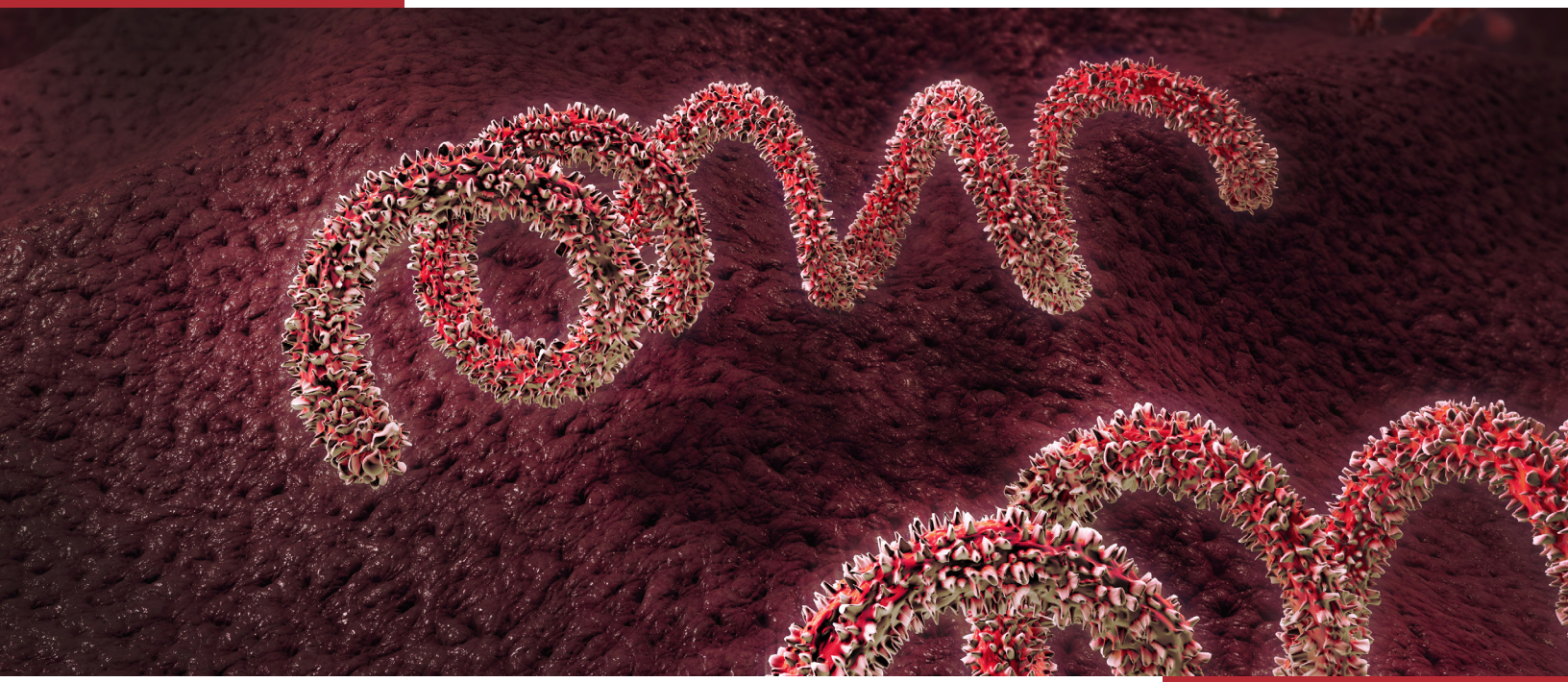
Sexually Transmitted Diseases Testing in Public Health Laboratories

2017 APHL Survey Report



JANUARY 2020

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

Acronyms in this Report

CLIA-Waived POC – Clinical Laboratory Improvement Amendments waived point-of-care test

