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UPGRADE Chlamydia NAA Test
Effective **February 1, 2010**

Chlamydia trachomatis (CT)/Neisseria gonorrhoeae (GC) BD Qx Amplified DNA Assay
A Nucleic Acid Amplification Test (NAAT)

- The acceptable specimens for the UPGRADED Chlamydia NAA test are:
  - Urine (male and female)
  - Cervical/Endocervical Swab (female) - **NEW**
  - Urethral Swab (male) - **NEW**

Swabs REQUIRE a **NEW** specimen collection kit effective February 1, 2010

Contact the DHMH Laboratories Administration, Specimen Mailing Assemblies (Outfit Room) at 410-767-6120 or 410-767-6121
Chlamydia Testing Allocation System for Chlamydia NAAT

Chlamydia Testing Allocation Stickers

Distribution of 2010 stickers to the County’s “Sticker Steward”

Acknowledgement of Receipt

- 2010 Allocation stickers are yellow.
- There is only one of each serial number.
- Affix the one sticker to the original lab slip.
- Yellow stickers are valid from Jan 1, 2010 to Dec. 31, 2010.

P.O. FY 2010 (July 2009 – June 2010)

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

Please list the submitter names/sites on the P.O. request.

If you do not have an established MOU by February 15, 2010, specimens without stickers will be rejected.
2010 Chlamydia Allocation Sticker
Affix ONE yellow sticker

Pre-printed address labels with ID

ALERT
This is different from 2009

Only ONE yellow sticker required per specimen.
Specimen Collection and Submission Guidelines

Urine
Specimen Collection and Transport Procedures for Chlamydia NAAT

Swab
Specimen Collection and Transport Procedures for Chlamydia NAAT
| **URINE** | The specimen must be processed within 7 days of collection.  
It must reach the laboratory registration area by no later than the 5th day (except Friday) to be tested within the 7 day allowance. |
| **SWABS** | The specimen must be processed within 30 days of collection.  
It must reach the laboratory registration area by no later than the 25th day (except Friday) to be tested within the 7 day allowance. |

**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 **transport** at ambient 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.

3. The patient should collect 20-60 ml of the voided urine (first part of the urine stream, NOT mid-stream). Urine volume less than 2 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 **ONE** Chlamydia Testing Allocation Stickers on the:
     - Original Copy 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.”
Affix one STICKER on the Original forms.

Collect Date must be completed.

CHLAMYDIA TESTING ALLOCATION SYSTEM 2010 (STICKERS)
Effective 01/01/2010

Must be completed.
Pre-printed address labels with ID

Must be Completed.

Collect Date must be completed.

Exact first and last names must also be on the specimen container.

Fill-in race, ethnicity and gender

Write specimen code in the Chlamydia trachomatis only/NAAT box.

Stickers CANNOT be used for the combo assay “Chlamydia trachomatis/GC NAAT”
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 and transport to the laboratory in an insulated container with cold packs (2-8°C.) Specimen may **not** be stored or transported at room temperature.

9. Order the test/s in MyLIMS.
Print packing slip and submit with specimens.
WHAT’S NEW ABOUT THE SWAB COLLECTION KIT EFFECTIVE FEBRUARY 1, 2010?

The lab will switch to an updated assay (Qx) resulting in:

– a new swab collection kit: (no change for urine)
– designated with Qx and a purple stripe in addition to the yellow and green stripes on the old kits.
– gender specific kits have color coded swab shafts (pink-female, blue-male)
– cleaning swab is no longer huge—it is the white one
– bloody specimens are no longer rejected (unless >60% blood)
**SWAB** Specimen Collection and Transport Procedures

Swabs REQUIRE a **NEW** specimen collection kit effective February 1, 2010

- Cervix/endocervix and male urethra are the only approved swab collection sites in use for this assay.
  
  Please use the appropriate gender kit.
  - If this is not followed, the specimen will be rejected.

