The lab's crucial role in CT/NG screening and detection

*How Roche **cobas**® CT/NG testing equips your lab to meet the demand of a growing epidemic*

The lab acts as a sentinel for the community, with reported test results providing a clear picture of population health, such as prevalence of various disease states, high-risk age groups and segments, and more. That makes having the correct assays and analyzers crucial to not only accurately detect disease in patients, but also aid clinicians in prescribing the right course of action and treatment. What's more, having accurate results — particularly among high-risk population segments and in low- to high-prevalence areas — helps guide the Centers for Disease Control and Prevention (CDC) screening recommendations for various diseases.

This vigilance is especially crucial when it comes to sexually transmitted infections (STIs) in general, and chlamydia and gonorrhea in particular.

TABLE OF CONTENTS

The burden: Chlamydia and gonorrhea on the rise

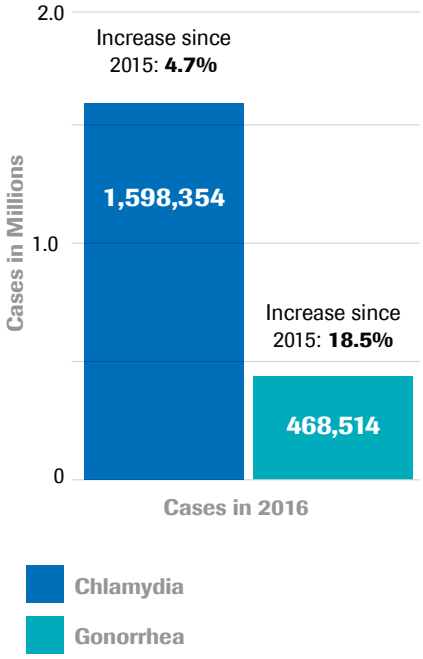
Since 2015, the number of *Chlamydia trachomatis* (CT) cases in the United States has increased by 4.7 percent, reaching 1,598,354 last year.[1] And those are just the instances reported to the CDC. That makes CT the most common of the notifiable STIs in the country, a startling statistic given that chlamydia tends to be asymptomatic[2] — that means the statistics might not reflect the true burden of infection. When CT is left untreated, infection can result in ectopic pregnancy, chronic pelvic pain and pelvic inflammatory disease (PID), a major cause of infertility. Infection present during pregnancy can be passed on to the infant during delivery and may result in blindness and pneumonia.

The rate of reported gonorrhea cases is also on the rise, experiencing a year-over-year increase for more than a decade and ultimately reaching 468,514 in 2016.[3] As with chlamydia, infection with *Neisseria gonorrhoeae* (NG) tends to be asymptomatic. When symptomatic, in men, infection may result in dysuria, a white, yellow or green urethral discharge, or testicular or scrotal pain.[4] In women, symptoms tend to be mild or nonspecific, resulting in a diagnosis of infection in the bladder or vagina. However, regardless of the severity of symptoms, women with gonorrhea are at risk of developing serious complications, including PID. Untreated gonorrhea or chlamydia can also increase a person's risk of acquiring or transmitting human immunodeficiency virus (HIV).[5,6]

The dangers of undiagnosed sexually transmitted infections (STIs), such as chlamydia and gonorrhea, are profound, causing 24,000 women to become infertile each year. In fact, of new infections among young adults, it is estimated that only 35 percent of gonorrhea cases and 56 percent of chlamydia cases are actually diagnosed and reported.[7] What makes this finding even more worrisome is the disproportionate distribution of the infections among age groups. The CDC estimates that adolescents and adults (ages 15 to 24) account for just over 25 percent of the sexually active population, but make up half of the STIs in the United States each year. These young adults are at greater risk due to the lack of access to sufficient screening and healthcare, concerns with confidentiality, biological susceptibility of young women to STIs, and high-risk behavior such as multiple sexual partners.

CT/NG in the United States

The number of reported cases of chlamydia and gonorrhea in the United States is on a steady year-over-year incline, making screening programs, adaquate testing, diagnosis and treament crucial to population health.



Source: Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2016.* Atlanta: U.S. Department of Health and Human Services; 2017.

Beyond the social stigma and long-term health consequences of STIs, the economic burden of these infections is staggering. The total direct medical cost of the eight major STIs (chlamydia, gonorrhea, hepatitis B virus [HBV], herpes simplex virus type 2 [HSV-2], human immunodeficiency virus [HIV, human papillomavirus [HPV], syphilis and trichomoniasis) was $15.6 billion in 2010, with 19.7 million reported cases.[8,9]

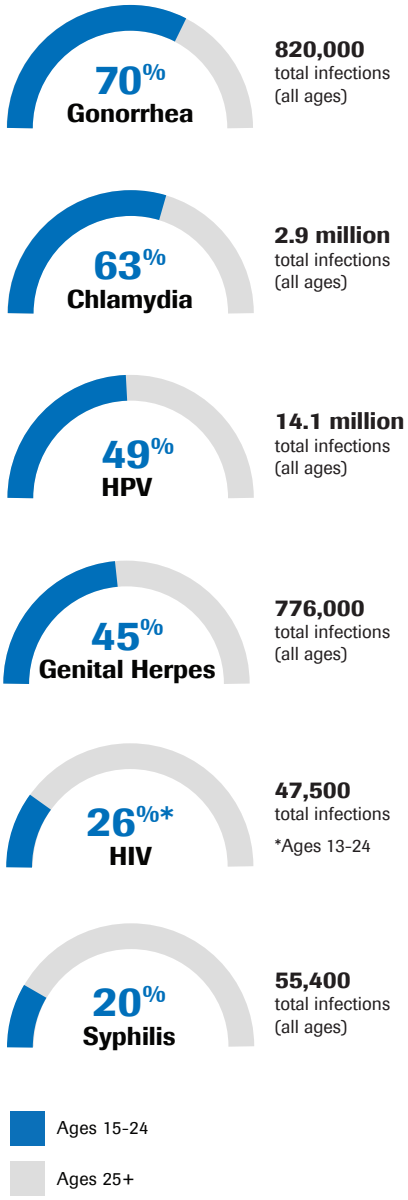
The billions spent each year don't reflect the indirect costs — lost productivity, psychological and emotional injury caused by PID, chronic pelvic pain, infertility or ectopic pregnancy — of such a diagnosis.[10] Moreover, the tangible and intangible costs account for a substantial portion of the total economic burden of disease and highlight the need for programs aimed at prevention and effective screening, diagnosis and treatment.

