

Chlamydia Testing Allocation System Training Sessions

**Maryland DHMH
Laboratories Administration
January 12-15, 2009**

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Chlamydia Test Technology Change Effective February 2, 2009

- Upgrade Chlamydia screening technology from ELISA antigen capture assay to Nucleic Acid Amplification (NAA) test



- The ELISA based Chlamydia antigen detection will **NO** longer be available effective February 2, 2009, but will be replaced by the Chlamydia NAA testing.

Chlamydia Test Technology Change Effective February 2, 2009

- The acceptable specimens for the Chlamydia NAA test are:
 - urine
 - endocervical or cervical swab
 - male urethral swab

Requires a **NEW** specimen collection kit effective
February 2, 2009

Contact the DHMH Laboratories Administration,
Specimen Mailing Assemblies (Outfit Room) at
410-767-6120 or 410-767-6121

Chlamydia Testing Allocation System

Chlamydia Testing Allocation for Chlamydia
NAAT (Address, MyLIMS ID and Password,
Stickers, MOU/PO)

Specimen Collection and Submission Guidelines

How to View Reports On-line

How to Generate a Packing Slip

Chlamydia Testing Allocation System for Chlamydia NAAT

Submitters Names and Addresses

Any changes: Please contact Cesar Pena at cpena@dhmh.state.md.us

Chlamydia Testing Allocation Stickers

Distribution of stickers to the County's "Sticker Steward"

Acknowledgement of Receipt

Stickers Usage Tracking

MyLIMS ID and Password

To be provided to the County's "Sticker Steward"

MOU/PO

Please contact Mr. Kenneth Keys at keys@dhmh.state.md.us

Specimen Collection and Submission Guidelines

Urine

**Specimen Collection and Transport
Procedures for Chlamydia NAAT**

Swab

**Specimen Collection and Transport
Procedures for Chlamydia NAAT**

URINE	<p>The specimen must be processed within 7 days of collection.</p> <p>It must reach the laboratory registration area by <u>no later than the 6th day</u> (except Friday) to be tested within the 7 day allowance.</p>
SWABS <i>endocervical</i> <i>cervical</i> <i>male urethral</i>	<p>The specimen must be processed within 6 days of collection.</p> <p>It must reach the laboratory registration area by <u>no later than the 5th day</u> (except Friday) to be tested within the 6 day allowance.</p>

Specimens received on a Friday will not be tested until Monday (Tuesday, if Monday is a holiday.)

Specimen Transport

Transport to the laboratory in insulated containers with **cold packs** (2-8C)

**Do NOT store or transport
at room temperature**

URINE Specimen Collection and Transport Procedures

1. The patient should not have urinated for at least 1 hour prior to specimen collection.
2. Collect the urine specimen in a plastic, sterile, preservative-free, specimen collection cup. Do not collect bloody or highly pigmented urine as these interfere with the assay, and will be rejected.
3. The patient should collect 15-60 ml of the **first part** of the urine stream (not mid-stream). Urine volume less than 4 ml or greater than 60 ml will be rejected.
4. Verify that the cap is properly aligned and tightly closed. Leaking specimens will be rejected.
5. Label the cup with the collection date and time, and the patient's name (i.e. John Doe). (Please ensure that the name on the cup exactly matches the name on the **Infectious Agents: Culture/Detection lab slip**).

6. Complete the **Infectious Agents: Culture/Detection lab slip.**

- Affix both Chlamydia Testing Allocation Stickers (same serial number) on the:
 - Original Copy Form
 - Copy # 1 Form
- Place preprinted submitter labels with DHMH Lab Administration Client ID.
- Be sure to include the source of the specimen (urine) in the box next to the test requested “Chlamydia NAAT Only.”

7. Double bag urine specimens.

Seal the cup in the zip locked section of a plastic bag with absorbent material.

Seal this bag in the zip locked section of a biohazard transport bag and place the form in the outside pocket.

8. Refrigerate the specimen immediately.

9. Order the test/s in MyLIMS.

Print packing slip and submit with specimens.

