

2013 CHLAMYDIA AND GONORRHEA CLINICAL LABORATORY PRACTICES SURVEY

SUMMARY DATA REPORT

August 2018



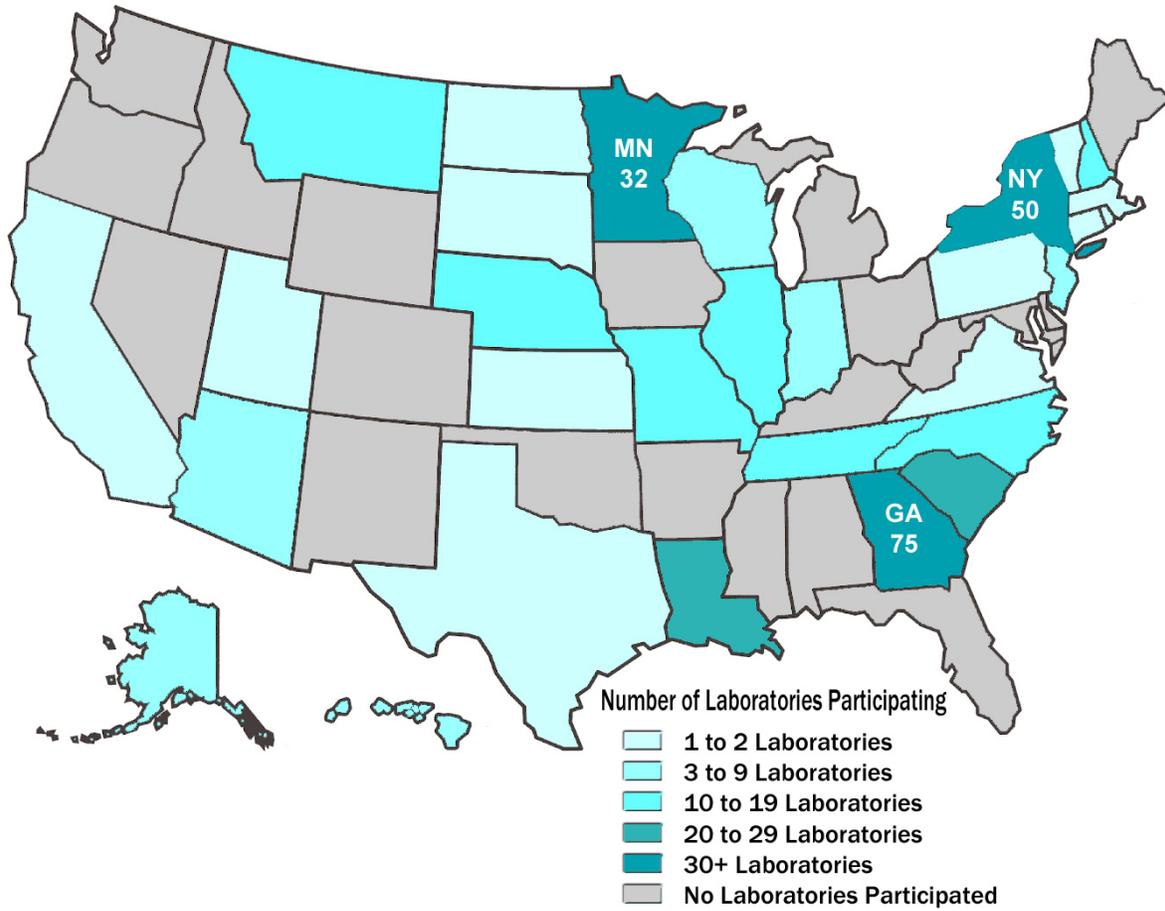
Introduction

Identifying cases of sexually transmitted diseases (STDs), particularly *Chlamydia trachomatis* (CT) and *Neisseria gonorrhoeae* (GC), requires screening to be of high quality, following national recommendations for appropriate methodology and specimen type. Clinical laboratories located in single facilities, as well as those that are large multi-site laboratories, provide testing for patients all over the United States. These clinical laboratories have become key partners in STD prevention, as screening for STDs is increasingly being performed in the private sector and outside of the public health laboratory (PHL). It is important to understand STD testing practices used in clinical laboratories to determine if national testing recommendations are being followed, and to identify trends in clinical laboratory capacities and capabilities, primarily in the performance of CT and GC tests.

