West Virginia Department of Health and Human Resources
OFFICE OF LABORATORY SERVICES
167 11th Avenue | South Charleston, WV 25303
Phone: (304) 558-3530 | FAX: (304) 558-2006

INSTRUCTIONS FOR THE COLLECTION, SUBMISSION FORM, AND MAILING OF CHLAMYDIA/GONORRHEA URINE SPECIMENS

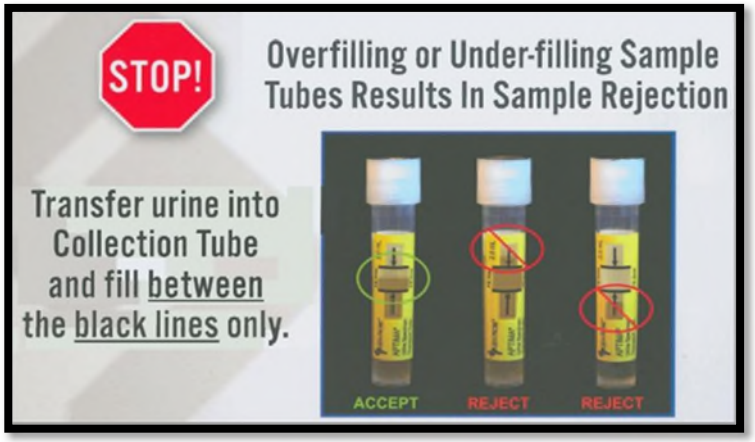
The Office of Laboratory Services (OLS) provides the following supplies in our collection kits:

1. Hologic Gen-Probe urine specimen transport tube and plastic transfer pipette
   - These are prepackaged by the company in boxes of fifty (50)
2. Specimen collection cups and lids
   NOTE: OLS provides equal numbers of transport devices and specimen cups.
3. Providers can access the "Requisition Form for Specimen Mailing Kits" from the OLS website: www.dhhr.wv.gov/ols
4. A copy of the Diagnostic Immunology test request submission form.
   - **TIP** – Facilities can fill in the submitter data section and then make copies of the form for use.
   - **TIP –** Some sites copy forms onto a specific color of paper for easy recognition. If your site chooses to do this, OLS recommends the use of pastel colors to prevent eye strain when filling out and performing data entry from the form.

Urine Specimen Collecting Instructions:

1. Best Practice: The patient should not have urinated for at least one (1) hour prior to the specimen collection.
2. Female patients should not cleanse the labial area prior to providing the specimen.
3. Best Practice: At a minimum, label the collection cup and the urine specimen transport tube with the patient's name and collection date.
   - The use of pre-printed labels is acceptable (the information on the cup, tube, and form must match exactly).
4. Direct the patient to provide "first-catch" urine into the urine collection cup.
5. After patient returns the sample, the clinician should remove the cap from the pre-labeled Hologic urine transport tube and transfer approximately 2mL of urine from the urine cup into the tube using the disposable pipette provided.
   - When the fluid level is between the black fill lines on the urine specimen transport tube label, the correct volume of urine has been added.

   NOTE: Overfilling or underfilling sample tubes results in sample rejection!



6. Best Practice: To ensure best results, package and send specimens to the lab immediately after collection.

NOTE: Badly hemolyzed (bloody) and/or bacterial contaminated urine can produce unreliable results.

- **Sites using labels should not cover the side of the tube that shows the urine level.**

Form Instructions:

PLEASE PRINT LEGIBLY.

The Clinical Laboratory Improvement Amendment of 1988 (CLIA) requires the following information for the lab to be able to process the specimen for testing. If any of this information is missing, by federal law, the lab cannot perform the test.

a. **A unique identifier on both the form and the specimen;**
b. **Address of submitter;**
c. **Date of birth or age of patient;**
d. **Sex of patient;**
e. **The test to be performed;**
f. **The source of the specimen (i.e. blood/serum, urine);**
g. **Date of collection;**
h. **Any additional information relevant to testing (i.e. information necessary by the program).**

NOTE: For your convenience, a fillable form is available on our website.

1. **Patient Information**
   a. **Patient ID** --- This refers to a chart number, medical record number, or some other internal ID that your facility uses to identify patients. A maximum of 15 characters is allowed
   b. **Last Name, First Name, MI** --- Patients' full name. (i*nformation on tube and form must match)*
   c. **Date of Birth** --- CLIA requires DOB or AGE of Patient
   d. **Social Security Number** *(optional)* --- last 4 digits only
   e. **County of Residence** --- The patient's county of residence is not always the same as the provider's county. *(required by program)*
   f. **Sex** --- at birth *(required by CLIA)*
   g. **Street Address, City, State, Zip Code ---** *(required by program)*
   h. **Patient Phone Number – include area code** *(required by program)*
   i. **Race** --- More than one can be marked *(required by program)*
   j. **Ethnicity** --- *(required by program)*

PATIENT INFORMATION

PATIENT ID (Chart #, etc.) *(optional)*		
LAST NAME	FIRST NAME	MI
DATE OF BIRTH	SS# (last 4 digits only)	
COUNTY OF RESIDENCE	SEX (at birth) ❑ Female ❑ Male	
STREET ADDRESS		
CITY	STATE	ZIP
PATIENT PHONE NO. (include area code)		
RACE ❑ White ❑ Asian ❑ Black ❑ Other ❑ American Indian/Alaskan ❑ Native Hawaiian or other Pacific Islander	ETHNICITY ❑ Not Hispanic or Latino ❑ Hispanic or Latino ❑ Unknown	