CF – Complement fixation

CIA – Chemiluminescence immunoassay

DFA – Direct fluorescent antibody

EIA – Enzyme immunoassay

FTA-ABS – Fluorescent treponemal antibody absorption

MIA/MBIA - Microsphere

MIF – Microimmunofluorescence

NAAT – Nucleic acid amplification testing

PHL – Public health laboratory

RPR – Rapid plasma reagin

TPPA – *Treponema pallidum* particle agglutination

TRUST – Toluidine Red Unheated Serum Test

USR – Unheated serum reagin

VDRL – Venereal Disease Research Laboratory

Acknowledgments

The data from this survey was also used for a peer-reviewed manuscript: Davis A, Gaynor A. Testing for Sexually Transmitted Diseases in US Public Health Laboratories, 2016. Sex Transm Dis. 2020 Feb;47(2):122-7 which is available at: https://journals.lww.com/stdjournal/Fulltext/2020/02000/Testing_for_Sexually_Transmitted_Diseases_in_US.9.aspx

Table of Contents

EXECUTIVE SUMMARY

This report provides a summary of the responses received from a web-based survey conducted among public health laboratories (PHLs) on the volume and type of testing for sexually transmitted diseases in the United States in 2017. The survey was conducted in May-August 2017 and responses were received from 77.1% (81 out of 105) of all invited participants.

Overall in 2017, 2,242,728 chlamydia tests, 2,298,596 gonorrhea tests, 1,235,037 syphilis tests, 177,571 trichomonas tests, 37,101 HSV tests, and 8,707 HPV tests were performed in surveyed laboratories. Table 1 shows the number of laboratories that offer tests for each type of sexually transmitted pathogen.

Table 1. Number of public health laboratories that offer pathogen testing by type, 2017 (N=81)

Type of Pathogen	Total (N=81) N (%)	State PHL (N=51) N (%)	Local PHL (N=30) N (%)
Syphilis (*Treponema pallidum*)	73 (90.1%)	47 (92.2%)	26 (86.7%)
Gonorrhea (*Neisseria gonorrhoeae*)	72 (88.9%)	47 (92.2%)	25 (83.3%)
Chlamydia (*Chlamydia trachomatis*)	68 (84.0%)	44 (86.3%)	24 (80.0%)
Lymphogranuloma venereum	12 (14.8%)	8 (15.7%)	4 (13.3%)
Herpes Simplex Virus	43 (53.1%)	28 (54.9%)	15 (50.0%)
Trichomoniasis (*Trichomonas vaginalis*)	34 (42.0%)	12 (23.5%)	22 (73.3%)
Human Papilloma Virus	3 (3.7%)	3 (5.9%)	0 (0.0%)

INTRODUCTION

In the United States, rates of sexually transmitted diseases (STDs) are on the rise. According to US Centers for Disease Control and Prevention (CDC) data from 2017, chlamydia rates increased 6.9%, gonorrhea rates increased 18.56, syphilis rates increased 10.2%, and congenital syphilis rates increased 43.7%.[1] Between this survey conducted in 2017 and the previous survey conducted in 2011, CDC published important updates to changes in laboratory testing guidelines for STDs.[2]

Laboratory technology to detect STDs is continuously evolving. To better understand current public health laboratory test usage and procedures, the Association of Public Health Laboratories (APHL) surveyed member PHLs throughout the US from May 2017 to August 2017 to collect information about the volume and type of testing for STDs. Similar surveys were conducted in 2011, 2007, 2005, and 2001. This summary report presents information gathered from the 2017 survey from all PHLs that responded.

METHODOLOGY

Sample

State and local PHLs who were members of APHL during the survey period were included in this survey.

Development of Survey Instrument

A web-based survey was developed using the previous 2011 survey instrument as a template. The survey included questions on types of tests offered for different types of STDs, number of tests offered in the previous calendar year, and number of samples that tested positive for each STD. The survey was determined to be not human subjects research and exempt from IRB.

Survey Administration

An email was sent to the laboratory directors that included a letter of introduction and a direct link to a web-based survey with a unique User ID and password to access the survey. The laboratories were asked to complete the survey in four weeks. Follow-up reminders were sent via email to non-responders one week before the planned closure (June 30). The deadline was then extended to July 14 via an email notification. Laboratories that had not completed the survey by July 14 were contacted individually until the end of August, at which point the survey was closed.

Data Analysis

Descriptive statistics were calculated for all survey items. Tables and figures were generated to illustrate the types of STD testing used and testing volumes in APHL member laboratories that participated in this survey.