In 2014, members of the APHL STD Subcommittee—a subcommittee of the Infectious Diseases Committee—developed a clinical laboratory survey based on previous STD testing practice surveys of US PHLs.^{1,2} The survey was fielded to US clinical laboratories with the assistance of state PHLs that maintain contact lists of clinical laboratories as part of Public Health Emergency Preparedness (PHEP) funding. Clinical laboratories were asked to provide CT and GC test data from January 1, 2013 through December 31, 2013. In addition to assessing testing practices in clinical laboratories in 2013, the data collected was used as baseline data for determining any changes to testing practices as a result of new [Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*—2014](#).³

A total of 376 clinical laboratories responded to the survey. Representation is not uniform with some states having numerous respondents and no responses from clinical labs in several states, notably in the southeast and western regions. Additional data from this survey, grouped by pathogen and filterable by testing volume of the laboratories, can be found [online](#).

States Represented in 2013 Survey



Chlamydia Testing Practices

Of the 376 responding clinical laboratories, 212 (56.4%) performed at least one method of CT testing in-house. Nucleic Acid Amplification Tests (NAATs) were the preferred method for performing CT screening ([CT Figure 1](#)). Of the 363 laboratories that ensured access to NAAT testing approximately half (50.4%, 189) performed NAAT in-house. The most common NAAT assays used by laboratories that performed NAAT in-house were the Hologic Aptima® commercial assay (42.9%, 81/189), followed by Cepheid Xpert CT/NG (20.1%, 38/189), and BD ProbeTec™ CT/GC (11.6%, 22/189) ([CT Figure 2](#)), Filtered on [CT Figure 1](#) “NAAT,” “In-House Testing”). Hologic Aptima® assays were identified as the primary method used to detect CT (36.2%, 136/376) by all responding laboratories ([CT Figure 2](#)).

All respondents were asked to indicate the specimen types they received for CT NAAT, independent of whether they performed NAAT testing in-house or referred out. With that caveat in mind, the most frequently accepted specimen types for CT NAAT by the clinical laboratories (n=369) were urine (93%, 343), endocervical swab (92.7%, 342), male urethral swab (80.2%, 296) and vaginal swab (67.5%, 249) ([CT Figure 3](#)). Other specimens accepted for in-house testing included endocervical specimens submitted in liquid pap collectors (31.2%), rectal swabs (22%), throat swabs (20.9%) and ocular/conjunctival swabs (18.4%). If data for only those laboratories that performed NAAT in-house were analyzed (n=189), the specimen types followed a similar pattern with urine (96.3%, 182) being the most frequently accepted, followed by endocervical swabs (93.1%, 176), male urethral swabs (1.4%, 135), and vaginal swabs (64.2%, 122) ([CT Figure 3](#), Filtered on [CT Figure 1](#) “NAAT,” “In-House Testing”).

Culture capacity for CT is important for medical-legal testing and to test specimen types not approved for use with commercial NAAT assays. In 2013, the majority of CT culture (71.8%, 270) was referred out by clinical laboratories, and less than 10% of responding laboratories performed culture in-house ([CT Figure 1](#)). In the 63 clinical laboratories that receive 10,001 or more specimens per year for CT testing, 28.6% (18) performed culture compared to 54% (34) that referred culture ([CT Figure 1](#), Filtered by “d-10,001+.”). Less than 5% of all responding laboratories performed in-house testing by additional methodologies (direct fluorescent antibody, rapid diagnostic kits, immunoassay, microimmunofluorescence, hybrid capture and complement fixation).

A laboratory’s estimated testing volume impacts whether testing is performed in-house or referred to another laboratory. Testing volume data was provided by 354 (94.1%) of the responding clinical laboratories. A majority of these laboratories performed no more than 10,000 tests for CT (82.2%, 291), with 67 (18.9%) performing between 1 and 100 tests, 99 (28%) performing between 101 and 1,000 tests and 125 (35.3%) performing 1,001-10,000 tests. The remaining 17.8% of laboratories performed 10,001 or greater CT tests annually.

The vast majority (85.1%, 57/67) of the smallest volume laboratories (1-100 tests) typically referred out all methods of testing or the testing was not available ([CT Figure 1](#), Filtered on “a 1-100”). A small percentage offered only one method in-house: 8 (11.9%) laboratories performed NAAT, 4 (6.0%) laboratories performed rapid diagnostic kits, and 3 (4.5%) laboratories performed culture. Notably, a single laboratory in this group did perform multiple methodologies in-house.

Of the 63 largest volume laboratories (10,001 or greater), 62 (98.4%) performed NAAT testing in-house, 18 (28.6%) offered culture, and 6 (9.5%) offered direct fluorescent antibody (DFA) testing. Further examination of the data can be performed by toggling the filter volume on the [Chlamydia Testing Dashboard](#).

