Maryland
DEPARTMENT OF HEALTH

Larry Hogan, Governor · Boyd K. Rutherford, Lt. Governor · Dennis R. Schrader, Secretary

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

DATE: August 3, 2022

TO: Medical Lab Directors, Local Health Departments, and Healthcare Providers

FROM: Robert A. Myers, Ph.D.
Director, Laboratories Administration

RE: Monkeypox Testing Updates

The Maryland Department of Health Laboratories Administration is issuing the following Monkeypox testing updates.

All specimens sent to the Laboratories Administration for orthopox testing still MUST have prior approval for testing from the State Epidemiologists or their authorized designee. Specimens sent without proper approval will not be tested. Please contact the State Epidemiologists at 410-767-6700 (during normal business hours) or 410-795-7365 (after hours) for consultation.

Febrile Rash Low to Moderate Risk Specimen Collection kits have been distributed to the Local Health Departments (LHD's). Please contact your LHD for information regarding specimen collection kits. Please ensure that the kits being used/distributed are within their expiration date. Specimens submitted in expired tubes will be rejected. A previous batch of kits that was distributed has an expiration date of 08/07/22. Unused expired kits are to be returned to the Laboratories Administration for recycling and reuse of the unexpired kit components. Five additional collection kits were distributed to each LHD this week.

Specimens collected for testing at the Laboratory Administration must be kept refrigerated until delivered to the MD Laboratory within 72 hours of collection. Specimens must be kept frozen (at least -20°C) if they are not received at the MD laboratory within 72 hrs. of collection. This is to ensure the integrity of the specimens received for testing.

For the safety of all who handle specimens submitted for monkey pox testing, specimens must be packaged using Category B shipping requirements, even if specimens are sent via routine or private couriers. See below for basic triple-packaging instructions.

The attached specimen collection guidance can be followed in the event that a health care provider is unable to obtain an allocated Specimen Collection Kit from their Local Health Department. The Febrile Rash Form test request form is available on the Laboratories Administration's website: https://health.maryland.gov/laboratories/Pages/Home.aspx

Please contact your Local Health Department or the State Epidemiologists with any other questions or concerns. General questions may be submitted to mdh.monkeypox@maryland.gov.

Guidelines for Orthopox Rule-Out Specimen Submission

MDH Infectious Disease Epidemiology
(Consult Required Prior to specimen submission)

MDH Epi Line (Business Hours) 410-767-6700
MDH Epi/Physician After Hours On-Call at 410-795-7365

MDH Laboratories Administration

Office of Laboratory Emergency Preparedness and Response

Monday – Friday 8:00 a.m. - 4:30 p.m. (Dial in order)	**AFTER HOURS** (Dial in order)
443-681-3788 - Office phone	**410-925-3121 - Cell Phone**
410-925-3121 - Cell Phone	**410-408-7521 - Pager**
443-681-3789 - Office phone	
410-408-7521 - Pager	

Requested Specimens

Specimen Type	**Collection Materials**	**Instructions**	**Storage Conditions**
A minimum of **2* swabs** of base of lesion (NO transport media) **Required by CDC** *Note: One dry swab may be tested at an LRN Reference laboratory for presumptive results. CDC can provide *Monkeypox virus*-specific testing on the second dry swab specimen if the first dry swab is presumptive positive at the LRN laboratory.	Sterile nylon, polyester, or Dacron swab with a plastic, wood, or thin aluminum shaft. Place in a sterile container with NO transport media. Use **2*** swabs per lesion. Place each swab in dry, sterile container and label appropriately. (i.e. body site, description, etc.)	** Prior to specimen collection, sanitize area with alcohol and let dry.** 1. Use a disposable scalpel (or a sterile 26 Gauge needle) to open and remove the top of the vesicle or pustule (do not send the scalpel or needle). Retain lesion roof for testing. (See below) 2. Swab the base of the lesion with a sterile polyester or Dacron swab. 3. Place swabs in individual sterile containers. DO NOT ADD ANY VIRAL OR UNIVERSAL TRANSPORT MEDIA. 4. Collect specimens from lesions at different anatomic locations if possible	Refrigerate after collection at 2-8C. Deliver immediately to MDH.
1 swab of base of a lesion (in viral transport media) **Required by MDH** (Used for reflex testing if no orthopox viruses found)	Sterile nylon, polyester, or Dacron swab with a plastic, shaft. Tube of viral transport media. Use multiple containers when collecting specimens from multiple lesions.	Same as above EXCEPT place swab in viral transport media in order to allow testing for other viral pathogens if the above specimens test negative for orthopox viruses.	