Survey Limitations

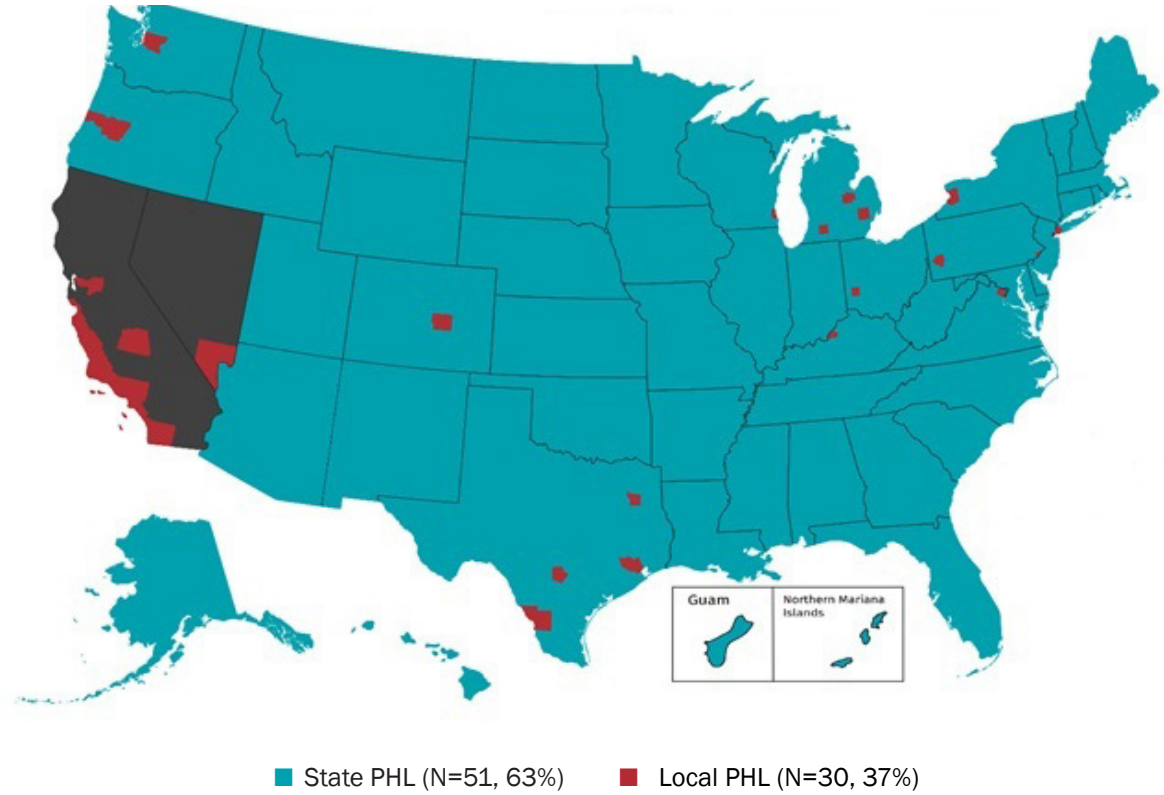
The questions for this survey were modeled after questionnaires from previous surveys in an effort to increase the utility of the data and add considerably to the general body of knowledge about STD testing. This survey was also updated to reflect current market availability of STD test technology.

