Chlamydia Testing Technology Change effective February 2, 2009

Maryland DHMH
Laboratories Administration

DHMH Laboratories Administration

Dr. Robert Myers

Deputy Director for Scientific Services
MyersR@dhmh.state.md.us

Dr. Maria Paz Carlos

Chief
Division of Virology and Immunology
CarlosM@dhmh.state.md.us

Ms. Susan Taylor

Lead Scientist
Chlamydia Testing Laboratory
TaylorS@dhmh.state.md.us

Mr. Steve Montgomery

Manager
Office of Information & Network Systems
MontgomeryS@dhmh.state.md.us

Ms. Denise Shackleford

Administrative Officer
Registration and Reports
ShacklefordD@dhmh.state.md.us

Mr. Kenneth N. Keys, Jr.

Fiscal Administrator
Fiscal Services
KeysK@dhmh.state.md.us

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**

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 6th day (except Friday) to be tested within the 7 day allowance.
SWABS *endocervical* *cervical* *male urethral*	The specimen must be processed within **6** days of collection. It must reach the laboratory registration area by no later than the 5th day (except Friday) to be tested within the 6 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 **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.**
   - 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 trachomatis NAAT Only” or “Chlamydia trachomatis/GC NAAT.”

Must be completed.
Pre-printed address labels with ID

Must be completed

Fill-in race, ethnicity and gender

Collect Date must be completed.

UR or CX or URE

Specimen code must be completed.

62167

oratories Administration MD DHMH
201 W. Preston St. • Baltimore, MD 21201
.O. Box 2355 • Baltimore MD, 21203-2355
410-767-6100 www.dhmh.state.md.us/labs
John M. DeBoy, Dr. P. H., Director

STATE LAB
Use Only

INFECTIOUS AGENTS: CULTURE/DETECTION

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

☐EH ☐FP ☐MTY/PN ☐NOD ☐STD ☐TB ☐CD ☐COR

Patient SS# (last 4 digits):
Last Name ☐SR ☐JR ☐Other
First Name M.I. Maiden:
Date of Birth (mm/dd/yyyy) / /
Address
City County
State Zip Code
Contact Name
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 # DOC# Outbreak # Submitter Lab #
Collect Date: Collect Time: ☐am ☐pm 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

BACTERIOLOGY/MYCOLOGY
- Bacterial Culture - Routine
- Additional specimen codes: ____ ____
- *Bordetella pertussis*
- Group A Strep
- Group B Strep Screen
- *C. difficile* Toxin
- Diphtheria
- Foodborne Pathogens (*B. cereus, C. perfringens, S. aureus*)
- Fungus Culture:
- Fungus Smear:
- Gonorrhea Culture:Incubated?☐yes ☐no
- Hrs. incubated:___ Add'l specimen codes:___ ___
- MRSA (rule out)
- VRE (rule out)

ENTERIC INFECTIONS
- Campylobacter
- *E. coli* O157 typing
- Enteric Culture - Routine (Salmonella, Shigella, *E. coli* O157, Campylobacter)
- Salmonella typing
- Shigella typing
- *V. parahaemolyticus*
- Yersinia

REFERENCE MICROBIOLOGY
- ABC'S (BIDS) #
- Organism:
- Aerobic Actinomycete for ID
- Bacteria Referred Culture for ID
- Specify:
- Mold for ID
- Yeast for ID

SPECIMEN CODE

SPECIAL BACTERIOLOGY
- Legionella Culture
- Leptospira
- Mycoplasma

MYCOBACTERIOLOGY/AFB/TB
- AFB/TB Culture and Smear
- AFB/TB Referred Culture for ID
- AFB/TB Referred Culture-Sensitivities
- *M. tuberculosis* Referred Culture for Genotyping
- Nucleic Acid Amplification Test for *M. tuberculosis* Complex (MTD)

PARASITOLOGY
- Blood Parasites:
- Country visited outside US:
- Ova & Parasites:Immigrant?☐yes☐no
- Cryptosporidium
- Cyclospora/Isospora
- Microsporidium
- Pinworm

VIRUS/CHLAMYDIA
- Adenovirus*
- Arbovirus Panel (WNV, EEEV, SLEV)
- *Chlamydia trachomatis*
- Cytomegalovirus (CMV)
- Enterovirus (Inc. Echo & Coxsackie)
- Herpes Simplex Virus (Types 1 & 2)
- Influenza (Types A & B)*
- Parainfluenza (Types 1, 2 & 3)*
- Respiratory Syncytial Virus (RSV)*
- Varicella (VZV)

*MAY INCLUDE RESPIRATORY SCREENING PANEL.

Comments:

SPECIMEN CODE

RESTRICTED TESTS
Pre-approved submitters only
- [illegible] *Chlamydia trachomatis* only/NAAT
- Norovirus ** (see comment on back)

UR

OTHER TESTS FOR INFECTIOUS AGENTS
- Test name:

Prior arrangements have been made with the following DHMH Laboratories Administration employee:

SPECIMEN CODE:
PLACE CODE IN BOX NEXT TO TEST

B	Blood
BW	Bronchial Washing
CSF	Cerebrospinal Fluid
CX	Cervix/Endocervix
E	Eye
F	Feces
N	Nasopharynx/Nasal
P	Penis
R	Rectum
SP	Sputum
T	Throat
URE	Urethra
UR	Urine
V	Vagina
W	Wound
O	Other:

760047870

DHMH 4676 Revised 1/08

ORIGINAL

760047870 760047870 760047870 760047870 760047870 760047870
760047870 760047870 760047870 760047870 760047870 760047870

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. 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.**
   – Be sure to include the source of the specimen (urine) in the box next to the test requested "Chlamydia trachomatis NAAT Only" or "Chlamydia trachomatis/GC NAAT."