Specimen Type	Collection Materials	Instructions	Storage Conditions
Crust, scab, or biopsy of lesion (If able to remove crust/roof during swab collection, send as additional specimen)	Sterile tube with O ring seal (As needed, sterile scalpel, 26 gauge needle, and forceps.)	1. Sanitize lesion with an alcohol wipe, allow to dry. 2. Use a disposable scalpel (or a sterile 26 Gauge needle) to open and remove the top of the vesicle or pustule (do not send the scalpel or needle). Retain lesion roof for testing. 3. Place specimen in a 1.5 or 2 mL screw-capped tube with O-ring. DO NOT ADD ANY VIRAL TRANSPORT MEDIA. 4. Collect specimens from lesions at different anatomic locations if possible	Refrigerate after collection at 2-8C. Deliver immediately to MDH. Specimens may be kept at 2-8C for up to 72 hrs, after which point they must be frozen at minimum -20C. They may stay frozen for up to two months.

Required Personal Protective Equipment (PPE) to collect specimens

- Disposable Gown
- Gloves
- Fit tested N95 or PAPR *Surgical mask if not available
- Eye protection- face shield or goggles (note that eye-glasses are not eye protection)

Alcohol based hand sanitizer or sink with soap and water for hand hygiene

Required Data Elements on Specimens and Requisition Forms

- All specimens may be listed out on the **FEBRILE RASH (LOW TO MODERATE RISK) form (Appendix 2). Use one Tube ID for each body site/specimen type.**
- Each individual specimen must be labeled with the following:
  - Patient name
  - DOB
  - Collection date
  - Specimen site
- Unlabeled specimens will be AUTOMATICALLY REJECTED.
- Under Presumptive Clinical Diagnosis, specify Other: Monkeypox
- Test Request Authorized By is your ordering provider. Please only list an MD, DO, PA-C, or CRNP.
- Health Care Provider is the submitting facility name.
- All patient demographic elements are required.
- Consult with MDH Epidemiology to determine risk category.
- Ship packages using Category B Shipping (See below).
- Address package to MDH Labs, "For Monkey Pox testing, ATTN:Amy Armitage or Sali Lukula"