10. Transport to the laboratory in an insulated container with **cold packs** (2-8C.) .

SWAB Specimen Collection and Transport Procedures

Use ONLY BD ProbeTec ET CT/GC Amplified DNA Assay Collection Kit for:

Endocervical or Cervical Specimens (**female-pink**)

Male Urethral Specimens (**male-blue**)

- Please use the appropriate gender kit.
 - If this is not followed, the specimen will be rejected.
- Cervix and male urethra are the only approved swab collection specimen for this assay.
- **NOTE: For any other collection sites (i.e. rectal, vaginal, throat), test request should be Chlam Trans for cell culture. This test is limited to medical legal cases, rectal or oral specimens.**

MALE URETHRAL SWABS

1. Remove the swab from the packaging and insert the swab 2-4 cm into the urethra and rotate for 3-5 seconds. Withdraw the swab. Continue with Step #5 below.

FEMALE ENDOCERVICAL SWABS

1. Remove the cleaning swab (large one) from the packaging.
2. Using the cleaning swab, remove excess mucus from the cervical os. Discard cleaning swab.
3. Remove the collection swab (smaller one) from the packaging and insert the collection swab into the cervical canal and rotate for 15-30 seconds.
4. Withdraw the swab carefully. Avoid contact with the vaginal mucosa.

5. Uncap the CT/GC diluent tube and fully insert the collection swab.
6. Break the shaft of the swab at the score mark (do not cut it off shorter) using care to avoid splashing and tightly recap.
7. Label the tube with the collection date and time, and the patient's name (i.e. John Doe). (Please ensure that the name on the tube exactly matches the name on the **Infectious Agents: Culture/Detection lab slip**).
8. Complete the **Infectious Agents: Culture/Detection lab slip**.
 - Affix both Chlamydia Testing Allocation Stickers (same serial number) on the:
 - Original Copy Form
 - Copy # 1 Form
 - Be sure to include the source of the specimen in the box next to the test requested.

**Affix
STICKERS
on both the
Original and
Copy #1
forms.**



**Must be completed.
Pre-printed address
labels with ID**

**Must be
Completed.**

STATE LAB
Use Only

INFECTIOUS AGENTS: CULTURE/DETECTION

LABORATORIES ADMINISTRATION MD DHMH
301 W. Preston St. • Baltimore, MD 21201
P.O. Box 2355 • Baltimore MD, 21203-2355
410-767-6100 www.dhmm.state.md.us/labs
John M. DeBoy, Dr. P. H., Director

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TYPE OR PRINT REQUIRED INFORMATION OR PLACE LABELS ON ALL FOUR COPIES

DEH OFF DMTP/PN QNOD QSTD QTB QCD QCOR Patient SS# (last 4 digits):
 Submitter: Last Name: CSR QJR QOther
 Address: First Name: I.D. Number:
 City: Date of Birth (mm/dd/yyyy)
 State: Zip Code: Address: City: County:
 Contact Name: State: Zip Code
 Phone #: Fax #:

Ethnicity: Hispanic/Latino Not Hispanic/Latino Unknown Sex: Male Female Transgender
 Race: White African American Asian/Pacific American Indian/Alaska Native Multiracial Not Specified Other

Case # _____ Outbreak # _____ Submitter Lab # _____
 Collect Date: _____ Collect Time: _____ Onset Date: _____
 Reason for Test: Screening Diagnosis Contact Test of Cure 2-3 Months Post Rx Suspected Carrier Isolate for ID Release
 Therapy/Drug Treatment: No Yes Therapy/Drug Type: _____ Therapy/Drug Date: _____