Gonorrhea Testing Practices

In 2013, the top two most common in-house testing methods for gonorrhea provided by clinical laboratories were GC culture with 72.1% (271) and gram stain smears with 69.9% (263) ([GC Figure 1](#)). Only 20.2% (76) of responding laboratories referred cultures for testing, and 12.5% (47) referred gram stains. Due to high rates of antibiotic resistance in GC, the need to maintain culture capacity is greater than that for chlamydia testing. Additionally, gram stain of male urethral discharge is an acceptable and rapid method for detecting GC, and can easily be performed in-house.

A vast majority of responding laboratories (97.3%, 366) provided access to GC NAATs either through in-house testing (50.5%, 190) or referral (46.8%, 176). Other methods of GC testing were mostly not available (>63%) or offered by referral ([GC Figure 1](#)). Culture and gram stain smears were the testing service most frequently offered in-house overall. However, when each laboratory indicated the primary methodology performed in-house they ranked as follows (n=321): Hologic Aptima® NAATs (41.7%, 134), culture (15.9%, 51), BD ProbeTec™ CT/GC (13.4%, 43), and Cepheid Xpert CT/NG (12.5%, 40) ([GC Figure 2](#)).

Similar to the CT NAAT question, all respondents were asked to indicate the specimen types they received for GC NAAT, independent of whether they performed NAAT testing in-house or referred out. With that caveat in mind, the most frequently accepted specimen types for GC NAAT were (n=361); endocervical swabs (92.8%, 335), urine (89.8%, 324), male urethral swabs, expressed discharge (79.2%, 286), and vaginal swabs (69%, 249) ([GC Figure 3](#)). Endocervical specimens submitted in liquid pap collectors (29.9%), rectal swabs (25.8%), throat swabs (23.8%) and ocular/conjunctival swabs (18.3%) were accepted less frequently. If data for only those laboratories that offered NAAT in-house were analyzed (n=190), the most frequently accepted specimen types for NAAT were: urine (96.3%,182), endocervical swab (93.1%, 176), male urethral swab, expressed discharge (70.9%,134), and vaginal swabs (64.6%, 122) ([GC Figure 3](#), Filtered on [GC Figure 1](#): “NAAT”, “In-House Testing”)

GC culture is an important method for both antibiotic susceptibility testing as well as testing of a wide variety of specimen types that are not acceptable for commercially available NAATs. Laboratories were asked which specimen types were accepted for culture. Male urethral swabs and endocervical swabs were tied for the most frequently accepted specimen types (83.8%, 284), followed by vaginal swabs (83.5%, 283), throat swabs (71.7%, 243), rectal swabs (69.6%, 236), and ocular/conjunctival swabs (65.8%, 223) by laboratories ([GC Figure 4](#)). In addition, the “other” specimen types received was joint or synovial fluid.

Similar to CT testing, in-house methodologies and referral testing is influenced by specimen volume ([GC Figure 1](#)). Testing volume data was provided by nearly all (94.4%, 355) of the clinical laboratories. Although there were slight differences, the number of laboratories based on testing volume was quite similar to that reported for CT. The smallest volume laboratories (1-100 specimens) made up 22.5% (80) of clinical laboratories, 29.3% (104) of laboratories performed

between 101 and 1000 tests in a year, 30.7% (109) laboratories performed between 1001 and 10,000 tests and the largest volume laboratories (10,001 or greater) made up the remaining 17.5% (62) of labs reporting testing volumes. Further examination of the data can be performed by toggling the filter volume on the [Gonorrhea Testing Dashboard](#).

Of the 80 smallest volume laboratories (1-100 tests/year), 44 (55.0%) performed culture in-house, 50 (62.5%) performed gram stain smears in-house, and 10 (12.5%) performed NAATs in-house, with seven of the 10 laboratories using the Cepheid Xpert CT/NG method ([GC Figure 1](#), Filtered on "a 1-100"). In comparison, of the 62 largest volume (10,001 or greater/year) laboratories, 61 (98.4%) performed NAATs, with the majority (66.7, 40/60%) using the Hologic/Aptima® (Tigris, Panther or DTS) method, followed by the BD Viper™ XTR™ method (20%, 12/60); only one laboratory in this group utilized the Cepheid Xpert CT/NG method ([GC Figure 1 and 2](#), Filtered on "d-10,001+").

Susceptibility testing for isolates of GC is performed in just less than half (42.8%, 161/376) of the laboratories ([GC Figure 5](#)), with beta-lactamase screening as the primary method, (84.8%, 134/158) ([GC Figure 6](#)). Of the 24 laboratories that performed susceptibility testing with a method other than beta-lactamase screening, the most common method was disc diffusion (10) followed by Etest (9). Three laboratories reported performing susceptibility testing but didn't provide the method. The most common antibiotics used in susceptibility testing in the laboratories that responded to this question (n=145) were penicillin (26.2%, 38), ceftriaxone (17.2%, 25), ciprofloxacin (15.9%, 23), tetracycline (12.4%, 18), and cefixime (7.6%, 11/158) ([GC Figure 7](#)). Due to the way the question was asked the results also include those that performed beta-lactamase testing or did not perform susceptibility testing. In order to filter those out, please select the method of interest in [GC Figure 6](#) and then you will be able to see the antibiotics used by the specific laboratories using that method in [GC Figure 7](#).