A costly condition

The CDC calculated that the eight most common STDs resulted in a total direct medical cost of $15.6 billion in 2010.

STI prevalence in young people

In the United States, adolescents and young adults account for a substantial proportion of new sexually transmitted infections.



Source: Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2016.* Atlanta: U.S. Department of Health and Human Services; 2017.

Screening programs are essential to reducing prevalence

Given the short- and long-term health risks for patients who go undiagnosed, adequate screening is imperative to population health. CT and NG are the two most common notifiable communicable diseases in the United States. Because the majority of these infections are asymptomatic, most infected individuals remain unaware of the disease, potentially spreading it to others.

The CDC updated its guidelines for the screening and treatment of sexually transmitted diseases in 2015,[11] highlighting the need for routine risk assessment to identify, screen and diagnose symptomatic and asymptomatic individuals infected or at risk for infection with STIs. For chlamydia and gonorrhea, it is recommended that all sexually active women younger than 25 years of age, and those older than 25 years of age if at risk, be tested, and then retested approximately three months after treatment.

CDC screening recommendations for women

Population	*C. trachomatis*	*N. gonorrhoeae*
<25 years	If sexually active	If sexually active
≥25 years	If at risk	If at risk
Pregnant	First prenatal visit if <25 and older women at risk Retesting in third trimester if <25 at risk Retested if positive 3-4 weeks after treatment and then retested within 3 months	First prenatal visit if <25 and older women at risk Retesting in third trimester if <25 at risk Retested if positive within 3 months

Among pregnant women, the CDC recommends those younger than 25 years of age, or those at risk, be tested at the onset of the pregnancy, and again during the third trimester. Among men, screening should be considered for young men in high-prevalence clinical settings or those with a high burden of risk, such as men who have sex with men (MSM). Men in this risk group should be tested at least annually, or every three to six months, depending on risk.[12] In addition, the growing availability of urine testing and extragenital testing has resulted in an increased number of chlamydial-infection testing and diagnoses for this group.[13]

Due to the high pervasiveness and the significant consequences associated with chlamydia, the Healthcare Effectiveness Data and Information Set (HEDIS) specifically contains a measure that assesses chlamydia screening coverage of sexually active young women who receive medical care through commercial or Medicaid managed care organizations.[14] Despite these measures, many women who are at risk for chlamydia are still not being tested — reflecting the need for increased awareness among healthcare providers and patients. Such screening initiatives have been shown to lead to a reduction in the incidence of PID, and tend to target young adult women, a high-risk group for chlamydia and gonorrhea.[15,16]

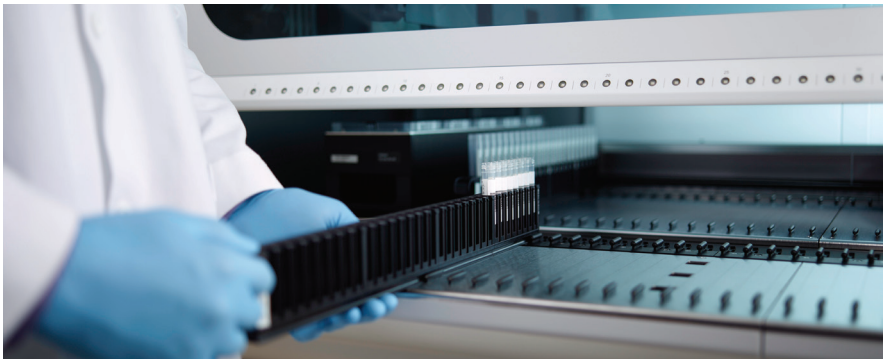
Source: Workowski, K.A. and G.A. Bolan. (2015). Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep* 64(3).

Testing technologies

In 2014, the CDC revised its recommendations regarding screening tests and technologies to detect CT and NG infections.[17] Direct detection of the pathogen can be performed using culture or nonculture methods. Culture for CT and NG had long been held as the reference standard against which all other diagnostic tests were compared. Multiple issues with cultures (including the need for viable organisms, transport and storage, difficulty in standardizing tissue culture methods for CT, technical demands, costs and lack of sensitivity of cultures) left a necessity for testing that could overcome these barriers.[18]

That's where nucleic acid amplification tests (NAATs) come in. NAATs are based on the amplification of specific nucleic acid target sequences — in this case, CT-specific or NG-specific sequences.[19] With the ability to specifically amplify sequences directed to bacterial species of choice, NAATs have led to a significant increase in sensitivity compared to conventional methods.

This high level of sensitivity is the reason NAATs are now used routinely in CT/NG screening.[20] NAATs have greater accuracy in detecting an active infection than serologic tests that detect a systemic immune response.[21] They also allow for a more rapid diagnosis with ease of specimen collection and transport.



These attributes are the reason why NAATs are the only nonculture tests recommended for routine use.[22]

Note that available NAATs differ in their amplification techniques and the nucleic acid sequence they target.