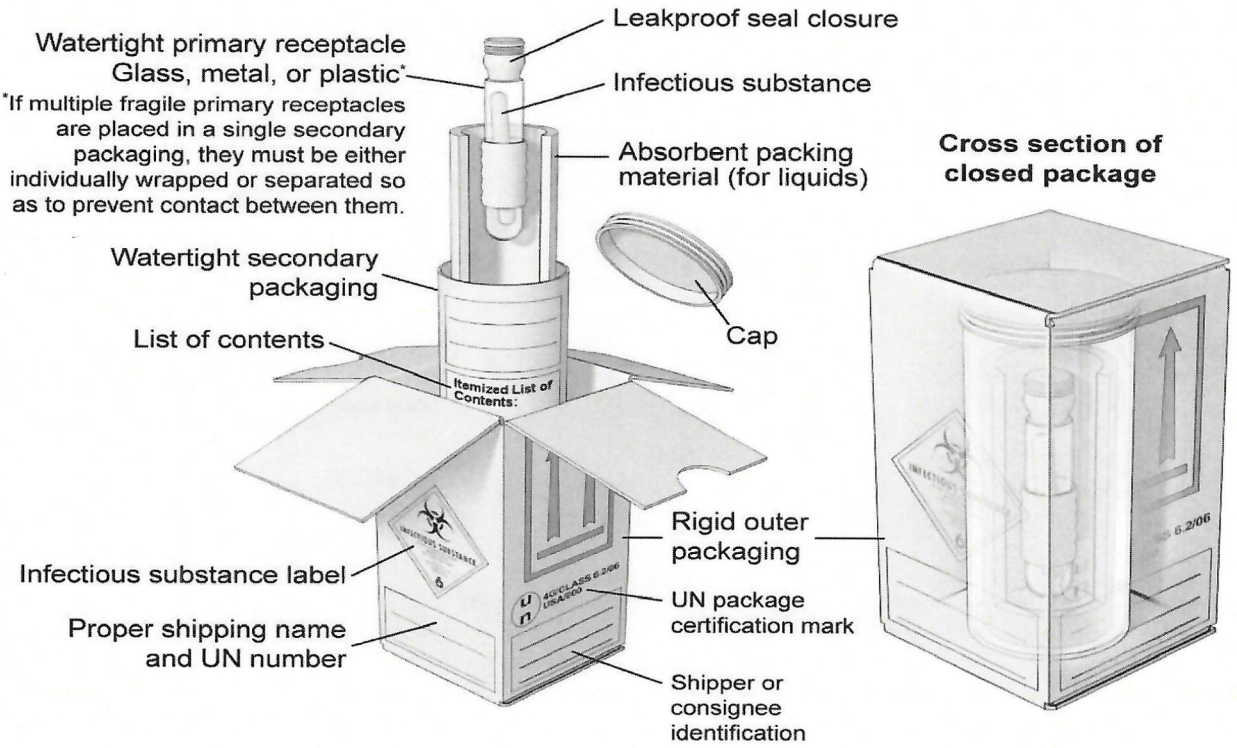
Appendix 1: Packaging and Shipping

Specimens must be shipped using Category B shipping requirements.

Refer to the attached document (**Basic Triple Packaging**) for packaging and shipping guidelines. If necessary, the MDH Laboratories Administration will arrange for an emergency courier, but will only do so after consultation with the patient's physician and MDH Physician-On-Call or Epidemiologist.

BASIC TRIPLE PACKAGING

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.



BASIC TRIPLE PACKAGING:

- A watertight primary receptacle.
- A watertight secondary receptacle.
- 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.

Appendix 2: Febrile Rash (Low and Moderate Risk) Form

MARYLAND Department of Health

Laboratories Administration
1770 Ashland Ave
Baltimore, Maryland 21205

Robert A. Myers, Ph.D., Director

FEBRILE RASH (Low and Moderate Risk)

Health Care Provider	
Address	
City	County
State	Zip Code
Contact Name	
Phone#	Fax#
Test Request Authorized by:	

TYPE OR PRINT

Patient's SS# (last 4 digits) _____ Case#

Patient _____ Lab No. _____
Last Name First Middle

Date of Birth __/____/____ Sex M ☐ F ☐

Address _____

City _____ County _____ State _____ Zip _____

Risk Category: Low Risk Moderate Risk

For **Low Risk** and **Moderate Risk** testing, collect the following specimens:

REMEMBER TO PLACE ONLY ONE LESION PER TUBE

tube id	*collection device*	*specimen type needed*	*body site of collection (arm, chest, face, etc.)*	*description of site (vesicle, pustule, etc.)*
1	tube with transport media	swab of base of lesion		
2		swab of base of lesion		
3	long tube with swab and no liquid	swab of base of lesion		
4		swab of base of lesion		
5	small empty tube with O ring seal	crusUscab of lesion		
6		crusUscab of lesion		
7		crusUscab of lesion		
8		crusUscab of lesion		

Presumptive Clinical Diagnosis: Chickenpox Herpesvirus Smallpox

Smallpox vaccine (Vaccinia) Other: _____
(specify)

Date of Onset: _____/_____/_____
(Month / Day / Year)

Date Specimen Collected _____ Reported _____

MDH4746-A