



## **MEMORANDUM**

**To:** OSF System Laboratory Ordering Providers

**From:** James Siebert, M.D. – Laboratory Medical Director

**Subject:** Chlamydia (CT) and Gonorrhea (GC) testing

**Date:** December 2, 2016

Beginning December 6, 2016, the OSF System Laboratory will replace the BD Viper system with the Roche Cobas® 4800 system for amplification and detection of CT/GC (*Chlamydia trachomatis*/*Neisseria gonorrhoeae*) in female genital samples (cervical/vaginal swabs and PAP ThinPreps) and urine samples from both men and women. The new system employs polymerase chain reaction (PCR) technology which provides greater specificity for the detection of these pathogens in genital and urine samples as compared to our current strand displacement amplification (SDA) system method. The new system also has the added advantage of minimizing swabs for genital samples in women since PCR testing can be performed on the ThinPrep sample collected during a routine PAP exam.

The new system will require new collection kits for BOTH genital samples (*i.e.*, cervical/vaginal swabs) and urine specimens. The new collection kits are available from OSF System Laboratory. Discard your obsolete swabs on 12/6/2016 and follow standard supply ordering protocols for new collection kits.

### **Women (Genital, Urine, or ThinPrep PAP vial):**

1. **Genital** (Cervical or vaginal) **swab:** Use the Cobas® PCR Female swabs included in the Swab Sample Kit and follow the manufacturer's instructions.
  - **Cervical:** Using one of the swabs in the kit, remove excess mucous from the cervical os and surrounding mucosa and discard this cleaning swab. Using the other swab in the kit, insert the swab into the endocervical canal and gently rotate 5 times.
  - **Vaginal:** insert one collection swab 2 inches into the vaginal opening and turn while rubbing the swab against the wall of the vagina. (NOTE: a cleaning swab is NOT needed for vaginal collections).
- Remove the cap from PCR media tube and lower the swab specimen into the tube until the visible dark line on the swab shaft is aligned with the tube rim. The tip of the swab should be just above the media surface.
- Carefully leverage the swab against the tube rim to break the swab shaft at the dark line.
- Recap the tube, mix adequately & send the swab in the transport tube provided.

2. **NEW – ThinPrep PAP Sample (only used if a PAP is also ordered):** Cobas® PCR testing for both Chlamydia and Gonorrhea can be done on the same ThinPrep cytology solution collected during a routine PAP exam. **The US preventative service task force (USPSTF) recommends chlamydia and gonorrhea screening for all sexually active women younger than 25 years, even if they are not engaging in high-risk sexual behaviors.**<sup>1-2</sup>
- Submit cervical specimen collected in ThinPrep PreservCyt solution using an endocervical brush/spatula (2.0 mL minimum).
  - PAP testing and CT/GC testing are ordered at the same time but with separate test orders. Cytology exam will NOT be performed if an order for a PAP is not placed.
  - Follow manufacturer's instructions for sample collection protocols for the ThinPrep vial.
  - DO NOT contaminate sample with interfering substances such a lubricant. Lubricant is NOT recommended for use in conjunction with the ThinPrep PAP Test. (see attached complete PAP procedure guide)
  - CT/GC testing on ThinPrep samples must be performed before PAP processing so CT/GC orders must be placed together on date of collection. Specifically, when a PAP only was ordered and performed at OSF Laboratory, it would not be allowable for a later, add-on order for CT/GC testing.

**Men & Women:** (male urethral swabs will no longer be accepted for CT/GC testing)

**Urine:** Use the Cobas® PCR Urine Sample Collection kit. The patient should not have urinated for at least one hour prior, and he/she should collect first-catch urine (minimum 10 mL of the initial urine stream) into the collection kit. If a Cobas® PCR Urine Sample Collection kit is not available, a standard 50 mL sterile urine container may be used, but the sample MUST arrive in the lab for same day testing. **IF A DELAY in transport of the urine to the lab is anticipated, with possible next day arrival/receipt at OSF System Laboratory then the Cobas® PCR Urine Sample Collection Kit will be required.**

Fortunately, this move to improve patient testing in the OSF System lab will NOT result in any changes in the process of electronic test ordering. The ordering test code remains the same (see below).