2. **Submitter Information:**
   a. **Facility Name** --- The official name of the site as listed on the Memorandum of Understanding (MOU) or application to the STD program. **Do not use just the initials of your site.** *(required by CLIA)*
   TIP: Fill in submitter information section and then make copies of the form.
   b. **Street Address, City, State, Zip Code** --- *(required by CLIA)*
   c. **County** --- (*required by program)*

d. Attention To --- This line is to be filled out if the results are to go to a specific individual or department within the facility. *(optional)*
NOTE: This will not appear in the address field on the final report.

e. Phone Number and Fax Number – include area code *(required by program)*

SUBMITTER INFORMATION		
FACILITY NAME		
MAILING ADDRESS		
CITY	STATE	ZIP
COUNTY		
ATTENTION TO:		
PHONE NO. (include area code)		
FAX NO. (include area code)		

3. Comments: This section is for any additional information or notes.

4. Date of Collection – (*required by CLIA)* The date that the specimen was collected.

DATE OF COLLECTION:

5. Program/Clinic Type

NOTE: Programs not eligible for CT/NG testing have been marked out in these instructions.

PROGRAM/CLINIC TYPE: (Select ONE Only)	
❑ ~~APC (For anonymous HIV testing only)~~	❑ ~~HIV Clinic~~
❑ College / University – FP	❑ Jail / Prison
❑ College / University – STD	❑ Juvenile Detention Center
❑ Family Planning	❑ STD Clinic / STD Services
❑ ~~Hospital~~	❑ Project HRP
❑ Project # _____	

~~**a. APC (for Anonymous HIV testing only)**~~

b. College / University – FP --- if your site is sponsored by the Family Planning Program.

c. College / University – STD --- if your site is sponsored by the STD Program.

d. Family Planning --- if your site has a MOU with the Family Planning Program and provides no charge testing to clients.

~~**e. Hospital**~~

~~**f. HIV Clinic**~~

g. Jail / Prison --- if your site is approved to provide testing by the STD and HIV Programs.

h. Juvenile Detention Center --- if your site is approved to provide testing by the STD and HIV programs.

i. STD Clinic / STD Services --- if your site provides STD testing at no charge to the patient.

j. Project HRP --- if your site provides syringe service or harm reduction services to patients.

k. Project # ____ --- for special projects such as outbreaks, investigations, or outreach events (*assigned by OLS*).

6. Test Requested (*required by CLIA*)

a. CT/NG Amplified NAAT --- Chlamydia and Gonorrhea testing by nucleic acid amplification.

TEST REQUESTED: (Select ONE Only)	
❑ CT/NG Amplified NAAT	❑ ~~Rubella Screen~~
	❑ ~~Syphilis Screen (RPR)~~
❑ ~~HIV Confirmation Test (for Rapid HIV Program ONLY)~~	❑ ~~HIV~~

~~**b. HIV**~~

~~**c. Rubella Screen**~~

~~**d. Syphilis Screen**~~

~~**e. HIV confirmation Test (for Rapid HIV program ONLY)**~~

7. Source of Specimen

(mark the appropriate box on the form)

a. For CT/NG Amplified NAAT --- urine

~~**b. Bood/Serum**~~

SOURCE OF SPECIMEN:	
❑ ~~Blood / Serum~~	❑ Urine

8. Is patient pregnant?

If yes, mark box and include due date.

Is patient pregnant? ❑ NO ❑ YES (due date _____)

9. CT/GN INFORMATION – REASON FOR TEST (as per guidelines)

Family Planning female patients age 26 and over are NOT routinely tested. A reason for testing **must** be indicated. Mark the appropriate reason in this box.

CT/NG INFORMATION – REASON FOR TEST (as per guidelines)	
❑ Any symptom of STD	❑ Re-screen of previous positive (*minimum of three [3] months after treatment*)
❑ Known contact to STD	❑ Suspect / Possible contact to STD (*new partner, multiple partners, polygamous partner*)
❑ IUD Insertion	

NOTE: HIV Information is covered in the "Instructions for the Collection, Submission Form, and Mailing of Blood Specimens" document.

Mailing Instructions:

The Office of Laboratory Services provides testing supplies ordered by using the DI Supply Requisition Form that is available on our website or by calling 304-558-3530. Packaging provided by OLS meets current Department of Transportation (DOT) and all other federal regulations.

Preparing Specimen(s) for Mailing:

Using mailing tubes:

a. Place blood tube(s) in the inner plastic container (maximum 8 tubes per container).

b. Make sure that two (2) absorbent pads are in the inner plastic container with the tubes.

c. Screw lid on plastic container.

d. Fold the DI requisition form in half, length-wise and wrap forms around the outside of the plastic container.

e. Place inner container and forms into outer cardboard container, screw lid on container, apply postage, and mail.

At this time, the Office of Laboratory Services does not supply return postage for the shipment of specimens. The facility is responsible for the cost to ship the container to us for testing. If your facility is interested in setting up a FedEx account with reduced state contract pricing, please contact us for more details.

NOTE: If your site is sending less than eight (8) tubes and concerned about the tubes 'rattling' around in the container during transport, we suggest adding some additional padding such as a paper towel to the inner container.

Should you have any questions or need any additional information, please contact the Diagnostic Immunology Section at 304-558-3530 extension 2405 or 2407. Our normal business hours are Monday through Friday from 8:00am to 4:30pm. OLS is closed on weekends and state holidays.