- **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

Use the Male (blue) Urethral Specimen Collection Kit for the BD ProbeTec™ CT/GC Qx Amplified DNA Assays.

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 #4 under the Female Endocervical Swab section.
FEMALE ENDOCERVICAL SWABS

Use the Female (pink) Endocervical Specimen Collection Kit for the BD ProbeTec™ CT/GC Qx Amplified DNA Assays.

1. Remove the **cleaning** swab (polyester fiber-tipped with **white** shaft) from the packaging and use it to remove excess blood and mucus from the cervical os. Discard the used cleaning swab.

2. Remove the **pink** shafted **collection** swab from the packaging and insert it into the cervical canal and rotate for 15-30 seconds.

3. Withdraw the swab carefully. Avoid contact with the vaginal mucosa.
4. Uncap the CT/GC Qx swab diluent tube and fully insert the collection swab into the tube.

5. Break the shaft of the swab at the score mark (DO NOT cut the shaft shorter) using care to avoid splashing and tightly recap.

6. Label the tube with the patient’s name (matching the lab slip exactly) and the collection date/time.

7. Complete the **Infectious Agents: Culture/Detection lab slip.**
   - Affix ONE Chlamydia Testing Allocation Stickers on the:
     • Original Copy Form
   - Place preprinted submitter labels with DHMH Lab Administration Client ID.
   - Be sure to include the source of the specimen (CX/URE) in the box next to the test requested “Chlamydia NAAT Only.”
Affix one STICKER on the Original forms.

Must be completed. Pre-printed address labels with ID

Collect Date must be completed.

Must be completed.

Write specimen code in the Chlamydia trachomatis only/NAAT box.

Stickers CANNOT be used for the combo assay “Chlamydia trachomatis/GC NAAT”
8. Seal the tube in the zip lock section of a biohazard transport bag and place the form in the outside pocket.

9. Swab specimens must be stored and transported to the lab at 2-30 °C within 30 days of collection.

10. Please transport to the laboratory in an insulated container with cold packs to insure that the acceptable temperature range is not exceeded.

11. Order the test/s in MyLIMS.
    Print packing slip and submit with specimens.
Specimen Rejection Criteria for Chlamydia NAAT

- Missing information required to determine specimen adequacy: source, collection date, gender.
- Too old. Urine>7 days, Swabs>30 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 white 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.

• Mismatched names on slip/specimen.

• Highly mucoid specimen, which cannot be pipetted.

• Illegible slip and/or specimen such that matching ID cannot be established.
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 shackleford@dhmh.state.md.us.
<table>
<thead>
<tr>
<th>Tests Requested</th>
<th>Tests Requested On-Line (MyLIMS)</th>
<th>Infectious Agents: Culture/Detection Lab Slip Form</th>
<th>Transport Conditions</th>
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<tbody>
<tr>
<td>Chlamydia trachomatis only/NAAT</td>
<td>Chlamydia nucleic acid amplification</td>
<td><strong>Original (white)</strong></td>
<td><strong>Cold Packs</strong></td>
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<tr>
<td>Herpes Simplex Virus (Types 1&amp;2)</td>
<td>Pan Herpes Simplex Virus PCR</td>
<td><strong>Affix sticker to white.</strong></td>
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<td>Chlamydia trachomatis</td>
<td>Chlamydia Cell Culture</td>
<td><strong>Copy #1 (yellow)</strong></td>
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<tr>
<td>Bacteria Culture</td>
<td>Bacteriology Clinical</td>
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<tr>
<td>Gonorrhea Culture</td>
<td>GC Culture</td>
<td><strong>Copy #2 (pink)</strong></td>
<td><strong>Room Temp</strong></td>
</tr>
</tbody>
</table>
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
Please check the Maryland DHMH Laboratories Administration website for any updates and additional guidelines. 