Must be completed.
Pre-printed address labels with ID

Must be Completed.

Fill-in race, ethnicity and gender

Collect Date must be completed.

UR or CX or URE

Specimen code must be completed.

62167

ratories Administration MD DHMH
1 W. Preston St. • Baltimore, MD 21201
O. Box 2355 • Baltimore MD, 21203-2355
410-767-6100 www.dhmh.state.md.us/labs
John M. DeBoy, Dr. P. H., Director

STATE LAB
Use Only

INFECTIOUS AGENTS: CULTURE/DETECTION

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

☐EH ☐FP ☐MTY/PN ☐NOD ☐STD ☐TB ☐CD ☐COR

Patient SS# (last 4 digits):
Last Name ☐SR ☐JR ☐Other
First Name M.I. Maiden:
Date of Birth (mm/dd/yyyy) / /
Address
City County
State Zip Code
Contact Name
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 # DOC# Outbreak # Submitter Lab #
Collect Date: Collect Time: ☐am ☐pm 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

BACTERIOLOGY/MYCOLOGY
- Bacterial Culture - Routine
- Additional specimen codes: ____ ____
- *Bordetella pertussis*
- Group A Strep
- Group B Strep Screen
- *C. difficile* Toxin
- Diphtheria
- Foodborne Pathogens (*B. cereus, C. perfringens, S. aureus*)
- Fungus Culture:
- Fungus Smear:
- Gonorrhea Culture:Incubated?☐yes ☐no
- Hrs. incubated:___ Add'l specimen codes:___ ___
- MRSA (rule out)
- VRE (rule out)

ENTERIC INFECTIONS
- Campylobacter
- *E. coli* O157 typing
- Enteric Culture - Routine (Salmonella, Shigella, *E. coli* O157, Campylobacter)
- Salmonella typing
- Shigella typing
- *V. parahaemolyticus*
- Yersinia

REFERENCE MICROBIOLOGY
- ABC'S (BIDS) #
- Organism:
- Aerobic Actinomycete for ID
- Bacteria Referred Culture for ID
- Specify:
- Mold for ID
- Yeast for ID

SPECIMEN CODE

SPECIAL BACTERIOLOGY
- Legionella Culture
- Leptospira
- Mycoplasma

MYCOBACTERIOLOGY/AFB/TB
- AFB/TB Culture and Smear
- AFB/TB Referred Culture for ID
- AFB/TB Referred Culture-Sensitivities
- *M. tuberculosis* Referred Culture for Genotyping
- Nucleic Acid Amplification Test for *M. tuberculosis* Complex (MTD)

PARASITOLOGY
- Blood Parasites:
- Country visited outside US:
- Ova & Parasites:Immigrant?☐yes☐no
- Cryptosporidium
- Cyclospora/Isospora
- Microsporidium
- Pinworm

VIRUS/CHLAMYDIA
- Adenovirus*
- Arbovirus Panel (WNV, EEEV, SLEV)
- *Chlamydia trachomatis*
- Cytomegalovirus (CMV)
- Enterovirus (Inc. Echo & Coxsackie)
- Herpes Simplex Virus (Types 1 & 2)
- Influenza (Types A & B)*
- Parainfluenza (Types 1, 2 & 3)*
- Respiratory Syncytial Virus (RSV)*
- Varicella (VZV)

*MAY INCLUDE RESPIRATORY SCREENING PANEL.

Comments:

SPECIMEN CODE

RESTRICTED TESTS
Pre-approved submitters only
- Neisseria gonorrhoeae (GC)
- *Chlamydia trachomatis* only/NAAT
- Norovirus ** (see comment on back)

OTHER TESTS FOR INFECTIOUS AGENTS
- Test name:

Prior arrangements have been made with the following DHMH Laboratories Administration employee:

SPECIMEN CODE:
PLACE CODE IN BOX NEXT TO TEST

B	Blood
BW	Bronchial Washing
CSF	Cerebrospinal Fluid
CX	Cervix/Endocervix
E	Eye
F	Feces
N	Nasopharynx/Nasal
P	Penis
R	Rectum
SP	Sputum
T	Throat
URE	Urethra
UR	Urine
V	Vagina
W	Wound
O	Other:

760047870

DHMH 4676 Revised 1/08

ORIGINAL

760047870 760047870 760047870 760047870 760047870 760047870
760047870 760047870 760047870 760047870 760047870 760047870

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. 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

Maryland Department of Health and Mental Hygiene
Laboratories Administration
P.O. Box 2355 • Baltimore, Maryland 21203-2355 John M. DeBoy, Dr. P.H., Director
www.dhmh.state.md.us/labs/

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

DHMH 4676

Multiple Tests Submission

Denise Shackleford

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.

MOU/PO

For governmental entities that are not covered by the test allocation system but were pre-approved to submit specimens for testing if they establish a billing arrangement with the DHMH Laboratories Administration, please contact the Fiscal Officer, Mr. Ken Keys at keysk@dhmh.state.md.us.

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

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

Thank you.