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CHLAMYDIA TRACHOMATIS & NEISSERIA GONORRHOEAE NUCLEIC ACID AMPLIFICATION TESTING INFORMATION SHEET

USE OF ASSAY

Detection of Chlamydia trachomatis and Neisseria gonorrhoeae by nucleic acid amplification technology has been shown to have a sensitivity and specificity superior to that of culture. It also has the advantage of being able to detect non-viable organisms, which would be missed by culture; this is a particularly important consideration when specimens need to be transported under conditions which may not easily be controlled.

SPECIMEN COLLECTION

The following specimens are suitable for testing: male and female urine, self-collected vaginal swab specimens, clinician-collected vaginal swab specimens, endocervical swab specimens, oropharyngeal (throat) swab specimens, and anorectal swab specimens, all collected in cobas PCR Media (Roche Molecular Systems, Inc.), and cervical specimens collected in PreservCyt (ThinPrep) Solution.

Since Chlamydia trachomatis specifically infects columnar epithelial cells, specimens must be collected from sites where these cells are present. Optimal performance of this test requires adequate specimen collection and handling.

Urine has been shown to be as sensitive as an endocervical swab for the demonstration of *C.trachomatis* and *N. gonorrhoeae*. The patient must not have urinated for two hours before 10-50 mL of a first catch sample is collected into a sterile, dry specimen jar. The specimen is stable at room temperature for 24 hours or may be held at 2-8°C for up to four days. Endocervical, vaginal, oropharyngeal, and anorectal swabs and male urethral swabs may be collected using dry swabs and may be held at 2-8°C for up to 72 hours before testing. Samples collected into cobas PCR Media are stable at room temperature for up to one year, or until media expiry date.

LIMITATIONS

- Will not detect plasmid free variants of *C. trachomatis*
- There are reports that other Neisseria sub-species present as normal flora may contribute to false positive results. In settings with a high prevalence of STD, positive results have a high likelihood of being true positives.
- Urine and swab specimens with >5% blood, highly pigmented substances eg. Bilirubin (10mg/mL), or leukocytes (swab only) >2.5x105 cells/ml may cause indeterminate or false negative results.

FREQUENCY OF TESTING

This assay is normally performed daily (Monday to Friday).
Results available same day of testing.