
Detect it in here. Stop it out there.

# Xpert® CT/NG

Three targets, 90 minutes. No repeat testing.

CE IVD In Vitro Diagnostic Medical Device

Cepheid®
*A better way.*

*"For the first time, we are able to offer highly accurate results we can act upon while the patient is still in the clinic. This may have far-reaching effects, such as improving contact tracing and reducing ongoing spread of infection in the community, as well as being popular with our patients. I am impressed with the highly accurate results obtained with Xpert® CT/NG. The simplicity of sample prep and the easy-to-use format of the GeneXpert® cartridge provide same-day results in around 90 minutes."*

*Dr. Simon Goldenberg*
*Consultant Microbiologist, Guy's & St. Thomas' NHS Foundation Trust, London*

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## The Need

**According to the European Centers for Disease Control and Prevention (ECDC), the rate of chlamydia infections reported doubled during the last decade. Gonorrhea rates are also rising, often as a co-infection. Both carry severe health consequences if left untreated.**

The human and workflow impact of current CT/NG tests is high:

- Current tests require confirmation
- Stat has become ordinary test mode, slowing other processes
- Contamination is an issue

## The Solution

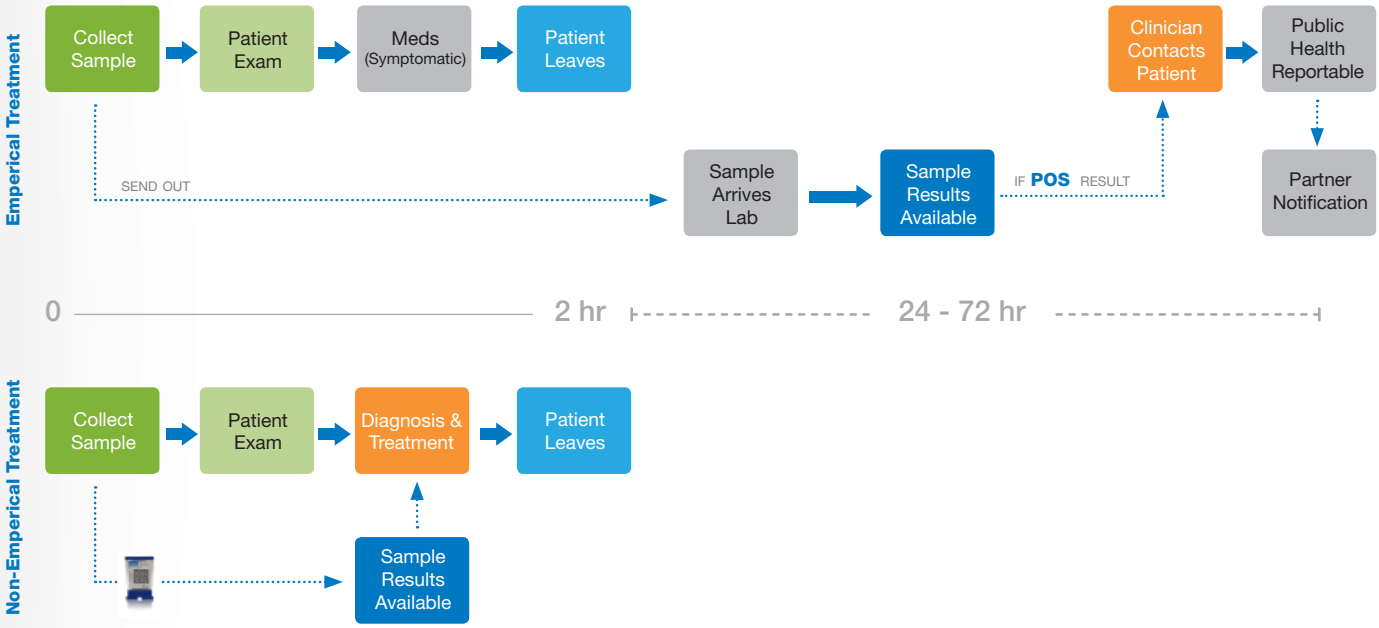
**On-demand molecular testing – an ideal solution.**