SPECIMEN CODE	SPECIMEN CODE	SPECIMEN CODE
BACTERIOLOGY/MYCOLOGY	SPECIAL BACTERIOLOGY	RESTRICTED TESTS
Bacterial Culture - Routine	Legionella Culture	Pre-approved submitters only
Additional specimen codes:	Leptospira	UR or CX or URE
<i>Bordetella pertussis</i>	Mycoplasma	<i>Chlamydia trachomatis</i> only/NAAT
Group A Strep	MYCOBACTERIOLOGY/AFB/TB	<i>Herpesvirus</i> (see comment on back)
Group B Strep Screen	AFB/TB Culture and Smear	OTHER TESTS FOR INFECTIOUS AGENTS
<i>C. difficile</i> Toxin	AFB/TB Referred Culture for ID	Test name: _____
Diphtheria	AFB/TB Referred Culture-Sensitivities	Prior arrangements have been made with the following DHMH Laboratories Administration employee: _____
Foodborne Pathogens (<i>B. cereus</i> , <i>C. perfringens</i> , <i>S. aureus</i>)	<i>M. tuberculosis</i> Referred Culture for Genotyping	
Fungus Culture:	Nucleic Acid Amplification Test for <i>M. tuberculosis</i> Complex (MTD)	
Fungus Smear:	PARASITOLOGY	
Gonorrhea Culture: Incubated? <input type="checkbox"/> Yes <input type="checkbox"/> No	Blood Parasites:	SPECIMEN CODE: PLACE CODE IN BOX NEXT TO TEST
MRSA (rule out)	Country visited outside US:	B Blood
VRE (rule out)	Ova & Parasites: Immigrant? <input type="checkbox"/> Yes <input type="checkbox"/> No	BW Bronchial Washing
ENTERIC INFECTIONS	Cryptosporidium	CSF Cerebrospinal Fluid
Campylobacter	Cyclospora/Isospora	CX Cervix/Endocervix
<i>E. coli</i> O157 typing	Microsporidium	E Eye
Enteric Culture - Routine (Salmonella, Shigella, <i>E. coli</i> O157, Campylobacter)	Pinworm	F Feces
Salmonella typing	VIRUS/CHLAMYDIA	N Nasopharynx/Nasal
Shigella typing	Adenovirus*	P Penis
<i>V. parahaemolyticus</i>	Arbovirus Panel (WNV, EEEV, SLEV)	R Rectum
Yersinia	<i>Chlamydia trachomatis</i>	SP Sputum
REFERENCE MICROBIOLOGY	Cytomegalovirus (CMV)	T Throat
ABC'S (BIDS) # _____	Enterovirus (Inc. Echo & Coxsackie)	URE Urethra
Organism: _____	Herpes Simplex Virus (Types 1 & 2)	UR Urine
Aerobic Actinomycete for ID	Influenza (Types A & B)*	V Vagina
Bacteria Referred Culture for ID	Parainfluenza (Types 1, 2 & 3)*	W Wound
Specify: _____	Respiratory Syncytial Virus (RSV)*	O Other:
Mold for ID	Varicella (VZV)	
Yeast for ID	*MAY INCLUDE RESPIRATORY SCREENING PANEL	
	Comments: _____	

DHMH 4676 Revised 1/08

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**Collect Date
must be
completed.**

**Fill-in
race, ethnicity
and gender**

**Specimen
code must be
completed.**



9. Seal the tube in the zip lock section of a biohazard transport bag and place the form in the outside pocket.
10. Refrigerate the specimen immediately.
- 11. *Order the test/s in MyLIMS.
Print packing slip and submit with specimens.***
12. Transport to the laboratory in an insulated container with cold packs (2-8C.) . Specimen may **not be stored or transported at room temperature.**

Specimen Rejection Criteria for Chlamydia NAAT

- **Missing information required to determine specimen adequacy: source, collection date, gender.**
- Too old. Urine >7 days, Swabs >6 days
- Missing name or ID from the specimen tube or cup.
- Missing ID of submitter and/or patient on the form.
- Leaked in transit-whether partial or full leakage.
- Quantity not sufficient: urine <4ml or excessive: urine >60ml.
- Swab tube is without a swab.
- Expired swab transport tube or tube with missing expiration date.
- Transported outside of the appropriate temperature range (2-8°C)
- No specimen received with the lab request slip or no slip received with the specimen.

Specimen Rejection Criteria for Chlamydia NAAT

- Wrong swab used. Must use the one provided in the collection kit, but not the large cleaning swab in the female kit. It will be rejected if sent.
- Inappropriate collection site. Only acceptable sites are male and female urine, endocervical/cervical swab, or male urethral swab.
- Specimen is in the wrong transport assembly. Must be plastic (no glass), sterile, preservative free urine cup or the gender appropriate BD swab collection kit. Opposite gender kits will be rejected.
- Bloody urine/swabs or highly pigmented urine. (Interferes with assay)
- Mismatched names on slip/specimen.
- Highly mucoid specimen, which cannot be pipetted.
- Illegible slip and/or specimen such that matching ID cannot be established.

