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NEISSERIA GONORRHOEAE AND CHLAMYDIA TRACHOMATIS CONFIRMATORY TESTING

by Wesley J. Kim, M.D.

Screening for Neisseria gonorrhoeae (NG) and Chlamydia trachomatis (CT) is currently performed by nucleic acid amplification testing (NAAT) on the Roche COBAS Amplicor PCR platform. The use of NAAT testing offers higher sensitivity, compared to culture or probe, and helps minimize the risk for disease sequelae and continued transmission of infections as a result of false-negative screening results. Equally important however, is the potential for adverse consequences (substantial psychosocial or legal consequences) caused by a false-positive test result, particularly in areas where the prevalence of NG and/or CT is low (in Hawaii the prevalence of NG is approximately 3% and the prevalence of CT is approximately 5%) or in cases where the clinical suspicion is low. In such cases, routine confirmatory testing to improve the predictive value of a positive screening test must be considered. False-positive results might occur for multiple reasons: cross reactivity of the test with other microorganisms, signal generation in absence of the target, contamination, or clerical error. Various approaches are available for additional testing, however, because of the greater sensitivity of NAATs compared to culture or probe, the CDC states that a second NAAT is the only additional test that can be used to verify a result from an initial NAAT test. Up to this point, Diagnostic Laboratory Services (DLS) has recommended testing a second sample using a different NAAT which is sent to local laboratory outside of DLS. While effective in improving specificity and positive predictive value, it required collection of a second specimen necessitating a second visit for the patient. Often, the patient may have already been treated with antibiotics by the time a second sample is obtained. Turn-around times for final confirmed results were prolonged, and initial screening results were still being reported, including potential false-positives that could generate significant psychosocial consequences despite the eventual results of outside confirmatory testing.

DLS is pleased to announce that as of April 24 2006 the lab is now performing confirmatory testing for both Neisseria gonorrhoeae and Chlamydia trachomatis in-house. The confirmatory testing will be performed using an in-house validated PCR method on the Roche Lightcycler platform. This assay exhibits high sensitivity equal to that of the screening test, but differs in that it employs primers and probes that amplify and detect a different segment of the genome specific for NG and CT, thus reducing false-positives and improving specificity and PPV. In addition, the Lightcycler platform also allows for melting-curve analysis, a process by which end-products of PCR are subjected to increasing temperature, resulting in separation of the amplified product. Both NG and CT have specific and unique melting curve temperatures. By performing melting-curve analysis on all positive results, the lab can ensure that amplified products match the characteristics for NG and/or CT and further heighten the specificity and predictive value of a final positive test. Logistically, there will be no need for calling the patient back for collection of a second sample as confirmatory testing will be performed on the original sample. Confirmatory testing will be automatically performed on all initial screen positive samples prior to reporting of any results. This ensures that results you receive from the lab are final and will have already been confirmed if positive.

As with the screening test, the following samples have been validated in-house by DLS for confirmatory testing when indicated: female and male urine, endocervical swabs in M-4 transport media, male urethral swabs, and Sure-Path liquid based cytology samples. Vaginal swab specimens, rectal swab specimens, pharyngeal specimens, ocular specimens, or specimens related to possible sexual assault or abuse are not approved, validated, or recommended for either screening or confirmatory testing by NAAT methods. Culture is the method of choice for these sample types.

If you have any additional questions or concerns please contact DLS client services at 589-5101, your marketing representative, or Dr. Wesley Kim at 589-5131.

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