**CHLAMYDIA & GC DNA PROBE**

**LAB826 (CGPRB)**

Any questions or concerns may be addressed to your designated clinical client representative or:

John Farrell, MD – Medical Director of Clinical Microbiology & Serology Labs  
OSF System Laboratory  
(309) 624-9127

1. Screening for chlamydial infection: U.S. Preventive Services Task Force recommendation statement. *Ann Intern Med.* 2007;147(2):128-134.
2. U.S. Preventive Services Task Force. Screening for gonorrhea: recommendation statement. *Ann Fam Med.* 2005;3(3):263-267.

## Quick ordering tips, version 12/2/2016

### **EPIC and Atlas Electronic Ordering Facilities/Sites:**

**Option 1:** If CT/GC testing only is needed: collect a genital (females) or urine (females or males) sample and order:

**\*Order CHLAMYDIA & GC DNA PROBE LAB826 (CGPRB)**

To improve ease of ordering, we have consolidated the list of genital sites in women to include “Endocervix/cervix/vaginal” and added “THINPREP PreserveCYT”.

Note: For males, urethral swabs are no longer accepted using this method. Urine only.

**Labeling:** Label should be placed on collection device.

**Option 2:** For females, if ordering both a PAP and CT/GC, collect in a ThinPrep vial.

**\*Order CHLAMYDIA & GC DNA PROBE LAB826 (CGPRB)**

**\*Select THINPREP PreserveCYT as the site**

**\*Order GYNECOLOGIC CYTOLOGY, PAP TEST: LAB1768 (APPAP)**

- Note/reminder: CT/GC testing on ThinPrep samples must be performed before PAP processing so CT/GC orders must be placed together on the date of collection.
- Specifically, when a PAP only was ordered and performed at OSF Laboratory, it would not be allowable for a later, add-on order for CT/GC testing.
- Note: for females, do not routinely use a ThinPrep vial for CT/GC when testing is not accompanied with a PAP order.

**Labeling:** Two labels and two paper requisitions will print when ordering both a PAP and CT/GC. The PAP label is to be placed on the specimen vial. The additional CT/GC label and printed paper requisitions should be placed in front pocket of specimen bag.

**Option3:** For females, if ordering both a PAP and HPV, collect in a ThinPrep vial.

**\*Order GYNECOLOGIC CYTOLOGY, PAP TEST: LAB1768 (APPAP)**

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- Specifically, when a PAP only was ordered and performed at OSF Laboratory, it would not be allowable for a later, add-on order for CT/GC testing.

**\*Order HUMAN PAPILLOMA VIRUS (HPV): LAB1192 (HPVIRS)**

- Note: HPV testing can be ordered with PAP orders on the date of collection or as an add-on up to three months from date of collection.

**Labeling:** Two labels and two paper requisitions will print when ordering both a PAP and HPV. The PAP label is to be placed on the specimen vial. The additional HPV label and printed paper requisitions should be placed in front pocket of specimen bag.

**Option 4:** For females, if ordering all three PAP, CT/GC, and HPV, collect in a ThinPrep Vial.

**\*Order CHLAMYDIA & GC DNA PROBE LAB826 (CGPRB)**

**\*Select THINPREP PreserveCYT as the site**

**\*Order GYNECOLOGIC CYTOLOGY, PAP TEST: LAB1768 (APPAP)**

- Note/reminder: CT/GC testing on ThinPrep samples must be performed before PAP processing so CT/GC orders must be placed together on the date of collection.
- Specifically, when a PAP only was ordered and performed at OSF Laboratory, it would not be allowable for a later, add-on order for CT/GC testing.
- Note: for females, do not routinely use a ThinPrep vial for CT/GC when testing is not accompanied with a PAP order.

