviridae, and Bunyaviridae. For more information, see the CDC link at: https://www.cdc.gov/ncezid/dvbd/ Patients with travel history supporting suspicion of other arboviruses will be sent to the CDC for testing. Purpose of Test: For the presumptive detection of antibodies to Japanese Encephalitis Virus. Confirmatory testing by PRNT may be required. EIA (Screening) & PRNT (Plaque Reduction Neutralization Test) referral to the Centers for Method: Disease Control and Prevention (CDC). **Interfering Substances:** Processing Site for CDC referral: MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205 Comment: Other Arboviral testing not available at the state lab will be forwarded to the CDC based on patient's travel history and onset date.

MD Department of Health-Laboratories Administration

TEST:	Legionella Antigen Detection
Synonym:	Legionella Urinary Antigen
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	5 business days
Specimen Required:	Urine
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml Urine (First void preferred)
Specimen Volume (Minimum):	0.5 ml Urine
Collect:	Sterile container
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Transport urine in a leak proof container at 2-8°C on cold packs or frozen (-2°C or colder) and ship on dry ice.
Specimen Rejection Criteria:	Unlabeled specimen, leaking container, insufficient volume, mismatch between labeling of specimen and test request form, and bloody specimens.
Availability:	Monday through Friday
Results and Interpretation:	<b>POSITIVE</b> – Presumptive evidence of <i>L. pneumophila</i> serogroup 1 antigen in urine,
	suggesting current or past infection.
	NEGATIVE—No evidence of L. pneumophila serogroup 1 antigen in urine suggesting no
	recent or current infection. Legionnaires' disease cannot be ruled out since other
	serogroups and species may also cause disease.
Additional Information:	Only detects <i>L. pneumophila</i> serogroup 1. All other serogroups and other Legionella species must be detected by culture.
	Refer to CDC website: <u>http://www.cdc.gov/legionella/index.html</u>
Purpose of Test:	Detect presence of Legionella pneumophila serogroup 1 antigen in urine.
Method:	EIA
Interfering Substances:	Specimens may produce a false positive result from patients with bacteremia (Streptococcus pneumonia) pulmonary conditions and urinary tract infection ( <i>Escherichia coli, Enterobacter cloacae</i> ).
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Some individuals have been shown to excrete antigen for an extended period of time, so a positive ELISA reaction may reflect a recent but not active infection.
	Early treatment with appropriate antibiotics may also decrease antigen excretion in some individuals.
	Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required.

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TEST:	Legionella Culture
Synonym:	Legionella pneumophila culture isolation/identification
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	10-14 days from receipt in the laboratory
Specimen Required:	Sputum, lung tissue, other body tissue, pleural fluid, transtracheal aspiration, lung
	exudate, lung biopsy/autopsy, lung abscess material.
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	1 ml sputum; trans tracheal aspirate, biopsy;1 gram lung tissue; 1 ml lung exudate; 1 cc
	lung biopsy; 50 ml bronchoalveolar lavage (BAL); 1 ml lung abscess material; 7 ml blood
	in an isolator tube; collect in sterile container.
Specimen Volume (Minimum):	Half of the optimum amount
Collect:	Specimen in sterile screw capped container. Prevent specimen from drying. DO NOT
	USE SALINE IN SPECIMEN COLLECTION. BAL specimens containing saline are acceptable.
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Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport within 48 hours of collection at 2-8°C; if shipping is delayed beyond 48 hours after collection, transport at -20°C or colder and ship on dry ice. Place each specimen in a separate, individually sealed bag.
Specimen Rejection Criteria:	Specimen received after prolonged delay (more than 48 hours after collection), Swab specimen, improper labeling; specimen received in grossly leaking transport container; urine, stool, wounds, or other culture material from non-respiratory sites.
Availability:	Monday through Friday.
Results and Interpretation:	POSITIVE: Presence of Legionella pneumophila or Legionella spp. NEGATIVE: Legionella not isolated
Reference Range:	Culture negative for Legionella species.
Additional Information:	http://www.cdc.gov/legionella/index.html
Purpose of Test:	Isolation and identification of Legionella species.
Method:	Culture, staining, biochemical testing.
Interfering Substances/Limitations:	Avoid contamination with normal respiratory flora.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Culture staining can distinguish between some Legionella pneumophila serogroups.

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TEST:	Leptospira Serology
Synonym:	Leptospira Antibody, Leptospirosis
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	5 business days
Specimen Required:	Serum, plasma
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer (Serum) or Lavender-top vacutainer (Plasma)
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form. Date specimen collected <b>MUST</b> be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: WHOLE BLOOD CANNOT BE FROZEN. Based on NCCLS procedures for handling and processing Blood Specimens - Transport whole blood, separated serum or plasma at 2-8°C on cold packs. Serum and plasma can also be transported at -2°C or colder and shipped on dry ice.
Specimen Rejection Criteria:	Hemolysis; insufficient volume, specimen collected > 7 days prior to arrival without being frozen
Availability:	Monday through Friday
Results and Interpretation:	<b>Reactive:</b> Indicates presence of IgM antibodies. Antibody presence alone cannot be used for diagnosis as antibodies from prior exposure may circulate for a prolong period of time. <b>Non-reactive:</b> IgM antibody is not present in the sample or is below the detection level.
Additional Information:	Borderline:         A second specimen should be collected in 14 days.           Titers generally fall below detectable levels within 9 months to 1 year.           http://www.cdc.gov/leptospirosis/
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Purpose of Test:	Detect antibodies to Leptospira species
Method:	ImmunoDOT
Interfering Substances:	Hemolysis, lipemia
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Antibody titers to leptospirosis may be delayed or substantially decreased by early and intensive antibiotic treatment. Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required.

TEST:	Listeria monocytogenes (ABCs (previously BIDS))
Synonym:	Active Bacterial Core Surveillance (ABCs) (Bacterial Invasive Disease Surveillance) Listeria <i>monocytogenes</i> is handled as an ABCs isolate and evaluated by the National Antimicrobial Resistance Monitoring Systems (NARMS) Program. Refer to instructions for <b>ABCs (previously BIDS)</b> .
Laboratory/Phone:	Microbiology 443-681-3952

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TEST:	Lyme Serology
Synonym:	Borrelia burgdorferi: Refer to instructions for Borrelia burgdorferi serology.
Laboratory/Phone:	443-681-3938/3931

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TEST:	Malta Fever
Synonym:	Bang's Disease; Undulant fever; Malta Fever; Rock of Gibraltar Fever: Refer to
	instructions for Brucella serology or Brucella species, culture.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

TEST:	Malaria Identification and Quantitation
Synonym:	Plasmodium species identification and determination of percent parasitemia
	(quantitation).
Laboratory/Phone:	443-681-3952
Turnaround Time:	5-7 business days
Specimen Required:	Thin and thick film slides (preferably stained) and whole blood (EDTA)
Specimen Identification:	The specimen/sample must be properly labeled and include patient's name and a second
	identifier (date of birth or a unique identifier such as medical record number); these
	identifiers must match the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml (whole blood)
Specimen Volume (Minimum):	0.5 ml (whole blood)
Collect:	Lavender top (EDTA) vacutainer
Form:	Maryland Department of Health Infectious Agents Form# 4676; select Blood Parasites
	test, enter B for specimen source (blood), indicate Malaria speciation and patient's
	recent travel history. (Order Forms: 443-681-3777 or form may be downloaded from
	MDH Laboratory website).
	Glass slides must be enclosed in an appropriate slide carrier (plastic or cardboard) to
Packaging and Shipping*:	prevent breakage. Blood specimens must be packaged in a triple packaging system to
	ensure that under normal conditions of transport they cannot break, be punctured, or
	leak their contents (Refer to pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
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Transport Conditions:	Transport at room/ambient temperature (2-30°C) for both glass slides and blood specimen (although blood specimens transported at 2-30°C with cold packs are acceptable).
Specimen Rejection Criteria:	Broken glass slides, excessively hemolyzed blood, insufficient volume, frozen blood
Availability:	Monday through Friday
Results and Interpretation:	Plasmodium species (P. falciparum, P. malariae, P. vivax, P. ovale or P. knowlesi) detected/not detected and percentage of red blood cells infected
Reference Range:	Plasmodium species not detected
Additional Information:	
Purpose of Test:	To identify/verify the presence or absence of a Plasmodium species infection and enumerate the number for red blood cells that are infected (% parasitemia).
Method:	Microscopic examination
Interfering Substances:	Hemolysis or clotting of blood
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	

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TEST:	Measles Virus Culture
Synonym:	Measles Virus culture: Refer to instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934

TEST:	Measles IgG Antibody–Measles Immunity Screen
Synonym:	Anti Rubeola IgG; Measles IgG antibody; Rubeola / Measles immunity test
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum)
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer.
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" next to Rubeola (Measles) Immunity Screen or MMRV Immunity Screen.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Whole blood or separated serum transport at 2-8°C on cold packs up to 9 days after collection. <b>Separated Serum only:</b> For >9 days after collection transport -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic; lipemic; gross bacterial contamination. Specimens collected > 9 days prior to arrival without being frozen.
Availability:	Service available only to state and local health departments Monday to Friday.
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Results and Interpretation:	Negative: Indicates no detectable IgG antibody to Measles virus. A negative result
	indicates no current or previous infection with Measles virus. Such individuals are
	presumed to be susceptible to primary infection. However, specimen taken too early
	during a primary infection may not have detectable levels of IgG antibody. If primary
	infection is suspected, another specimen (convalescent) should be taken in 8-14 days and
	tested concurrently in the same assay with the original (acute) specimen to look for
	seroconversion. If acute specimen is negative and convalescent specimen is positive,
	seroconversion has taken place and a primary Measles virus infection is indicated.
	Equivocal: Equivocal results are indeterminate. Patient may or may not have immunity to
	Measles Virus. This result is not acceptable proof of immunity.
	Positive: Indicates evidence of Measles IgG antibodies. This suggests past or current
	infection with Measles virus, via acquired immunity or immunization and probable
	protection from clinical infection (immunity).
Additional Information:	For more information, see the CDC link at: <u>https://www.cdc.gov/measles/index.html</u>
Purpose of Test:	For detection of IgG antibodies to Measles virus. The test can be used to evaluate single
	sera for immune status.
Method:	Chemiluminescent Immunoassay (CLIA)
Interfering Substances:	Test results in immunocompromised patients should be interpreted with caution.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	A diagnosis should not be made on the basis of anti-Measles results alone. Test results
	should be interpreted in conjunction with the clinical evaluation and the results of other
	diagnostic procedures. The antibody titer of a single serum specimen cannot be used to
	determine a recent infection. Paired samples (acute and convalescent) should be collected
	and tested concurrently to demonstrate seroconversion. Samples collected too early in
	the course of an infection may not have detectable levels of IgG. In such cases, a second
	sample may be collected after 2-7 weeks and tested concurrently with the original sample
	to look for seroconversion. A positive Measles IgG test in neonates should be interpreted
	with caution since passively acquired maternal antibody can persist for up to 6 months.

TEST:	Measles IgM EIA
Synonym:	Anti-Measles IgM; Rubeola/Measles IgM antibody.
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum)
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer.
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Write "Measles IgM" on form. Indicate specimen type using the "Specimen Code".
	Prior approval by MDH Epidemiology (410-767-6628) required.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: Whole blood or separated serum transport at 2-8°C on cold
	packs up to 2 days after collection. Separated Serum only: For >2 days after collection
	transport -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic;
	lipemic; gross bacterial contamination. Specimens collected > 2 days prior to arrival
	without being frozen.
Availability:	Monday to Friday. Test available only to MDH epidemiologists for outbreak
-	investigations. Prior approval by MDH Epidemiology (410-767-6628) required.
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Results and Interpretation:	Negative: No detectable Measles IgM antibodies. A negative result indicates no current
	infection with Measles virus. However, specimens taken too early during a primary
	infection may not have detectable levels of IgM antibody. If a primary infection is
	suspected, another specimen should be taken within 7 days and tested concurrently in the
	same assay with the original specimen to look for seroconversion.
	Equivocal: Equivocal specimens are indeterminate. Another specimen should be collected
	after 7 days and retested.
	Positive: Indicates evidence of Measles IgM antibodies. This suggests primary or
	reactivated infection with Measles virus.
Additional Information:	For more information, see the CDC link at: <u>https://www.cdc.gov/measles/index.html</u>
Purpose of Test:	For detection of IgM antibodies to measles virus.
	Test available only to MDH epidemiologists for outbreak investigations. Prior approval
	by MDH Epidemiology (410-767-6628) required.
Method:	ELISA
Interfering Substances:	High levels of Measles IgG and Rheumatoid factor can cause false positive or negative
	results. CMV IgM, HSV1 IgM, and HSV2 IgM antibodies cross react and may lead to false
	positive results. Some antinuclear antibodies have been found to cause a false positive
	reaction. Potential cross-reactivity with RSV and parainfluenza cannot be ruled out.
	Test results from immunocompromised patients should be interpreted with caution.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Results of the Measles IgM ELISA are not by themselves diagnostic and should be
	interpreted in light of the patient's clinical condition and results of other diagnostic
	procedures. Samples taken too early during the course of a primary infection may not
	have detectable levels of Measles specific IgM. A negative result does not rule out a
	primary infection with virus. The Measles IgM ELISA cannot distinguish the difference
	between vaccine-induced antibody and antibody resulting from a natural infection. False
	positive IgM results may be obtained from patients with autoimmune disease. The
	performance of the Measles IgM ELISA has not been validated using neonatal samples.

TEST:	Melioidosis (Burkholderia pseudomallei)
Synonym:	Burkholderia (formerly Pseudomonas) pseudomallei; B. pseudomallei; Melioidosis: Refer to
	instructions for Burkholderia mallei and Burkholderia pseudomallei.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Methicillin Resistant Staph aureus (MRSA) culture
Synonym:	MRSA (rule out), Methicillin Resistant Staph aureus (MRSA) culture
Laboratory/Phone:	Microbiology 443-681-3952
Turnaround Time:	2-3 days [from specimen receipt in the Laboratory]
Specimen Required:	Nasal swab; nasopharyngeal swab, tissue
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	One (1) swab
Specimen Volume (Minimum):	N/A
Collect:	Culturette tube with transport medium, tissue in sterile specimen container
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at room/ambient temperature 2-30°C.
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results	
	and to avoid misleading information that might lead to misdiagnosis and inappropriate	
	therapy. A request for a new specimen will provide appropriate materials and clinically	
	relevant information to support good patient care.	
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>	
	<ul> <li>Non-sterile or leaking container</li> </ul>	
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>	
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>	
	<ul> <li>Mismatched form and specimen</li> </ul>	
	<ul> <li>Broken specimen/sample container</li> </ul>	
	<ul> <li>The wrong specimen for test request</li> </ul>	
	<ul> <li>Inappropriate outfit for requested test</li> </ul>	
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>	
	Expired transport media	
	<ul> <li>Specimen received after prolonged delay (usually more than 72 hours)</li> </ul>	
Availability:	Monday through Friday	
Results and Interpretation:	MRSA isolated and identified	
Reference Range:	MRSA was not detected	
Additional Information:	N/A	
Purpose of Test:	Detect the presence of MRSA	
Method:	Broth amplification, plate culture, isolation and identification, Cefoxitin disc screen to	
	identify methicillin resistance.	
Interfering Substances:	N/A	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory	
	1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	N/A	

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TEST:	MRSA (rule out)
Synonym:	Methicillin Resistant Staph aureus (MRSA) culture: Refer to instructions for Methicillin
	Resistant Staph aureus (MRSA) culture.
Laboratory/Phone:	Microbiology 443-681-3952

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TEST:	Mumps Virus Culture
Synonym:	Mumps Virus culture: Refer to instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934
Specimens:	1 Buccal swab in VTM with a requisition for each specimen. Refer to instructions for Virus Culture.

