



Xpert[®]
CT/NG

Detect it in here. Stop it out there.

Xpert[®] CT/NG

The only test for same-day consultation
and treatment.

 **Cepheid.**
A better way.



*An on-demand test capable of delivering accurate results while patients are still present in the clinic provides a much-needed advantage in our efforts to control infectious diseases such as chlamydia and gonorrhea. Delays in treatment can lead to complications in about 1 in 25 infected women awaiting test results. In addition, the availability of results in less than **90 minutes** is especially important for patients presenting to Emergency Departments and in managing patients who may not return for treatment.”*

Dr. Edward W. Hook III

Professor of Medicine and Epidemiology at the University of Alabama, Birmingham, and Director of the STD Control Program for the Jefferson County Department of Health



THE NEED

According to the Centers for Disease Control (CDC), Chlamydia (CT) and Gonorrhea (NG) are the most commonly reported sexually transmitted diseases (STDs). If left untreated, complications can include pelvic inflammatory disease, infertility, proctitis, urethritis, complications during pregnancy, and infections in newborns.

The 2015 updated CDC guidelines now recommend the following:

- Women: Annual CT/NG screening of women under 25 or older women with risk factors. Patients with positive results should be retested after 3 months
- Heterosexual Men: CT screening should be considered in high prevalence settings
- MSM: CT/NG nucleic acid amplification testing (NAAT) is recommended

NAATs are recognized by the CDC as the most sensitive tests.¹

What would help laboratories offering CT/NG testing?

- Accurate, reliable, and reproducible tests
- Fast test results for immediate patient treatment
- Less time preparing samples and reagents
- More test choices, fewer platforms



THE SOLUTION

Healthcare staff in moderate complexity environments can run a CT/NG test with minimal training. Each test cartridge contains everything you need, including three controls to ensure test integrity and performance. With Xpert® CT/NG's fast results in 90 minutes, same day diagnosis and treatment are possible for immediate patient care.

On-demand CT/NG testing — a next generation solution:


- Sample adequacy control confirms patient sample is genuine
- CT target unique to Cepheid; selected for superior inclusivity
- Double your confidence with two independent NG targets
- Broader menu of tests
- The GeneXpert® System handles a range of testing— from low volume to high volume




CLINICAL PERFORMANCE*

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


Patient Collected Vaginal Swabs

| | CT | NG |
|---|-------|-------|
|  Sensitivity | 99.5% | 100% |
| Specificity | 99.1% | 99.9% |

Urine

| | CT | NG |
|---|-------|--------|
|  Sensitivity | 98.1% | 94.4% |
| Specificity | 99.8% | >99.9% |

Endocervical Swabs

| | CT | NG |
|---|-------|--------|
|  Sensitivity | 96.0% | 100% |
| Specificity | 99.6% | >99.9% |

Urine

| | CT | NG |
|---|-------|-------|
|  Sensitivity | 98.5% | 98.3% |
| Specificity | 99.8% | 99.9% |

* All performance results at 95% confidence interval. For details, refer to Package Insert.



IMPACT ON LABORATORY

One Platform for Multiple Tests

| | CT/NG | GBS | GBS LB | TV | Flu | MRSA | C. difficile |
|------------|---|--|---|--|---|---|---|
| GeneXpert® |  |  | | | | | |
| Hologic |  |  | — |  |  | — |  |
| BD |  |  |  |  | — |  |  |
| Roche |  | — | — | — |  |  | — |



WORKFLOW:

3 EASY STEPS

Total hands-on time: <1 Minute

1

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



2

Transfer the sample to the cartridge



3

Insert cartridge and start test



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

CATALOG INFORMATION

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

SPECIMEN KITS REQUIRED FOR PRIMARY SAMPLE COLLECTION AND TREATMENT:

| | |
|---|------------|
| Xpert Vaginal/Endocervical Specimen Collection Kits (50 ready-to-use individual kits) | SWAB/A-50 |
| Xpert Urine Specimen Collection Kits (50 ready-to-use individual kits) | URINE/A-50 |

Reference:

1. Workowski KA, Bolan G. CDC. Sexually Transmitted Diseases Treatment Guidelines, 2015. MMWR Recomm Rep 2015;64(No.3):72.

For In Vitro Diagnostic Use.

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