

Xpert[®]
CT/NG

Xpert[®]
TV

Don't Risk It.

 **Xpert[®] CT/NG & Xpert[®] TV**

Fast and Accurate Diagnosis of Chlamydia,
Gonorrhea, and Trichomoniasis.

 **Cepheid[®]**
A better way.



Xpert[®] CT/NG & Xpert[®] TV

On-demand STD results. You **want** it. They **need** it.

The majority of *Trichomonas vaginalis* (TV), *Chlamydia trachomatis* (CT), and *Neisseria gonorrhoeae* (NG) infections are **asymptomatic**.¹

→..... The Need

Trichomoniasis, chlamydia, and gonorrhea are the three most prevalent, treatable STDs in the U.S. If left untreated, complications can include infertility, pelvic inflammatory disease, pregnancy complications, and increased risk of HIV acquisition.¹

CDC recommends:¹

- Annual CT/NG screening of all sexually active women under 25
- Screening of other at-risk individuals including MSM*
- Testing for chlamydia, gonorrhea, & trichomoniasis using NAATs[^] (PCR)
- Same-day testing and treatment

→.... The Solution

- Accurate on-demand PCR results are ready when you need them
- On-demand and in-visit results reduce patient call-backs, overtreatment, undertreatment and patients lost to follow-up
- Patient collected specimens can create operational efficiencies
- Same patient sample can be utilized for all tests

→..... The Impact

Provide fast patient results to:

- Lessen patient anxiety with immediate results
- Improve patient satisfaction
- Prevent disease spread in the community
- Reduce unnecessary use of antibiotics



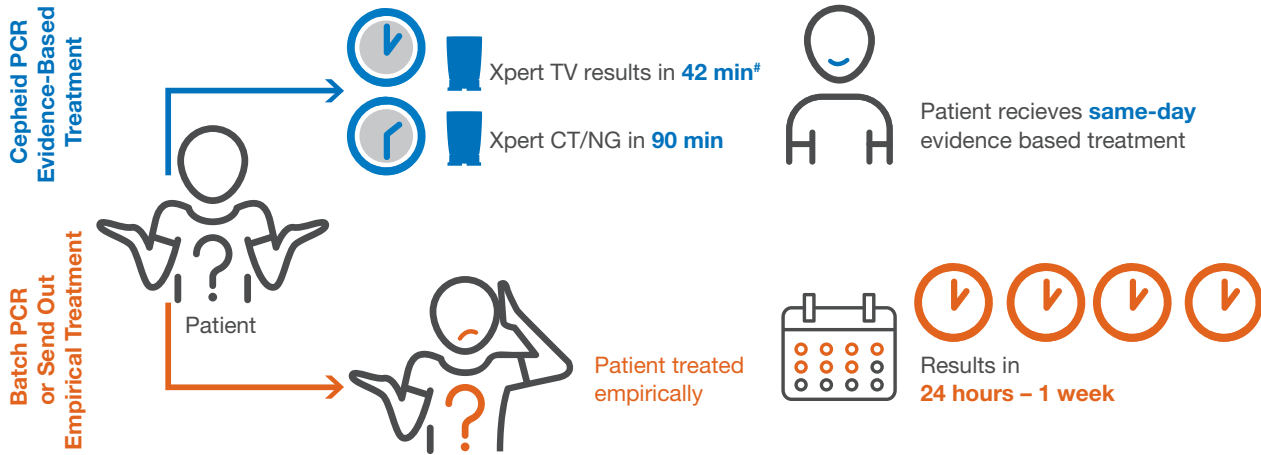
NAATs are recognized as the most sensitive testing option for CT, NG & TV, often detecting **3-5x more** TV than wet-mount microscopy.¹

* MSM – men who have sex with men
[^] NAAT – nucleic acid amplification test

Impact on Patient Pathway

Improving patient satisfaction

Xpert® CT/NG and Xpert® TV provide medically actionable information to clinicians to enable same-day treatment for chlamydia, gonorrhea, and trichomoniasis



Xpert CT/NG & Xpert TV

On-demand results for CT/NG or TV in 90 minutes or less

All specimen types are cleared for **asymptomatic and symptomatic** patients

→ **Rectal and pharyngeal swabs** now available for use with Xpert CT/NG

Xpert TV is the **first and only** NAAT cleared for **male and female urine**

Clinical Performance[†]

| | Xpert CT/NG | | Xpert TV | Xpert CT/NG | | Xpert TV |
|---|-------------|--------|----------|-------------|-------|----------|
| | CT | NG | TV | CT | NG | TV |
| ♀ Patient Collected Vaginal Swab | | | | | | |
| Sensitivity | 99.5% | 100% | 98.9% | | | |
| Specificity | 99.1% | 99.9% | 98.9% | | | |
| ♀ Endocervical Swab | | | | | | |
| Sensitivity | 96.0% | 100% | 98.9% | | | |
| Specificity | 99.6% | >99.9% | 98.9% | | | |
| ♂ Male Urine | | | | | | |
| Sensitivity | | | | 98.5% | 98.3% | 89.6% |
| Specificity | | | | 99.8% | 99.0% | 99.3% |
| ♂♀ Pharyngeal Swab | | | | | | |
| Sensitivity | | | | 95.9% | 94.7% | |
| Specificity | | | | 99.7% | 98.8% | |
| ♂♀ Rectal Swab | | | | | | |
| Sensitivity | | | | 86.0% | 91.2% | |
| Specificity | | | | 99.4% | 99.6% | |

Early assay termination (EAT) for positive results.

† All performance results at 95% confidence interval. For details refer to Package insert. Pharyngeal and rectal swabs are only FDA-cleared for use with Xpert CT/NG.

Simple Implementation into Existing Workflows

As simple as 1, 2, 3 – Hands-on time < 1 min

1
Obtain either urine or swab samples stored in the Cepheid Transport Reagent



2
Transfer sample to cartridge



3
Insert cartridge and start test



➤ **Xpert® CT/NG** is on-demand detection and differentiation of *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (NG)

| | | |
|-------------------------------|---------------------|-------------|
| Xpert CT/NG (10 tests) | CATALOG INFORMATION | GXCT/NG-10 |
| Xpert CT/NG (120 tests) | | GXCT/NG-120 |

➤ **Xpert® TV** is on-demand *Trichomonas vaginalis* (TV) testing for men and women

| | | |
|---------------------------|---------------------|---------|
| Xpert TV (10 tests) | CATALOG INFORMATION | GXTV-10 |
|---------------------------|---------------------|---------|

SPECIMEN KITS REQUIRED FOR PRIMARY SAMPLE COLLECTION AND TREATMENT:

| | | |
|--|---------------------|------------|
| Xpert® Swab Specimen Collection Kit (50 tests ready-to-use individual kits) | CATALOG INFORMATION | SWAB/G-50 |
| Xpert® Urine Specimen Collection Kit (50 tests ready-to-use individual kits) | | URINE/A-50 |

➤ **CPT Code Information**

| TEST NAME | DESCRIPTION | CPT CODE |
|--------------|--|------------------|
| Xpert® CT/NG | <i>Chlamydia trachomatis</i> , amplified probe technique | CT: 87491 |
| | <i>Neisseria gonorrhoeae</i> , amplified probe technique | NG: 87591 |
| Xpert® TV | <i>Trichomonas vaginalis</i> , amplified probe technique | 87661 |

Reference:

1. Workowski KA, et al. Sexually transmitted diseases treatment guidelines, 2015. MMWR Recomm Rep. 2015 Jun 5;64(RR-03):1-137.

For *In Vitro* Diagnostic Use.

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