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TEST:	Mumps Antibody IgG EIA (Mumps Immunity Screen)
Synonym:	Anti-Mumps IgG; Mumps immunity test
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum)
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer.
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" next to Mumps Immunity Screen or
	MMRV Immunity Screen.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
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Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Whole blood or separated serum transport at 2-8°C on cold packs up to 9 days after collection. <b>Separated Serum only:</b> For > 9 days after collection transport -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic; lipemic; gross bacterial contamination. Specimens collected > 9 days prior to arrival without being frozen.
Availability:	Service available only to state and local health departments Monday to Friday.
Results and Interpretation:	<ul> <li>Negative: Indicates no detectable IgG antibody to Mumps virus. A negative results indicate no current or previous infection with Mumps virus. Such individuals are presumed to be susceptible to primary infection. Specimen taken too early during a primary infection may not have detectable levels of IgG antibody. If primary infection is suspected, another specimen (convalescent) should be taken in 8-14 days and tested concurrently in the same assay with the original (acute) specimen to test for seroconversion. If acute specimen is negative and convalescent specimen is positive, seroconversion has taken place and a primary Mumps virus infection is indicated.</li> <li>Equivocal: Equivocal results are indeterminate. Patient may or may not have immunity to Mumps Virus. It is not acceptable proof of immunity.</li> <li>Positive: Indicates evidence of Mumps IgG antibodies This suggests past or current infection with Mumps virus, via acquired immunity or vaccination and probable protection from clinical infection (immunity).</li> </ul>
Additional Information:	For more information, see the CDC link at: <u>https://www.cdc.gov/mumps/</u>
Purpose of Test:	For detection of IgG antibodies to Mumps virus, the test can be used to evaluate single sera for immune status.
Method:	Chemiluminescent Immunoassay(CLIA)
Interfering Substances:	Test results from an immunocompromised patients should be interpreted with caution.
Testing Site:	MDH Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	A diagnosis should not be made on the basis of the anti-Mumps results alone. Test results should be interpreted in conjunction with the clinical evaluation and the results of other diagnostic procedures. The antibody titer of a single serum specimen cannot be used to determine a recent infection. Paired samples (acute and convalescent) should be collected and tested concurrently to demonstrate seroconversion. Samples collected too early in the course of an infection may not have detectable levels of IgG. In such cases, a second sample may be collected after 2-7 weeks and tested concurrently with the original sample to test for seroconversion. A positive Mumps IgG test in neonates should be interpreted with caution since passively acquired maternal antibody can persist for up to 6 months.

#### TEST: **Mumps IgM Antibody IFA** Synonym: Anti-Mumps IgM; Mumps IgM IFA Laboratory/Phone: Vaccine Preventable Disease/443-681-3889 **Turnaround Time:** 2-5 business days Specimen Required: Serum The specimen/sample must be properly labeled and include patient's name or unique Specimen identification: patient/sample identifier matching the test requisition or electronic test order. 5 ml. (Whole blood) or 4 ml. (Serum) Specimen Volume (Optimum): Specimen Volume (Minimum): 3 ml. (Whole blood) or 2 ml. (Serum) Collect: Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer. MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be Form: downloaded from MDH Laboratory website). Write "Mumps IgM" on form. Indicate specimen type using the "Specimen Code". Prior approval by MDH Epidemiology (410-767-6628) required. Packaging and Shipping\*: Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). \*Refer to current Federal regulations for specific shipping requirements. Continued Next Page>

Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Whole blood or separated serum transport at 2-8°C on cold packs up to 7 days after collection. <b>Separated Serum only:</b> For > 7 days after collection transport at -20°C on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic; lipemic; gross bacterial contamination. Specimens collected > 7 days prior to arrival without being frozen.
Availability:	Monday to Friday. Test available only to MDH epidemiologists for outbreak investigations. Prior approval by MDH Epidemiology (410-767-6628) required.
Results and Interpretation:	<b>Negative:</b> No significant level of Mumps IgM antibodies detected. A negative result indicates no current infection with Mumps virus. However, specimens taken too early during a primary infection may not have detectable levels of IgM antibody. If a primary infection is suspected, another specimen should be taken within 7 days and tested concurrently in the same assay with the original specimen to look for seroconversion <b>Positive:</b> Evidence of Mumps IgM antibodies detected and indicative of current or recent infection.
Additional Information:	For more information, see the CDC link at: <u>https://www.cdc.gov/mumps/</u>
Purpose of Test:	For the detection of IgM antibodies to Mumps virus. <b>Test available only to MDH</b> epidemiologists for outbreak investigations. Prior approval by MDH Epidemiology (410- 767-6628) required.
Method:	IFA
Interfering Substances:	Blood should be collected at least one hour after meals to avoid lipemic serum, as excess lipids may cause false negative results. IgM anti-cell antibodies, if present in the serum, may interfere with the Mumps IgM test. Antibodies to Parainfluenza viruses may cross- react. High Mumps IgG or Rheumatoid factor may cause false positive or negative results. Test results in an immunocompromised patients should be interpreted with caution.
Testing Site:	MDH Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Results of the Mumps IgM IFA are not by themselves diagnostic and should be interpreted in light of the patient's clinical condition and results of other diagnostic procedures. Samples taken too early during the course of a primary infection may not have detectable levels of mumps specific IgM. A negative result does not rule out a primary infection with mumps virus. False positive anti-mumps IgM results may be obtained from patients with autoimmune disease. The performance of the Mumps IgM IFA has not been validated using neonatal samples.

TEST:	Mycobacterium tuberculosis culture
Synonym:	AFB culture, Acid Fast Bacteria Identification (Acid Fast Bacilli)
Laboratory/Phone:	Microbiology - Mycobacteriology / 443-681-3942
Turnaround Time:	AFB smear: 24 hours [Note all times are from specimen receipt in the Laboratory] Nucleic Acid Amplification (GeneXpert): 48 hours Positive culture: 14-21 days. Reported as soon as detected. Negative culture: 8 weeks Susceptibility Testing: up to 17 days from culture positivity
Specimen Required:	Preferred: Sputum Other Acceptable: respiratory aspirate, bronchial wash, bronchoalveolar lavage (BAL), body fluids, CSF, tissue, urine, lymph node.
Specimen identification:	Specimen should be labeled with patient's last and first name, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Sputum, aspirate or CSF: 3-5 mls Body fluid: < 10 mls
Specimen Volume (Minimum):	Sputum aspirate or CSF: > 1 ml Body Fluid: > 5 mls
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### MD Department of Health-Laboratories Administration

ID Department of Health-Laboratories Ac	Iministration The J. Mehsen Joseph Public Health Laboratory
Collect:	In a sterile, leak-proof container, e.g., a 50 ml conical tube, collection of early morning sputum specimens on each of three (3) consecutive days is optimum.
	For optimal pulmonary specimens, collect sputum from the lung after a deep, productive cough. Do not pool specimens. Label induced sputum specimens as "induced" since they resemble saliva.
	Gastric lavage specimens should be collected in a hospital and sent to the Central Laboratory immediately for processing. If specimen transport is delayed, recovery of mycobacteria is severely compromised (since mycobacteria die rapidly in gastric washing). Indicate source of specimen on the lab form. Note: If > 1 hour delay, neutralize specimen with 100 mg sodium carbonate.
	Tissue: Submit skin lesions or other tissue; keep moistened with sterile saline.
	Store refrigerated. Do not use waxed container. Keep blood and CSF at room/ambient temperature (2-30°C). Blood in SPS (yellow top) or Heparin (green top) vacutainer.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance).
Transport Conditions*:	*Refer to current Federal regulations for specific shipping requirements. Receipt by Central Laboratory within 24 hours after collection preferred.
*Blood and CSF should be kept at	Preferred: Transport at 2-8°C on cold packs.
room temperature	Other Acceptable: Transport at room/ambient temperature (2-30 °C).
Specimen Rejection Criteria: Availability: Results and Interpretation:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> <li>Broken specimen for test request</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> </ul> Monday through Friday, 8:00 A.M. to 4:30 P.M. AFB Smear: Acid-fast bacilli seen on smears from this specimen. The acid-fast stain does not differentiate M. tuberculosis from other non-tuberculous mycobacteria.
·	not differentiate <i>M. tuberculosis</i> from other non-tuberculous mycobacteria.
	AFB Culture: Positive culture – Mycobacterial identification given.
	Negative culture – No mycobacteria were recovered from this specimen by culture.
	Client is notified of positive smear/culture, MTD or first positive M. tuberculosis complex culture.
Referred isolate for identification:	Provide specimen collection body site and date collected.
Reference Range:	Complete identification of clinically significant isolates. Antimicrobial susceptibilities performed on all initial isolates of <i>M. tuberculosis</i> complex. Drug resistant isolates will be tested for susceptibility to second-line anti-mycobacterial drugs. Anti-microbial susceptibilities performed on Mycobacterium other than <i>M. tuberculosis</i> complex isolated by request with justification for testing (immunocompromised patient, multiple site isolates, HIV patient, etc.).
Additional Information:	All mycobacterial identification performed by Vitek MS MALDI-TOF.
Purpose of Test:	The AFB smear can determine the presence of mycobacteria in clinical specimens by microscopic examination. AFB smears are made from the sediments of specimens that have been decontaminated and concentrated by centrifugation for culture. Special solid and liquid growth media are inoculated with the concentrated specimen for isolation and identification of mycobacteria.
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Method:	Standard reference procedures for stain and culture.
Interfering Substances:	Propylene glycol, waxed containers, tap water (may contain saprophytic mycobacteria), antimicrobial therapy, food particles, mouthwash.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Nucleic Acid Amplification Assay:	Will be performed by Cepheid GeneXpert done on all new smear positive patient specimens or referred specimen concentrates on patients with a high suspicion for active tuberculosis. Patient must be on treatment < three (3) days or not at all. Test should not be requested routinely. Please contact the laboratory at 443-681-3942 for further ordering guidance.

TEST:	Mycoplasma Serology
Synonym:	Mycoplasma pneumoniae
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer tube
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form. Date specimen collected
	MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: For up to 48 hours after collection, transport whole blood or
	separated serum at 2-8°C on cold packs. If > 48 hours after collection, transport serum at
	-20°C or colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Grossly hemolyzed or lipemic specimens, unlabeled specimen, leaking container,
	insufficient volume, mismatch between labeling of specimen and test request form,
	specimen collected > 2 days prior to arrival without being frozen.
Availability:	Monday through Friday
Results and Interpretation:	NEGATIVE—No significant amount of IgG/IgM antibodies detected, no presumptive
	evidence of current/previous infection.
	<b>POSITIVE</b> —IgG/IgM antibodies detected, evidence of a past/recent infection
	EQUIVOCAL—Immunological status cannot be determined. Please redraw patient in 1-3
	weeks
Additional Information:	http://www.cdc.gov/pneumonia/atypical/mycoplasma/
Purpose of Test:	Detect antibodies to Mycoplasma pneumoniae
Methods:	EIA
Interfering Substances:	Hemolysis, lipemia
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	May not detect a recent infection. If suspicion of a Mycoplasma infection, take a second
	sample at least 14 days later for additional testing.
	Serologic results should not be used as a sole means for diagnosis, treatment, or for the
	assessment of a patient's health. Clinical correlation is required.

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TEST:	Neisseria gonorrhoeae Culture
Synonym:	GC Culture; Gonorrhea Culture; N. gonorrhoeae Culture: Refer to instructions for
	Gonorrhea Culture.
Laboratory/Phone:	Microbiology 443-681-3952

TEST:	Neisseria meningitidis (ABCs - previously BIDS))
Synonym:	Active Bacterial Core Surveillance (ABCs) (Bacterial Invasive Disease Surveillance) Neisseria meningitidis: Refer to instructions for ABCs (previously BIDS).
Lab/Phone:	Microbiology 443-681-3952

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TEST:	Newborn Screening
Synonym:	PKU
Laboratory/Phone:	443-681-3900
Turnaround Time:	3 calendar days (72hrs)
Specimen Required:	Dried Blood Spot (DBS)
Specimen Identification:	Specimen must be submitted on a properly completed approved Newborn Screening
	Collection Device.
Specimen Volume (Optimum):	N/A
Specimen Volume (Minimum):	N/A
Collect:	Approved Newborn Screening Collection Device.
Form:	Form 77 (Newborn Screening) & Form 79 (Subsequent Specimen)
	Specimens must be packaged in a triple packaging system to ensure that under normal
Packaging and Shipping*:	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at room/ambient temperature (2-30°C) or frozen at -20°C or colder on dry ice
Availability:	Monday through Saturday
Results and Interpretation:	Refer to section F. Guide to Interpretation of Hereditary Disorders
Reference Range:	Refer to section F. Guide to Interpretation of Hereditary Disorders
Additional Information:	N/A
Purpose of Test:	Screening for congenital and hereditary disease in newborns and children
Method:	Immunoassay, HPLC, Tadem Mass Spec, PCR, Biochemical, Colorimetric, Fluorometric, IEF
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Birthing hospitals are billed for newborn screening testing.

TEST:	Ohara's disease
Synonym:	Francisella tularensis, Pasteurella tularensis, tularemia, rabbit fever, deerfly fever, Ohara's
	disease, Francis disease: Refer to instructions for <i>Francisella tularensis</i> culture or
	Francisella tularensis Antibody.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Ova and Parasites Microscopic Examination
Synonym:	Amebiasis, Giardia, Parasitic identification, worm identification
Laboratory/Phone:	Microbiology 443-681-3952 or 443-681-4570
Turnaround Time:	5 business days [Note time is from specimen receipt in the Laboratory]
Specimen Required:	Feces: Minimum of three (3) specimens collected over a 7-10 day period.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Please refer to the directions available with stool collection kit. There is no maximum limit
	on the amount of stool collected.
Specimen Volume (Minimum):	Please refer to the directions available with stool collection kit. As a minimum amount,
	collect several grams (or teaspoon amounts).
Collect:	Please refer to the directions available with the Para-Pak ULTRA EcoFix stool collection kit.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured, or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Para-Pak ULTRA EcoFix Collection Kit packet insert: Store and transport at
	room/ambient temperature (2-30°C).
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results
	and to avoid misleading information that might lead to misdiagnosis and inappropriate
	therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Genus and species
Reference Range:	No Ova or Parasites found
Additional Information:	Collect all fecal specimens prior to the administration of antibiotics or anti-diarrheal agents.
	Avoid contamination with urine or water from the toilet.
Purpose of Test:	Diagnosis of intestinal parasite
Method:	Microscopic: Wet mount and permanent stain using Eco-fix and Eco-stain.
Interfering Substances:	Avoid the use of mineral oil, bismuth and barium prior to fecal collection since all of these
-	substances may interfere with detection or identification of intestinal parasites.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
-	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

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TEST:	Parainfluenza Virus (Types 1, 2, and 3) Viral Culture
Synonym:	Parainfluenza Virus (Types 1, 2, and 3): Refer to instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934

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TEST:	Parasitic examination (Ova and Parasites Microscopic Examination)	
Synonym:	Amebiasis, Giardia, Entamoeba, Parasite identification, worm identification: Refer to	
	instructions for Ova and Parasites Microscopic Examination.	
Laboratory/Phone:	Microbiology 443-681-3952	
Laboratory/Phone:	Microbiology 443-681-3952	

TEST:	Pasteurella tularensis (Francisella tularensis) culture	
Synonym:	Pasteurella tularensis, tularemia, rabbit fever, deerfly fever, Ohara's disease, Francis	
	disease: Refer to instructions for Francisella tularensis culture.	
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:	
	410-925-3121 (24/7 emergency contact number)	
	Select Agents Microbiology Laboratory: 443-681-3954	
	Division of Microbiology Laboratory: 443-681-3952	

TEST:	Pertussis (Bordetella pertussis) PCR & Culture
Synonym:	B. pertussis, pertussis, Whooping Cough Refer to instructions for Bordetella pertussis PCR and culture.
Laboratory/Phone:	Molecular Biology: 443-681-3924 Microbiology 443-681-3952

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TEST:	Pertussis Serology (Bordetella pertussis)
Synonym:	IgG Anti-Bordetella pertussis toxin assay. Refer to instructions for Bordetella Pertussis
	Toxin IgG Antibody
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889