- Two independent NG DNA targets deliver high specificity
- CT target exclusively selected for superior inclusivity
- Flexible test ordering with each cartridge for CT, CT/NG or NG

# The Impact

- Achieve same-day containment and improve patient management
  - Confidence in a single test
  - On-demand flexibility to meet your lab's needs
  - Free up highly trained resources
  - Deliver needed same-day results to Clinicians

# Impact on Patient Pathway




# The Xpert® CT/NG Advantage

## TRUSTED RESULTS IN 90 MINUTES

- Moderately complex test can be run by most lab personnel
- Random access for flexibility and workflow optimization
- Fully integrated reagent and instrument system for accuracy and reproducibility

# Accuracy

Clinical performance characteristics of the Xpert® CT/NG Assay were determined in a multi-site prospective investigational study at 36 US and UK institutions by comparing the Xpert CT/NG Assay to a patient infected status (PIS) algorithm based on results from two currently marketed NAAT tests.

## Self-Collected Vaginal Swab

### CT

| Xpert | PIS* + | PIS* − | |
|---|---|---|---|
| + | 78 | 10 | 88 |
| − | 1 | 1624 | 1625 |
| | 79 | 1634 | 1713 |

Sensitivity: 98.7% (95% CI 93.1-100)
Specificity: 99.4% (95% CI 98.9-99.7)
Accuracy: 99.4% (95% CI: 98.9-99.7)
PPV: 88.6% NPV: 99.9%

### NG

| Xpert | PIS + | PIS − | |
|---|---|---|---|
| + | 22 | 2 | 24 |
| − | 0 | 1689 | 1689 |
| | 22 | 1691 | 1713 |

Sensitivity: 100% (95% CI: 87.3-100)
Specificity: 99.9% (95% CI: 99.6-100)
Accuracy: 99.9% (95% CI: 99.6-100)
PPV: *91.7%* NPV: *100%*

## Urine

### CT

| Xpert | PIS + | PIS − | |
|---|---|---|---|
| + | 80 | 3 | 83 |
| − | 2 | 1633 | 1635 |
| | 82 | 1636 | 1718 |

Sensitivity: 97.6% (95% CI: 91.5-99.7)
Specificity: 99.8% (95% CI: 99.5-100)
Accuracy: 99.7% (95% CI: 99.3-99.9)
PPV: *96.4%* NPV: *99.9%*

### NG

| Xpert | PIS + | PIS − | |
|---|---|---|---|
| + | 22 | 1 | 23 |
| − | 1 | 1694 | 1695 |
| | 23 | 1695 | 1718 |

Sensitivity: 95.6% (95% CI: 78.1-99.9)
Specificity: 99.9% (95% CI: 99.7-100)
Accuracy: 99.9% (95% CI: 99.6-100)
PPV: *95.7%* NPV: *99.9%*

## Endocervical Swab

### CT

| Xpert | PIS + | PIS − | |
|---|---|---|---|
| + | 76 | 7 | 83 |
| − | 2 | 1625 | 1627 |
| | 78 | 1632 | 1710 |

Sensitivity: 97.4% (95% CI: 91.0-99.7)
Specificity: 99.6% (95% CI: 99.1-99.8)
Accuracy: 99.5% (95% CI: 99.0-99.8)
PPV: *91.6%* NPV: *99.9%*

### NG

| Xpert | PIS + | PIS − | |
|---|---|---|---|
| + | 22 | 0 | 22 |
| − | 0 | 1688 | 1688 |
| | 22 | 1688 | 1710 |

Sensitivity: 100% (95% CI: 87.3-100)
Specificity: 100% (95% CI: 99.8-100)
Accuracy: 100% (95% CI: 99.8-100)
PPV: *100%* NPV: *100%*

## Urine

### CT

| Xpert | PIS + | PIS − | |
|---|---|---|---|
| + | 79 | 1 | 80 |
| − | 2 | 1304 | 1306 |
| | 81 | 1305 | 1386 |