- **Becton Dickinson ProbeTec CT Q^x Amplified DNA Assay and ProbeTec GC Q^x Amplified DNA Assay** — Strand displacement amplification (SDA) is an isothermal process that utilizes DNA polymerase, a restriction enzyme and a series of primers to exponentially amplify the unique nucleic acid sequence. There are two phases or segments in SDA: a target generation phase and exponential amplification. However, the primers used for NG testing have issues with cross-reactivity, and may detect nongonococcal *Neisseria* species.[23]

- **Hologic/Gen-Probe Aptima Combo 2** — Uses transcription-mediated amplification (TMA) to detect a specific 23S ribosomal RNA (rRNA) target.[23] TMA is an isothermal amplification test that uses RNA polymerase and reverse transcriptase to amplify target RNA.[24] It is a single-tube test using two enzymes with a reaction that is directed against rRNA.

- **Abbott RealTime CT/NG** — Uses real-time PCR. Unlike other NAATs, PCR relies on cycles of denaturing and new DNA synthesis to amplify DNA segments.[25]

- **Roche Diagnostics cobas CT/NG** — Uses real-time PCR. The Roche assay is also the only test with dual targets for CT & NG with an internal control.

Polymerase chain reaction (PCR) is a quick, easy way to create unlimited copies of DNA from a single original strand. One of the most important scientific advances of the 20th century,[26] PCR was awarded the Nobel Prize in Chemistry in 1993. Roche Molecular Diagnostics remains the leader and trailblazer of this technology today.

NAATs comparison

Below is an overview of the five major NAATs commercially available and FDA-cleared for the detection of CT and NG, along with their target sequences and possible false reactions and cross-reactivity.

FDA-CLEARED NAAT	NUCLEIC ACID TARGET FOR CT	NUCLEIC ACID TARGET FOR NG	INTERNAL CONTROLS	CONTAMINATION CONTROL
Abbott RealTime CT/NG	Two distinct, specific sequence regions within cryptic plasmid DNA The test does not detect plasmid-free CT No cross-reactivity based on analytical specificity testing	48 base pair sequences No cross-reactivity based on analytical specificity testing	Noninfectious linearized DNA plasmid in a buffer solution	None
Becton Dickinson ProbeTec CT Q^x Amplified DNA Assay **ProbeTec GC Q^x Amplified DNA Assay**	One distinct sequence within cryptic plasmid DNA The test does not detect plasmid-free CT No cross-reactivity based on analytical specificity testing	Chromosomal pilin gene-inverting protein homologue *N. cinerea* and *N. lactamica* might result in cross-reactivity based on analytical specificity testing	Extraction Control (EC) oligonucleotide is labeled with a different dye than that used for detection of the CT-specific target and is used to confirm the validity of the extraction process	None Recommends the use of bleach
Hologic/Gen-Probe Aptima Combo 2	Specific region within 23S from CT (Aptima Combo 2 assay) Specific region with 16S rRNA from CT (Aptima CT assay) Both assays detect nvCT The test does not detect plasmid-free CT No cross-reactivity based on analytical specificity testing	Specific region within 16S rRNA from NG (Aptima Combo 2 assay) Specific region with 16S rRNA from NG that is distinct from the Aptima Combo 2 assay target (Aptima GC assay) No cross-reactivity based on analytical specificity testing	None	None Recommends the use of bleach
Roche Diagnostics cobas CT/NG testing	CT primers define a sequence of approximately 206 nucleotides within the cryptic plasmid DNA CT primers CTMP101 and CTMP102 define a sequence of approximately 182 nucleotides within the chromosomal DNA No cross-reactivity based on analytical specificity testing The test detects plasmid-free CT, all 14 serovars, cryptic plasmid and plasmid-less strains	NG primers NG514 and NG519 define a sequence of ~190 nucleotides to define a second sequence of approximately 215 nucleotides No cross-reactivity based on analytical specificity testing	**cobas CT/NG v2.0 Test** Two non-infectious recombinant plasmid DNAs, each with primer binding regions identical to those of either the CT or the NG genomic target sequences **cobas CT/NG** Selective amplification of DNA-IC is achieved by the use of sequence-specific forward and reverse primers which are selected to have no homology with either the CT or NG target regions.	AmpErase® enzyme

Sources: Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMWR* 63(2). Abbott RealTime CT/NG IFU 8L07-91, 51-608362/R1. ProbeTec™ Chlamydia trachomatis (CT) Q^x Amplified DNA Assay PI 8081408(05) 2015-08. **cobas** CT/NG v2.0 Test IFU 01/2017 07127553001-09 Doc Rev. 9.0. **cobas** CT/NG for the **cobas** 6800/8800 IFU 04/2018 07998007001-01EN, Doc Rev. 1.0

FDA-cleared specimen types

Across NAATs, approved specimen types for CT/NG testing vary.
Here's an at-a-glance chart comparing approved types for each assay.