RESULTS

Response Rate

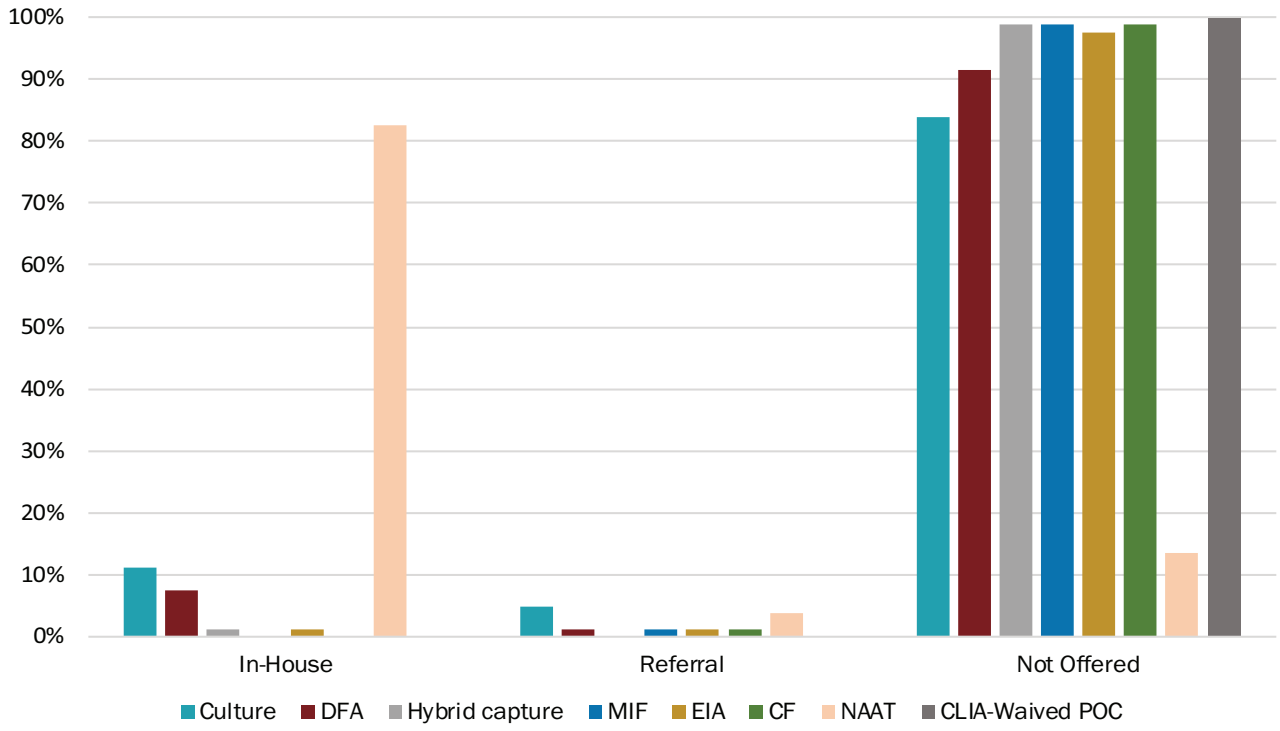
One hundred and five PHLs were invited to participate in this survey. The survey was completed by 81 of 105 PHLs, for an overall response rate of 77.1%. Out of 54 state PHLs, 51 (94.4%) completed the survey. Only 30 out of 51 local PHLs (58.8%) completed the survey. Figure 1 shows the state and local PHLs that completed the survey. The counties highlighted represent the jurisdictions providing data independent of the state PHLs.

Figure 1. Map of State and Local Public Health Labs That Completed Survey (N=81)



Of the 81 PHLs, 51 (63.0%) were state and 30 (37.0%) were local PHLs (Figure 2). On average, laboratories had a mean of 6.55 full-time employees (FTEs) per lab, ranging from 0-29 FTEs (median: 5; interquartile range 3.75-8). State PHLs had a mean of 6.88 FTEs per lab, ranging from 0-29 FTEs (median: 5; interquartile range 4-7). Local PHLs had a mean of 5.98 FTEs per lab, ranging from 0-20 FTEs (median: 4.75; interquartile range: 2.73-9.25).

Figure 2. Percent of Labs Offering Different Types of CT Tests (N=81)



