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## Sexually Transmitted Infections

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Sex *Transm Infect* doi:10.1136/sti.2008.033142

## 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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Published Online First 5 December 2008

### 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.

### Articles citing this article

Emergence of the new variant of *Chlamydia trachomatis* in a defined area of Sweden before 2002?