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TEST: **Pinworm Examination** Clear Cellulose tape preparation for Enterobius vermicularis Synonym: Microbiology 443-681-3952 Laboratory/Phone: Turnaround Time: 24 hrs. [from specimen receipt in the Laboratory] Monday through Friday Specimen Required: Clear Cellulose tape preparation from the skin of the perianal area. - DO NOT USE FROSTED TAPE Specimen identification: Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order. Specimen Volume (Optimum): N/A Specimen Volume (Minimum): N/A Collect: To obtain a sample from the perianal area, peel back the tape by gripping the labeled end, and, with the tape looped (adhesive side outward) over a wooden tongue depressor that is held firmly against the slide and extended about 2-5 cm beyond it, press the tape firmly several times against the right and left perianal folds. Smooth the tape back on the slide, adhesive side down. Label with patient's name and date. MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or Form: form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Specimens must be packaged in a triple packaging system to ensure that under normal Packaging and Shipping\*: conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). \*Refer to current Federal regulations for specific shipping requirements. **Transport Conditions:** Transport at room/ambient temperature 2-30°C. Continued Next Page>

Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results	
	and to avoid misleading information that might lead to misdiagnosis and inappropriate	
	therapy. A request for a new specimen will provide appropriate materials and clinically	
	relevant information to support good patient care.	
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>	
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>	
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>	
	<ul> <li>Mismatched form and specimen</li> </ul>	
	<ul> <li>Broken specimen/sample container</li> </ul>	
	<ul> <li>The wrong specimen for test request</li> </ul>	
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>	
Availability:	Monday through Friday	
Results and Interpretation:	Organism and stage	
Reference Range:	Enterobius vermicularis NOT found	
Additional Information:	Pinworm eggs are usually infectious. The female pinworm deposits eggs on the periana	
	skin only sporadically, without multiple tapes (taken consecutively, each morning), it is not	
	possible to determine if the patient is positive or negative for the infection.	
Purpose of Test:	Detection of human pinworm infections	
Method:	Microscopic	
Interfering Substances:	Opaque tape	
Testing Site: MD Department of Health Laboratories Administration, Central Laborator		
	1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	N/A	

TEST:	РКО
Synonym:	Refer to instructions for Newborn Screening
Laboratory/Phone:	443-681-3900

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TEST:	Plague (Yersinia pestis)
Synonym:	Plague; Yersinia pestis; Pasteurella pestis: Refer to instructions for Yersinia pestis culture.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Polio Virus, Virus Culture
Synonym:	Polio Virus Culture (Enterovirus, including Echovirus, Coxsackie, and Polio): Refer to
	instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934

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TEST:	Powassan Virus IgM Serology
	(Tick-borne Disease Panel)
Synonym:	Tick-borne virus
	Refer to instructions in Tick-Borne Disease Panel
Laboratory/Phone:	443-681-3931/3936
Specimen Required:	Serum; CSF
Results and Interpretation:	
Additional Information:	https://www.cdc.gov/ticks/tickbornediseases/powassan.html
Purpose of Test:	For the detection of IgM antibodies to Powassan virus
Methods:	MAC-ELISA
Comment:	The results are used for EPIDEMIOLOGICAL purposes and a report will not be issued.

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TEST:	Q-fever serology
Synonym:	Coxiella burnetii, Q-fever: Refer to instructions for Coxiella Serology.
Laboratory/Phone:	443-681-3938/3931

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TEST: **QuantiFERON Plus** Interferon-gamma release assay, IGRA Synonym: Laboratory/Phone: (443) 681-3942 **Turnaround Time:** 5 business days from receipt of specimen. 1 mL of blood collected in assay-specific collection tubes. Specimen Required: Specimen Identification: Specimen must be labeled with patient name and one other unique identifier, such as date of birth. Specimen Volume (Optimum): 1 mL Specimen Volume (Minimum): 0.8 mL Collect: 1 mL of blood into each of four (4) specialized QuantiFERON blood collection tubes. All tubes must be vigorously shaken and incubated at 37° C within sixteen (16) hours of collection. Form: MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Specimens must be packaged in a triple packaging system to ensure that under normal Packaging and Shipping\*: conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). \*Refer to current Federal regulations for specific shipping requirements. **Transport Conditions:** Must be transported at 4 to 27° C per FDA assay packet insert. Specimen Rejection Criteria: The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care. Unlabeled or improperly labeled specimen Insufficient specimen volume Inappropriate or expired specimen collection tubes Improper specimen collection and handling Availability: Monday through Friday, 8:00 A.M. to 4:30 P.M., only to local health departments having received previous training on the proper collection and processing of specimens. Please contact the testing laboratory at (443)681-3942 for further information. **Results and Interpretation:** Positive: Positive for previous exposure to M. tuberculosis complex (note: does not crossreact with the BCG vaccine). Negative: Negative for previous exposure to *M. tuberculosis* complex. Indeterminate: Unable to yield a valid test result due to poor patient immune response or improper specimen processing. **Reference Range:** An increase in interferon-gamma of 0 to 0.34 IU/mL in whole blood serum after exposure to M. tuberculosis complex-specific antigens. An increase of 0.35 IU/mL or greater indicates a positive test result. Additional Information: All positive and indeterminate test results are repeated for confirmation of findings before a result is reported. Purpose of Test: The assay detects previous exposure to M. tuberculosis complex, indicating the possibility of latent infection. The assay may be used in all instances when performing a tuberculin skin test (TST) would be deemed appropriate. Method: Enzyme Linked Immunosorbent Assay (ELISA) is performed as per the assay's FDA-cleared instructions. **Interfering Substances:** Administering a live-virus vaccine prior to collection of blood for this assay may increase the instances of false-positive or indeterminate test results. MD Department of Health Laboratories Administration, Central Laboratory Testing Site: 1770 Ashland Avenue, Baltimore, Maryland 21205 Comment:



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TEST:	Rabbit fever
Synonym:	Francisella tularensi; Pasteurella tularensis, tularemia, deerfly fever, Ohara's disease,
	Francis disease: Refer to instructions for Francisella tularensis culture or Francisella
	tularensis Antibody.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

TEST:	Rabies Antibody Titer (RFFIT)
Synonym:	RFFIT Test
Laboratory/Phone:	Division of Virology and Immunology/Rabies Lab 443-681-3771/443-681-3773
Turnaround Time:	15 working days
Specimen Required:	Serum/Blood
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier, date of birth, and specimen collection date matching the test
	requisition or electronic test order.
Specimen Volume (Optimum):	5 ml whole blood or 2 ml of serum
Specimen Volume (Minimum):	2 ml whole blood or 1 ml serum
Collect:	Red-top vacutainer or Zebra-top serum separator vacutainer
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Whole blood specimens or separated serum transport on cold packs at 2-8°C (refrigerated)
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled tube; insufficient
	quantity of serum for testing; hemolysis; lipemia; gross bacterial contamination.
Availability:	Monday through Friday
Results and Interpretation:	Positive 0.5 IU/mL or greater (immunity)
	Negative indicates no detectable antibody to the rabies virus or the presence of
	detectable antibody < 0.5 IU/mL.
Reference Range:	Patient's with a titer > 0.5 IU/mL. is considered to have adequate immune response.
Additional Information:	Provide patient's rabies vaccination history.
Purpose of Test:	For detection of rabies antibody
Method:	Rapid Fluorescent Focus Inhibition Test (RFFIT)
Interfering Substances:	Icteric, hemolyzed, lipemic or heat inactivation of specimen
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Restricted Test: Services provided to State and Local government employees (e.g. animal
	control, etc.). Maryland residents requiring testing refer to the Rabies Laboratory
	website: https://health.maryland.gov/laboratories/Pages/Rabies.aspx

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TEST:	Rat Bite Fever
Synonym:	Streptobacillus moniliformis Culture; Haverhill Fever: Refer to instructions for
	Streptobacillus moniliformis Culture.
Laboratory/Phone:	Microbiology 443-681-3952

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TEST:	Respiratory Syncytial Virus (RSV) Virus Culture
Synonym:	Respiratory Syncytial Virus (RSV) : Refer to instructions for Virus Culture.
Laboratory/Phone:	Virology: 443-681-3934
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TEST:	Rock of Gibraltar Fever
Synonym:	Brucellosis, Bang's Disease, Undulant fever, Malta Fever: Refer to instructions for Brucella
	serology or Brucella species culture.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

TEST:	Rickettsia (Spotted Fever Group) Serology (Tick-borne Disease Panel)
Synonym:	RMSF IgG serology; Rocky Mountain spotted fever, <i>Rickettsia rickettsii</i> <b>Refer to instructions in Tick-Borne Disease Panel</b>
Laboratory/Phone:	443-681-3938/3931
Specimen Required:	Serum
Results and Interpretation:	Titers $\geq$ 1:64 are suggestive of possible early infection, declining titers due to past exposure, or cross-reactivity with a related organism.
Additional Information:	https://www.cdc.gov/ticks/tickbornediseases/rickettsiosis.html https://www.cdc.gov/ticks/tickbornediseases/rmsf.html
Purpose of Test:	For the detection of IgG antibodies to Rickettsia (spotted fever group)
Method:	Immunofluorescence assay (IFA)
	Cross reaction between <i>Rickettsia</i> Spotted Fever Group species occurs. Serology cannot differentiate between the species.
Comment:	A four-fold increase in titer between acute and convalescent serum specimens supports the diagnosis of recent infection. Acute phase sera should be collected within the first week after onset of illness, and convalescent phase sera, 2-4 weeks after onset.

TEST:	Rubella IgG (Rubella Immunity Screen).
Synonym:	Anti-Rubella IgG; German Measles IgG antibody; Rubella immunity test
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum)
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer.
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" next to Rubella Immunity Screen or MMRV Immunity Screen.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Whole blood or separated serum transport at 2-8°C on cold packs up to 3 days after collection. <b>Separated Serum only:</b> For > 3 days after collection transport at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic; lipemic; gross bacterial contamination. Specimens collected > 3 days prior to arrival without being frozen.

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Availability:	Service available only to state and local health departments Monday to Friday.
Results and Interpretation:	Negative: Indicates no detectable IgG antibody to Rubella virus. A negative results
	indicates no current or previous infection with Rubella virus. Such individuals are
	presumed to be susceptible to primary infection. However, specimen taken too early
	during a primary infection may not have detectable levels of IgG antibody. If primary
	infection is suspected, another specimen (convalescent) should be taken in 8-14 days and
	tested concurrently in the same assay with the original (acute) specimen to look for
	seroconversion. If acute specimen is negative and convalescent specimen is positive,
	seroconversion has taken place and a primary rubella virus infection is indicated.
	<b>Equivocal:</b> Equivocal results are indeterminate. Patient may or may not have immunity to
	Rubella Virus. It is not acceptable proof of immunity.
	Positive: Indicates evidence of Rubella IgG antibodies. This suggests past or current
	infection with Rubella virus, via acquired immunity or vaccination and probable protection
	from clinical infection (Immunity).
Additional Information:	For more information, see the CDC link at: <u>https://www.cdc.gov/rubella/</u>
Purpose of Test:	For detection of IgG antibodies to Rubella virus. The test can be used to evaluate single
	sera for immune status or paired sera to demonstrate seroconversion.
Method:	Chemiluminescent Immunoassay (CLIA)
Interfering Substances:	Test results in an immunocompromised patients should be interpreted with caution.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	A diagnosis should not be made on the basis of anti-Rubella results alone. Test results
	should be interpreted in conjunction with the clinical evaluation and the results of other
	diagnostic procedures. The antibody titer of a single serum specimen cannot be used to
	determine a recent infection. Paired samples (acute and convalescent) should be collected
	and tested concurrently to demonstrate seroconversion. Samples collected too early in
	the course of an infection may not have detectable levels of IgG. In such cases, a second
	sample may be collected after 2-7 weeks and tested concurrently with the original sample
	to look for seroconversion. A positive rubella IgG test in neonates should be interpreted
	with caution since passively acquired maternal antibody can persist for up to 6 months.

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TEST:	Rubella IgM Antibody
Synonym:	Anti-Rubella IgM; Rubella IgM antibody for Rubella/ German Measles - acute infection
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889
Turnaround Time:	2-5 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum)
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum)
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer.
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Write "Rubella IgM" on form. Indicate specimen type using the "Specimen Code". Prior
	approval by MDH Epidemiology (410-767-6628) required.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: Whole blood or separated serum transport at 2-8°C on cold
	packs up to 48 hours after collection. Separated Serum only: For >48 hours after
	collection transport at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic;
-	lipemic; gross bacterial contamination. Specimens collected > 48 hours prior to arrival
	without being frozen.
Availability:	Monday to Friday. Test available only to MDH epidemiologists for outbreak
	investigations. Prior approval by MDH Epidemiology (410-767-6628) required.

Results and Interpretation:	Negative: Indicates no detectable Rubella IgM antibodies. A negative result indicates no
	current infection with rubella virus. However, specimens taken too early during a primary
	infection may not have detectable levels of IgM antibody. If a primary infection is
	suspected, another specimen should be taken within 7 days and tested concurrently in the
	same assay with the original specimen to look for seroconversion
	Equivocal: Equivocal specimens are indeterminate. Another specimen should be collected
	after 7 days and retested.
	Positive: Indicates evidence of Rubella IgM antibodies.
	This suggests primary or reactivated infection with Rubella.
Additional Information:	For more information, see the CDC link at: <a href="https://www.cdc.gov/rubella/">https://www.cdc.gov/rubella/</a>
Purpose of Test:	Test available only to MDH epidemiologists for outbreak investigations. Prior approval
	by MDH Epidemiology (410-767-6628) required.
Method:	ELISA
Interfering Substances:	High anti-Rubella IgG or Rheumatoid factor may cause false negative or false positive
	results. Test results in an immunocompromised patients should be interpreted with
	caution. Heterotypic IgM antibody responses may occur in patients infected with Epstein-
	Barr virus, and sera from patients with infectious mononucleosis may have false positive
	results. Patients with autoimmune disease may present with false positive results.
Testing Site:	MDH Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Results of the Rubella IgM ELISA are not by themselves diagnostic and should be
	interpreted in light of the patient's clinical condition and results of other diagnostic
	procedures. Samples taken too early during the course of a primary infection may not
	have detectable levels of rubella specific IgM. A negative result does not rule out a
	primary infection. This assay cannot distinguish the difference between vaccine-induced
	antibody and antibody resulting from a natural infection. The performance of the Rubella
	IgM EIA has not been validated using neonatal samples.

