cobas® CT/NG v2.0 test
Factsheet: Chlamydia trachomatis and Neisseria gonorrhoeae testing

This document contains key information for the testing of Chlamydia trachomatis and Neisseria gonorrhoeae. Utilize this factsheet as a reference for additional detail when developing the following documents:

• New test announcement
• Client information packets
• Client educational materials
• Website listings
• Newsletter articles and bulletins
• Laboratory marketing materials
• Outreach sales educational materials

This document includes the following categories of information:

• Chlamydia trachomatis and Neisseria gonorrhoeae Overview
• Chlamydia trachomatis infections in the US continue to rise
• Routine screening is essential to reduce the burden of infection, CDC testing recommendations
• HEDIS measures
• Specimen types recommended by the CDC for CT/NG testing
• Why self-collected specimens?
• The cobas® CT/NG test
• Test codes
• Specimen collection
• Testing methodology
• Innovative test design delivers results that are sensitive and specific
Chlamydia trachomatis and Neisseria gonorrhoeae testing

Overview

*Chlamydia trachomatis (CT)* and *Neisseria gonorrhoeae* (NG) infections are two of the most common sexually transmitted infections in the United States.

**Chlamydia Trachomatis**

In 2010, 1.3 million cases of *Chlamydia trachomatis* infection were reported to the Centers for Disease Control and Prevention (CDC), the largest number of cases ever reported to the CDC for any condition. Prevalence of CT is highest in persons 25 years of age or younger. In women, chlamydial infections can result in Pelvic Inflammatory Disease (PID), a major cause of infertility, ectopic pregnancy, chronic pelvic pain, and increased risk of becoming infected with HIV. Pregnant women infected with chlamydia can pass the infection to their infants during delivery, potentially resulting in eye and lung complications. Screening programs can lead to as much as a 60% reduction in the incidence of PID.¹

Complications among men are rare. Infection sometimes spreads to the epididymis (the tube that carries sperm from the testis), causing pain, fever, and, rarely, sterility.²

**Neisseria gonorrhoeae**

The most common site of *Neisseria gonorrhoeae* infection is the urogenital tract, men may experience dysuria with penile discharge (usually symptomatic), and women may have mild vaginal discharge, severe pelvic pain, or no symptoms. Women with gonorrhea can develop ascending infection that causes acute salpingitis and or PID. PID can lead to tubal infertility, ectopic pregnancy, and chronic pelvic pain. In addition, epidemiologic and biologic studies provide strong evidence that gonococcal infections facilitate the transmission of HIV infection.

Chlamydia trachomatis infections in the US continue to rise

- *Chlamydia trachomatis* (CT) is the most frequently reported bacterial STD in the US
- 1.3 million cases of Chlamydia and 300,000 cases of *Neisseria gonorrhoeae* (NG) were reported in 2009¹
- Untreated Chlamydia infection can cause:
  - Pelvic inflammatory disease (PID)
  - Infection and inflammation of the uterus, fallopian tubes, ovaries, or adjacent peritoneum
  - Ectopic pregnancy, which is potentially fatal, and infertility in women
  - Epididymitis, infertility in men
Routine screening is essential to reduce the burden of infection

CDC testing recommendations

For women:

<table>
<thead>
<tr>
<th></th>
<th>C. trachomatis</th>
<th>N. gonorrhoeae</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25 yrs.</td>
<td>If sexually active.</td>
<td>If at risk.</td>
</tr>
<tr>
<td>&gt;25 yrs.</td>
<td>If at risk.</td>
<td>If at risk.</td>
</tr>
<tr>
<td>Pregnant</td>
<td>First prenatal visit.</td>
<td>First prenatal if at risk or high prevalence.</td>
</tr>
<tr>
<td></td>
<td>Re-testing in 3rd trimester if at risk, ≤25 yrs. or positive in 1st visit.</td>
<td>Re-testing in 3rd trimester if at risk or positive in 1st visit.</td>
</tr>
</tbody>
</table>

For men ages 15-25, who carry the burden of the highest chlamydia rates:

<table>
<thead>
<tr>
<th></th>
<th>C. trachomatis</th>
<th>N. gonorrhoeae</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;25 yrs.</td>
<td>If sexually active, high prevalence, and does not hinder screening of women.</td>
<td>N/A</td>
</tr>
<tr>
<td>&gt;25 yrs.</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td>MSM*</td>
<td>At least annually for urethral or rectal infection.</td>
<td>At least annually for urethral, rectal or oral infection.</td>
</tr>
</tbody>
</table>

Chlamydia is easily detected and treated, but screening remains underutilized

HEDIS measure (Healthcare Effectiveness Data and Information Set)

This measure looks at the percentage of non-pregnant, sexually active women 24 years of age and younger who are screened annually for chlamydia, as recommended by the U. S. Preventive Services Task Force.

- Only 57.5% of Medicaid patients are screened for chlamydia
- Only 43.1% of patients of commercial HMOs

And yet the estimated annual cost of chlamydia infections is ~ $647 million. Following the recommended chlamydia screening guidelines has the potential to prevent:

- 60,000 cases of PID
- 8,000 cases of Chronic Pelvic Pain
- 7,500 cases of Infertility
Specimen types recommended by the CDC for CT/NG testing

For women:
- Vaginal swabs; provider-collected or self-collected specimens
- Endocervical swabs specimens
- Urine specimens
- Liquid-based cytology specimens

A self- or clinician-collected vaginal swab is the recommended sample type. Self-collected vaginal swab specimens are an option for screening women when a pelvic exam is not otherwise indicated. An endocervical swab is acceptable when a pelvic examination is indicated. A first catch urine specimen is acceptable but might detect up to 10% fewer infections when compared with vaginal and endocervical swab samples.

For men:
- Urine specimen
- Urethral swab

Overwhelming evidence described the performance of male first catch urine samples as equivalent to, and in some situations superior to, urethral swabs. Use of urine samples is highly acceptable and might improve the likelihood of uptake of routine screening in men.

Note: The cobas® CT/NG v2.0 test is not cleared for use with urethral swab specimens.

Nucleic Acid Amplification Testing

Nucleic acid amplification tests (NAATs) that are cleared by the Food and Drug Administration (FDA) are recommended for detection of genital tract infections caused by Chlamydia trachomatis and Neisseria gonorrhoeae infections in men and women with and without symptoms.

The performance of NAATs with respect to overall sensitivity, specificity, and ease of specimen transport is better than that of any of the other tests available for the diagnosis of chlamydial and gonococcal infections.
The cobas® CT/NG v2.0 Test

The cobas® CT/NG v2.0 Test is an automated, in vitro nucleic acid amplification test for the qualitative detection of *Chlamydia trachomatis* (CT) and/or *Neisseria gonorrhoeae* (NG) DNA in urogenital specimens. The Test utilizes the Polymerase Chain Reaction (PCR) for the detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* DNA in male and female urine, self-collected vaginal swab specimens (collected in a clinical setting) clinician collected vaginal swab specimens, and endocervical swab specimens, all collected in cobas® PCR Media, and cervical specimens collected in PreservCyt® solution. This test is intended as an aid in the diagnosis of chlamydial and gonococcal disease in both symptomatic and asymptomatic individuals.

### Test Codes

<table>
<thead>
<tr>
<th>Test Code</th>
<th>Test Name</th>
<th>Specimen Requirements</th>
</tr>
</thead>
<tbody>
<tr>
<td>cobas® CT/NG test</td>
<td>Female swab or urine in cobas® PCR Media tube</td>
<td></td>
</tr>
<tr>
<td>cobas® CT test</td>
<td>Female swab or urine in cobas® PCR Media tube</td>
<td></td>
</tr>
<tr>
<td>cobas® NG test</td>
<td>Female swab or urine in cobas® PCR Media tube</td>
<td></td>
</tr>
<tr>
<td>cobas® CT/NG test</td>
<td>Cervical specimen collected in PreservCyt® solution</td>
<td></td>
</tr>
<tr>
<td>cobas® CT test</td>
<td>Cervical specimen collected in PreservCyt® solution</td>
<td></td>
</tr>
<tr>
<td>cobas® NG test</td>
<td>Cervical specimen collected in PreservCyt® solution</td>
<td></td>
</tr>
</tbody>
</table>

### Specimen collection

Specimen collection guides in English and Spanish are available upon request.

