Chlamydia, N.gonorrhoeae, HPV Methodology/Collection Changes

June 6, 2016 St. Luke’s Lab will begin performing HPV, Chlamydia trachomatis and Neisseria gonorrhea testing on the Hologic Panther®, a new, state of the art molecular diagnostic instrument. The Panther® uses RNA transcript detection. The RNA transcript detection demonstrates increased specificity versus DNA detection.

This methodology has a high sensitivity and specificity that will reduce the number of inhibitory, equivocal, and false-positive results. The Panther® is fully automated for improved turn-around time. This new instrument will also allow us to offer, in the future, a (NAAT) test for the detection of Trichomoniasis.

The new updated methodology will allow for several improvements:
- Decreased specimen volumes resulting in less possibility of needing re-collection
- Easier specimen handling and transportation
- More efficient testing platform
- Increased sensitivity and specificity of the test method
- Improved turnaround times
- Multiple assays on the same patient sample

In order to accomplish this, you will need to:
- Use and stock different collection and transport devices
- Possibly change your collection techniques based on which testing you require.

HPV, Chlamydia and N. gonorrhoeae Testing:

The ThinPrep® Pap vial will be used to perform PAP, HPV, HPV genotype, Chlamydia & N. gonorrhoeae testing. There will be no change to the ordering of HPV testing. This test allows providers to make immediate treatment decisions in cases of discordant co-testing. All Thin Prep Pap specimens will be aliquoted into a special collection tube in order to facilitate additional or reflex testing for either Chlamydia/GC or HPV. These specimens will be held 2 weeks.

Chlamydia/GC Collection options other than PAP vials are:
Chlamydia, N.gonorrhoeae, HPV Methodology/Collection Changes

Females:
- Vaginal swab- Carefully insert the swab into the vagina about 2 inches (5cm) past the introitus and gently rotate the swab for 10-30 seconds. Make sure the swab touches the walls of the vagina so that moisture is absorbed by the swab and then withdraw the swab without touching the skin. Remove cap from transport media and place specimen collection swab into transport tube; break swab at score line and replace cap.

<table>
<thead>
<tr>
<th>Vaginal Swab</th>
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<td>Used for Chlamydia, Neisseria gonorrhoeae</td>
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Males:
- Urine-Male patient should not have urinated for at least one hour prior to specimen collection. Collect 20 to 30 ml first-catch urine into preservative free collection cup Transfer 2 ml urine into transport tube using the disposable pipette; the fluid level should be between the black fill lines on the tube.

<table>
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<th>Urine Collection</th>
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<td>Used for male Chlamydia, Neisseria gonorrhoeae</td>
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Testing Locations: HPV, Chlamydia trachomatis and Neisseria gonorrhoeae testing is shared between St. Luke’s Microbiology and Cytology Laboratories. For questions contact Cytology 249-5315 or Microbiology 249-5319.

Laboratory Medical Directors: Should you have any immediate questions or concerns, please contact Dr. Lundeen, Dr. Steinhauer or Dr. Eastep at (218)249-5208.

Chlamydia/GC PAP vial collection options:

Pap/HPV Specimen Collection (Acceptable for Chlamydia & GC)
**Brush/Spatula Protocol**

Obtain…
...an adequate sampling from the ectocervix using a plastic spatula. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary. Select contoured end of plastic spatula and rotate it 360 degrees around the entire exocervix while maintaining tight contact with exocervical surface.

Rinse...
...the spatula as quickly as possible into the PreservCyt solution vial by swirling the spatula vigorously in the vial 10 times. Discard the spatula.

Obtain...
...an adequate sampling from the endocervix using an endocervical brush device. Insert the brush into the cervix until only the bottommost fibers are exposed. Slowly rotate 1/4 or 1/2 turn in one direction. DO NOT OVER-ROTATE.

Rinse...
...the brush as quickly as possible in the PreservCyt solution by rotating the device in the solution 10 times while pushing against the PreservCyt vial wall. Swirl the brush vigorously to further release material. Discard the brush.

Tighten...
...the cap so that the torque line on the cap passes the torque line on the vial.

Record...
...the patient’s name and ID number on the vial, and the patient information and medical history on the cytology requisition form.

Place...
...the vial and requisition in a specimen bag for transport to the laboratory.

*Courtesy of Hologic ThinPrep® Pap Test™ Quick Reference Guide –*

**Chlamydia/GC PAP vial collection options:**
Pap/HPV Specimen Collection (Acceptable for Chlamydia & GC)
Broom-Like Device Protocol

Obtain…

...an adequate sampling from the cervix using a broom-like device. If desired, use lukewarm water to warm and lubricate the speculum. Water-soluble gel lubricant sparingly applied to the posterior blade of the speculum can be used if necessary. Insert the central bristles of the broom into the endocervical canal deep enough to allow the shorter bristles to fully contact the ectocervix. Push gently, and rotate the broom in a clockwise direction five times.

Rinse…

…the broom as quickly as possible into the PreservCyt solution vial by pushing the broom into the bottom of the vial 10 times, forcing the bristles apart. As a final step, swirl the broom vigorously to further release material. Discard the collection device.

Tighten…

…the cap so that the torque line on the cap passes the torque line on the vial.

Record…

…the patient's name and ID number on the vial, and the patient information and medical history on the cytology requisition form.

Place…

…the vial and requisition in a specimen bag for transport to the laboratory.

Courtesy of Hologic ThinPrep® Pap Test™ Quick Reference Guide