Infectious Agents: Culture/Detection Lab Slip

Back of Form Instructions

INSTRUCTIONS

Clinics	
EH-Employee Health Clinic	STD-Sexually Transmitted Disease Clinic
FP-Family Planning Clinic	TB-Tuberculosis Clinic
MTY/PN-Maternity/Prenatal Clinic	CD-Communicable Disease Clinic
NOD-Nurse of Day	COR-Correctional Facilities

****NOROVIRUS:**

Norovirus testing is appropriate for outbreak and epidemiological investigations only and is not done for clinical diagnostic purposes. A DHMH outbreak number is required for Norovirus testing. Please contact your local health department for an outbreak number.

MOST IMPORTANT:

- ✓ TYPE OR PRINT LEGIBLY AND PRESS FIRMLY, THIS IS A FOUR PART FORM
- ✓ IF USING PRE-PRINTED LABELS, PLACE LABELS ON ALL 4 COPIES
- ✓ COLLECTION DATE AND TIME ARE REQUIRED BY LAW
- ✓ PLACE SPECIMEN CODE IN BOX NEXT TO TEST
- ✓ USE A SEPARATE BIOBAG FOR EACH TEMP/STORAGE/SHIPPING REQUIREMENT

USING BIOBAGS/PACKAGING SPECIMENS/MULTIPLE SPECIMENS:

Fold the completed test request form(s) in half and place in the outer pouch (protects it from contamination); then place the properly labeled and sealed specimen(s) in the zipper portion of the biobag and seal. **PLEASE: DOUBLE-BAG ALL URINE SPECIMENS.**

Bag specimens according to temperature/storage/shipping requirements. If the temperature and shipping requirements are the same, it is acceptable to submit multiple specimens from the same patient in one biobag with the appropriate form(s).

MULTIPLE SPECIMENS FROM THE SAME PATIENT WITH MULTIPLE TEMPERATURE/STORAGE/SHIPPING REQUIREMENTS:

If multiple specimens with different temperature/storage/shipping requirements are collected on the same patient THEY CANNOT BE SUBMITTED IN THE SAME BIOBAG. First, complete the top part of the form. Then use the back copy (or make a photocopy) of the form to submit with each specimen requiring a different temperature/storage/shipping condition. Place each specimen with its respective lab form in a separate biobag. **ENSURE THAT SPECIMENS ARE INDIVIDUALLY LABELED AS TO SOURCE.**

If you have any questions/comments on the use of the specimen bags or temperature/storage/shipping requirements, please contact the Registration Unit at 410-767-6116 or shacklefordd@dhmh.state.md.us.

SPECIFIC TEST REQUIREMENTS:

Please refer to the Laboratories Administration's "Guide to Public Health Laboratory Services" for specific test requirements. The "Guide" is available online at www.dhmh.state.md.us/labs/.

Lab Use Only

Multiple Tests Submission

Denise Shackelford

MULTIPLE SPECIMENS FROM THE SAME PATIENT WITH MULTIPLE TEMPERATURE/STORAGE/SHIPPING REQUIREMENTS:

If multiple specimens with different temperature/storage/shipping requirements are collected on the same patient **THEY CANNOT BE SUBMITTED IN THE SAME BIOBAG.** First, complete the top part of the form. Then use the back copy (or make a photocopy) of the form to submit with each specimen requiring a different temperature/storage/shipping condition. Place each specimen with its respective lab form in a separate biobag. **ENSURE THAT SPECIMENS ARE INDIVIDUALLY LABELED AS TO SOURCE.**

If you have any questions/comments on the use of the specimen bags or temperature/storage/shipping requirements, please contact the Registration Unit at 410-767-6116 or shackelfordd@dnhm.state.md.us.

Tests Requested Infectious Agents: Culture/ Detection Lab Slip	<i>Tests Requested On-Line</i>	Infectious Agents: Culture/Detection Lab Slip Form	Transport Conditions
Chlamydia trachomatis only/NAAT	<i>Chlamydia nucleic acid amplification</i>	Original (white) Copy #1 (yellow) Affix stickers	Cold Packs
Herpes Simplex Virus (Types 1&2)	<i>Pan Herpes Simplex Virus PCR</i>		
Chlamydia trachomatis	<i>Chlamydia Cell Culture</i>		
Bacteria Culture	<i>Bacteriology Clinical</i>		
Gonorrhea Culture	<i>GC Culture</i>	Copy #2 (pink)	Room Temp