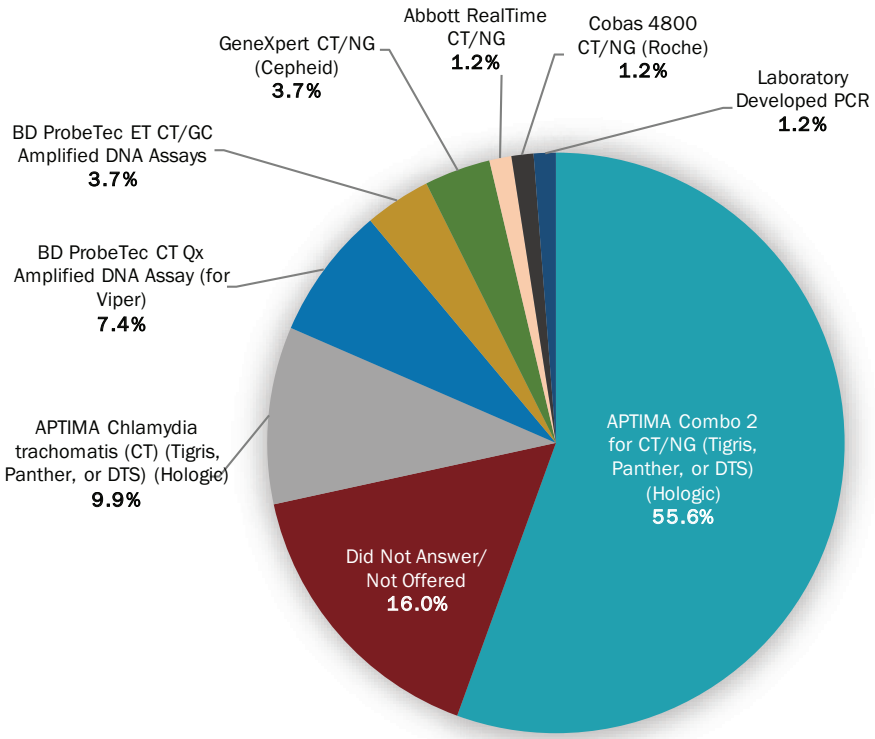
Chlamydia trachomatis Testing

On average, PHLs collected 32,981 specimens for *Chlamydia trachomatis* (CT) testing during calendar year 2017, with a range of 66 to 208,737 specimens collected (median: 20,536; interquartile range: 8,616-48,047). Of all specimens collected, 9.8% tested positive on average with a range of 0-40.9% testing positive (median: 9.3%; interquartile range: 7.5-10.5%).

Of the 81 responding PHLs, 68 (84.0%) performed at least one method of CT testing in-house. Most laboratories (n=67, 82.7%) performed nucleic acid amplification testing (NAAT) for CT in-house (Figure 2). A few laboratories also performed CT culture (n=9, 11.1%) or direct fluorescent antibody (DFA) (n=6, 7.4%) testing in-house. One PHL performed hybrid capture and one PHL performed enzyme immunoassay (EIA) testing in-house. Referral for all testing types was low. Several methods, such as microimmunofluorescence, complement fixation, or a CLIA-waived point-of-care method were not offered through in-house testing or referral, reflecting testing methods that are no longer widely available or utilized. Only four laboratories (4.9%) reported conducting drug susceptibility testing for CT.

The APTIMA Combo 2® for CT/NG (Tigris, Panther, or DTS) (Hologic) was most commonly reported as the primary test used to detect CT (55.6%) (Figure 3).

Figure 3. Primary Testing Method Used for CT (N=81)