		SPECIMEN TYPES: FEMALE						SPECIMEN TYPES: MALE	
TEST		**Endo-cervical**	**Clinician-collected vaginal**	**Patient-collected vaginal**	**Urine**	**Gynecological specimens collected in PreservCyt**	**Gynecological specimens collected in SurePath**	**Urethral swabs**	**Urine**
Abbott RealTime CT/NG	Asymptomatic		●	●	●				●
	Symptomatic	●	●	●	●			●	●
Becton Dickinson ProbeTec CT Q^{x} and ProbeTec GC Q^{x} Amplified DNA Assay	Asymptomatic	●		●	●	● prior to processing*	● prior to processing*	●	●
	Symptomatic	●		●	●	● prior to processing*	● prior to processing*	●	●
Hologic/ Gen-Probe Aptima Combo 2	Asymptomatic	●	●	●	●	● pre- and post-cytology**		●	●
	Symptomatic	●	●	●	●	● pre- and post-cytology**		●	●
Roche Diagnostics **cobas** CT/NG testing	Asymptomatic	●	●	●	●	● v2.0, pre- and post-cytology ● 6800/8800, pre-cytology			●
	Symptomatic	●	●	●	●	● v2.0, pre- and post-cytology ● 6800/8800, pre-cytology			●

*An aliquot is transferred to a Liquid-Based Cytology Specimen (LBC) Dilution Tube

**1 mL of PreservCyt is transferred to an Aptima Specimen Transfer Tube

Sources: Abbott: RealTime CT/NG Test Package Insert, 8L07-91, 51-608362/R1, July 2010, REF-06712. Becton Dickinson: ProbeTec™ CT Q^{x} Amplified DNA Assay Package Insert, 8081408(05) 2015-08, REF-06959; ProbeTec™ NG Q^{x} Amplified DNA Assay Package Insert, 8081409(04) 2015-08, REF-06990. Hologic: APTIMA Combo 2® Assay (Panther® System) Package Insert, 502446-IFU-PI_004_01_June 2018 REF-09502; APTIMA Combo 2® Assay (Tigris / DTS system) Package Insert, 501798 Rev 002 2017-03, REF-08314. Roche: **cobas** CT/NG v2.0 Test IFU 01/2017 07127553001-09 Doc Rev. 9.0. **cobas** CT/NG for the **cobas** 6800/8800 IFU 04/2018 07998007001-01EN, Doc Rev. 1.0

Put to the test: Sensitivity and specificity

While each NAAT assay is used to diagnose the same disease state, they each vary in sensitivity and specificity — two very important performance criteria that determine the performance and impact of false positive and false negative results. Roche conducted one of the largest screening trials for chlamydia and gonorrhea. The VENUS trial (Vaginal, Endocervical and Urine Screening Trial for CT/NG) evaluated the **cobas** CT/NG v2.0 Test through 18 collection sites (OB/GYN, family planning and STI clinics) and seven testing facilities. Enrolled in the study were 6,045 men and women, including 202 evaluable pregnant women, a critical screening population, according to the CDC. Results from the study indicated excellent clinical sensitivity and specificity across all specimen types, regardless of the prevalence of infectious agent.[27]

Designed for sensitivity, the test is the only assay with dual targets for CT, NG and the internal control to minimize the risk of false negative results and ensure accuracy — results aren't affected by disease prevalence in the community. The dual targets allow inclusivity across all major types of that specific target — the more targets added, the better the inclusivity, which also leads to improved specificity.

Furthermore, the internal control is automatically added to every reaction to prove that amplification took place, thus helping to ensure that a negative reaction is truly a negative result.

The VENUS Trial: Sensitivity and specificity across all specimen types in cobas CT/NG v2.0 Test

SAMPLE TYPE	CT			NG		
	N	Sens %	Spec %	N	Sens %	Spec %
Endocervical Swab	2,926	**94.9%**	**99.4%**	5,104	**96.6%**	**99.9%**
Female Urine	2,945	**94.0%**	**99.6%**	5,127	**95.6%**	**99.7%**
Vaginal Swab (Clinician-collected)	1,902	**98.2%**	**99.1%**	3,138	**100.0%**	**99.7%**
Vaginal Swab (Self-collected)	2,037	**97.6%**	**99.3%**	2,037	**96.7%**	**100.0%**
PreservCyt (Pre-ThinPrep)	2,937	**94.2%**	**99.7%**	5,131	**96.7%**	**99.9%**
PreservCyt (Post-ThinPrep)	2,878	**93.7%**	**99.5%**	4,868	**95.6%**	**99.7%**
Male Urine	738	**98.4%**	**99.2%**	738	**100.0%**	**99.3%**

Source: cobas CT/NG v2.0 Test Package Insert, v9 2017.

Sensitivity and specificity across all specimen types in cobas CT/NG Test on cobas 6800/8800

For laboratories that require a high-throughput system, **cobas**® CT/NG for use with the **cobas**® 6800/8800 systems provides a **moderate complexity** test that is highly sensitive and specific.

SAMPLE TYPE	CT Overall Performance			NG Prospective & Archived Performance		
	N	Sens %	Spec %	N	Sens %	Spec %
Endocervical Swab	3,843	**93.3%**	**99.4%**	3,948	**97.0%**	**99.9%**
Female Urine	3,859	**95.6%**	**99.7%**	4,054	**94.8%**	**99.9%**
Vaginal Swab (Clinician-collected)	1,936	**98.6%**	**99.1%**	1,936	**100%**	**99.7%**
Vaginal Swab (Self-collected)	1,906	**99.2%**	**99.0%**	1,907	**100%**	**99.7%**
PreservCyt (Pre-ThinPrep)	3,851	**92.5%**	**99.6%**	3,922	**96.6%**	**99.9%**
Male Urine	1,192	**100%**	**99.7%**	1,192	**100%**	**99.5%**

A total of 5,197 subjects were prospectively enrolled, of which 5,105 were eligible for inclusion. Of the 5,105 eligible subjects contributing prospective specimens, 5,053 (99.0%) (3,860 females and 1,193 males) were evaluable and were included in the data analyses. Note: Archived prospectively collected specimens were from COB-CTNG-282 study and included female PIS positive subjects that have available sample with adequate volume for testing.