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TEST:	Salmonella Culture Enteric Culture, Routine (Salmonella, Shigella, Campylobacter, and Shiga toxins– producing <i>E. coli</i> )
Synonym:	Stool culture for enteric pathogens; enteric pathogens; stool culture and sensitivity; feces culture: Refer to instructions for Enteric Culture, Routine (Salmonella, Shigella, Campylobacter, and Shiga toxins–producing <i>E. coli</i> ).
Laboratory/Phone:	Microbiology-Enterics 443-681-4570

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TEST:	Salmonella typing
Synonym:	Salmonella isolate for typing (referral isolate)
Laboratory/Phone:	Microbiology-Enterics 443-681-4570
Turnaround Time:	For epidemiological purposes only. CDC TAT: 8 weeks. For additional questions, contact the laboratory 443-681-4570
Specimen Required:	Pure culture on agar slant in screw cap tube.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Salmonella isolated from culture
Specimen Volume (Minimum):	N/A
Collect:	N/A
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Store and transport isolate at room/ambient temperature (2-30°C).
	Continued Next Page>

Specimen Rejection Criteria:	<ul> <li>The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care.</li> <li>Unlabeled or improperly labeled specimen</li> <li>Non-sterile or leaking container</li> <li>Inappropriate specimen transport conditions</li> <li>Illegible, or no submitter information on the request form</li> <li>Mismatched form and specimen</li> <li>Broken specimen for test request</li> <li>Inappropriate outfit for requested test</li> <li>Illegible or no patient information on the specimen</li> <li>Expired transport media</li> <li>Specimen frozen</li> </ul>
Availability:	Monday through Friday
Results and Interpretation:	Salmonella somatic and flagellar antigens identified.
Reference Range:	N/A
Additional Information:	SUBCULTURE TO AGAR SLANT BEFORE TRANSPORTING. DO NOT SEND CULTURE PLATES. MAKE SURE CULTURE IS GROWING/VIABLE.
Purpose of Test:	Salmonella serotyping
Method:	Isolate is subcultured to confirm purity. Salmonella serological testing is performed by slide agglutination and tube agglutination tests using somatic (O) and flagella (H) antisera. Biochemical identification also.
Interfering Substances/ Limitations:	Submission of isolate on inhibitory media.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

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TEST:	SARS-CoV-2 Assay (Aptima)
Synonym:	SARS-CoV-2 Assay (Aptima)
Laboratory/Phone:	Virus Isolation Laboratory / 443-681-3937
Turnaround Time:	2 Days
Specimen Required:	Nasopharyngeal, Oropharyngeal (including throat swab) in Viral Transport Media
Specimen Identification:	Label specimen with full name exactly matching test requisition and date of collection. The specimen must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	3ml
Specimen Volume (Minimum):	1ml
Collect:	Collect Nasopharyngeal, Oropharyngeal (including throat swab) in Viral Transport Media according to standard technique using a polyester rayon or nylon tipped swab. Immediately place swab specimen into 3ml of Viral Transport Media (VTM) or Universal Transport Media (UM). VTM can be ordered by the local health department by calling 443-681-3777 and submitting via email or fax the Outfit Supply Requisition form. NOTE: Do not collect NP swabs in saline or MTM.
Form:	MDH Form #4676 Infectious Agents: Culture/ Detection (Order forms: 443-681-3777 or form may be downloaded from the MDH Laboratory Website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: After specimen collection store and transport on cold packs at 2-8°C for up to 96 hours. For >96 hours after collection store and transport at -70°C or colder on dry ice.
Specimen Rejection Criteria:	Specimen collected greater than 96 hours and not frozen
Availability:	Monday – Friday
Results and Interpretation:	Negative: SARS-CoV-2 not detected Positive: SARS-CoV-2 detected Invalid: Specimen failed in the Aptima SARS-CoV-2 nucleic acid amplification assay. Please re-collect and submit another specimen for testing.
Reference Range:	Qualitative Infectious Assay. Healthy individuals should be negative.
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Additional Information:	
Purpose of Test:	Qualitative detection of RNA from SARS-CoV-2
Method:	Transcription Mediated Amplification (TMA)
Interfering Substances:	Guanidinium Thiocynate or Guanidine materials
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	

TEST: SARS-CoV-2 Real Time rt-PCR (Refer to Influenza & SARS-CoV2 – Molecular **Detection (qPCR)** SARS2, Coronavirus 2, COVID, and COVID-19. Refer to instructions for Influenza & Synonym: SARS-CoV2 – Molecular Detection (qPCR) Laboratory/Phone: 443-681-3924

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TEST:	SARS-CoV-2 Serology
Synonym:	SARS-CoV-2 antibody
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	3 working days
Specimen Required:	Serum; EDTA plasma
Specimen Identification:	The specimen/sample must be properly labeled and include patient's name or unique
	patient/sample identifier matching the test requisition or electronic test order
Specimen Volume (Optimum):	2mL (whole blood)
Specimen Volume (Minimum):	1 mL (whole blood)
Collect:	Red-top vacutainer tube; purple-top vacutainer tube
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured, or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: For up to 2 days after collection: transport whole blood,
	separated serum, or plasma at 15-30°C. If 2 to 7 days after collection: transport whole blood, separated serum or plasma at 2-8°C on cold packs. If > 7 days after collection transport serum or plasma at -2°C or colder and ship on dry ice. WHOLE BLOOD CANNOT BE FROZEN.
Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, insufficient
	volume, mismatch between labeling of specimen and test request form, specimen collected > 7 days prior to arrival without being frozen.
Availability:	Monday through Friday (APPROVED SUBMITTERS ONLY)
Results and Interpretation:	The specimen will be tested for antibodies against different antigens of the virus. Abbott ARCHITECT assay detects antibodies to the nucleocapsid antigen of SARS-CoV-2. This antibody may be present after infection with the virus. The DiaSorin LIAISON assay detects antibodies to the spike antigen of SARS-CoV-2. This antibody may be present after infection with the virus or vaccination.
	<b>NEGATIVE:</b> Antibodies to SARS-CoV-2 have not been detected and there is a high probability of non-infection or an early infection with low level of antibody present. <b>POSITIVE:</b> Antibodies to SARS-CoV-2 were detected.
Additional Information:	https://www.cdc.gov/coronavirus/2019-ncov/lab/serology-testing.html
Purpose of Test:	Detect antibodies which may be due to SARS-COV-2 infection

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Interfering Substances:	Hemoloysis
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required.

TEST:	Shiga toxins-producing <i>E. coli</i> Culture
Synonym:	Stool culture for enteric pathogens; enteric pathogens; stool culture and sensitivity; feces culture: Refer to instructions for Enteric Culture, Routine (Salmonella, Shigella, Campylobacter, and Shiga toxins–producing <i>E. coli</i> ).
Laboratory/Phone:	Microbiology-Enterics 443-681-4570

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TEST:	Shigella Culture
Synonym:	Stool culture for enteric pathogens; enteric pathogens; stool culture and sensitivity; feces culture: Refer to instructions for Enteric Culture, Routine (Salmonella, Shigella, Campylobacter, and Shiga toxins–producing <i>E. coli</i> ).
Laboratory/Phone:	Microbiology - Enterics 443-681-4570

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TEST:	Shigella typing
Synonym:	Shigella isolate for typing (referral isolate)
Laboratory/Phone:	Microbiology - Enterics / 443-681-4570
Turnaround Time:	Usually 3-5 days [from receipt in the Laboratory]. CDC TAT: 8 weeks
Specimen Required:	Pure culture on agar slant in screw cap tube.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB,
	specimen type/source, and the date and time of collection. The specimen/sample must be
	properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Shigella isolated from culture
Specimen Volume (Minimum):	N/A
Collect:	N/A
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Store and transport isolate at room/ambient temperature (2-30°C).
Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results
	and to avoid misleading information that might lead to misdiagnosis and inappropriate
	therapy. A request for a new specimen will provide appropriate materials and clinically
	relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	<ul> <li>Expired transport media</li> </ul>
A	Specimen frozen
Availability:	Monday through Friday
Results and Interpretation:	Shigella somatic antigens identified
Reference Range:	N/A

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Additional Information:	SUBCULTURE TO AGAR SLANT BEFORE TRANSPORTING. DO NOT SEND CULTURE PLATES.
	MAKE SURE CULTURE IS VIABLE/GROWING.
Purpose of Test:	Shigella serotyping
Method:	Isolate is subcultured to confirm purity. Shigella serological testing is performed by a slide agglutination test using somatic (O) antisera. Biochemical analysis performed to verify Shigella identification.
Interfering Substances/Limitations:	Submission of isolate on inhibitory media.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	N/A

TEST:	St. Louis Encephalitis Virus (SLEV) (Arbovirus Endemic Panel)
Synonym:	Arthropod-borne virus: SLEV (St. Louis Encephalitis Virus):
	Refer to instructions for Arbovirus Endemic Panel.
Laboratory/Phone:	Virology: 443-681-3931/3936

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TEST:	Staph aureus Culture
Synonym:	Staph aureus Culture: Refer to instructions for Foodborne Pathogens, Foodborne
	Pathogenic Microorganisms, Stool Culture.
Laboratory/Phone:	Microbiology 443-681-3952

TEST:	Stool Culture Enteric Culture, Routine (Salmonella, Shigella, Campylobacter, and Shiga toxins– producing <i>E. coli</i> )
Synonym:	Stool culture for enteric pathogens; enteric pathogens; stool culture and sensitivity; feces culture: Refer to instructions for <b>Enteric Culture</b> , <b>Routine</b> (Salmonella, Shigella,
	Campylobacter, and Shiga toxins–producing <i>E. coli</i> )
Laboratory/Phone:	Microbiology-Enterics 443-681-4570

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TEST:	Streptobacillus moniliformis Culture
Synonym:	Rat Bite Fever; Haverhill Fever.
Laboratory/Phone:	Microbiology 443-681-3952
Turnaround Time:	2-3 weeks [from specimen receipt in the Laboratory]
Specimen Required:	Blood is the specimen of choice. Joint fluid, abscess fluid, wound exudates and lymph node are also acceptable.
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.
Specimen Volume (Optimum):	Draw enough blood into the blood culture bottle to make about 20% of the total volume. If citrated blood is collected, draw a total of 10 ml.
Specimen Volume (Minimum):	N/A
Collect:	Follow the blood culture kit instructions.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Transport at room/ambient temperature 2-30°C.
Availability:	Monday through Saturday
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Results and Interpretation:	S. moniliformis present
Reference Range:	S. moniliformis NOT found.
Additional Information:	Because special enrichment of media is necessary, the laboratory needs to know that an
	infection with S. moniliformis is suspected.
Purpose of Test:	Cultural confirmation of rat bite fever is very helpful for diagnosis, since the disease is not
	commonly seen.
Method:	Culture, convention and biochemicals.
Interfering Substances:	SPS in blood culture broth.
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
-	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Serological tests are not readily available

TEST:	Streptococcus pneumoniae (ABCs - previously BIDS))
Synonym:	Active Bacterial Core Surveillance (ABCs) (Bacterial Invasive Disease Surveillance)
	Streptococcus pneumoniae: Refer to instructions for ABCs (previously BIDS)
Laboratory/Phone:	Microbiology 443-681-3952

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TEST:	Streptococcus pyogenes culture
Synonym:	Group A Strep culture; Throat culture for Group A Strep Beta; Strep culture; Streptococcus
	pyogenes culture: Refer to instructions for Group A Strep Culture.
Laboratory/Phone:	Microbiology 443-681-3952

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TEST:	Syphilis Serology (Reflex Test)
Synonym:	Treponema pallidum IgG/IgM Antibody
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	3 business days
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer (Serum)
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected
	MUST be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert: Transport whole blood or separated serum at 2-8°C on cold
	packs. If shipping is delayed beyond 7 days after collection serum must be transported at -20°C or colder and shipped on dry ice. WHOLE BLOOD CANNOT BE FROZEN
Specimen Rejection Criteria:	Grossly hemolyzed, icteric, or lipemic specimens, unlabeled specimens, leaking container, insufficient volume, mismatch between labeling of specimen and test request form, specimen collected > 7 days prior to arrival without being frozen.
Availability:	Monday through Friday
Results and Interpretation:	NEGATIVE—Very low or no antibody is present in the sample. Does not rule out a recent or current infection         POSITVE—Antibody is present as a result of previous or current infection with T. pallidum         EQUIVOCAL—Suspect for infection with T. pallidum. Please submit another specimen in 2 weeks for retesting.
Additional Information:	http://www.cdc.gov/std/syphilis/
Purpose of Test:	Detect antibodies (IgM/IgG) which may be due to Treponema pallidum
Methods:	CLIA—Chemiluminescent Immunoassay
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Interfering Substances:	Hemolysis, lipemia, icterus
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	All treponemal tests tend to remain reactive following treponemal infection; therefore, they should not be used to evaluate response to therapy. Because of the persistence of reactivity, probably for the life of the patient, the treponemal tests are of no value to the clinician in determining relapse or re-infection in a patient who has had a reactive result. Serologic results should not be used as a sole means for diagnosis, treatment, or for the
	assessment of a patient's health. Clinical correlation is required.

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TEST:	Syphilis-RPR Serology
Synonym:	Rapid Plasma Reagin, Detect reagin antibodies associated with syphilis
Laboratory/Phone:	443-681-3938/3931
Turnaround Time:	3 business days
Specimen Required:	Serum/Plasma
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.
Specimen Volume (Optimum):	2 ml. (Whole Blood)
Specimen Volume (Minimum):	1 ml. (Whole Blood)
Collect:	Red-top vacutainer (Serum) or Lavender-top vacutainer (Plasma)
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be
	downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form. Date specimen collected <b>MUST</b> be provided.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per FDA Assay Packet Insert:
	Transport whole blood or separated serum at 2-8°C on cold packs within 7 days of collection. If shipping of serum is delayed beyond 7 days after collection transport at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN
	Transport plasma at 2-8°C on cold packs within 5 days of collection. If shipping of plasma is delayed beyond 5 days after collection transport at -20°C or colder on dry ice.
Specimen Rejection Criteria:	Hemolysis; insufficient volume, specimen collected > 7 days prior to arrival without being frozen
Availability:	Monday through Friday
Results and Interpretation:	REACTIVE- Non-Treponemal antibodies detected. NON-REACTIVE- Non-Treponemal antibodies not detected. False negatives occur in incubating primary and in latent syphilis
Additional Information:	
Purpose of Test:	Detect non-treponemal antibodies which may be due to syphilis, or to quantify reagin antibodies associated with syphilis infections, or to monitor response to treatment.
Method:	RPR (Rapid Plasma Reagin)
Interfering Substances:	Hemolysis, lipemia
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
resung site:	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	RPR tests may be non-specifically reactive in other conditions. Absence of reaginic antibody
	does not necessarily indicate inactive infection.
	Reactive specimens are quantitatively tested and reflexed to a Syphilis IgG/IgM
	chemiluminescent immunoassay for further serological study.
	Serologic results should not be used as a sole means for diagnosis, treatment, or for the
	assessment of a patient's health. Clinical correlation is required.

TEST:	Syphilis Serology -VDRL	
Synonym:	Venereal Disease Research Laboratory	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	5 business days	
Specimen Required:	Cerebrospinal fluid (CSF)	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	2 ml.	
Specimen Volume (Minimum):	1 ml.	
Collect:	Sterile CSF	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	<b>Per CDC Guidelines:</b> Transport sterile CSF at 2-8°C on ice packs or at -20°C or colder on dry ice. Specimens must be tested within 5 days of collection. If shipping is delayed beyond 5 days, CSF must be transported at -20°C or colder on dry ice.	
Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, insufficient volume, mismatch between labeling of specimen and test request form, specimen collected > 5 days prior to arrival without being frozen.	
Availability:	Monday through Friday	
Results and Interpretation:	<ul> <li>NON-REACTIVE — May indicate that the patient does not have neurosyphilis.</li> <li>REACTIVE VDRL test on CSF, free of blood or other contaminants, almost always indicates past or present syphilis infection of the central nervous system.</li> </ul>	
Additional Information:	This test is only performed on Cerebrospinal fluid (CSF)	
Purpose of Test:	Detect antibodies which may be due to syphilis	
Methods:	Slide flocculation test	
Interfering Substances:	Traces of blood or any particulate matter	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	The VDRL is a non-treponemal test to detect lipoidal antigen to T. pallidum. VDRL is run on spinal fluid specimens only, for suspected neurosyphilis.	

