

## Changes to Gonorrhea/Chlamydia Nucleic Acid Testing at Methodist Pathology

The Methodist Pathology Center will be performing Chlamydia and Gonorrhea (CTNG) nucleic acid testing in-house starting 4/1/15. Previously, this testing was performed at an outside laboratory using the Aptima system. The in-house test will be performed on the Cobas 4800.

**Test Availability:** Performed once daily, M-F

**Specimen Collection:** Please note that the collection kits and the recommended sample types have changed. Collection kits specific for the Cobas 4800 method will be provided for all clinics and clients. The following are the FDA approved specimen types:

	<u>Sensitivity %</u>	<u>Specificity %</u>
<b><u>Female</u></b>		
• Vaginal swab (clinician collected)	CT 98.2 NG 100	CT 99.1 NG 99.7
• Vaginal swab (self-collected)	CT 97.6 NG 96.7	CT 99.4 NG 100
• Cervical swab	CT 94.9 NG 96.6	CT 99.4 NG 99.9
• Urine	CT 94.0 NG 95.6	CT 99.6 NG 99.7
<b><u>Male</u></b>		
• Urine	CT 98.4 NG 100	CT 99.2 NG 99.3

**NOTES:**

- Urine is the only acceptable specimen type for male patients. Male urethral swabs are not FDA approved by this method.
- This test is not intended for use with throat, rectal, or other sources/specimen types not listed above. Call client services, (402)-354-4541 or 1-888-432-8980, if PCR testing is needed for a non-FDA approved source.
- Of the approved female specimen types, sensitivity is highest for vaginal swabs with this method.
- Submit urine in the Cobas Urine Sample Kit or unpreserved in a sterile container (unpreserved urine is only acceptable if less than 24 hours old).
- Vaginal and cervical swabs must be collected using the Cobas Female Swab Sample Kit.
- Please contact Methodist Pathology the week of March 23, 2015, to request inventory for the new collection supplies.

**REFERENCES:**

1. Cobas 4800 CT/NG v2.0 Product Insert. 2014. Roche Diagnostics. Indianapolis, IN.
2. Centers for Disease Control and Prevention. Sexually Transmitted Disease Surveillance 2011. Atlanta: U.S. Department of Health and Human Services. <http://www.cdc.gov/std/stats>
3. Schachter J et al. *Vaginal swabs are the specimens of choice when screening for Chlamydia trachomatis and Neisseria gonorrhoeae: results from a multicenter evaluation of the APTIMA assays for both infections.* 2005. Sex Transm Dis.

Please contact Methodist Pathology Client Support Services at (402)354-4541 or 1-888-432-8980, if you have questions regarding these changes.