organisms. Analytical sensitivity was determined using titered, purified CT elementary bodies and cultured NG cells.

**Results** The Xpert CT/NG assay detects all CT serovars, new variant CT, and 48 geographically diverse NG strains.

The CT primers and probes do not cross-react with DNA or RNA from non-trachomatis species. All non-gonococcal *Neisseria* species yielded negative results, including *N. mucosa* and *N. cinerea*, because both NG targets must be PCR positive for a “NG DETECTED” result.

The LoDs for the Xpert CT/NG Assay for CT serovar D in male urine and vaginal swab matrix respectively were 75 and 84 Eb/mL; for CT serovar H, LoDs were 134 and 161 Eb/mL. In both matrices, the LoD for two NG strains was approximately 2 cfu/mL.

**Conclusion** The Xpert CT/NG assay is highly specific and sensitive. The ease of use and fast time to result could lead to reduced time to treatment of CT and NG infections.

**P2.016 EVALUATION OF THE TRIPLEX REAL-TIME PCR ASSAY FOR DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORROHEAE IN URINE AND VAGINAL SWABS**


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**Background** Chlamydia trachomatis and Neisseria gonorrhoeae are among the most common causes of sexually transmitted bacterial infections worldwide. Infection with these organisms is mostly asymptomatic, however serious complications are also observed. Screening of the diseases is necessary to identify, treat and control the infection. In this study, we evaluated the performance of the triplex real-time PCR assay with internal control for detection of *C. trachomatis* and *N. gonorrhoeae* infections in urine and vaginal swabs.

**Methods** The performance of TaqMan probe-based triplex real-time PCR targeting the cryptic plasmids of *C. trachomatis* (pCHL1) and *N. gonorrhoeae* (pJDI) and beta-globin gene as an internal control was assessed using 188 urine specimens and 118 vaginal swabs. The triplex real-time PCR was compared with the Roche COBAS AMPLICOR CT/NG assay. The urine specimens were further tested using real-time PCR targeting the *N. gonorrhoeae* porA pseudogene.

**Results** For urine specimens, the sensitivity and specificity of the triplex real-time PCR were 100% and 97.6%, respectively, for *C. trachomatis*, and 100% and 95.2%, respectively, for *N. gonorrhoeae*. For vaginal swabs, the sensitivity and specificity were 100% and 100%, respectively, for *C. trachomatis*, and 100% and 98.1%, respectively, for *N. gonorrhoeae*. There were 5 (2.84%) from 176 urine specimens and 5 (4.26%) from 118 vaginal swabs that were negative for cryptic plasmid, but positive for *N. gonorrhoeae* porA pseudogene.

**Conclusion** The performance of the triplex real-time PCR assay was comparable to that of the Roche COBAS AMPLICOR CT/NG assay. This assay is easy to perform and the results can be achieved in 3–4 hours, including sample preparation. The estimated cost of triplex real-time PCR was less than 20 USD. Taken together with using non-invasive urine sampling, this assay is convenient and suitable for epidemiological studies in screening large number of samples.

**P2.017 CLINICAL EVALUATION OF THE PELVOCHECK® CT/NG FOR THE DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORROHEAE**


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**Background** In the present study the performance of the PelvoCheck® CT/NG, a microarray-based nucleic acid amplification assay for the detection of Chlamydia trachomatis (CT) and Neisseria gonorrhoeae (NG), was evaluated in single and pooled urine specimen of young women.

**Methods** A total of 1649 female urine specimens were collected and examined for urogenital chlamydia infections. Because of a low prevalence (2.12%), 50 CT-negative urine specimens were enriched with CT reference material mimicking the natural chlamydial distribution in female urine. The results were compared to those of the Roche COBAS® TaqMan® CT assay as the first and the Abbott RealTime CT/NG assay as the second reference method.

Similarly, NG pre-screened female urine specimens (60 NG-positive and 60 NG-negative specimens) were analysed with the PelvoCheck® CT/NG test and compared to a validated in-house Q-PCR method and the Abbott RealTime CT/NG assay.

Furthermore, the PelvoCheck® CT/NG assay was tested for pooled urine specimens (52 CT-negative and 85 CT-positive specimens). Each pool consisted of either five individual CT-negative specimens or four CT-negative and one CT-positive individual specimens.

**Results** For the detection of CT the overall positive agreement (sensitivity) and overall negative agreement (specificity) of the PelvoCheck® CT/NG were 98.8% and 100%, for the detection of NG 98.3% and 98.2%, respectively.

The comparison of data obtained with the PelvoCheck® CT/NG for pooled urine specimens resulted in a positive agreement of 90.9% and a negative agreement of 100%. Four CT-positive pooled specimens with final CT-concentrations of 0.05 – 0.13 IFU/ml were not detected.