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TEST:	Throat Culture (Group A Strep Culture)	
Synonym:	Throat culture for Group A Strep Beta; Strep culture; Streptococcus pyogenes culture: Refer	
	to instructions for Group A Strep Culture.	
Laboratory/Phone:	Microbiology 443-681-3952	

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TEST:	Throat culture (Bacterial Culture, Routine)	
Synonym:	Aerobic culture, routine culture, throat culture: Refer to instructions for <b>Bacterial Culture</b> , <b>Routine</b> .	
Laboratory/Phone:	Microbiology 443-681-3952	

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Arthropod Identification; Tick identification/Ectoparasite: refer to instructions for	
ntification.	
143-681-3952	

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TEST:	Tick-borne Disease Panel	
	Panel includes: Anaplasmosis, Babesiosis, Ehrlichiosis, Lyme disease,	
	Powassan virus, Rickettsia (spotted fever group & Typhus Fever), Tularemia,	
Synonym:	Vector-borne disease panel	
Laboratory/Phone:	Virology: 443-681-3938/3931	
Turnaround Time:	5 working days (excluding PRNT Testing)	
Specimen Required:	Sworking days (excluding PRNT resting)	
Specimen identification:	The specimen/sample must be properly labeled and include the patient's name or	
•	unique patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	5 ml serum	
Specimen Volume (Minimum):	3 ml serum	
Collect:	Red top vacutainer tube, transfer serum to sterile tube.	
Form:	MDH Form# 4677 Serological Testing (Order Forms: 443-681-3777)	
	For testing to be initiated, the following information MUST be provided: date of	
	onset, and date specimen collected.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal	
	conditions of transport they cannot break, be punctured or leak their contents (Refer	
	to pages 9 & 10 for triple packing guidance).	
	*Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Transport whole blood or separated serum at 2-8°C on cold packs within 5 days of collection. If shipping of serum is delayed beyond 5 days	
	after collection transport at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN	
Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, and mismatch	
	between labeling of specimen and test request form, specimen collected > 7 days prior	
	to arrival without being frozen.	
Availability:	Monday through Friday.	
Results and Interpretation:	Anaplasma, Babesia, Ehrlichia, Rickettsia (Spotted Fever & Typhus Fever) titer	
	provided	
	Lyme disease, Powassan virus—Positive, Negative, Equivocal	
	Tularemia—Negative, Positive (with titer)	
Additional Information:	https://www.cdc.gov/ticks/tickbornediseases/index.html	
Purpose of Test:	For the presumptive detection of tick-borne diseases. Confirmatory testing by PRNT	
	may be required.	
Method:	IFA, CLIA, EIA, PRNT, Western Blot	
Interfering Substances:		
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770	
	Ashland Avenue, Baltimore, Maryland 21205	
Comment:	Serology testing for Anaplasma, Babesia, Ehrlichia, Lyme disease, Powassan virus,	
	Rickettsia, and Tularemia will be performed on all serum specimens. Convalescent	
	specimen for additional testing may be required. NOTE: The results for Powassan	
	virus are used for EPIDEMIOLOGICAL purposes and report will not be issued.	

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Toxocara serology (CDC Referral) TEST: Toxocara canis, Toxacara cati, Toxocariasis, Larva migrans, parasite Synonym: Laboratory/Phone: 443-681-3938/3931 Turnaround Time: 18 business days (CDC Referral) Specimen Required: Serum The specimen/sample must be properly labeled and include patient's name or unique Specimen identification: patient/sample identifier matching the test requisition or electronic test order. Specimen Volume (Optimum): 2 ml. (Whole Blood) Specimen Volume (Minimum): 1 ml. (Whole Blood) Collect: Red-top vacutainer (Serum) MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be Form: downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Continued Next Page>

Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to	
	pages 9 & 10 for triple packing guidance).	
	*Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	Per CDC guidelines: For up to 7 days after collection: transport whole blood and separated	
	serum at 2-8°C on cold packs. If > 7 days after collection and up until 8 weeks, transport	
	serum at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN.	
Specimen Rejection Criteria:	Hemolysis; insufficient volume	
Availability:	Monday through Friday	
Results and Interpretation:	Given on CDC report	
Additional Information:	http://www.cdc.gov/parasites/toxocariasis/	
Purpose of Test:	Detect antibodies which may be due Toxocara canis infections.	
Methods:	EIA, ELISA, Antibody Detection	
Interfering Substances:	Icteric, hemolyzed, lipemic specimen	
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory	
	1770 Ashland Avenue, Baltimore, MD 21205	
Comment:	Contact the MD Department of Health Epidemiologist at (410)767-6700 for prior approval	
	of specimen submission. Required supplemental information: Exposure and travel	
	history, include other relevant risk factors; clinical symptoms, treatment and relevant lab	
	results.	

TEST:	Toxoplasma gondii Serology	
Synonym:	Toxoplasma gondii IgG or IgM antibody	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	5 business days	
Specimen Required:	Serum	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	2 ml. (Whole Blood)	
Specimen Volume (Minimum):	1 ml. (Whole Blood)	
Collect:	Red-top vacutainer	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Date specimen collected MUST be provided.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Transport whole blood or separated serum at 2-8°C on cold packs within 7 days of collection. If shipping of serum is delayed beyond 7 days after collection transport at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN	
Specimen Rejection Criteria:	Grossly hemolyzed or lipemic specimens, unlabeled specimens, leaking container, insufficient volume, mismatch between labeling of specimen and test request form, specimen collected > 7 days prior to arrival without being frozen.	
Availability:	Monday through Friday	
Results and Interpretation:	NEGATIVE—No detectable IgG/IgM antibody to Toxoplasma gondii         POSITIVE—Detectable IgG/IgM antibody to Toxoplasma gondii indicating current or previous infection         EQUIVOCAL—Immunological status cannot be determined. Please submit a new specimen within 3 weeks for retesting	
Additional Information:		
Purpose of Test:	Detect antibodies to <i>Toxoplasma gondii</i> (IgG or IgM)	
Methods:	CLIA—Chemiluminescent Immunoassay	
Interfering Substances:	Hemolysis, lipemia	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205	
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Comment:	Serologic results should not be used as a sole means for diagnosis, treatment, or for the assessment of a patient's health. Clinical correlation is required. The presence of IgG antibody against a particular virus or organism may not assure protection from that disease.
	protection from that disease.

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TEST:	Tuberculosis Bacteriology Culture (AFB/Mycobacterium Identification)	
Synonym:	Acid Fast Bacteria Identification (Acid Fast Bacilli); M. Tuberculosis culture: Refer to	
	instructions for <i>Mycobacterium tuberculosis</i> culture.	
Laboratory/Phone:	Microbiology - Mycobacteriology 443-681-3942	

TEST:	Tularemia	
Synonym:	Francisella tularensis culture, Pasteurella tularensis, rabbit fever, deerfly fever, Ohara's	
	disease, Francis disease: Refer to instructions for Francisella tularensis culture.	
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:	
	410-925-3121 (24/7 emergency contact number)	
	Select Agents Microbiology Laboratory: 443-681-3954	
	Division of Microbiology Laboratory: 443-681-3952	

TEST:	Typhus Fever Serology (Refer to Tick-borne Disease Panel)	
Synonym:	(Murine typhus); Typhus Fever Antibody; R. typhi serology	
	Refer to instructions in Tick-Borne Disease Panel	
Laboratory/Phone:	443-681-3938/3931	
Turnaround Time:	5 business days	
Specimen Required:	Serum	
Results and Interpretation:	Titers ≥ 1:64 are suggestive of possible early infection, declining titers due to past exposure,	
	or cross-reactivity with a related organism.	
Additional Information:	A second specimen will usually demonstrate a diagnostic four fold rise in titer for patients	
	with active disease	
Purpose of Test:	Detect Rickettsia typhi antibodies (IgG).	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory	
-	1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	Results are for epidemiological purposes only. Serologic results should not be used as a sole	
	means for diagnosis, treatment, or for the assessment of a patient's health. Clinical	
	correlation is required.	

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TEST:	Undulant fever
Synonym:	Brucellosis, Bang's Disease, Malta Fever, and Rock of Gibraltar Fever: Refer to instructions
	for Brucella serology or Brucella species, culture.
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

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TEST:	Urine culture (Bacterial Culture, Routine)
Synonym:	Aerobic culture, routine urine culture, urine culture: Refer to instructions for Bacterial
	Culture, Routine
Laboratory/Phone:	Microbiology 443-681-3952
Laboratory, Hone.	1110100101057 110 001 0002

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TEST:	Varicella Antibody IgG (Varicella Immunity Screen)	
Synonym:	Anti-Varicella/ Varicella Zoster Virus (VZV)/Chickenpox IgG; Varicella immunity test.	
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889	
Turnaround Time:	2-5 business days	
Specimen Required:	Serum	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique	
	patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum)	
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum)	
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer.	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be	
	downloaded from MDH Laboratory website).	
	Indicate specimen type using the "Specimen Code" next to Varicella Immunity Screen or	
	MMRV Immunity Screen.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal	
	conditions of transport they cannot break, be punctured or leak their contents (Refer to	
	pages 9 & 10 for triple packing guidance).	
	*Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	Per FDA Assay Packet Insert: Whole blood or separated serum transport at 2-8°C on cold	
	packs up to 7 days after collection. <b>Separated Serum only:</b> For > 7 days after collection	
	transport at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN.	
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic;	
	lipemic; gross bacterial contamination. Specimens collected > 7 days hours prior to arrival	
	without being frozen.	
Availability:	Service available only to state and local health departments Monday to Friday.	
Results and Interpretation:	Negative: Indicates no detectable Varicella IgG antibodies. A negative results indicate no	
	current or previous infection with Varicella virus. Such individuals are presumed to be	
	susceptible to primary infection. However, specimen taken too early during a primary	
	infection may not have detectable levels of IgG antibody. If primary infection is suspected,	
	another specimen (convalescent) should be taken in 8-14 days and tested concurrently in	
	the same assay with the original (acute) specimen to look for seroconversion. If acute	
	specimen is negative and convalescent specimen is positive, seroconversion has taken	
	place and a primary varicella virus infection is indicated.	
	Equivocal: Equivocal results are indeterminate. Patient may or may not have immunity to	
	Varicella Virus. It is not acceptable proof of immunity.	
	Positive: Indicates evidence of Varicella IgG antibodies. This suggests past or current	
	infection with Varicella virus via acquired immunity or vaccination and probable protection	
	from clinical infection (Immunity).	
Additional Information:	For more information, see the CDC link at: <u>https://www.cdc.gov/chickenpox/index.html</u>	
	https://www.cdc.gov/shingles/index.html	
Purpose of Test:	For detection of IgG antibodies to Varicella virus. The test can be used to evaluate single	
N 4 - +    -	sera for immune status.	
Method:	Chemiluminescent Immunoassay (CLIA)	
Interfering Substances:	Test results in an immunocompromised patients should be interpreted with caution.	
Testing Site:	MDH Laboratories Administration, Central Laboratory	
Commont:	1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	A diagnosis should not be made on the basis of anti-Varicella results alone. Test results should be interpreted in conjunction with the clinical evaluation and the results of other	
	should be interpreted in conjunction with the clinical evaluation and the results of other diagnostic procedures. The antibody titer of a single serum specimen cannot be used to	
	diagnostic procedures. The antibody filer of a single serum specimen cannot be used to determine a recent infection. Paired samples (acute and convalescent) should be collected	
	and tested concurrently to demonstrate seroconversion. Samples collected too early in the	
	course of an infection may not have detectable levels of IgG. In such cases, a second sample	
	may be collected after 2-7 weeks and tested concurrently with the original sample to look	
	for seroconversion. A positive Varicella IgG test in neonates should be interpreted with	
	caution since passively acquired maternal antibody can persist for up to 6 months.	
	caution since passively acquired maternal antibody can persist for up to 0 months.	

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TEST:	Varicella Antibody (IgM)	
Synonym:	Anti-Varicella IgM; Varicella Zoster Virus/VZV antibody.	
Laboratory/Phone:	Vaccine Preventable Disease/443-681-3889	
Turnaround Time:	Serum	
Specimen Required:	Serum	
Specimen identification:	The specimen/sample must be properly labeled and include patient's name or unique patient/sample identifier matching the test requisition or electronic test order.	
Specimen Volume (Optimum):	5 ml. (Whole blood) or 4 ml. (Serum)	
Specimen Volume (Minimum):	3 ml. (Whole blood) or 2 ml. (Serum)	
Collect:	Red-top vacutainer or Serum Separator ("Tiger" or gold top) vacutainer.	
Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Write "VZV IgM" on form. Indicate specimen type using the "Specimen Code". Prior	
Packaging and Shipping*:	approval by MDH Epidemiology (410-767-6628) required.Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance).*Refer to current Federal regulations for specific shipping requirements.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	<b>Per FDA Assay Packet Insert:</b> Whole blood or separated serum transport at 2-8°C on cold packs up to 48 hours after collection. <b>Separated Serum only:</b> For > 48 hours after collection transport at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN.	
Specimen Rejection Criteria:	Discrepancy between name on tube and name on form, unlabeled specimen; hemolytic; lipemic; gross bacterial contamination. Specimens collected > 48 hours prior to arrival without being frozen.	
Availability:	Monday to Friday. Test available only to MDH epidemiologists for outbreak investigations. Prior approval by MDH Epidemiology (410-767-6628) required.	
Results and Interpretation:	Negative:No detectable Varicella IgM antibodies. A negative result indicates no current infection with Varicella virus. However, specimens taken too early during a primary infection may not have detectable levels of IgM antibody. If a primary infection is suspected, another specimen should be taken within 7 days and tested concurrently in the same assay with the original specimen to look for seroconversionEquivocal:Equivocal specimens are borderline. Another specimen should be collected after 7 days and retested.Positive:Indicates evidence of Varicella IgM antibodies. This suggests primary or reactivated infection with Varicella.	
Additional Information:	For more information, see the CDC link at: <u>https://www.cdc.gov/chickenpox/index.html</u>	
Purpose of Test:	For detection of IgM antibodies to Varicella virus. <b>Test available only to MDH</b> epidemiologists for outbreak investigations. Prior approval by MDH Epidemiology 410-767-6628) required.	
Method:	ELISA	
Interfering Substances:	<ul> <li>High anti-VZV IgG or Rheumatoid factor may cause false negative or false positive results.</li> <li>Test results in an immunocompromised patients should be interpreted with caution.</li> <li>Patients with autoimmune disease may present with false positive results. Test results in an immunocompromised patients should be interpreted with caution.</li> </ul>	
Testing Site:	MDH Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	Results of the Varicella IgM ELISA are not by themselves diagnostic and should be interpreted in light of the patient's clinical condition and results of other diagnostic procedures. Samples taken too early during the course of a primary infection may not have detectable levels of Varicella specific IgM. A negative result does not rule out a primary infection with rubella virus. This assay cannot distinguish the difference between vaccine- induced antibody and antibody resulting from a natural infection. The performance of the Varicella IgM ELISA has not been validated using neonatal samples.	