Source: cobas CT/NG for the **cobas** 6800/8800 IFU 04/2018 07998007001-01EN, Doc Rev. 1.0

Beyond the design features of the **cobas** CT/NG Test (i.e., internal control and dual targets), there is the inclusion of the AmpErase® enzyme. AmpErase reduces the risk of false positive results from carryover contamination by differentiating amplification products from target molecules. It also removes the burden for decontamination with bleach off the user.

All three features — unique to the assay — minimize false positive and false negative results, delivering confidence because the **cobas** CT/NG Test is designed with layers of safeguards to help ensure accurate results.

"The multi-tiered strategy of placing engineering controls, chemical controls and laboratory workflow controls is essential and absolutely minimizes the risk for contamination."

— Nathan Ledeboer, Ph.D.,
Associate Professor of Pathology,
Medical College of Wisconsin,
Medical Director of Clinical Microbiology,
Wisconsin Diagnostic Laboratories
and Froedtert Hospital

Built-in process control with the cobas CT/NG Test

Proper quality control is a daily requirement for CAP and CLIA laboratories. Three layers of control are monitored with each individual run.

Positive control:
Plasmids encoding both CT and NG wild-type targets are automatically added to each run, controlling for potential system inhibition.

Negative control:
Buffered solution without plasmids is automatically added to each run, controlling for potential system contamination.

Internal control:
The Internal Control, used to monitor the entire sample preparation and PCR amplification process, is introduced into each specimen during sample processing.

Source: CAP 2016 Microbiology Checklist: MIC.63262, Daily QC. 08/17/2016. CLIA Equivalent QC Procedures: http://www.cms.gov/RegulationsandGuidance/Legislation/CLIA/Downloads/6066bk.pdf.

Delivering value through productivity

When implementing the recommendations for screening and testing of STIs, laboratories may have to overcome specific hurdles of space, cost and workflow to accommodate the latest automated diagnostic systems. Factors to be taken into account when selecting a system for a laboratory include menu, assay performance, reagent costs, methodology, complexity/ease of use, system capacity for reagent storage and throughput, maintenance and workflow. Comparative workflow studies for these systems provide quantifiable and objective metrics that may assist in determining hands-on time during specimen handling and processing, reagent preparation, return visits and maintenance, and test turnaround time and throughput. Furthermore, laboratories must take into account on an individual basis the complexity of the system, potential demand for specialized or trained personnel, and the need for multifunctional systems.

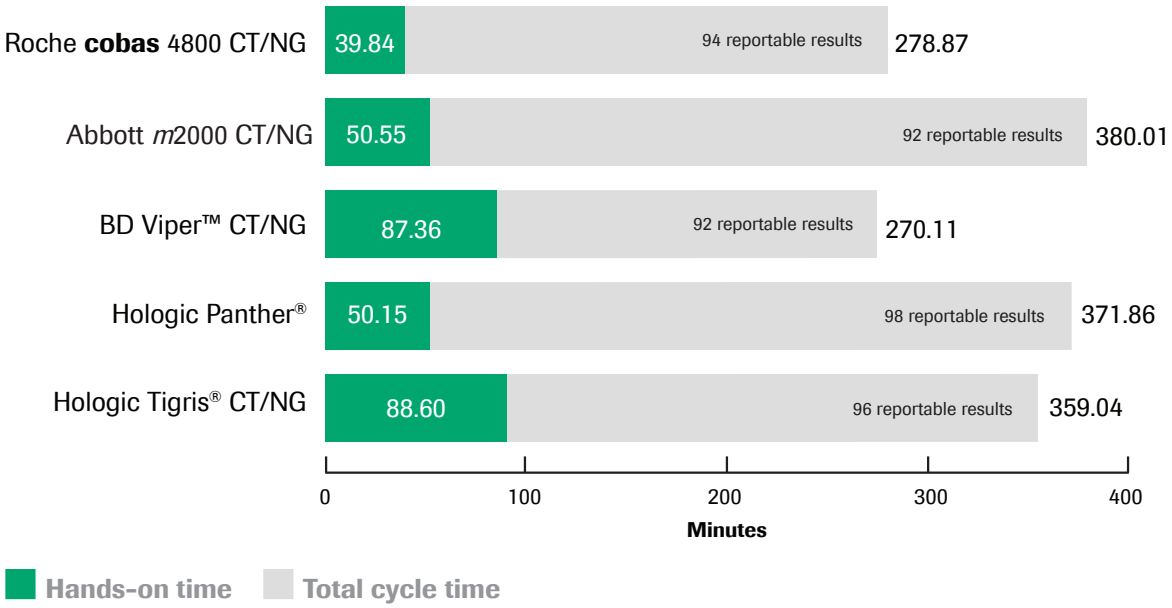
One study used objective time techniques to determine workflow characteristics for processing 96 samples (92 patient samples and four controls) each on the Abbott Molecular m2000 RealTime, Becton Dickinson Viper XTR, Roche Molecular Diagnostics **cobas** 4800, and Hologic Gen-Probe Tigris DTS and Panther platforms using second-generation assays for CT and NG. In terms of run time, the **cobas** 4800 system delivers results efficiently, with 94 reportable results in 4.6 hours, with minimal hands-on time, at just under 40 minutes.[28]

Run time: Side-by-side platform comparison

Not all platforms perform the same. Here's a rundown of hands-on time and turnaround time for each of the five major platforms.