**\*Order HUMAN PAPILLOMA VIRUS (HPV): LAB1192 (HPVIRS)**

- Note: HPV testing can be ordered with PAP and CT/GC orders on the date of collection or as an add-on up to three months from date of collection.

**Labeling:** Three labels and three paper requisitions will print when ordering PAP, CT/GC and HPV. The PAP label is to be placed on the specimen vial. The additional CT/GC, HPV label and printed paper requisitions should be placed in front pocket of specimen bag.

## **Manual/Paper Requisition Orders:**

**Option 1:** If CT/GC testing only is needed: collect a genital (females) or urine (females or males) sample and select on the clinical paper requisition:

**CHLAMYDIA & GC DNA PROBE      CGPRB      LAB826**

- Note: For females, endocervical, cervical, vaginal, or urine specimens are accepted. The specimen collection site should be included in the box labeled "Site".
- Note: For males, urethral swabs are no longer accepted using this method. Urine only. Urine should be indicated as the specimen collection site in the box labeled "Site".

**Option 2:** For females, if ordering both a PAP and CT/GC, collect in a ThinPrep vial and select the following options from the pathology requisition:

**\*Source: Vaginal, Cervical or Endocervical**

**\*Screening or      Diagnostic**

**\*Pap APPAP      LAB1768**

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- Specifically, when a PAP only was ordered and performed at OSF Laboratory, it would not be allowable for a later, add-on order for CT/GC testing.
- Note: For females, do not routinely use a ThinPrep vial for CT/GC when testing is not accompanied with a PAP order.

**\*GC/Chlamydia   CGPRB      LAB826**

**Option3:** For females, if ordering both a PAP and HPV, collect in a ThinPrep vial and select the following options from the pathology requisition:

**\*Source: Vaginal, Cervical or Endocervical**

**\*Screening or      Diagnostic**

**\*Pap APPAP      LAB1768**

- Note/reminder: CT/GC testing on ThinPrep samples must be performed before PAP processing so CT/GC orders must be placed together on the date of collection.
- Specifically, when a PAP only was ordered and performed at OSF Laboratory, it would not be allowable for a later, add-on order for CT/GC testing.

**\*Reflex High Risk HPV, if ASCUS Pap      or      HPV HPVIRS      LAB1193**

- Note: When Reflex High Risk HPV, if ASCUS Pap is selected, HPV testing will only be performed when the Pap diagnosis is ASCUS. When HPV Co-test is selected, HPV testing will be performed regardless of the Pap diagnosis.
- Note: HPV testing can be ordered with PAP orders on the date of collection or as an add-on up to three months from date of collection.

**Option 4:** For females, if ordering all three PAP, CT/GC, and HPV, collect in a ThinPrep Vial and select the following options from the pathology requisition:

**\*Source: Vaginal, Cervical or Endocervical**

**\*Screening or      Diagnostic**

**\*Pap APPAP      LAB1768**

- Note/reminder: CT/GC testing on ThinPrep samples must be performed before PAP processing so CT/GC orders must be placed together on the date of collection.
- Specifically, when a PAP only was ordered and performed at OSF Laboratory, it would not be allowable for a later, add-on order for CT/GC testing.
- Note: for females, do not routinely use a ThinPrep vial for CT/GC when testing is not accompanied with a PAP order.

**\*Reflex High Risk HPV, if ASCUS Pap    or    HPV HPVIRS    LAB1193**

- Note: When Reflex High Risk HPV, if ASCUS Pap is selected, HPV testing will only be performed when the Pap diagnosis is ASCUS. When HPV Co-test is selected, HPV testing will be performed regardless of the Pap diagnosis.
- Note: HPV testing can be ordered with PAP orders on the date of collection or as an add-on up to three months from date of collection.

**\*GC/Chlamydia    CGPRB      LAB826**