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TEST:	Varicella Zoster Virus (VZV) Viral Culture	
Synonym:	Varicella Zoster Virus (VZV) culture: refer to instructions for Virus Culture.	
Laboratory/Phone:	Virology: 443-681-3934	

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TEST:	Vibrio culture
Synonym:	Vibrio spp. Enteric Culture: Refer to instructions for Enteric Culture, Routine (Salmonella,
	Shigella, Campylobacter, and Shiga toxins-producing E. coli).
Laboratory/Phone:	Microbiology-Enterics 443-681-4570

TEST:	Vibrio parahaemolyticus culture
Synonym:	Vibrio spp. Enteric Culture: Refer to instructions for Enteric Culture, Routine (Salmonella,
	Shigella, Campylobacter, and Shiga toxins-producing E. coli).
Laboratory/Phone:	Microbiology-Enterics 443-681-4570

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TEST:	Virus Culture
Synonym:	Viral Culture, Virus isolation for: Adenovirus, Cytomegalovirus (CMV), Enterovirus (including Echovirus, Coxsackie, and Polio), Herpes Simplex Virus (HSV Types 1 & 2), Influenza (Types A & B), Measles, Mumps, Parainfluenza (Types 1,2 & 3), Respiratory Syncytial Virus (RSV), Varicella Zoster Virus (VZV)
Laboratory/Phone:	Virology: 443-681-3934
Turnaround Time:	3-28 business days
Specimen Required:	One specimen per test requested, collected during the acute phase of the disease: blood, cerebrospinal fluid (CSF), skin lesion, eye, genital, mucosal, oral, upper and lower respiratory tract, stool, tissue/biopsy, urine
Specimen identification:	Specify the source of the specimen. Label container with patient's last name, first name, DOB, specimen type, date and time of collection.
Specimen Volume (Optimum):	Fluid: ≥ 1 ml Swab/tissue in viral transport media (VTM) Unpreserved fresh stool: 4 grams in sterile container
Specimen Volume (Minimum):	
	Continued Next Page>

Collect:	Specimen	Collect	Container
	CSF	Collect <u>&gt;</u> 2 ml aseptically.	Sterile container with leak-proof screw top lid.
	Eye	Collect aseptically and leave swab in VTM.	Viral transport media (VTM)
	Nasopharyngeal aspirate	Aspirate using #8 French catheter and trap	Sterile container with leak-proof screw top lid.
	Oral	Swab inner side of both cheeks behind upper molars and floor of mouth, including any ulcerated areas. Leave swab in VTM.	Viral transport media (VTM)
	Buccal	Swab inner side of both cheeks. Leave swab in VTM	Viral transport media (VTM) Notify MD Department of Health Epidemiology and send to laboratory ASAP after collection.
	Rectal	Insert swab at least 5 cm into orifice and rotate the swab. Leave swab in VTM.	Viral transport media (VTM)
	Stool	4-8 grams	Sterile container with leak-proof screw top lid.
	Throat	Swab tonsillar area and back of pharynx. Leave swab in VTM.	Viral transport media (VTM)
	Tissue	Collect biopsy and autopsy specimens aseptically	Sterile container with leak-proof screw top lid. If possible, add viral transport media.
	Urine	Clean catch, midstream urine	Sterile container with leak-proof screw top lid. For recovery of CMV, send to lab within 2-3 hours after collection on cold ice packs. DO NOT
			FREEZE!
Form:	form may be dow Indicate the spec		
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance).		
	*Refer to current F		requirements.
Transport Conditions:	Stool specimens f on cold packs.	ederal regulations for specific shipping or enterovirus (Polio, Coxsackie, an	d Echovirus) culture transport at 2-8°C
Transport Conditions:	Stool specimens f on cold packs. Specimens for CN	ederal regulations for specific shipping or enterovirus (Polio, Coxsackie, an	d Echovirus) culture transport at 2-8°C 8°C on cold packs immediately after
Transport Conditions:	Stool specimens f on cold packs. Specimens for CN collection (within Varicella-Zoster V Syncytial Virus, an after collection. It	ederal regulations for specific shipping for enterovirus (Polio, Coxsackie, an AV culture specimen transport at 2- 2-3 hours). <b>DO NOT FREEZE specin</b> Yirus, Influenza, Parainfluenza, Ader and HSV culture specimens transport	d Echovirus) culture transport at 2-8°C 8°C on cold packs immediately after nens for CMV culture. novirus, Measles, Mumps, Respiratory at 2-8°C on cold packs for up to 3 days at -2°C or colder on dry ice. Seal the
Transport Conditions: Specimen Rejection Criteria:	Stool specimens f on cold packs. Specimens for CN collection (within Varicella-Zoster V Syncytial Virus, ai after collection. It specimen contair Bacterial swab, di container, expired specimen and tes	ederal regulations for specific shipping for enterovirus (Polio, Coxsackie, an AV culture specimen transport at 2- 2-3 hours). <b>DO NOT FREEZE specin</b> Yirus, Influenza, Parainfluenza, Ader and HSV culture specimens transport f >3 days after collection transport a ser tightly to prevent ingress of toxic ry swab, swab with wooden shaft, c d transport media, unlabeled specir	d Echovirus) culture transport at 2-8°C 8°C on cold packs immediately after <b>nens for CMV culture.</b> novirus, Measles, Mumps, Respiratory c at 2-8°C on cold packs for up to 3 days at -2°C or colder on dry ice. Seal the c carbon dioxide vapors. alcium alginate swab, leaking men, mismatch between labeling of bom temperature more than 2 hours,
Specimen Rejection Criteria: Availability:	Stool specimens f on cold packs. Specimens for CN collection (within Varicella-Zoster V Syncytial Virus, ai after collection. It specimen contair Bacterial swab, di container, expired specimen and tes	ederal regulations for specific shipping for enterovirus (Polio, Coxsackie, an AV culture specimen transport at 2- 2-3 hours). <b>DO NOT FREEZE specin</b> Arrus, Influenza, Parainfluenza, Ader and HSV culture specimens transport f >3 days after collection transport f >3 days after collection transport f ar tightly to prevent ingress of toxic arry swab, swab with wooden shaft, co d transport media, unlabeled specir at request form, specimen held at re- pore than 3 days or frozen CMV urin	d Echovirus) culture transport at 2-8°C 8°C on cold packs immediately after <b>nens for CMV culture.</b> novirus, Measles, Mumps, Respiratory c at 2-8°C on cold packs for up to 3 days at -2°C or colder on dry ice. Seal the c carbon dioxide vapors. alcium alginate swab, leaking men, mismatch between labeling of bom temperature more than 2 hours,
Specimen Rejection Criteria:	Stool specimens f on cold packs. Specimens for CN collection (within Varicella-Zoster V Syncytial Virus, an after collection. It specimen contair Bacterial swab, di container, expire specimen and tes refrigerated for n	ederal regulations for specific shipping for enterovirus (Polio, Coxsackie, an AV culture specimen transport at 2- 2-3 hours). <b>DO NOT FREEZE specin</b> Yirus, Influenza, Parainfluenza, Ader nd HSV culture specimens transport f >3 days after collection transport are tightly to prevent ingress of toxic ry swab, swab with wooden shaft, c d transport media, unlabeled specir t request form, specimen held at ro nore than 3 days or frozen CMV urin Friday. If virus) isolated.	d Echovirus) culture transport at 2-8°C 8°C on cold packs immediately after <b>nens for CMV culture.</b> novirus, Measles, Mumps, Respiratory c at 2-8°C on cold packs for up to 3 days at -2°C or colder on dry ice. Seal the c carbon dioxide vapors. alcium alginate swab, leaking men, mismatch between labeling of bom temperature more than 2 hours,

VID Department of Health-Laborat	ories Administration The J. Mensen Joseph Public Health Laboratory
Purpose of Test:	Virus isolation to determine probable cause of infection and aid in the diagnosis of viral disease or to further characterization for epidemiological purposes.
Method:	Cell culture, viruses detected by cytopathic effect and/or antibody/fluorescent staining.
Interfering Substances:	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	The two most important steps in viral isolation are specimen collection and specimen transportation. Since the detection of viruses is more likely to be achieved early in the illness, specimens for most viral diseases should be collected as soon as a viral infection is suspected and submitted to the laboratory as soon as possible.
	Submission of adequate specimen and patient history is essential. A blanket request for "Virus Study" should not be submitted. Information must specify the group of viruses suspected. Please indicate suspected infecting agent as well as additional information such as chief symptoms, clinical test results, epidemiology data, immunizations, etc. This will guide the laboratory in choosing which virological procedures and host systems should be inoculated. Since many viruses die rapidly once they have been separated from host tissue, specimens must be delivered to the Virology Laboratory immediately after collection.
	Isolation of a virus from clinical material does not establish an etiologic diagnosis per se. The significance of such a virus depends upon the source of the isolate. For example, isolation of a virus from the brain in encephalitis or from the spinal fluid in aseptic meningitis provides direct evidence of an etiological association. Likewise isolation of an influenza virus from throat washings of a patient ill with an influenza-like disease strongly suggests that the virus is the causative agent since this virus is only isolated from throat washings in acute influenza. In contrast, the isolation of an enteric virus from the stool of a patient suffering from aseptic meningitis does not by itself indicate an etiological relationship, as enteroviruses are sometimes found in the feces of healthy individuals. Occasionally a virus other than the one ordered is detected since any reaction in the host system is investigated.
	A negative viral culture report does not preclude the possibility of the suspect virus or another virus being involved in the patient's disease. The cultures may be negative because of specimen procurement problems, such as prolonged transportation or processing delays, procurement of sample too late in the course of the disease, or inability of some viruses or viral strains to adapt to growth in the tissue culture cell lines selected. For a more rapid diagnosis, Real-Time PCR detection tests for Influenza A virus, Influenza B virus, and Herpes simplex virus I and II are available.

TEST:	VRE Culture	
Synonym:	Vancomycin-Resistant <i>Enterococcus</i> culture; rule out Vancomycin-Resistant <i>Enterococcus faecium</i> ; rule out Vancomycin-Resistant <i>Enterococcus faecalis</i>	
Laboratory/Phone:	Microbiology 443-681-3952	
Turnaround Time [from specimen receipt in the Laboratory]:	2-3 days	
Specimen Required:	Rectal swab; perianal swab, stool	
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection. The specimen/sample must be properly labeled and match the test requisition or electronic test order.	
Specimen Volume (Optimum):	One (1) swab	
Specimen Volume (Minimum):	N/A	
Collect:	Culturette tube with transport medium	
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form.	
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.	
Transport Conditions:	Transport at room/ambient temperature 2-30°C.	
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Specimen Rejection Criteria:	The following rejection criteria are designed to prevent the reporting of inaccurate results and to avoid misleading information that might lead to misdiagnosis and inappropriate therapy. A request for a new specimen will provide appropriate materials and clinically relevant information to support good patient care. Unlabeled or improperly labeled specimen Non-sterile or leaking container Inappropriate specimen transport conditions Illegible, or no submitter information on the request form Mismatched form and specimen Broken specimen/sample container The wrong specimen for test request Inappropriate outfit for requested test Illegible or no patient information on the specimen Expired transport media Specimen received after prolonged delay (usually more than 72 hours)	
Availability:	Monday through Friday	
Results and Interpretation:	VRE isolated and identified, Vancomycin resistance confirmed.	
Reference Range:	No VRE detected	
Additional Information:	N/A	
Purpose of Test:	Detect the presence of VRE	
Method:	N/A	
Interfering Substances:	N/A	
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory 1770 Ashland Avenue, Baltimore, Maryland 21205	
Comment:	N/A	

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TEST:	West Nile Virus IgM Equine EIA (Equine specimen)
Synonym:	Arthropod-borne virus: WNV (West Nile Virus)
Laboratory/Phone:	Virology: 443-681-3931/3936
Turnaround Time:	7 business days
Specimen Required:	Serum (blood)
Specimen identification:	Label container with horse's name, specimen type, date and time of collection.
Specimen Volume (Optimum):	2 ml serum; 2ml CSF
Specimen Volume (Minimum):	1 ml serum; 0.5 ml CSF
Collect:	Red top vacuum tube, transfer serum to sterile tube: CSF in sterile container with leak- proof cap.
Request Form:	Equine Arbovirus Testing Form [Order: 443-681-3777]
	For testing to be initiated, the ANIMAL INFORMATION box on the form must be filled out completely.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per Assay Packet Insert: Transport whole blood or separated serum at 2-8°C on cold packs within 7 days of collection. If shipping of serum is delayed beyond 7 days after collection transport at -20°C or colder on dry ice. WHOLE BLOOD CANNOT BE FROZEN
Specimen Rejection Criteria:	Grossly hemolyzed specimens, unlabeled specimen, leaking container, duplicate specimen type (e.g., two serum specimens collected on the same day-one tube will not be tested), and mismatch between labeling of specimen and test request form.
Availability:	Monday through Friday.
Results and Interpretation:	IgM: Negative, High Background, Equivocal, Positive Serum and CSF samples that tests positive for IgM is consistent with acute WNV infection
Additional Information:	The term "Arbovirus" has no taxonomic significance, but is a shortened name given to viruses that are transmitted by blood feeding arthropods (mosquitoes, ticks, etc.). For more information, see the CDC link at: <a href="http://www.cdc.gov/ncidod/dvbid/arbor/arbdet.htm">http://www.cdc.gov/ncidod/dvbid/arbor/arbdet.htm</a>
Purpose of Test:	
Method:	ELISA
Interfering Substances:	
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Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
resting site.	mb bepartment of health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	

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TEST:	West Nile Virus (WNV) (Arbovirus Endemic Panel)
Synonym:	Arthropod-borne virus: WNV (West Nile Virus)
	Refer to instructions for Arbovirus Endemic Panel.
Laboratory/Phone:	Virology: 443-681-3936/3931

TEST:	Western Equine Encephalitis (CDC Referral)
Synonym:	Arthropod-borne virus: Western Equine Encephalitis (WEE)
Laboratory/Phone:	Virology: 443-681-3936/3931
Turnaround Time:	3 weeks
Specimen Required:	Serum
Specimen identification:	The specimen/sample must be properly labeled and include:
	<ol> <li>The patient's name or unique patient/sample identifier matching the test requisition or electronic test order,</li> <li>If appropriate, the date and time of specimen/sample collection, and</li> <li>Any additional information relevant and necessary for the test.</li> </ol>
Specimen Volume (Optimum):	2 ml serum
Specimen Volume (Minimum):	1 ml serum
Collect:	Red top vacutainer tube, transfer serum to sterile tube
Request Form:	MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website). Indicate specimen type using the "Specimen Code" on form. Write "S" for serum in the "Other Tests Request" and indicate Western Equine Encephalitis.
	For testing to be initiated the following information MUST be provided: date of onset, date specimen collected, travel history, and flavivirus vaccination history. Also please provide: patient's date of birth, diagnosis, symptoms, fatality, and whether patient is immunocompromised.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	Per CDC Guidelines: Transport separated serum at 2-8°C on cold packs or at -20°C or
	colder on dry ice.
Specimen Rejection Criteria:	Grossly hemolyzed specimen, unlabeled specimen, leaking container, mismatch between labeling of specimen and test request form/electronic test order, and does not meet epidemiological criteria required for testing (e.g. travel history, etc.)
Availability:	Specimens shipped to the CDC Monday-Wednesday.
Results and Interpretation:	Serum that tests positive for IgM and negative for IgG is consistent with acute Western Equine Encephalitis infection. A positive Western Equine Encephalitis EIA is confirmed by PRNT (plaque reduction neutralization). A positive IgG antibody and a negative IgM antibody are consistent with infection in the distant past and are not consistent with acute infection.
Additional Information:	The term "Arbovirus" has no taxonomic significance, but is a shortened name given to viruses that are transmitted by blood feeding arthropods (mosquitoes, ticks, etc.). Arboviruses that cause human encephalitis are members of three virus families: The Togaviridae (genus Alphavirus), Flaviviridae, and Bunyaviridae. For more information, see the CDC link at: <u>https://www.cdc.gov/ncezid/dvbd/</u> Patients with travel history supporting suspicion of other arboviruses will be sent to the CDC for testing.
Purpose of Test:	For the presumptive detection of antibodies to Western Equine Encephalitis Virus. Confirmatory testing by PRNT may be required.
Method:	EIA (Screening) & PRNT (Plaque Reduction Neutralization Test) referral to the Centers for Disease Control and Prevention (CDC).
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Interfering Substances:	
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Other Arboviral testing not available at the state lab will be forwarded to the CDC based on patient's travel history and onset date.

TEST:	Whooping Cough
Synonym:	B. pertussis, pertussis, Whooping Cough Refer to instructions for Bordetella pertussis PCR and Culture.
Laboratory/Phone:	Molecular Biology: 443-681-3924; Microbiology 443-681-3952

TEST:	Woolsorters' Disease
Synonym:	Bacillus anthracis, Cutaneous Anthrax: Refer to instructions for Anthrax, Cutaneous
	(Woolsorters' disease).
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952

TEST:	Yellow Fever (CDC Referral)
	CDC test available based on patient's travel history.
Synonym:	Arthropod-borne virus: Bunyavirus
Laboratory/Phone:	Virology: 443-681-3931/3936
Turnaround Time:	3 weeks (CDC Referral)
Specimen Required:	Serum
Specimen identification:	<ul> <li>The specimen/sample must be properly labeled and include:</li> <li>1. The patient's name or unique patient/sample identifier matching the test requisition or electronic test order,</li> <li>2. If appropriate, the date and time of specimen/sample collection, and</li> <li>3. Any additional information relevant and necessary for the test.</li> </ul>
Specimen Volume (Optimum):	2 ml serum
Specimen Volume (Minimum):	1 ml serum
Collect:	Red top vacutainer tube, transfer serum to sterile tube
Request Form:	<ul> <li>MDH Form #4677 Serological Testing (Order Forms: 443-681-3777 or form may be downloaded from MDH Laboratory website).</li> <li>Indicate specimen type using the "Specimen Code" on form.</li> <li>Write "S" for serum in the "Other Tests Request" and indicate Yellow Fever.</li> <li>For testing to be initiated, the following information MUST be provided: date of onset, date specimen collected, travel history, and flavivirus vaccination history. Also please provide: patient's date of birth, diagnosis, symptoms, fatality, and whether patient is immunocompromised.</li> </ul>
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal conditions of transport they cannot break, be punctured or leak their contents (Refer to pages 9 & 10 for triple packing guidance). *Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	<b>Per CDC Guidelines:</b> Transport separated serum at 2-8°C on cold packs or at -20°C or colder on dry ice.
Specimen Rejection Criteria:	Grossly hemolyzed specimen, unlabeled specimen, leaking container, mismatch between labeling of specimen and test request form/electronic test order, and does not meet epidemiological criteria required for testing (e.g. travel history, etc.)
Availability:	Specimens shipped to the CDC Monday-Wednesday.