Lowest hands-on time and faster turnaround time

*when compared to other systems**

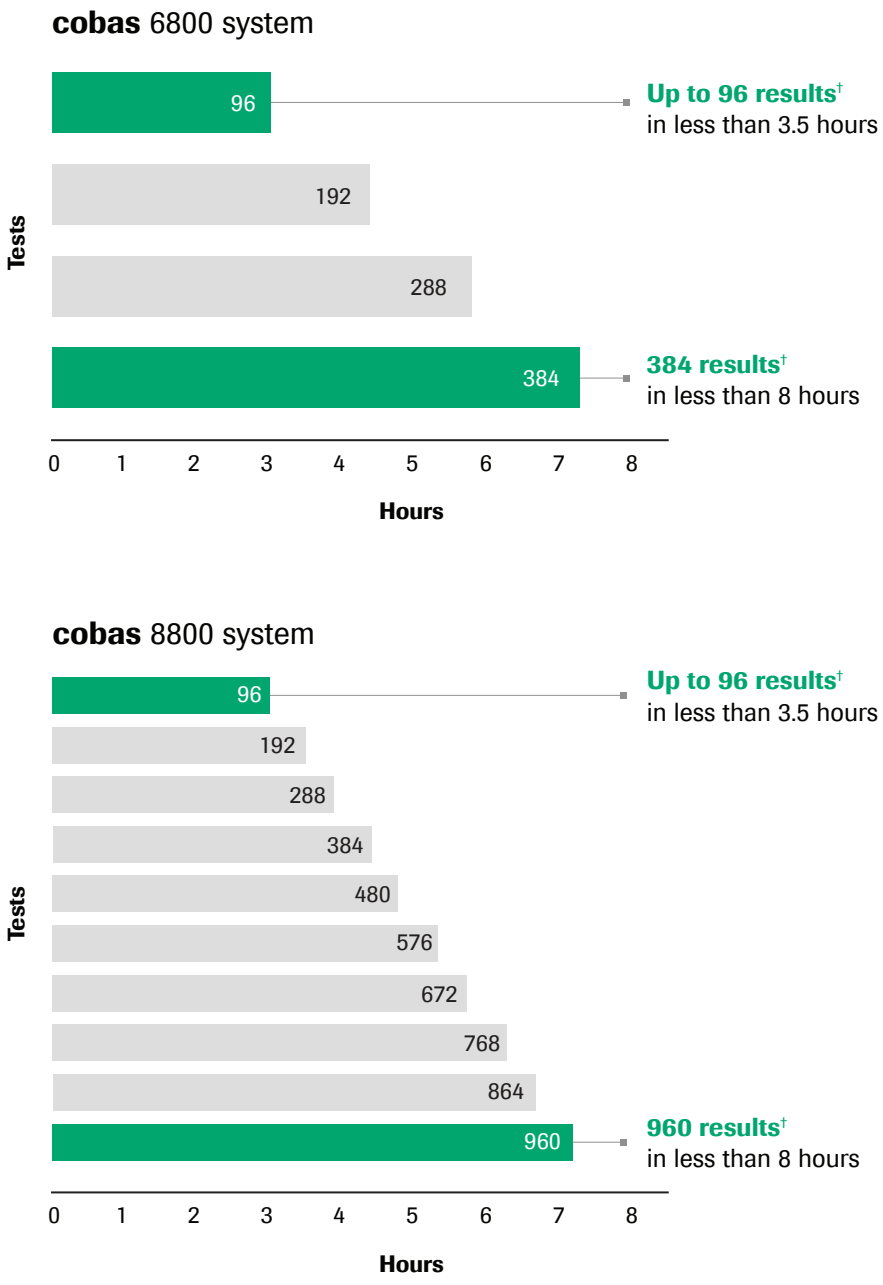


*Argent Global Services. CT/NG Comparison Study. 2012. Roche data on file.

In addition to quick run time and minimal hands-on time, the **cobas** 4800 system provides laboratories with the flexibility they need to manage daily workflow and varying throughput demands with a broad menu including CT/NG, HSV, HPV, MRSA/SA, *C. diff*, BRAF, EGFR, KRAS and Factor II/V as well as an open channel. It is the only system with primary vial loading for all specimen types: endocervical swabs, vaginal swabs (clinical or self-collected in a clinical setting), cervical specimens, and male and female urine. Along with the advantage of walk-away sample preparation, the system has low maintenance requirements — less than 10 minutes required daily or weekly and no monthly maintenance. The easy-to-use system accepts multiple primary vial formats, and its load-and-go functionality eliminates complex reagent preparation procedures. There's also no need for post-run decontamination with bleach.

The **cobas** 6800/8800 systems are built upon the innovation of the **cobas** AmpliPrep, **cobas** TaqMan® and **cobas** 4800 systems to automate the preparation and analysis of samples for both quantitative and qualitative nucleic acid testing using real-time PCR technology. These systems deliver the opportunity for true platform consolidation for HIV, HCV, HBV, CMV, CT/NG, TV/MG* and HPV* testing.

Unparalleled turnaround time and throughput



*In development. Product is not available in the United States.

Source: Lucic, D. et al. (2013). *Journal of Clinical Microbiology* 51(12):4050–4054. †May vary based on workflow demands. Roche data on file.

Both the **cobas** 6800 system and the **cobas** 8800 system are designed to handle continuous loading, allowing samples, reagents and consumables to be loaded throughout the day (including new samples) while the instruments are running. In fact, the system's on-board refrigerator has storage positions for up to 12 reagent cassettes (maximum of 5,760 CT/NG tests) and up to eight control cassettes can be stored on board. Consumables for up to 384 samples may be stored on the **cobas** 6800 system, providing eight hours of work-away time and up to 768 tests on the **cobas** 8800 system, with four hours of work-away time.

Due to relatively minimal run time, hands-on time and turnaround time, the **cobas** 4800, 6800 and 8800 systems allow for easy integration into existing laboratories and help improve workflow rather than impede progress. When paired with the **cobas** CT/NG Test, laboratories and clinicians are better equipped to meet the increasing demand for chlamydia and gonorrhea testing.

