# 2010 Chlamydia Testing Allocation System Guidance

Maryland DHMH
Laboratories Administration
January 2010

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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) <u>NEW</u>
  - Urethral Swab (male) <u>NEW</u>

Swabs REQUIRE a <u>NEW</u> 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 <u>Stickers</u>**

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 <a href="keysk@dhmh.state.md.us">keysk@dhmh.state.md.us</a>.

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**

10CT26001	10CT26014	10CT26027	10CT26040	10CT26001	10CT26014	10CT26027	10CT26040
EXPRIATION DATE: 12/01/00/00	EXPORATION DATE: 12/01/00/00	EXPERATION DATE: 12/01/2018	EXPRATION DATE: 12/91/00/05	EXPERTION DATE: 12/01/00/00	EXPORATION DATE: 12/01/02/02	EXPERATION DATE: 12/01/2018	EXPRATION DATE: 12/21/2015
10CT26002	10CT26015	10CT26028	10CT26041	10CT26002	10CT26015	10CT26028	10CT26041
EXPRIATION DATE: 12/01/2010	EXPRATION DATE: 12/04/2010	EXPRATION DATE: 1201/0010	EXPRESSION DATE 12/01/2015	EXPRIATION DATE: 12/01/2019	EXPRATION DATE: 12/24/2010	EXPRATION DATE: 1201/0010	EXPRIATION DATE 12/31/00/15
10CT26003	10CT26016	10CT26029	10CT26042	10CT26003	10CT26016	10CT26029	10CT26042
EXPRATION DATE: 12/05/09/09	EXPRATION DATE 12/21/2010	EXPIRATION DATE: 12/01/0910	EXPRIATION DATE: 12/01/2010	EXPRATION GATE 12/05/2010	EXPRATION DATE 12/21/2010	EXPIRATION DATE: 12/01/0910	EXPHIATION DATE: 12/01/09/09
10CT26004	10CT26017	10CT26030	10CT26043	10CT26004	10CT26017	10CT26030	10CT26043
EXPRIATION DATE: 12/01/2018	EXPRATION DATE 12/21/02/12	ENDERTATION CATE TRIBUDES	EXPRATION DATE: QCHORGE	EXPRATION DATE: 1201(8HI)	EXPRATION DATE 10/01/00/03	ENDERTATION CATE TRIBUDES	EMPHATION DATE: 12/2H00HE
10CT26005	10CT26018	10CT26031	10CT26044	10CT26005	10CT26018	10CT26031	10CT26044
EXPRATION DATE: 12/01/0910	EXPRATION DATE 12/21/2010	EXPRATION DATE: 1201/0010	EXPRATION DATE 12/31/00/16	EXPRATION DATE: (2010010	EXPRATION DATE 12/21/2010	EXPRATION DATE: 1201/0010	EXPIRATION DATE: 12/31/00/16
10CT26006	10CT26019	10CT26032	10CT26045	10CT26006	10CT26019	10CT26032	10CT26045
EXPRATION DATE: 12/31/08/8	EXPRATION DATE: 12/11/09/0	EXPRIATION DATE 12/91/00/0	EXPERIENCE STORIGORS	EXPRATION GATE 12/20/09/09	EXPRATION DATE: 12/11/09/0	EXPRIATION DATE 12/91/00/0	EXPRIATION DATE: 12010018
10CT26007	10CT26020	10CT26033	10CT26046	10CT26007	10CT26020	10CT26033	10CT26046
EXPURATION DATE: 12/15/2010	EXPERTION DATE: GENOME	EXPRIATION DATE: 12/21/2010	EXPIRATION DATE: 12/01/0818	EXPRATION DATE: SZCENBOIO	EXPERTION DATE: GENOME	EXPRIATION DATE: 12/21/2010	EXPRIATION DATE: 12/01/0818
10CT26008	10CT26021	10CT26034	10CT26047	10CT26008	10CT26021	10CT26034	10CT26047
EXPRATION DATE 10/01/2010	EXPRIATION DATE: 12/31/2010	EXPRIATION DATE: 12/01/00/0	EXPRIATION DATE 13/01/2019	EXPRATION DATE 10010010	EXPRIATION DATE: 12/31/2010	EXPRIATION DATE: 12/01/00/0	EXPRIATION DATE 12/31/2019
10CT26009	10CT26022	10CT26035	10CT26048	10CT26009	10CT26022	10CT26035	10CT26048
EXPRIATION DATE: 12(3) Q010	EXPRATION DATE 1001-0010	EXPERITION DATE 12/01/0018	EXPRATION DATE, 12/04/00/16	EXPRATION DATE: 12/31/2013	EXPRATION DATE 1001-0010	EXPERITION DATE 12/01/0018	EXPRATION DATE, 12/9 LISTING
10CT26010	10CT26023	10CT26036	10CT26049	10CT26010	10CT26023	10CT26036	10CT26049
EXPRATION DATE, 12:91.0010	EXPERTION DATE: 12/24/2012	EXPRATION DATE: 12/91/2018	EXPRIATION DATE: 12/01/0510	EXPERATION DATE, 12/24/2019	EXPRATION DATE: 12/21/2012	EXPRATION DATE: 12/91/2018	EXPRIATION DATE: 12/01/05/10
10CT26011	100726024	10CT26037	10CT26050	10CT26011	10CT26024	10CT26037	10CT26050
EXPRATION DATE 12010910	EXPRATION DATE 10010000	EXPRATION DATE TANDONS	EXPRIATION DATE STOTISTIS	EXPRIATION DATE (2010)10	EXPURITION DATE 10010010	EXPRATION DATE TANDONS	EXPRIATION DATE 12010016
10CT26012	10CT26025	10CT26038	10CT26051	10CT26012	10CT26025	10CT26038	10CT26051
699010SF 3TAD ICCTARRISS	EXPRIATION GATE 10/910018	EXPONATION DATE: 12/01/00/01	EXPRATION DATE: 12010016	EXPRATION DATE: 12/01/01/0	EXPRIATION GATE, 19/910018	EXPONATION DATE: 12/01/00/01	EXPRIATION DATE: 12010016
10CT26013	10CT26026	10CT26039	10CT26052	10CT26013	10CT26026	10CT26039	10CT26052
EXPRATION DATE: 12010016	EXPANATION DATE: 12/21/09/19	EXPERITION DATE 12/01/0018	EXPRATION DATE: 12/91/0010	EXPRATION DATE: 12010016	EXPANTION DATE: 12/21/09/09	EXPERITION DATE 12/01/0018	EXPERATION DATE: 12/91/2010