Sensitivity: 97.5% (95% CI: 91.4-99.7)
Specificity: 99.9% (95% CI: 99.6-100)
Accuracy: 99.8% (95% CI: 99.4-100)
PPV: *98.7%* NPV: *99.8%*

### NG

| Xpert | PIS + | PIS − | |
|---|---|---|---|
| + | 49 | 1 | 50 |
| − | 1 | 1335 | 1336 |
| | 50 | 1336 | 1386 |

Sensitivity: 98.0% (95% CI: 89.4-99.9)
Specificity: 99.9% (95% CI: 99.6-100)
Accuracy: 99.9% (95% CI: 99.5-100)
PPV: *98.0%* NPV: *99.9%*

** PIS: patient infected status*

# Confident and in Control

- Each self-contained Xpert® cartridge controls for three specific failure modes:
  - Sample Adequacy Control (SAC)
    - Confirms adequate patient sample is collected
    - Indicates sample is efficiently mixed and lysed
    - Deflects false negatives where no human cells are present
  - Sample Processing Control (SPC), ensures the sample was correctly processed
  - Probe Check Control (PCC), monitors reagent preparation and system in each and every cartridge

# Comprehensive

Analytical Inclusivity of the Xpert® CT/NG Assay was determined using the fifteen *Chlamydia trachomatis* (CT) serovars, 30 known CT positive clinical specimens, eleven urine specimens known to be positive for the new variant CT (nvCT) and a total of 50 *Neisseria gonorrhoeae* (NG) strains.

**ANALYTICAL SENSITIVITY (LIMIT OF DETECTION)***

**Limit of Detection of two CT serovars and two NG strains in Vaginal/Endocervical and Urine matrix backgrounds**

| | | *LoD 95% Confidence Interval* | | |
|---|---|---|---|---|
| *Organism* | *Matrix* | *LowCI* | *LOD estimate* | *UpperCI* |
| ***Chlamydia trachomatis serovar* D Eb/mL** | Vaginal/Endocervical | 6.8 | 8.0 | 11.4 |
| | Urine | 5.8 | 7.3 | 10.4 |
| ***Chlamydia trachomatis serovar* H Eb/mL** | Vaginal/Endocervical | 0.9 | 1.2 | 1.9 |
| | Urine | 1.0 | 1.4 | 3.0 |
| ***Neisseria gonorrhoeae* ATCC19424 cfu/mL** | Vaginal/Endocervical | 1.0 | 1.3 | 2.1 |
| | Urine | 1.5 | 2.0 | 4.0 |
| ***Neisseria gonorrhoeae* ATCC49226 cfu/mL** | Vaginal/Endocervical | 1.2 | 1.5 | 2.1 |
| | Urine | 0.8 | 1.1 | 1.9 |

**The 95% confidence interval for the analytical limit of detection (LoD) of this assay is defined as the lowest number of colony forming units (CFU) or elementary bodies (Ebs) per mL that can be reproducibly distinguished from negative samples with 95% confidence. Two NG strains, ATCC 19424 and ATCC 49226 and two CT serovars, D and H, were each tested in urine and vaginal/endocervical matrix backgrounds. Replicates of 20 were evaluated at six concentrations and the LoD was estimated by logistic regression. LoD was confirmed for the remaining CT serovars (A–C, E–G, I, J, LGV I–III) were detected at 10 –30 Ebs/mL, and for 30 additional NG strains at 1.5 –2 cfu/mL.*

**WORKFLOW:**

# 3 Easy Steps

## Total hands-on time: <1 Minute

**1**

Obtain either Urine or Swab samples previously stored in the Cepheid Transport Reagent

**2**

Transfer the sample to the cartridge

**3**

Insert cartridge and start assay

## Xpert® CT/NG is a qualitative real-time PCR test for automated and rapid detection of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG)

**CATALOGUE INFORMATION**

Xpert® CT/NG (10 tests) ..... GXCT/NG-CE-10

**SPECIMEN COLLECTION KITS REQUIRED (50 READY-TO-USE INDIVIDUAL KITS)**

Self-Collection Vaginal/Endocervical ..... CT/NGSWAB-50

Urine ..... CT/NGURINE-50

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