Seamless productivity with the **cobas** 6800/8800

Performance

- Throughput volume in an eight-hour shift
  - 6800: 384 tests
  - 8800: 960 tests

Automation

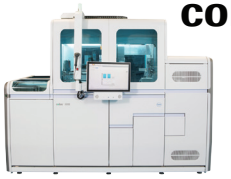
- Fully automated contamination control
- Minimal maintenance

Flexibility

- Internal controls
- Ready-to-use reagents
- Platform consolidation (HIV, HCV, HBV, CMV, CT/NG, TV/MG* and HPV*)

*In development. Product is not available in the United States.

Absolute automation, from sample tube onward



cobas 6800 system

8 hours

work-away time†

cobas 8800 system

4 hours

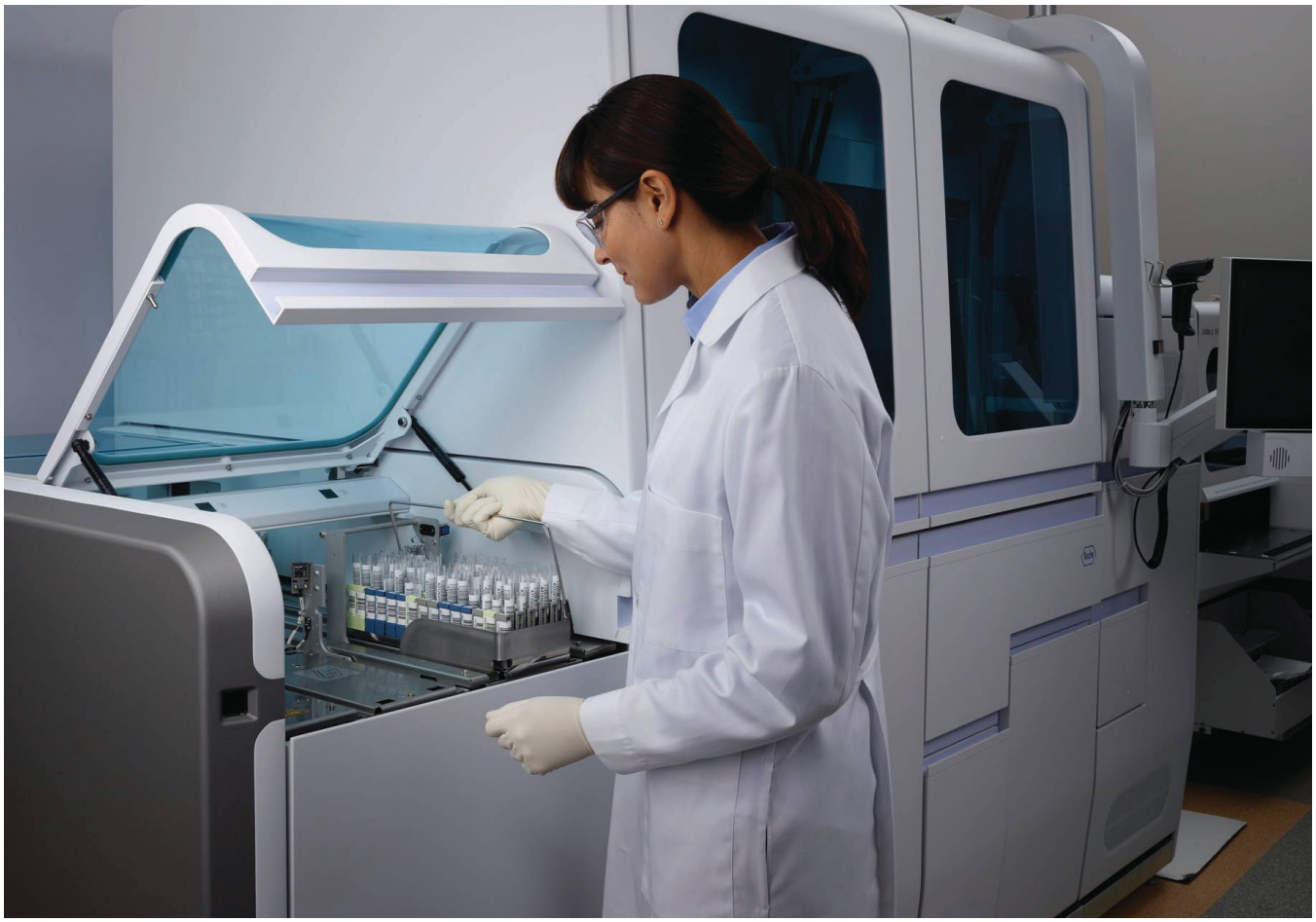
work-away time†

† May vary based on workload demands. Roche data on file.

The right test, right system, right care

With more than 1.5 million reported cases of chlamydia and nearly 500,000 reported cases of gonorrhea in 2016, it's clear that STIs affect a substantial portion of the U.S. population. The key to stemming the STI tide is twofold: (1) Educating people (particularly high-risk groups) about CDC screening recommendations and getting them tested and diagnosed, and (2) using the right assay paired with the right platform that can handle the throughput. Doing so helps encourage the adoption of and adherence to CDC recommendations for CT/NG screening and testing, ultimately leading to better diagnosis and treatment, and possibly reduced prevalence. ■

To learn more, **visit www.usdiagnostics.roche.com**



[1]"Sexually Transmitted Disease Surveillance 2016," Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2017 (accessed January 3, 2018).

[2]Chlamydia-CDC Fact Sheet, https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm (accessed January 3, 2018).

[3]"Sexually Transmitted Disease Surveillance 2016," Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2017 (accessed January 3, 2018).

[4]Gonorrhea-CDC Fact Sheet, https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm (accessed January 3, 2018).