Results and Interpretation:	Serum that tests positive for IgM and negative for IgG is consistent with acute Yellow Fever
·	infection. All positive Yellow Fever EIA are confirmed by PRNT (plague reduction
	neutralization). A positive IgG antibody and a negative IgM antibody are consistent with
	infection in the distant past and are not consistent with acute infection.
Additional Information:	The term "Arbovirus" has no taxonomic significance, but is a shortened name given to
	viruses that are transmitted by blood feeding arthropods (mosquitoes, ticks, etc.).
	Arboviruses that cause human encephalitis are members of three virus families: The
	Togaviridae (genus Alphavirus), Flaviviridae, and Bunyaviridae. For more information, see
	the CDC link at: <a href="https://www.cdc.gov/ncezid/dvbd/">https://www.cdc.gov/ncezid/dvbd/</a>
	Patients with travel history supporting suspicion of other arboviruses will be sent to the
	CDC for testing.
Purpose of Test:	Detection of Yellow Fever Virus antibodies.
Method:	EIA (Screening) & PRNT (Plaque Reduction Neutralization Test) referral to the Centers for
	Disease Control and Prevention (CDC).
Interfering Substances:	
Processing Site for CDC referral:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Other Arboviral testing not available at the state lab will be forwarded to the CDC based on
	patient's travel history and onset date.

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TEST:	Yersinia culture
Synonym:	Yersinia stool culture: Refer to instructions for Enteric Culture, Routine.
Laboratory/Phone:	Microbiology-Enterics 443-681-4570

TEST:	Yersinia enterocolitica
Synonym:	Yersinia enterocolitica culture: Refer to instructions for Enteric Culture, Routine.
Laboratory/Phone:	Microbiology-Enterics 443-681-4570

TEST:	Yersinia pestis
Synonym:	Plague
Laboratory/Phone:	Office of Laboratory Emergency Preparedness and Response:
	410-925-3121 (24/7 emergency contact number)
	Select Agents Microbiology Laboratory: 443-681-3954
	Division of Microbiology Laboratory: 443-681-3952
Turnaround Time [from specimen receipt in the Laboratory]:	3 -6 days
Specimen Required:	<ol> <li>Lower respiratory tract (pneumonic): Bronchial wash or transtracheal aspirate (&gt;1 ml). Sputum may be examined but this is not advised because of contamination by normal throat flora.</li> </ol>
	<ol> <li>Blood (septicemia): Collect appropriate blood volume and number of sets per established laboratory protocol. NOTE: In suspected cases of plague, an additional blood or broth culture (general nutrient broth) should be incubated at room temperature (22-28°C), the temperature at which Y. pestis grows faster.</li> </ol>
	<ol> <li>Aspirate of involved tissue (bubonic) or biopsied specimen: Liver, spleen, bone marrow, lung. NOTE: Aspirates may yield little material; therefore, a sterile saline flush may be needed to obtain an adequate amount of specimen. Syringe and needle of aspirated sample should be capped, secured by tape, and sent to the Laboratory.</li> </ol>
	4. Isolate
Specimen Identification:	Specimen should be labeled with patient's last and first name, patient's address, DOB, specimen type/source, and the date and time of collection.
Specimen Volume (Optimum):	N/A
Specimen Volume (Optimum):	N/A
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Collect:	1. Respiratory/sputum: Bronchial wash or transtracheal aspirate (>1.0 ml).
	2. Blood: Collect appropriate blood volume and number of sets as per routine laboratory protocol.
	3. Tissue aspirate/biopsy specimen: Add several drops of sterile saline to keep tissue moist.
	4. Isolate: Pure culture, 24 hours old, growing on a sheep blood agar plate or slant.
Form:	MDH Form #4676 Infectious Agents: Culture/Detection (Order Forms: 443-681-3777 or
	form may be downloaded from MDH Laboratory website).
	Indicate specimen type using the "Specimen Code" on form.
Packaging and Shipping*:	Specimens must be packaged in a triple packaging system to ensure that under normal
	conditions of transport they cannot break, be punctured or leak their contents (Refer to
	pages 9 & 10 for triple packing guidance).
	*Refer to current Federal regulations for specific shipping requirements.
Transport Conditions:	1. Respiratory/sputum: Transport to the laboratory within 1 hour of collection at
	room/ambient temperature (2-30 °C). For transport time > 1 hour, transport at 2-8°C
	on cold packs.
	2. Blood: Transport to the laboratory at room/ambient temperature (2-30 °C). DO NOT
	REFRIGERATE.
	3. Tissue aspirate/biopsy specimen: Transport to the laboratory within 1 hour of
	collection at room/ambient temperature (2-30 °C). For transport time > 1 hour,
	transport at 2-8°C on cold packs.
	4. Isolate: Transport the specimen at room/ambient temperature (2-30 °C) on a sealed
Specimen Rejection Criteria:	sheep blood agar plate or slant.           The following rejection criteria are designed to prevent the reporting of inaccurate results
Specimen Rejection Criteria:	and to avoid misleading information that might lead to misdiagnosis and inappropriate
	therapy. A request for a new specimen will provide appropriate materials and clinically
	relevant information to support good patient care.
	<ul> <li>Unlabeled or improperly labeled specimen</li> </ul>
	<ul> <li>Non-sterile or leaking container</li> </ul>
	<ul> <li>Inappropriate specimen transport conditions</li> </ul>
	<ul> <li>Illegible, or no submitter information on the request form</li> </ul>
	<ul> <li>Mismatched form and specimen</li> </ul>
	<ul> <li>Broken specimen/sample container</li> </ul>
	<ul> <li>The wrong specimen for test request</li> </ul>
	<ul> <li>Inappropriate outfit for requested test</li> </ul>
	<ul> <li>Illegible or no patient information on the specimen</li> </ul>
	Expired transport media
Availability:	24 hours/day, 7 days/week
Results and Interpretation:	Yersinia pestis isolated/detected
	Yersinia pestis not found
Additional Information:	Call 410-925-3121 before sending to the Laboratory.
Purpose of Test:	To confirm the diagnosis of plague.
Method:	LRN Protocols
Interfering Substances:	N/A
Testing Site:	MD Department of Health Laboratories Administration, Central Laboratory
	1770 Ashland Avenue, Baltimore, Maryland 21205
Comment:	Call 410-925-3121 before sending to the Laboratory.

TEST:	Zika Virus IgM Serology
	(Arbovirus Travel-Associated Panel)
Synonym:	Arthropod-borne virus: Zika Virus
	Refer to instructions in Arbovirus Travel-Associated Panel
Laboratory/Phone:	443-681-3931/3936
Results and Interpretation:	Negative: No detectable IgM antibody to Zika virus. This result does not rule-out Zika
	virus infection. Lack of serologic evidence of infection may reflect that the specimen was collected prior to the development of an antibody response. If indicated, please submit another serum specimen collected greater than 14 days after onset of illness for further testing.
	Other Flavivirus Positive:Specimen tested presumptively positive for IgM antibody to another flavivirus. There still may be low levels of Zika IgM antibody present and follow up testing is required; the possibility of co-infections must also be considered. Confirmatory testing of positive serology test results will be performed by Plague Reduction Neutralization Test (PRNT).
	<b><u>Positive</u></b> : Specimen tested presumptively positive for IgM antibody to Zika virus. Presumptive positive confirmatory testing will be performed by
	Plague Reduction Neutralization Test (PRNT). Virus specific IgM antibodies can be detectable equal to or greater than four days after onset of illness. It has been reported that IgM antibodies typically persist for approximately 2-12 weeks.
Additional Information:	https://www.cdc.gov/zika/index.html
Comment:	The results should not be used as the sole means of clinical diagnosis, treatment, or for patient management. Clinical correlation is required. Results from immunocompromised patients must be interpreted with caution. Single acute-phase specimen can be inconclusive. Cross-reactivity with other flaviviruses including Dengue virus can occur.

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## E. GUIDE TO INTERPRETATION OF RETROVIROLOGY SEROLOGICAL TESTS

#### RETROVIRUSES

Human Immunodeficiency Viruses (HIV)

## NORMAL/SIGNIFICANT RESULTS

Reactive results indicate presence of HIV antigen or antibody in serum/plasma. All screening test reactive specimens undergo testing using the Geenius HIV 1/2 Supplemental Assay for differentiation of HIV-1 and HIV-2 antibodies. An In-house developed HIV-1 NAAT assay is performed on the specimens that test reactive by the HIV antigen/ antibody screening test but are not confirmed as antibody positive in the Geenius assay.

## F. GUIDE TO INTERPRETATION OF HEREDITARY DISORDERS

#### F.1.TESTS

# SIGNIFICANT RESULTS

## F.1.a. Galactose 1-Phosphate uridyl Transferase (GALT)

1.)	< 7	days	old
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a.) Normal	Presence of enzyme activity
b.) Abnormal	Absence of enzyme activity

2.) ≥ 7 days old

a.) Normal	Presence of enzyme activity
b.) Abnormal	Absence of enzyme activity

## F.1.b. Total Galactose

1.) < 7 days old

a.) Normal	Less than 10 mg/dL
b.) Borderline	10 - 20 mg/dL
c.) Abnormal	20, 40, 60, 80, or greater mg/dL
	>40 mg/dL with abnormal GALT or
	>80 mg/dL = neonatal emergency
2.) ≥ 7 days old	
a.) Normal	Less than 10 mg/dL
b.) Borderline	10 - 20 mg/dL
c.) Abnormal	20, 40, 60, 80, or greater mg/dL

>40 mg/dL with abnormal GALT or >80 mg/dL = neonatal emergency

## F1.c. Biotinidase

1.) < 7 days old	
a.) Normal	Presence of enzyme activity
b.) Abnormal	Lack of enzyme activity
2.) ≥ 7 days old	
a.) Normal	Presence enzyme activity

,	
b.) Abnormal	Lack of enzyme activity

### F.1.d. Thyroxine

1.) < 7 days old

a.) Normal	≥ 6.5 μg/dL
b.) Borderline	3.0–6.49 μg/dL
c.) Abnormal	2.0 – 2.9 or < 2.0 μg/dL

## 2.) $\geq$ 7 days old

a.) Normal	≥ 4.0 µg/dL
b.) Borderline	3.0 – 3.9 μg/dL
c.) Abnormal	2.0 – 2.9 or < 2.0 μg/dL

# F.1.e. TSH

1.) < 7 days old

a.) Normal	≤ 20 μIU/mL
b.) Borderline	21 - 40 µIU/mL
c.) Abnormal	≥ 40 µIU/mL

2.)  $\geq$  7 days old

a.) Normal	≤ 20 μIU/mL
b.) Borderline	21 - 40 µIU/mL
c.) Abnormal	≥ 40 μIU/mL

## F.1.f. Hemoglobin

1.) < 7 days old

a.) Normal	FA hemoglobins or AF
b.) Trait	FAS, FAC, FAV, ACF, ASF, AVF, FA(C), FA(S), FACV, FASV
c.) Disease	FS, FC, FSC, F, FV, FSV, FCV, FSA, FVA

1.) ≥ 7 days old

a.) Normal	FA hemoglobins or AF
b.) Trait	FAS, FAC, FAV, ACF, ASF, AVF, FA(C), FA(S), FACV, FASV
c.) Disease	FS, FC, FSC, F, FV, FSV, FCV, FSA, FVA

### F.1.g. 17 Hydroxy Progesterone

1.) < 7 days old

a.) Normal	Varies with weight.
	Call laboratory at 443-681-3900
2.) ≥ 7 days old	Same as above

### F.1.h. Immuno Reactive Trypsinogen

1.) < 7 days old

a.) Normal	<60 ng / mL
b.) Borderline	≥ 60 ng / mL
c.) Abnormal	≥ 150 ng / mL
d.) Invalid	< 1500 grams Weight

# 2.) $\geq$ 7 days old.

a.) Normal	< 60 ng / mL
b.) Borderline	≥ 60 ng / mL
b.) Abnormal	≥ 150 ng / mL
c.) Invalid	< 1500 grams Weight

## F.1.i. Cystic Fibrosis (CF) mutational analysis of CFTR

1.) < 7 days old

a.) 0 mutations	Low probability of CF
b.) 1 mutation	Increased potential for CF, diagnostic testing required
c.) >1 mutation	High probability of developing CF

2.)  $\geq$  7 days old

a.) 0 mutations	Low probability of CF
b.) 1 mutation	Increased potential for CF, diagnostic testing required
c.) >1 mutation	High probability of developing CF

## F.1.j. T-Cell Receptor Excision Circle (TREC)

1.) < 7 days old

a.) Normal	Normal levels of TREC DNA detected
b.) Inconclusive	Insufficient DNA to measure TREC levels in the specimen
c.) Abnormal	Low levels of TREC DNA could indicate immunodeficiency
d.) Critical	Extremely low TREC DNA levels could indicate immunodeficiency
2.) ≥ 7 days old	
a.) Normal	Normal levels of TREC DNA detected
b.) Inconclusive	Insufficient DNA to measure TREC levels in the specimen
c.) Abnormal	Low levels of TREC DNA could indicate immunodeficiency
d.) Critical	Extremely low TREC DNA levels could indicate immunodeficiency

### F.1.k. Survival of Muscle Neuron 1 (SMN1)

1.) < 7 days old

a.) Normal	DNA from exon 7 of SMN1 detected
b.) Inconclusive	Insufficient DNA in the specimen to measure DNA from exon 7 of SMN1.
c.) Critical	DNA from exon 7 of SMN1 not detected, could indicate Spinal Muscular Atrophy
2.) $\geq$ 7 days old	
a.) Normal	DNA from exon 7 of SMN1 detected
b.) Inconclusive	Insufficient DNA in the specimen to measure DNA from exon 7 of SMN1.
c.) Critical	DNA from exon 7 of SMN1 not detected, could indicate Spinal Muscular Atrophy

## F.1.I. Lysosomal Storage Disorder (LSD) Enzymes

Enzyme Activity measured for: Acid Alpha-Glucosidase (GAA), Alpha-L-iduronidase (IDUA), and alpha-galactosidase A (GLA) (µmol/L/hr)

1.) < 7 days old

a.) Normal	Greater than the cutoff
b.) Abnormal	Less than the cutoff

The J. Mehsen Joseph Public Health Laboratory

c.) Inconclusive	2 or more LSD enzymes are below the cutoff
d.) Invalid	Age at collection <24 hours and/or gestational age <34 weeks and/or weight < 2000g
2.) ≥ 7 days old	
a.) Normal	Greater than the cutoff
b.) Abnormal	Less than the cutoff
c.) Inconclusive	2 or more LSD enzymes are below the cutoff
d.) Invalid	Gestational age <34 weeks and/or weight < 2000g

## F.2. GUIDE TO INTERPRETATION OF METABOLIC DISORDERS

ANALYTE	NORMAL RESULT		SIGNIFICANT RESULT	
	0-6 DAYS OLD	≥ 7 DAYS OLD	0-6 DAYS OLD	> 7 DAYS OLD
Arginine	≤ 70 μM	≤ 80 µM	> 70 μM	> 80 μM
Citrulline	≤ 40 μM	≤ 70 μM	> 40 µM	> 70 μM
Valine	≤ 400 μM	≤ 400 μM	NA	NA
Leucine	≤ 275 μM	≤ 305 μM	> 275 μM	> 305 μM
Methionine	≤ 75 μM	≤ 80 μM	> 75 μM	> 80 μM
Phenylalanine	≤ 120 μM	≤ 120 μM	> 150 μM	> 150 μM
Tyrosine	≤ 300 μM	≤ 300 μM	> 300 μM	> 300 μM
Acylcarnitine Profile (for 11 Organic Acidemias and 9 Fatty Acid Oxidation Disorders)	Contact Newborn Screening	Contact Newborn Screening	Contact Newborn Screening	Contact Newborn Screening