The cobas PCR Female swab and urine kits are the specimen collection kits that have been validated for the cobas CT/NG v2.0 test.

**cobas®PCR Female swab specimen collection kit**

Two swabs
- 1 cleaning swab
- 1 collection swab

*Note: the cleaning swab is not used when collecting a vaginal swab sample, dispose of the second swab*

**cobas PCR Media tube**

After collecting the specimen, place the swab in the PCR media tube and carefully lean the swab against the tube rim to break the swab shaft at the dark line.

Specimens in the cobas PCR media tube are stable at room temperature (2 - 30°C) for up to 1 year.
**Vaginal Specimen collection**

When collecting a self-collected vaginal swab specimen female patients are instructed to discard one swab, collect one swab and place the swab directly into the **cobas** PCR Media tube. See the collection guide for additional details.

**cobas PCR urine specimen collection kit**

Patients should not urinate 1 hour prior to specimen collection. Approximately 10 - 15 mL of urine should be collected from the **beginning** of the stream. Once collected the urine should be transferred to the **cobas** PCR media tube within 24 hrs.

![cobas PCR media tube with fill lines](image)

**Specimen stability**

Once the swab/urine is placed in the **cobas** PCR media tube the specimen is stable at room temperature for one year.

**Unacceptable specimens**

- **cobas** PCR media tubes with 2 swabs
- **cobas** PCR media tubes with urine below or above the urine fill lines
**Testing methodology**
CT/NG testing is performed with the [cobas® CT/NG test](#), a qualitative nucleic acid amplification test (NAAT), the method recommended by the CDC based on real-time PCR. Testing with NAATs are the preferred diagnostic tests because of their superior sensitivity and they can be performed on easily collected specimens, such as urine or vaginal swabs.  

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**cobas CT/NG v2.0 Test Performance**

<table>
<thead>
<tr>
<th>Sample Type</th>
<th>CT</th>
<th></th>
<th>NG</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Sens %</td>
<td>Spec %</td>
<td></td>
</tr>
<tr>
<td></td>
<td>N</td>
<td></td>
<td></td>
<td>N</td>
</tr>
<tr>
<td>Endocervical Swab</td>
<td>2,926</td>
<td>94.9%</td>
<td>99.4%</td>
<td>5,104</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Female Urine</td>
<td>2,945</td>
<td>94.0%</td>
<td>99.6%</td>
<td>5,127</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal Swab (Clinician-collected)</td>
<td>1,902</td>
<td>98.2%</td>
<td>99.1%</td>
<td>3,138</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Vaginal Swab (Self-collected)</td>
<td>2,037</td>
<td>97.6%</td>
<td>99.3%</td>
<td>2,037</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PreservCyt (Pre-ThinPrep)</td>
<td>2,937</td>
<td>94.2%</td>
<td>99.7%</td>
<td>5,131</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PreservCyt (Post-ThinPrep)</td>
<td>2,878</td>
<td>93.7%</td>
<td>99.5%</td>
<td>4,868</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male Urine</td>
<td>738</td>
<td>98.4%</td>
<td>99.2%</td>
<td>738</td>
</tr>
<tr>
<td></td>
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**Innovative design delivers results that are sensitive and specific:**

- Method based on real-time PCR
- Reliable assay performance from dual-probe design for both CT and NG
  - Detects the nvCT (CT Swedish strain)
  - No cross-reactivity with non-gonococcal strains of Neisseria
- Reduced risk of contamination and false positive results due to the AmpErase® enzyme that destroys previously generated amplicon
- Minimal risk of false-negative results provided by the Internal Control
- Unique kinetic algorithm for accurate data analysis
- Twelve months post collection room temperature specimen stability
References:

1. CDC STD Surveillance 2009
2. CDC Chlamydia Fact Sheet; CS226060A, Division of STD Prevention (DSTD)
   Centers for Disease Control and Prevention
4. CDC Grand Rounds: Chlamydia Prevention: Challenges and Strategies for Reducing Disease Burden and Sequelae; MMWR April 1, 2011.
8. cobas CT/NG v2.0 Test package insert, Roche Molecular Systems, 12/2013 Doc Rev. 1.0.

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