Evaluation of the new COBAS TaqMan CT Test v2.0 and the impact on the proportion of the new variant of Chlamydia trachomatis (nvCT) by introduction of diagnostics detecting nvCT (LightMix 480HT PCR) in Örebro county, Sweden

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Abstract
The new variant of Chlamydia trachomatis (nvCT), discovered in Sweden in 2006, contains a 377 bp cryptic plasmid deletion, which includes the targets for the COBAS Amplicor/TaqMan CT/NG and Abbott m2000rt CT/NG tests.

Objectives: To evaluate the new real-time COBAS TaqMan CT Test v2.0 (CTM CT v2.0) for C trachomatis diagnostics and to investigate if the proportion of nvCT was affected by the introduction of genetic diagnostics detecting nvCT (LightMix 480HT) in Örebro county, Sweden.

Methods: CTM CT v2.0 (Roche Diagnostics) compared to LightMix 480 HT PCR (TIB MOLBIOL) for diagnosis of C trachomatis was evaluated. Discrepant samples were analysed using BD ProbeTec ET and Abbott m2000rt RealTime CT II. All previously LightMix and cell culture positive samples were analysed using an nvCT-specific PCR.

Results: The sensitivity, specificity, negative predictive value, and positive predictive value of CTM CT v2.0 for examined samples (n=1058) was 100%, 99.8%, 100%, and 98.2%, respectively. Of 11577 consecutive PCR samples, 9.4% (n=1084) were positive and 34.3% (n=372) of these were nvCT. Of 2306 consecutive culture samples, 5.0% (n=116) were C trachomatis positive and 38.8% (n=45) of these were nvCT.

Conclusions: CTM CT v2.0 is a sensitive and specific method for C trachomatis detection. However, studies including larger number of symptomatic and asymptomatic patients as well as genital and extra-genital samples, and in comparison with other internationally validated and, ideally, FDA-approved C. trachomatis NAATs are imperative. The proportion of the nvCT remains high in Örebro county, Sweden despite the introduction of genetic diagnostics detecting the mutant.