Sticker Allocation Tracking and View Reports

- Tracking of sticker usage per client site
- Added benefit for clients to check reports on-line
- Access using MyLIMS ID and password per client site
- Request tests per client site in minutes
- Create packing list for shipping
- Stream-line submission process

Stream-line submission process

Create packing list for shipping

STARLIMS v10(STARLIMS10.DHMHENV.TEST) User: CARLOSM - Windows Internet Explorer

Samples Labels

Main Report

MyLims Samples Requested
By
DHMH-LABS ADM-DR DEBOY

Package Id: 2423015-40 [Barcode] Printed Date:

Submitter Name: DHMH-LABS ADM-DR DEBOY
Submitter Id: 2423015

A08115748 [Barcode]

Date Of Birth: Sex:
SSN#: DOC#: Pid:

Requested Tests:
A08115748001 -
ABC/EIP

A08115749 [Barcode]

Date Of Birth: Sex:
SSN#: DOC#: Pid:

Requested Tests:

Current Page No.: 1 Total Page No.: 1 Zoom Factor: 100%

Done Internet 100% 7:31 AM

Added benefit for clients to check reports on-line. Print reports.

The screenshot displays the STARLIMS v10 web application interface. The main window shows a patient report for a Chlamydia Antigen EIA test. The report includes patient information, specimen details, and the test result.

State of Maryland Department of Health and Mental Hygiene LABORATORIES ADMINISTRATION
Central Laboratory
201 West Preston Street
Baltimore, MD 21201
John M. DeBoy, Dr. P.H., Director
www.dhmh.state.md.us/labs

DHMH-LABS ADM-DR DEBOY
Dr. DeBoy
LOBBY LEVEL, RM L38
BALTIMORE, MD 21201

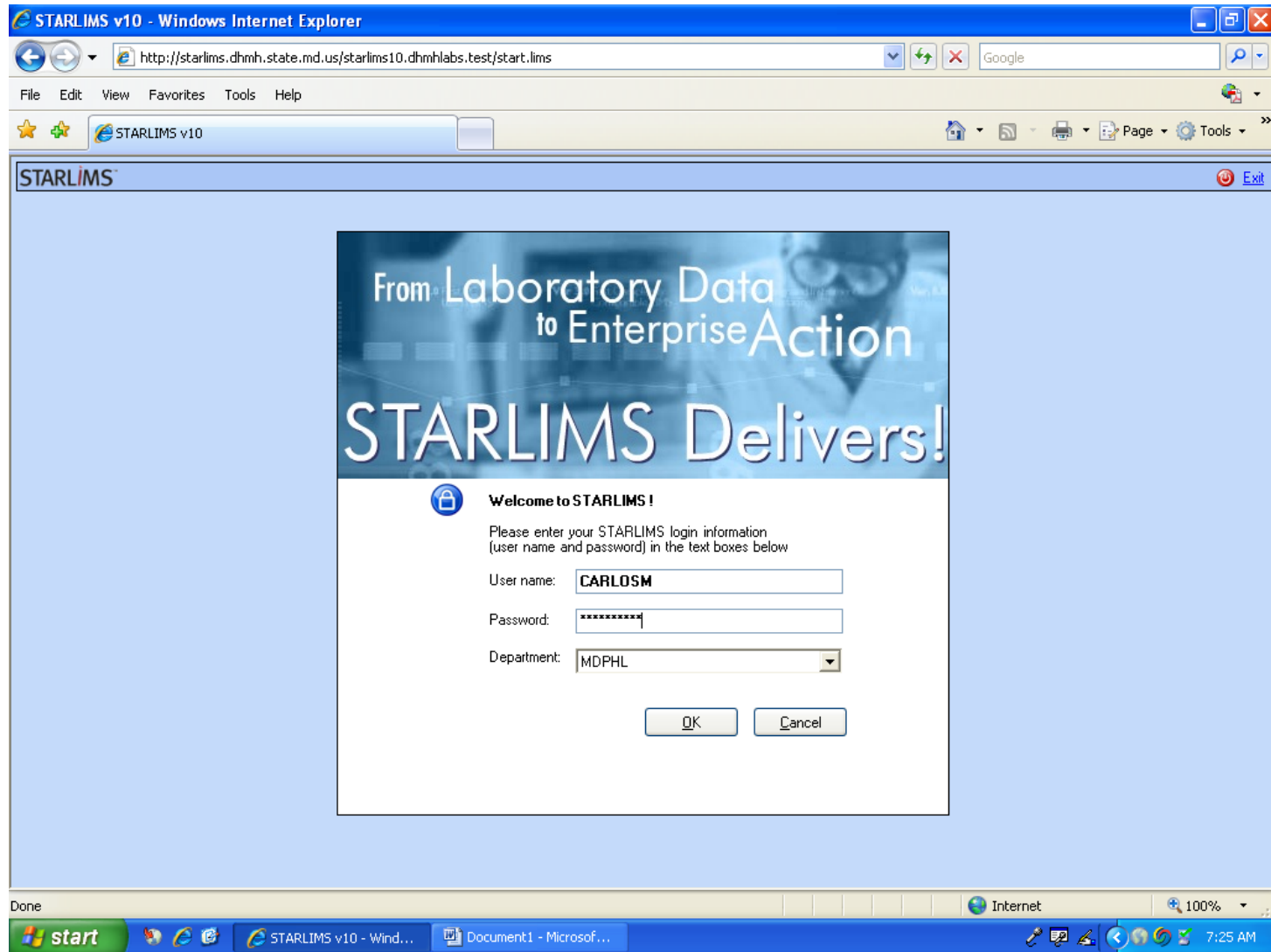
Specimen Number: A08115367001 Internal Lab Number:
Patient Name: TEST, MYLIMS Outbreak Number:
Patient Id: TEST, MYLIMS Specimen Source:
Birth Date: Date Collected:
Sex: Date/Time Received: 11/13/2008 09:03
SSN: Submitter Lab #
Patient Address:

Comments:

Test Name	Results	Date Reported
Chlamydia EIA	Chlamydial Antigen was NOT DETECTED by EIA	12/15/2008

The interface also shows a sidebar with navigation options like 'Dashboard', 'Edit Clinical', and 'Patient Search...'. A table in the sidebar lists 'Requested Panels' with 'Chlamydia Antigen EIA' and 'Test Results' with 'Done'.

Access with MyLIMS ID and password



The screenshot shows a Windows Internet Explorer browser window displaying the STARLIMS v10 login page. The browser's address bar shows the URL `http://starlims.dhmh.state.md.us/starlims10.dhmlabs.test/start.lims`. The page features a blue header with the STARLIMS logo and a large banner with the text "From Laboratory Data to Enterprise Action" and "STARLIMS Delivers!". Below the banner is a login form titled "Welcome to STARLIMS!" with a lock icon. The form includes a message: "Please enter your STARLIMS login information (user name and password) in the text boxes below". The login fields are: "User name:" with the value "CARLOSM", "Password:" with masked characters "*****", and "Department:" with a dropdown menu showing "MDPHL". There are "OK" and "Cancel" buttons at the bottom of the form. The browser's status bar at the bottom shows "Done" and "Internet". The Windows taskbar at the very bottom includes the Start button, several application icons, and the system tray showing the time as 7:25 AM.

How to view reports on-line and generate a packing slip



<http://starlims.dhmf.state.md.us/starlims10.dhmf labs.test/>

Steve Montgomery

Marcus Rottman

WebEx Presentation

MyLIMS Handout

Tests Requested Infectious Agents: Culture/ Detection Lab Slip	Tests Requested On-Line (MyLIMS)	<i>Infectious Agents: Culture/Detection Lab Slip Form</i>	<i>Transport Conditions</i>
Chlamydia trachomatis only/NAAT	Chlamydia nucleic acid amplification	<i>Original (white) Copy #1 (yellow) Affix stickers</i>	<i>Cold Packs</i>
Herpes Simplex Virus (Types 1&2)	Pan Herpes Simplex Virus PCR		
Chlamydia trachomatis	Chlamydia Cell Culture		
Bacteria Culture	Bacteriology Clinical		
Gonorrhea Culture	GC Culture	<i>Copy #2 (pink)</i>	<i>Room Temp</i>

On-Line HELPDESK

410-767-3573 (8:00 AM-4:30 PM)



Q & A



Please check the Maryland DHMH
Laboratories Administration website for
any updates and additional guidelines.

<http://dhmh.state.md.us/labs/>

Thank you.
