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EVALUATION OF NEW HYBEACON-BASED PCR ASSAYS FOR THE DIRECT DETECTION OF CHLAMYDIA TRACHOMATIS AND NEISSERIA GONORRHOEAE

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Objectives

Chlamydia trachomatis (CT) and *Neisseria gonorrhoeae* (NG) are the most frequently reported sexual transmitted infections worldwide. Rapid and accurate detection is crucial to prevent transmittance of these infectious agents. We evaluated the performance of the new FluoroType (FT) CT and FT NG assays (Hain Lifescience, Nehren, Germany) for the direct detection of CT and NG in genitourinary specimens. Results were compared to already established PCR assays and to conventional culture for NG.

Methods

In total 202 specimens (104 urines, 89 cervical swabs, 9 ejaculate samples) were investigated with the FT CT assay. For CT-DNA extraction the fully automated GenoXtract system and the manual Fluorolyse extraction kit (both Hain Lifescience) were compared. For NG 82 vaginal and urethral specimens were tested. For 46 specimens NG-DNA extraction was performed with the manual Fluorolyse kit (Hain Lifescience). The FT NG results were compared to culture. 36 samples were pre-purified DNA and were compared to an already established PCR method. Culture for NG was processed on Thayer-Martin, Chocolate and Columbia blood agar and incubated in a 5% CO_2-atmosphere for 48h. The new FT NG and CT tests are based on HyBeacon probe technology. PCR amplification and detection by melting curves is performed on the FluoroCycler (Hain Lifescience). Evaluation is done by the FluoroType software. All assays were performed according to manufacturer´s instructions.

Results

The FluoroType CT assay performed with the manual FluoroLyse CT-DNA purification method showed 85 congruent positive and 116 congruent negative results in comparison to the reference PCR assay. One specimen showed a discrepant result. The sensitivity of the FT CT assay was 100.0 % and the specificity was 99.14 %. The negative predictive value (NPV) was 100.0 % and the positive predictive value (PPV) was 98.83 %. The FluoroType CT assay performed with the automated GenoXtract DNA isolation protocol showed 89 congruent positive and 109 congruent negative results in comparison to the reference PCR assay. 3 specimens showed discrepant results. One FT CT result showed inhibition. A value of 100.0 % was calculated for sensitivity and 97.32 % for specificity. The NPV was 100.0 % and the PPV was 96.74 %.

23 specimens were culture-positive for NG. All of them were detected with the FT NG-assay directly in the patient specimens. 23 specimens were culture-negative, 3 of these showed a positive FT NG result. These positive results were confirmed by an 'inhouse' NG-specific PCR. Overall sensitivity and specificity of the FT NG were 100%. The 36 specimens which were compared to a reference PCR method showed 100 % agreement.

Conclusions

Both PCR-assays, the FluoroType CT and FT NG for the direct detection of *C. trachomatis* and *N. gonorrhoese* provide sensitive and specific results in about 3 hours.