#### **Affix ONE yellow sticker**

10CT26052			DHMH 201 2355 Tabs	STATE LAB Use Only		
	INFECTIOUS AGENTS	S: CULTURE/I	DETECTION			
7 (0	DEH DFP DMTY/PN DNOD DSTD	DTB DCD DCOR	Patient SS# (last 4 digits):			
PRINT REQUIRED INFORMATION E LABELS ON ALL FOUR COPIES	Subre-printed	address	Last Name			
CO	74001033		First Name	M.I. Maiden:		
E OH PRINT REQUIRED INFORMATION PLACE LABELS ON ALL FOUR COPIES	City labels wit	h ID	Date of Birth (mm/dd/yyyy)	) / /		
LLF	Didito Zip Coc	ie .	Address			
NA	Contact Name		City County			
SO	Phone # Fax #		State Zip Code			
ABE	Ethnicity: □Hispanic/Latino □Not Hispan					
EL	Race: □White □African American □Asia		Indian/Alaska Native			
LAG	Collect Date:	Collect Time:	□am □pm Ons			
OR PLAC				Suspected Carrier □Isolate for ID □Release		
- 0	Therapy/Drug Treatment: □No □Yes	Therapy/Drug Type:_		Therapy/Drug Date:		
	CIMEN CODE	♣ SPECIMEN CODE		↓ SPECIMEN CODE		
	BACTERIOLOGY/MYCOLOGY		BACTERIOLOGY	↓ RESTRICTED TESTS		
	acterial Culture - Routine nal specimen codes:	Legionella Cu Leptospira	ilture	Pre-approved submitters only  Chlamydia trachomatis/GC NAAT		
	ordetella pertussis	Leptospira Mycoplasma		Chlamydia trachomatis only/NAAT		
Gr	roup A Strep	MYCOBACTERIOLOGY/AFB/TB		Norovirus ** (see comment on back		
	roup B Strep Screen difficile Toxin		re and Smear	OTHER TESTS FOR INFECTIOUS AGENTS		
	phtheria	AFB/TB Referred Culture for ID  AFB/TB Referred Culture-Sensitivities		Test name:		
	podborne Pathogens (B. cereus,		sis Referred Culture for			
	perfringens, S. aureus) ingus Culture:	Genotyping	Amplification Test for	Prior arrangements have been made with the following DHMH Laboratories Administration employee:		
	ingus Culture.		is Complex (MTD)			
G	ionorrhea Culture:Incubated?□yes □no		ASITOLOGY			
	ubated:Add'l specimen codes: RSA (rule out)	Blood Parasit Country visite		SPECIMEN CODE: PLACE CODE IN BOX NEXT TO TEST		
	RE (rule out)		tes:Immigrant?□yes□no	B Blood		
	ENTERIC INFECTIONS	Cryptosporidium		BW Bronchial Washing CSF Cerebrospinal Fluid		
	ampylobacter	Cyclospora/Is		CX Cervix/Endocervix E Eye F Feces		
	coli O157 typing nteric Culture - Routine (Salmonella,	Microsporidiu Pinworm	m			
	nigella, E. coli O157, Campylobacter)	VIRUS/CHLAMYDIA		N Nasopharynx/Nasal P Penis		
	almonella typing	Adenovirus*		R Rectum SP Sputum T Throat		
	nigella typing parahaemolyticus	Chlamydia tra	nel (WNV, EEEV, SLEV)			
Ye	ersinia	Cytomegalovi		URE Urethra UR Urine		
	REFERENCE MICROBIOLOGY		nc. Echo & Coxsackie)	V Vagina 6		
	BC'S (BIDS) #	Herpes Simpl Influenza (Typ	ex Virus (Types 1 & 2)	W Wound O Other:		
	erobic Actinomycete for ID		(Types 1, 2 & 3)*	V Vagina 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0		
Ba	acteria Referred Culture for ID		yncytial Virus (RSV)*			
	oecify:old for ID	Varicella (VZ\	/) RATORY SCREENING PANEL.			
	east for ID	C nents:	HATORY SCHEENING PANEL.			
MH 4676	6 Revised I/08 76 870 86 87		104 0 7	6 047970		

