Evaluation of the platform cobas® 4800 CT/NG test for detecting Chlamydia trachomatis in urogenital samples

Bertille de Barbeyrac, Virginie Mehats, Maïthé Clerc, Chloé Le Roy, Cécile Bébéar

Université Bordeaux Segalen, INRA, USC Infections Humaines à mycoplasmes et à chlamydiae, Centre National de Référence des infections à chlamydiae, Bordeaux, France.

Introduction

Chlamydia trachomatis infections are the most prevalent bacterial sexually transmitted infections worldwide.

Nucleic acid amplification tests are the tests of choice for the diagnosis of genital infections because of their high sensitivity, specificity and suitability for non-invasively self-collected specimens (vulvovaginal swabs and first void urine) ideal for high throughput asymptomatic identification.

The cobas 4800 system consists in a platform including: the cobas x 480 instrument for fully automated sample preparation directly from primary sample tubes and the cobas z 480 analyser for real-time PCR based amplification and detection.

The cobas® 4800 CT/NG test is a qualitative in vitro nucleic acid amplification test for the qualitative detection of CT and/or NG in clinical samples.

This study investigated the clinical performance of the Roche cobas® 4800 CT/NG assay in urogenital samples obtained from the bacteriology department of the Bordeaux University Hospital.

Methods

Consecutive urogenital samples from the Bacteriology department of the Bordeaux University Hospital, France, from July to September 2010.

The cobas® 4800 CT/NG test:

Urine samples were prepared by adding 4.5 mL to 4.5 mL of cobas® PCR media.

Swabs specimens were discharged in 1 mL of cobas® PCR media (after a first discharge in 2SP for extraction by the reference method).

The cobas x 480 instrument is an automated multi-channel pipetting instrument used to extract, purify, and prepare target nucleic acid for subsequent PCR testing on the cobas z 480 analyser.

After completion of sample preparation, the cobas x 480 instrument automatically sets up the PCR in a microwell plate. The microwell plate with the PCR-ready samples is then manually unloaded, sealed, and transferred to the cobas z 480 analyser for amplification and detection using real-time PCR.

Reference methods:

Extraction

- Flocked swabs were discharged into 1 mL of 2SP medium solution and cervix or urethral swabs were collected in 3 mL of universal transport medium.

- Urine samples were frozen at -20°C overnight, then thawed urine (500 µL) were pelleted by centrifugation (10,000 rpm, 10 minutes) and homogenized in 200 µL of lysis buffer.

- Nucleic acids were extracted by the MagNa Pure LC instrument using the LC DNA isolation kit I (Roche Diagnostics) and eluted in 100 µL of elution buffer.

PCR amplification

- C. trachomatis detection was performed with the Cobas® TaqMan® CT Roche on the COBAS TaqMan 48 (Roche Diagnostics).

Discrepant analysis:

In case of discordance between the cobas® 4800 CT/NG test and the cobas® TaqMan 48 test, retest was performed with both techniques.

Results

Nature of urogenital samples

- 708 clinical specimens were analyzed.

<table>
<thead>
<tr>
<th></th>
<th>Women</th>
<th></th>
<th>Men</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix swab</td>
<td>356</td>
<td>Urethral swab</td>
<td>14</td>
</tr>
<tr>
<td>Vaginal swabs</td>
<td>356</td>
<td>Urine</td>
<td>293</td>
</tr>
<tr>
<td>Total</td>
<td>708</td>
<td>Total</td>
<td>307</td>
</tr>
</tbody>
</table>

Specimens labeled “failed” or “invalid”

<table>
<thead>
<tr>
<th>Specimens</th>
<th>Total</th>
<th>Failed results</th>
<th>Invalid results</th>
</tr>
</thead>
<tbody>
<tr>
<td>Male urines</td>
<td>293</td>
<td>0 (0.3%)</td>
<td>1 (0.3%)</td>
</tr>
<tr>
<td>Urethral swabs</td>
<td>14</td>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>Cervix swabs</td>
<td>45</td>
<td>3 (6.7%)</td>
<td>0</td>
</tr>
<tr>
<td>Vaginal swabs</td>
<td>356</td>
<td>15 (4.2%)</td>
<td>0</td>
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<tr>
<td>Total</td>
<td>708</td>
<td>18 (2.5%)</td>
<td>1 (0.1%)</td>
</tr>
</tbody>
</table>

Concordant results for C. trachomatis detection ≥ 98% (699 / 708).

Similar sensitivity for C. trachomatis detection between the cobas® 4800 CT/NG test and the cobas ® TaqMan CT test.

The prevalence of Chlamydia trachomatis infection was 7.7 % (55 / 708).

The cobas® 4800 CT/NG test is suitable for high throughput identification of the C. trachomatis infection.

Conclusions