General Testing Practices

Many of the commercial NAATs are available as combination assays and we wanted to understand how clinical laboratories handle testing for these pathogens and how frequently they are tested together or individually. A majority of the 376 respondents, (62.0%, 233), allowed providers to order CT or GC NAATs individually while 37.5% (141) required that the CT/GC NAAT be ordered in combination ([CT/GC Figure 1](#)).

Another testing practice that has been used to reduce the cost of NAATs in low prevalence populations is pooling, where multiple specimens—usually four to five—are tested together in one pooled assay. If the pooled sample is negative, then all the specimens making up that pool are reported as negative. However, if the pooled sample is positive, then the pool is deconstructed, and all the specimens in that pool are tested individually to find the positive sample(s). Of the clinical and reference laboratories that responded to this survey, 97.6% (365/374) do not pool specimens ([CT/GC Figure 2](#)).

Summary

Based on the data collected from 2013, approximately half of responding clinical laboratories perform nucleic acid amplification tests in-house for the detection of CT (50.4%) and GC (50.5%) from specimen types approved in commercial assays (endocervical swabs, urethral swabs, urine, and vaginal swabs). If in-house and referral testing for NAAT is combined nearly all clinical

laboratories have access to NAAT for CT (96.5%, 363/376) and GC (97.3%, 366/376). Since culture for CT requires tissue culture, it is not as readily available within a clinical laboratory (~10%) as is GC culture at 72.1%. Culture capability needs to be assured, either through in-house testing or referral for medical-legal cases, for specimens that are not listed as acceptable in commercial assays and, in the case of GC, for antibiotic susceptibility testing. For those few laboratories that isolate GC in culture, the majority refer the isolates for susceptibility testing, if requested. Beta-lactamase testing is performed in-house in many laboratories offering culture, but this testing may soon be discontinued due to the declining usefulness of penicillin as a treatment option. Despite the commercial development of combination NAATs for screening CT and GC, most providers have the option to order individual tests for CT and GC in clinical laboratories. Clinical laboratories generally do not pool specimens to reduce NAAT costs, which may be a reflection of the ability of clinical and reference laboratories to bill third party insurers for individual tests as part of a pooled sample.

The results of this survey will be used as baseline data, and the responding laboratories will be re-surveyed in 2016 (for data collected in calendar year 2015) to determine if there were any changes in testing practices as a result of [Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*— 2014](#).³

References

1. Van, T., et.al, STD Testing Practices in United States Public Health Laboratories poster, 2012 National STD Prevention Conference
2. Centers for Disease Control and Prevention and the Association of Public Health Laboratories, Volume and Type of Laboratory Testing Methods for Sexually Transmitted Diseases in Public Health Laboratories 2007, Summary Report 2011. Available at: <https://www.cdc.gov/std/general/labsurveyreport-2011.pdf>
3. Centers for Disease Control and Prevention. Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae*-2014. Morbidity and Mortality Weekly Report (MMWR), 2014;63(RR02),1-19. Available at: <https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6302a1.htm>

Acknowledgements

This survey report was prepared on behalf of the APHL Sexually Transmitted Diseases Subcommittee.

Association of Public Health Laboratories

The Association of Public Health Laboratories (APHL) works to strengthen laboratory systems serving the public's health in the US and globally. APHL's member laboratories protect the public's health by monitoring and detecting infectious and foodborne diseases, environmental contaminants, terrorist agents, genetic disorders in newborns and other diverse health threats.

This publication was 100% funded with federal funds from a federal program of \$494,498. This publication was supported by Cooperative Agreement # NU600E000103 funded by the US Centers for Disease Control and Prevention (CDC). Its contents are solely the responsibility of the authors and do not necessarily represent the official views of CDC or the Department of Health and Human Services.

National Center for Immunization and Respiratory Diseases (IP)
Office of Surveillance, Epidemiology and Laboratory Services (OSELS)
National Center for HIV, Viral Hepatitis, STDs and TB Prevention (PS)
National Center for Zoonotic, Vector-borne, and Enteric Diseases (CK)
National Center for Environmental Health (NCEH)
Coordinating Office for Terrorism Preparedness and Emergency Response (CTPER).



8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910
Phone: 240.485.2745
Fax: 240.485.2700
www.aphl.org