#### **ALERT**

This is different from 2009

Only <u>ONE</u>
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 5 <sup>th</sup> day (except Friday) to be tested within the 7 day allowance.
SWABS endocervical	The specimen must be processed within 30 days of collection.
cervical male urethral	It must reach the laboratory registration area by <u>no later</u> than the 25 <sup>th</sup> 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

#### <u>URINE</u> Specimen Collection and Transport Procedures

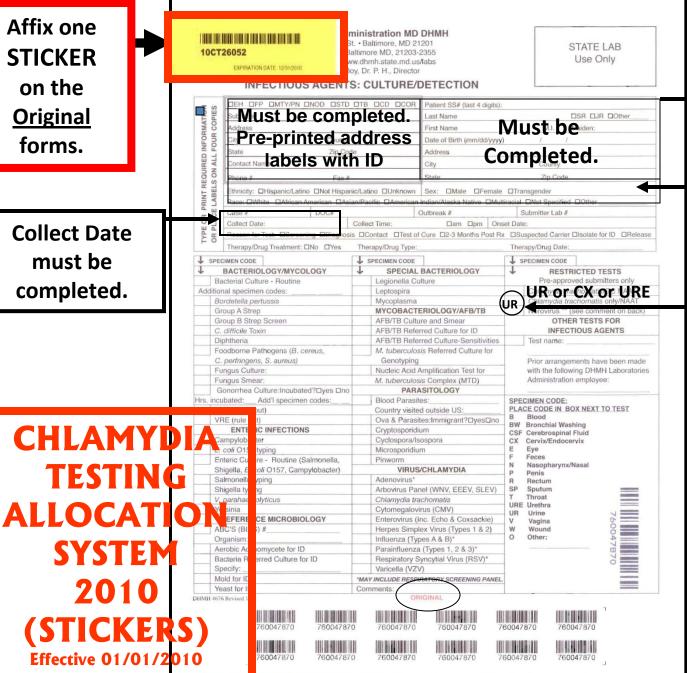
- 1. The patient should not have urinated for at least 1 hour prior to specimen collection.
- Collect the urine specimen in a plastic, sterile, preservative-free, specimen collection cup.
- The patient should collect 20-60 ml of the voided urine (<u>first part</u> of the urine stream, NOT mid-stream). 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 <u>Infectious Agents: Culture/Detection</u> 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."



**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"<sub>12</sub>

- 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 (pinkfemale, 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 <u>NEW</u> 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. <u>This test is</u> <u>limited to medical legal cases, rectal or oral specimens.</u>

#### MALE URETHRAL SWABS

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

 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**

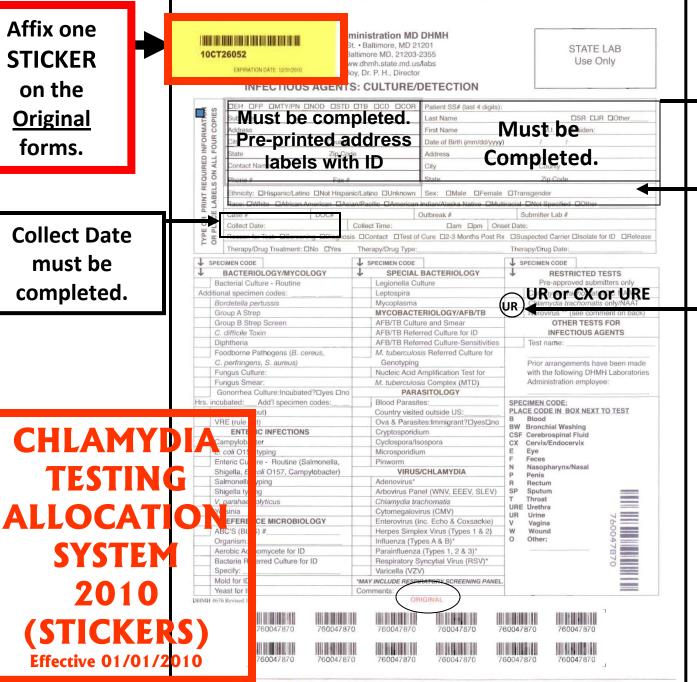
Use the Female (pink) Endocervical Specimen Collection Kit for the BD ProbeTec™ CT/GC Qx Amplified DNA Assays.

- 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."



**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"19

- 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 Tests Submission**

Contact 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 <a href="mailto:shacklefordd@dhmh.state.md.us">shacklefordd@dhmh.state.md.us</a>.

#### **Multiple Tests Submission Guidance**

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

#### Q & A



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

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

Thank you.



