

## The Use of Liquid Based Collection Methods in Women's Health Screening

**A**CM Global Central Laboratory encourages the use of liquid based collection methods not only for cervical cancer screening, but also for sexually transmitted diseases.

**Human Papilloma Virus (HPV) testing:** This testing can be ordered as a REFLEX test or as a primary screening tool. A REFLEX test is used to help aid clinicians in the management of patients with Atypical Squamous Cells of Undetermined Significance (ASCUS). When ordered, HPV testing is performed on any pap test with a diagnosis of ASCUS. If High Risk HPV is detected, this patient may be followed up with either a colposcopy or a repeat pap test in a shorter time frame. If High Risk HPV is not detected, the likelihood of this patient having a high grade squamous intraepithelial lesion is very low, and often this patient can return to routine screening.

Primary HPV testing can always be performed for any diagnosis, at the clinician's request. HPV testing can be performed for up to 30 days from the date of collection.

**Chlamydia and Neisseria Gonorrhoeae:** Disease due to Chlamydia and Neisseria gonorrhoeae represents the most frequently reported sexually transmitted diseases. In 2006, 1,030,911 chlamydial infections were reported to CDC from 50 states and the District of Columbia. Under-reporting is substantial because most people with chlamydia are not aware of their infections and do not seek testing. CDC estimates that more than 700,000 persons in the U.S. get new gonorrheal infections each year. Only about half of these infections are reported to CDC. As with Chlamydia up to 50% of patients can be asymptomatic.

If left untreated or undetected Chlamydia can cause pelvic inflammatory disease, salpingitis, urethritis, postpartum endometritis, infertility, and ectopic pregnancy. Similarly, untreated or undetected gonorrhea

infections can lead to pelvic inflammatory disease, tubal infertility, ectopic pregnancy and chronic pelvic pain. These infections lead to billions of dollars in direct and indirect health care costs. It is therefore imperative to detect all symptomatic and asymptomatic infections.

There are several test methods to detect Chlamydia and Neisseria gonorrhoeae. These include culture, direct DNA probe assays, and amplified nucleic acid tests. Culture for both organisms is difficult due to decreased viability in transport to the laboratory and the requirement for special transport devices. Studies have shown that culture lacks sensitivity when compared to the molecular tests.

Direct DNA probe assays offer better sensitivity. These tests are performed manually and are labor intensive. Commercially available nucleic acid amplification tests, using methods such as polymerase chain reaction, ligase chain reaction, strand displacement amplification, and transcription-mediated amplification, have a better sensitivity than the direct DNA probe tests and are now the "gold standard" for detection of Chlamydia and Neisseria gonorrhoeae. These amplified assays can be performed on automated instruments.

At ACM Global Central Laboratory we perform the amplified Aptima Chlamydia/Neisseria gonorrhoeae assay on a fully automated TIGRIS instrument. This assay uses a transcription-mediated amplification of ribosomal RNA that is amplified up to 10 billion copies. This results in a 7 to 10 times greater sensitivity over direct DNA probe assays. The sensitivity and specificity for each organism is given in the table below.

The assays for Chlamydia and Neisseria gonorrhoeae are FDA approved for genital specimens, urine, and most recently for specimens submitted in ThinPrep® vials. Once specimens are loaded onto the instrument results are available within 8 hours.

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This amplified assay is preferred over other methods since the entire testing is performed in a closed system thereby eliminating any possibility of cross contamination. The testing methodology also

eliminates any interfering substances from the specimen. Other amplified methods do not remove interfering substances and are therefore more prone to yield falsely negative results.

	<b>Sensitivity</b>	<b>Specificity</b>
<b>Chlamydia</b>	<b>95.9%</b>	<b>98.2%</b>
<b>Neisseria gonorrhoeae</b>	<b>97.8%</b>	<b>98.9%</b>

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