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Molecular bacterial typing methods

Evaluation of PelvoCheck® CT/NG (Greiner Bio-One): a new diagnostic microarray-based kit for the detection of Chlamydia trachomatis and Neisseria gonorrhoeae DNA in urogenital specimens

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Background: Pelvic inflammatory disease is the most common and severe complication of some sexually transmitted infections mostly caused by *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG). Pelv**oChec**k® CT/NG (Greiner Bio-One) is a new DNA microarray-based test for the detection of a 16S rRNA gene fragment including assay-controls for the monitoring of sampling/extraction, PCR and hybridisation. The assay has been validated using the oCheck® DNA extraction kit (Greiner Bio-One) which is a manual procedure that might be time consuming. In this evaluation the performance of the assay was compared with a validated reference in-house method (real-time qPCR: modified COBAS® TaqMan® CT Test v2.0, Roche and Tabrizi *et al*., Sex Transm Dis, 2005) using an alternative automated extraction platform

Material/methods: DNA from 28 patients (13 CT, 5 NG, 2 CT+NG positive and 8 negative) and 20 external quality controls (QCMD-INSTAND) was extracted using the MagNA Pure LC2 platform (Roche, DNA I High Performance protocol). 200 µl sample was used for extraction. DNA was eluted in 110 µl elution buffer and stored at -20°C until analysis. PCR and detection was performed according to the instructions of the manufacturer.
The assay was checked for accuracy, specificity, sensitivity and reproducibility, following the Belgian guidelines (Raymaekers *et al*., Acta Clinica Belgica, 2011).

Results: 25 out of 28 patients where concordant with the reference method. The three missed samples had a Cq (Quantification Cycle) value over 35 for CT. The aberrant NG strain described by Geeraerts *et al*. (J. Clin Microbiol, 2005), was correctly detected. Human DNA was detected in all the samples.

15 out of 20 external quality controls where concordant with the reference method. Three weak CT and two weak NG positive samples all with a Cq value over 35 were missed. Two were QCMD core samples for CT (424 copies/ml and 8620 copies/ml). The NG strain harbouring an *Neisseria meningitis porA* gene, the CT Swedish new variant, the serovars L and F, were all correctly detected. Negative samples were scored “failed” by the software because of the lack of human DNA in the QCMD panel.

No false positive results were obtained. There was no cross reaction with *Trichomonas vaginalis* and *Mycoplasma genitalium*.

Three samples (one positive for CT, one positive for NG and one positive for both pathogens) were analysed on three different days all giving the same result.

Conclusions: The Pelv**oCheck**® assay is easy to perform with little hands on time if DNA is extracted by an automatic platform. The assay appears to be analytically slightly less sensitive compared to the reference in-house method. The clinical significance of very weak positive samples (Cq > 35) can be a topic for further discussions.