[5]Gonorrhea-CDC Fact Sheet, https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm.

[6]Chlamydia-CDC Fact Sheet, https://www.cdc.gov/std/chlamydia/stdfact-chlamydia-detailed.htm.

[7]"Sexually Transmitted Disease Surveillance 2016," Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2017.

[8]"Sexually Transmitted Disease Surveillance 2016," Centers for Disease Control and Prevention, U.S. Department of Health and Human Services, 2017.

[9]Owusu-Edusei, K. et al. (2013). The estimated direct medical cost of selected sexually transmitted infections in the United States, 2008. *Sex Transm Dis* 40(3): 197–201.

[10]Blandford, J.M. and T.L. Gift. (2006). Productivity losses attributable to untreated chlamydial infection and associated pelvic inflammatory disease in reproductive-aged women. *Sex Transm Dis* 33(Suppl): S117–21.

[11]Workowski, K.A. and G.A. Bolan. (2015). Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep* 64(3).

[12]Workowski, K.A. and G.A. Bolan. (2015). Sexually transmitted diseases treatment guidelines, 2015. *MMWR Recomm Rep* 64(3).

[13]Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2016*. Atlanta: U.S. Department of Health and Human Services; 2017.

[14]National Committee for Quality Assurance. The state of healthcare quality 2016. http://www.ncqa.org/report-cards/health-plans/state-of-health-care-quality/2016-table-of-contents/chlamydia-screening (accessed January 3, 2018).

[15]Centers for Disease Control and Prevention. *Sexually Transmitted Disease Surveillance 2016*. Atlanta: U.S. Department of Health and Human Services; 2017.

[16]Satterwhite, C.L., E. Torrone, E. Meites et al. (2013). Sexually transmitted infections among US women and men: prevalence and incidence estimates. *Sex Transm Dis* 40(3):187–193. doi: 10.1097/OLQ.0b013e318286bb53.

[17]Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMWR* 63(2).

[18]Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMWR* 63(2).

[19]Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMWR* 63(2); Gaydos, C.A., M. Theodore, N. Dalesio, B.J. Wood and T.C. Quinn (2004). Comparison of Three Nucleic Acid Amplification Tests for Detection of *Chlamydia trachomatis* in Urine Specimens. *J Clin Microbiol* 42(7):3041–3045. doi: 10.1128/JCM.42.7.3041–3045.2004; S.N. Tabrizi, M. Unemo, A.E. Limnios, T.R. Hogan, S. Hjelmevoll, S.M. Garland and J. Tapsall. (October 2011). Evaluation of Six Commercial Nucleic Acid Amplification Tests for Detection of *Neisseria gonorrhoeae* and Other *Neisseria* Species. *J Clin Microbiol* 49(10):3610–3615. doi: 10.1128/JCM.01217-11.

[20]Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMWR* 63(2); Gaydos, C.A., M. Theodore, N. Dalesio, B.J. Wood and T.C. Quinn (2004). Comparison of Three Nucleic Acid Amplification Tests for Detection of *Chlamydia trachomatis* in Urine Specimens. *J Clin Microbiol* 42(7):3041–3045. doi: 10.1128/JCM.42.7.3041–3045.2004; S.N. Tabrizi, M. Unemo, A.E. Limnios, T.R. Hogan, S. Hjelmevoll, S.M. Garland and J. Tapsall. (October 2011). Evaluation of Six Commercial Nucleic Acid Amplification Tests for Detection of *Neisseria gonorrhoeae* and Other *Neisseria* Species. *J Clin Microbiol* 49(10):3610–3615. doi: 10.1128/JCM.01217-11.

[21]Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMWR* 63(2).

[22]Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMW.* 63(2); Gaydos, C.A., M. Theodore, N. Dalesio, B.J. Wood and T.C. Quinn (2004). Comparison of Three Nucleic Acid Amplification Tests for Detection of *Chlamydia trachomatis* in Urine Specimens. *J Clin Microbiol* 42(7):3041–3045. doi: 10.1128/JCM.42.7.3041–3045.2004; S.N. Tabrizi, M. Unemo, A.E. Limnios, T.R. Hogan, S. Hjelmevoll, S.M. Garland and J. Tapsall. (October 2011). Evaluation of Six Commercial Nucleic Acid Amplification Tests for Detection of *Neisseria gonorrhoeae* and Other *Neisseria* Species. *J Clin Microbiol* 49(10):3610–3615. doi: 10.1128/JCM.01217-11.

[23]Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMWR* 63(2).

[24]Mabey, D. and R. Peeling. (2013). Chlamydial Infections. In *Hunter's Tropical Medicine and Emerging Infectious Disease*, 9th Edition. A.J. Magill, E.T. Ryan, D.R. Hill and T. Solomon, 477–480. New York, NY: Elsevier Ltd., 2012; Y. Tong. (2014). Isothermal amplification of specific sequences. In *Biological Identification. DNA Amplification and Sequencing, Optical Sensing, Lab-on-chip and Portable Systems*, ed. R.P. Schaudies, 69–92. Cambridge, UK: Woodhead Publishing.

[25]Papp, J.R., J. Schachter, C.A. Gaydos and B. Van Der Pol. (2014). Recommendations for the laboratory-based detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* – 2014. *MMWR* 63(2); PCR Fact Sheet.

[26]Hughes, Mark R. Deputy Director of the National Center for Human Genome Research at the National Institutes of Health (Human Genome Project).

[27]**cobas** CT/NG v2.0 Test Package Insert, 07127553001-09EN 01/2017.

[28]Argent Global Services. CT/NG Comparison Study. 2012. Roche data on file.

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46256

usdiagnostics.roche.com