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An evaluation study for the simultaneous detection of 7 sexually transmitted pathogens

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Background: Sexually transmitted infections (STI) represent a growing relevant public health problem. Early accurate diagnosis is capable of preventing spread and severe complications of curable STIs through pathogen adapted antibiotic treatment regimens. Limitations of current STI diagnostic tools are the lack of simultaneous pathogen detections and quantification of results

Material/methods: All samples were processed with multiplex real-time PCR assay Anyplex™ II STI-7 (Seegene, Seoul, Korea), using thermal cycler CFX96™ (Bio-Rad Laboratories, Hercules, USA). The Anyplex™ II STI-7 detection assay covers *Chlamydia trachomatis (CT), Neisseria gonorrhoeae (NG), Mycoplasma genitalium (MG), Mycoplasma hominis (MH), Ureaplasma parvum (UP), Ureaplasma urealyticum (UU)* and *Trichomonas vaginalis (TG)* and is capable of detecting STI coinfections within one single run. This assay was used for a retrospective internal evaluation of known STI specimens (n=74) followed by a prospective analysis (January-November 2016) of clinical specimens (n=78, from 65 symptomatic patients) from different sites of urological, dermatological, gynaecological infections. Study samples (urethral/endocervical/rectal/oral swab samples; urine; intraoperatively processed ascites) were first tested using conventional gold standard methods, only for pathogen detection requested by clinicians. STI-7 results were compared to standard methods and transferred to the attending physician for treatment adjustment.

Results: Reported medical issues were urethritis, vaginitis, fever of unknown origin, screening/monitoring, and ovarian abscess. Among the tested samples, 29 of 78 (37%) were positive for at least one pathogen. Anyplex™ II STI-7 detected CT in ten (13%), NG in nine (12%), UP in thirteen (17%), MG in three (4%), MH in five (7%), UU in five (6%) and TV in none of the analysed samples. STI coinfection was detected in eleven samples, double infections in six (UU+UP; 2xUU+CT; UP+CT; MH+UP; NG+UP), triple infections in three (2xCT+MH+UP; CT+NG+UU) and fourfold infections in two samples (CT+MH+MG+UP; CT+MG+UP+UU). It missed one CT (vaginal swab) and one NG (urine) infection. Additional ten single infections and ten out of eleven multiple infections were detected using STI-7 panel. Compared to performed standard method results the assay achieved sensitivities from 88% to 100%, and specificities of 100%, with negative predictive values from 98% to 100%, and positive predictive values of 100%.

Conclusions: The Anyplex™ II STI-7 assay can easily be introduced into the microbiological laboratory work flow due to its short hands-on-time and the mutiplexicity of the PCR. The simultaneous detection of STI related pathogens provides a comprehensive profile for each patient, enabling the clinician to decide on the best treatment options, thus decreasing antibiotic misuse and the risk of the infection spreading. Semi-quantitative results might be useful to determine disease severity and might enable clinicians to gain a complete package of diagnostic information including disease diagnosis, degree of disease severity, and monitoring of treatment. Further clinical studies on this topic are needed