#### F.3. CLINICAL AND HEMOTOLOGIC ASPECTS OF SOME HEMOGLOBINOPATHIES

TRAIT 1	HB TYPES	CLINICAL SEVERITY	RED-CELL MORPHOLOGY	ANEMIA	SICKLING
Hb-S trait	A + S	+	Normal	+	+
Hb-C trait	A + C	-	Normal	-	-
Hb-E trait	A + E	-	Normal	+	-
DISEASE 2	HB TYPES	CLINICAL SEVERITY	RED-CELL MORPHOLOGY	ANEMIA	SICKLING
Homozygous					
Sickle cell anemia	S + S	+++	Normocytic Normochromic	+ + +	+
HbC disease	C + C	+	Slightly microcytic normochromic	+	-
HbD disease	D + D	-	Microcrytic normochromic	-	-
HbE disease	E + E	+	Microcytic normochromic	+	-
Mixed Heterozygous					
Sickle Cell HbC Disease	C + S (F*)	- to + + +	Slightly microcytic, slightly hypochromic	- to + + +	+
Sickle Cell HbD Disease	D + S (F*)	++		+ + +	+
Thalassemia Syndrome					
Thalassemia major	A + F	+ + + +	Microcytic hypochromic	+ + + +	-
Thalassemia HbS Disease	S + F + A	+ to + + + +	Microcytic hypochromic	+ + to + + + +	+
Thalassemia HbC Disease	A + C (F*)	+ to + +	Microcytic hypochromic	- to	-
Thalassemia HbE Disease	E + F	+ to + + + +	Microcytic hypochromic	+ to + + + +	-

References (to "Clinical and Hemotologic Aspects of Some Hemoglobinopathies")

 $^{1}$  Nurembgerg, S.T. Electrophoreseis, F. A. David Co. Philadelphia. 1966. p. 127

<sup>2</sup> Modified from Chernoff (1958)

\* F may be present

#### F.4. COMPARISON OF IRON-DEFICIENCY ANEMIA AND THALASSEMIA

PARAMETER	IRON-DEFICIENCY ANEMIA	BETA-THALASSEMIA MINOR
RBC	decreased	normal to increased
Hemoglobin	decreased	decreased
Hematocrit	decreased	decreased
Mean Corpuscular Volume (MCV) and Mean Corpuscular Hemoglobin (MCH)	decreased	decreased
Mean Corpuscular Hemoglobin Concentration (MCHC)	decreased	normal
Serum Iron	decreased	normal to increased
Total iron Binding Capacity (TIBC)	decreased	normal to increased
Response to parenteral iron administration	very rapid	negligible

## G. COMMON VIRAL AND RICKETTSIAL CLINICAL SYNDROMES

As a guide to the physician in submitting specimens for viral and rickettsial studies, the following chart has been included. It lists the common clinical syndromes, viruses which have been associated with each, and the clinical materials which should be collected. Every attempt should be made to obtain all of the materials listed for each illness, since this will greatly increase the chances of the laboratory in establishing an etiologic diagnosis.

MANIFESTATION			SOURCE OF SPECIMEN			
IVI	IANIFESTATION	AGENT	CLINICAL	AUTOPSY		
G.	G.1. CARDIOVASCULAR					
	a. Myocarditis and Pericarditis	Enteroviruses: (including Coxsackie A), (types 4, 14, 16) B-1 – B-5	Throat swab/washing Feces Pericardial fluid	Blood Pericardial fluid		
		ACENIT	SOURCE OF SPECIME	N		
IVI	IANIFESTATION	AGENT	CLINICAL	AUTOPSY		

a. Paralysis	Enteroviruses:	Throat	Brain
	Polioviruses types 1,2,3	swab/washing	Intestinal
	Coxsackie A-7, A-9	CSF	contents
	ECHO types 2 and 9	Feces	
b. Aseptic meningitis	Enteroviruses:	Throat	Brain
and/or	Poliovirus	swab/washing	Intestinal
encephalitis	Coxsackie Group A and B	CSF	contents
	ECHO viruses Herpes simplex	Feces	
		Mouth swab	Brain
		CSF	
	Mumps	Mouth swab of	Brain
		Swenson's ducts	Parotid
		CSF	
		Urine	
	Arboviruses	Blood	Brain
		Throat	
		CSF	
	Lymphocytic	Blood	Brain
	choriomeningitis	CSF	
	Lymphogranuloma	CSF	Brain
	venereum	Primary Lesion site	Liver
			Spleen
	Rabies	See CDC Rabies	See CDC Rabie
		Guidelines	Guidelines
	Adenoviruses	Throat swab	Brain
		CSF	
		Feces	
	Measles (Rubeola)	Blood	Brain
		CSF	
c. Guillain-Barré Syndrome	Coxsackie A	Throat	Brain cord
·	ECHO viruses	swab/washing CSF	
		Feces	
d. Subacute sclerosing Pan	Measles (Rubeola)	CSF	Brain
encephalitis (Dawson's		Blood	Brain
encephalitis)		biood	

		ACENIT	SOURCE OF SPECIMEN	
MANIFESTATION		AGENT	CLINICAL	
G.3.	EXANTHEMATOUS INFECTION			-
a	a. Skin and Mucous Membrane			
	(1.) Smallpox	Vaccinia variola	Crusts	Liver
	(2.) Chickenpox	Varicella zoster	Throat swab/washing Vesicle fluid Scrapings from vesicle base	Spleen (Lung also for varicella)
	(3.) Fever blisters	Herpes simplex	Mouth swab Vesicle fluid and scrapings	CNS
	(4.) Herpangina	Enterovirus: Coxsackie A	Vesicle fluid Throat swab/washing Feces Vaginal swab	
	(5.) Hand, foot and mouth disease	Enterovirus Coxsackie A	Vesicle fluid Throat swab/washing (types 5, 10, 16)	Feces
	(6.) Dengue fever	Dengue virus (types 1-4)	Blood	Blood
$\top$	b. Maculopapular Rash			
	(1.) Enterovirus		Throat swab/washing Feces	
	(2.) German measles	Rubella	Heparinized blood CSF Products of conception Throat swab/washing Urine	Lung Liver Spleen

		ACENIT	SOURCE OF SPECIMEN		
IVI	ANIFESTATION	AGENT	CLINICAL	AUTOPSY	
G4	. OCULAR (OPHTHALMIC DISEAS	jE)			
	a. Kerato-conjunctivitis	Adenoviruses (types 8, 19, and 37)	Eye swab	Throat swab/washing	
	b. Ocular Herpes	Herpes Simplex	Eye swab	CNS	
	c. Follicular Conjunctivitis	Adenoviruses (types 3, 7, and others)	Eye swab	Throat swab/washing Eye swab	
	d. Conjunctivitis	New Castle Disease Virus		Conjunctival scrapings	
<b>G.</b> !	5. RESPIRATORY INFECTION				
	a. Lower Tract				
	(1.) Bronchitis Laryngotracheo bronchitis (Croup)	Influenza Parainfluenza Respiratory syncytial virus (infants)	Nasopharyngeal Aspirate Sputum	Lung Bronchial scrapings (for influenza, add spleen, liver, and/or kidney)	
		Chlamydia	Sputum Pleural fluid Throat swab/washing	Lung Liver Spleen	
		Adenoviruses	Sputum Nasopharyngeal Aspirate Feces	Lung Bronchial scrapings	
		Enteroviruses	Throat swab/washing Feces	Intestinal contents	
G.	6. RICKETTSIAL INFECTIONS				
	a. Rocky Mountain Spotted Fever	Rickettsia rickettsii	Blood	Liver Spleen	
	b. Ehrlichiosis	Ehrlichia chaffeensis	Blood		
	c. Epidemic typhus	Rickettsia prowazekii	Blood		
	d. Murine typhus	Rickettsia typhi	Blood		
	e. Q Fever	Coxiella burnetii	Sputum Urine CSF Blood	Liver Spleen	
	f. Rickettsial pox	Rickettsia akari	Blood	Liver Spleen	

N 4	ANIEESTATION	ACENT	SOURCE OF SPECIMEN	
IVI	ANIFESTATION	AGENT	CLINICAL	AUTOPSY
G.	7. SEXUALLY TRANSMITTED DISEA	SES (STD)		·
	a. Acquired Immuo-Deficiency Syndrome (AIDS)	Human Immuno-Deficiency virus HIV1, HIV2	Whole blood	
	b. Genitourinary tract infection	Herpes Simplex 2	Lesion scraping Vaginal swab	
	c. Vulvovaginitis	Coxsackie B Herpes Simplex 2	Vaginal swab Lesion scraping	
	d. Lymphogranuloma venereum, cervicitis, urethritis	Chlamydia trachomatis	Fluid and pus Cervical swab Urethral swab Rectal swab	
G.	8. SYSTEMIC	•		•
		Cytomegalovirus	Urine, Saliva Throat swab/washing Heparinized blood CSF Lung Biopsy	Kidney Lung Liver Brain
		Adenoviruses	Throat swab/washing Sputum Feces Urine CSF	Intestinal contents Lung Brain Liver Kidney Heart
		Coxsackie B	Throat swab/washing CSF Feces, pleural, or as indicated	Brain Heart Lymph node Intestinal
м	ANIFESTATION	AGENT	SOURCE OF SPECIMEN	
c	9. MISCELLANEOUS		CLINICAL	AUTOPSY
<u>u</u> .	a. Infantile diarrhea	Coxsackie A (types 18, 20, 21, 22, 24)	Feces	
	b. Hepatitis	Enteroviruses (including Coxsackie A) (types 4, 9)	Throat swab/washing Feces Live	Intestinal contents

c. Hemolytic-uremic Syndrome	Coxsackie A (type 4)	Throat swab/washing Feces	Lung Kidney Intestinal contents
d. T cell leukemia	HTLV I, II	Heparinized blood	
e. Gastroenteritis	ECHO Coxsackie B Rotaviruses Norovirus	Feces Throat swab/washing Vomitus	
f. Orchitis and Epididymitis	Mumps Coxsackie	Urine Throat swab/washing Feces	Parotid
g. Intussusception	Adenovirus	Feces Mesenteric lymph node	
h. Colorado Tick Fever	CTF virus	Blood	
i. Acute Infectious Lymphocytosis	Epstein-Barr virus (EB) Coxsackie-like virus	Blood	
j. Post Perfusion Syndrome	Cytomegalovirus Epstein-Barr virus	Blood	

# H. DIRECTORY OF LOCAL HEALTH DEPARTMENTS

HEALTH DEPARTMENT	ADDRESS	TELEPHONE	EMERGENCY/ AFTER HOURS PHONE#	FAX NO.
Allegany	P.O. Box 1745 12501-12503 Willowbrook Rd. Cumberland MD 21501-1745	301-759-5000	301-759-3060	301-777-5674
Anne Arundel	Health Services Buildings 3 Harry S. Truman Parkway Annapolis MD 21401	410-222-7375	410-222-7095	410-222-4436
Baltimore City	1001 East Fayette Street Baltimore MD 21202	410-396-4387	410-396-3100	410-396-1617
Baltimore County	Drumcastle Government Center 6401 York Road, 3rd Floor Baltimore MD 21212	410-887-2243	410-832-7182	410-377-5397
Calvert	P.O. Box 980 975 Solomons Island Rd Prince Frederick MD 20678	410-535-5400	443-532-5973	410-535-5285

HEALTH DEPARTMENT	ADDRESS	TELEPHONE	EMERGENCY/ AFTER HOURS PHONE#	FAX NO.
Caroline	403 South 7th Street Denton MD 21629	410-479-8030	Comm. Disease 443-786-1398 Rabies 410-479-2232	410-479-0554
Carroll	290 S. Center Street Westminster MD 21157	410-876-2152	410-386-2260	410-876-4988
Cecil	John M. Byers Health Center 401 Bow Street Elkton MD 21921	410-996-5550	410-996-5550	410-996-5179
Charles	4545 Crain Highway White Plains MD 20695-1050 Mailing Address: P.O. Box 1050 White Plains MD 20695	301-609-6900	301-932-2222	301-934-4632
Dorchester	3 Cedar Street Cambridge MD 21613	410-228-3223	410-228-3223	410-228-9319
Frederick	350 Montevue Lane Frederick MD 21702	301-600-1029	301-600-0311	301-600-3111
Garrett	1025 Memorial Drive Oakland MD 21550	301-334-7777	301-334-1930	301-334-7771
Harford	120 South Hays Street P.O. Box 797 Bel Air MD 21014-0797	410-838-1500	Comm. Disease 443-243-5726 Environ. Health 410-638-3400	410-638-4952
Howard	8930 Stanford Boulevard Columbia, MD 21045	410-313-1412	410-313-2929	410-313-6108
Kent	125 S. Lynchburg Street Chestertown MD 21620	410-778-1350	Comm. Disease 410-708-5611 Environ. Health 410-778-1371	410-778-7913
Montgomery	401 Hungerford Drive, 5th Floor Rockville MD 20850	240-777-1741	240-777-4000	301-279-1692
Prince George's	1701 McCormick Drive Largo MD 20774	301-883-7834 301-883-7879	301-883-4748 301-883-7879	301-883-7896
Queen Anne's	206 N. Commerce Street Centreville MD 21617	410-758-0720	410-758-3476 410-778-5173	410-758-2838
Somerset	7920 Crisfield Highway Westover MD 21871	443-523-1700	443-523-1750	410-651-5680
St. Mary's	21580 Peabody Street, P.O. Box 316 Leonardtown MD 20650	301-475-4330	301-475-8016	301-475-4350

HEALTH DEPARTMENT	ADDRESS	PHONE#	EMERGENCY PHONE#	FAX NO.
Talbot	100 S. Hanson Street Easton MD 21601	410-819-5600	410-822-0095	410-819-5690
Washington	1302 Pennsylvania Avenue Hagerstown MD 21742	240-313-3260	301-573-6375	240-313-3201
Wicomico	108 East Main Street Salisbury MD 21801	410-543-6930	410-543-6996	410-543-6975
Worcester	P.O. Box 249 6040 Public Landing RD. Snow Hill MD 21863	410-632-1100	410-632-1311	410-632-0906

# I. ACRONYMS

AFB	acid fast bacillus
AFP	alpha fetoprotein
Ag	Antigen
вск	branch chain ketoacids
САН	congenital adrenal hyperplasia
CF	complement fixation
СНЅ	Childhood Screening
CMV	Cytomegalovirus
CSF	cerebrospinal fluid
DF	dark field
DFA	direct fluorescent antibody
EBNA	Epstein Barr virus nuclear antigen
EBV	Epstein Barr virus
EEE	Eastern Equine Encephalitis
EIA	enzyme linked immunosorbent assay
ELISA	enzyme linked immunosorbent assay
GALT	Galactose 1-phosphate uridyl transferase
HAVAb	Hepatitis A virus antibody
Hb	Hemoglobin
HIV	Human Immunodeficiency virus
HSV	Herpes Simplex virus
HTLV I/II	Human T Lymphocytic virus
IFA	indirect fluorescent antibody
IFA	Immunofluorescent antibody
lgG	Immunoglobulin G
lgM	Immunoglobulin M
IHA	indirect hemagglutination
ІМ	infectious mononucleosis
LCM	lymphocytic choriomeningitis

Lab Information Management System
lavender top tube
Mycobacterium avium complex
medium chain acyl-dehydrogenase deficiency
mean corpuscular hemoglobin concentration
milligram per deciliter
Newborn Screening
nasopharyngeal
polymerase chain reaction
pulsed-field gel electrophoresis
phenylketonuria
rapid fluorescent focus inhibition technique
rapid plasma reagin
Respiratory Syncytial virus
red top tube
Reverse-transcribed polymerase chain reaction
yellow blood collection tubes containing sodium polyanethol sulfonate
total iron binding capacity
Virology Immunology Division
viral capsid antigen
viral transport media
Varicella-Zoster virus
Western Blot
Western Equine encephalitis