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

Thank you.
State of Maryland
Department of Health and Mental Hygiene

Martin O’Malley, Governor
Anthony G. Brown, Lt. Governor
John M. Colmers, Secretary

Laboratories Administration
Monitoring and Assessing Community Health Since 1898
John M. DeBoy, Dr.P.H.,
Director, Laboratories Administration

H1N1 Novel Influenza Updates

- Up-date of Influenza Testing Guidelines (October 30, 2009)
- MD DHMH Influenza Virologic Surveillance Guidance to Sentinel Laboratories and Sentinel Providers (October 28, 2009)
- Interim Guidance for Influenza Surveillance: Prioritizing RT-PCR Testing in Laboratories October 9, 2009 11:00 AM ET
- Interim Recommendations for Clinical Use of: Influenza Diagnostic Testing During the 2009-2010 Influenza Season (September 29, 2009)
2010 MD Chlamydia NAAT Sticker Allocation System - DHMH Laboratory Updates & Teleconferences (January 11, 2010):

The 2010 Chlamydia Testing Allocation Stickers were distributed last month to the sticker stewards (except for Frederick County). Please note that the 2010 allocation stickers are yellow, and valid from Jan 1, 2010 to December 31, 2010.

We would also like to remind everyone that effective February 1, 2010 the Chlamydia NAAT will be upgraded. The acceptable specimen types are as follows:

Urine (male and female)

Cervical/Endocervical Swab (female) - requires a NEW COLLECTION KIT

Urethral Swab (male) - requires a NEW COLLECTION KIT

Note: The swabs require NEW specimen collection kits effective February 1, 2010. Please contact the DHMH Laboratories Administration, Specimen Mailing Assemblies (Outfit Room) at 410.767.6120 or 410.767.6121 as soon as possible.

The DHMH Laboratories Administration will hold two teleconferences to discuss these updates on:

January 19, 2010 (Tuesday), 1:00PM-2:00PM

January 28, 2010 (Thursday), 11:00 AM-12:00PM

The dial-in number is: 410-549-9411, and the meeting ID number is: 0560#. To ensure that we have adequate lines for the scheduled teleconferences, please inform us by e-mail if you will be attending.

The handouts for the teleconference, specimen collection procedures, and request forms are as follows:

Chlamydia Teleconference Handout January 19 and January 28
MARYLAND DEPARTMENT OF HEALTH AND MENTAL HYGIENE
LABORATORIES ADMINISTRATION
201 WEST PRESTON STREET, BALTIMORE MD 21201

Requisition for Specimen Assemblies

Person Ordering: ___________________________ Date: ______________
Name of Institution: ________________________ Phone: ______________
Address: __________________________________

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<th>Type</th>
<th>Description</th>
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<tbody>
<tr>
<td>KITS</td>
<td>1. Parworn Slides</td>
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<tr>
<td></td>
<td>2. Gastric (TE Culture) - CALL TO LAB</td>
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<tr>
<td></td>
<td>3. Chlamydia Media / SS INNER - CONT.</td>
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<td>4. Leptospira Culture / SS INNER - CONT.</td>
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<td>5. T Cell Kits</td>
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<td>6. Viral Culture Media / SS INNER - CONT.</td>
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<td>7. Sputum (TE Culture)</td>
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<td>8. Trichat Culture / SS INNER - CONT.</td>
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<td>9. Viral Load Kits</td>
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<td>10. Mycoplasma, Plasma Culture</td>
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<td>11. Chlamydia Media</td>
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<td>14. QC Plates</td>
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<td>18. Blood Culture</td>
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<td>20. Intestinal Parasite Media</td>
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<td>21. Viral Culture Media</td>
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<td>22. STIARTS' TRANSPORT MEDIA</td>
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CRITERIA / EASY TESTING KITS

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<td>FEMALE SWAB</td>
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<td>MALE SWAB</td>
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<td>FORMS</td>
<td>25. Microtainer TUBES...</td>
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FOR INFORMATION REGARDING OUTFIT ASSEMBLIES PHONE: (410) 774-4120 FAX: (410) 333-4019

Please fax completed form to (410)333-4019.

Date: ______________