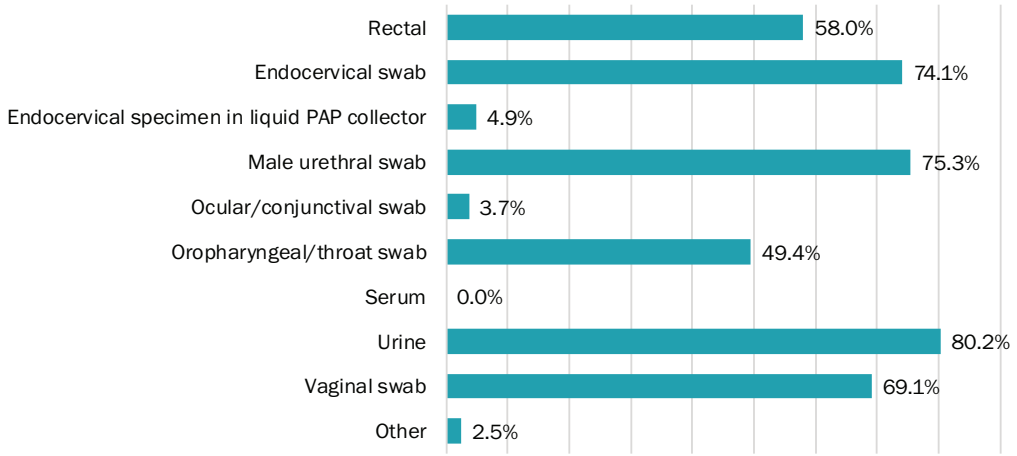


CT NAAT Testing

In 2002, CDC recommended that repeat testing be routinely performed after a positive NAAT test for CT.[2] This approach was advised to improve the positive predictive value of a NAAT test. However, studies since 2002 addressing the utility of routine repeat testing of positive specimens demonstrated >90% concurrence with the initial test for CT. Therefore, routine additional testing following a positive NAAT for CT is no longer recommended by CDC.[2] The majority of PHLs have testing practices that were aligned with CDCs recommendation to no longer perform repeat testing. Of the 67 PHLs that reported conducting NAAT testing for CT, 71.6% (n=48) reported that they did not conduct repeat testing on specimens that tested positive for CT by NAAT, 17.9% (n=12) reported that they occasionally conduct repeat testing on positive specimens, and 10.4% (n=7) reported they routinely conduct repeat testing.

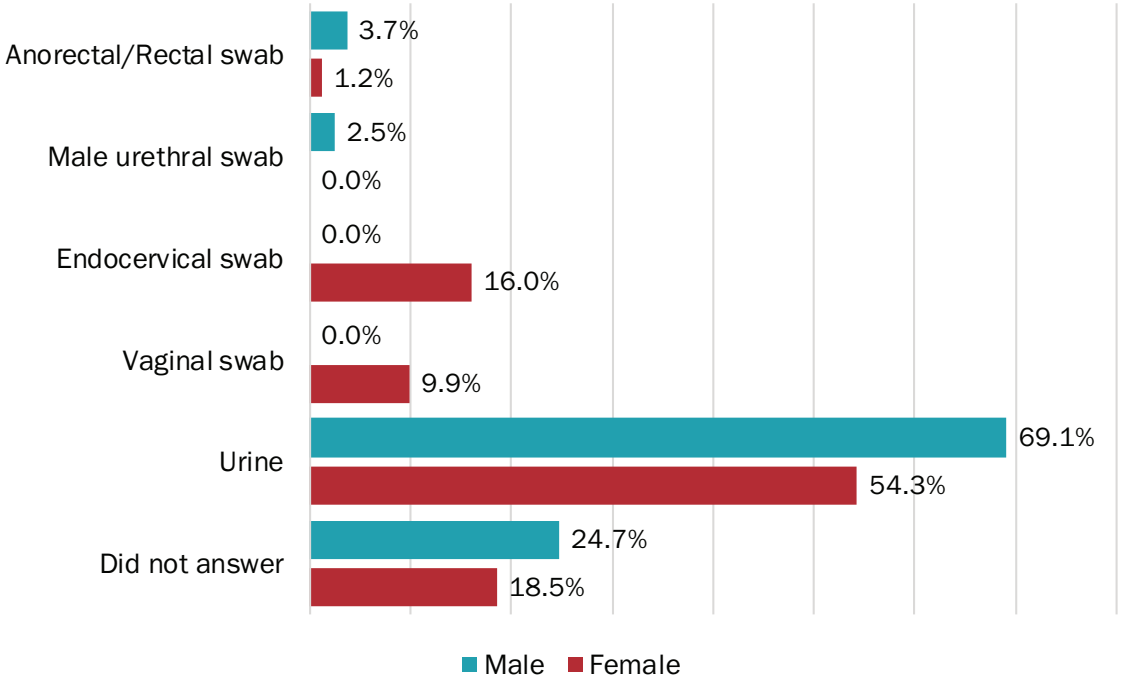
PHLs accept a variety of specimen types for CT NAAT testing, including urine (n=65, 80.2%), male urethral swabs (n=61, 75.3%), endocervical swabs (n=60, 74.1%), vaginal swabs (n=56, 69.1%), and rectal swabs (n=47, 58.0%) for CT NAAT testing (Figure 4). Almost half collected oropharyngeal/throat swabs (n=40, 49.4%).

Figure 4. Percent of Labs That Test the Following Samples for CT NAAT testing (N=81)



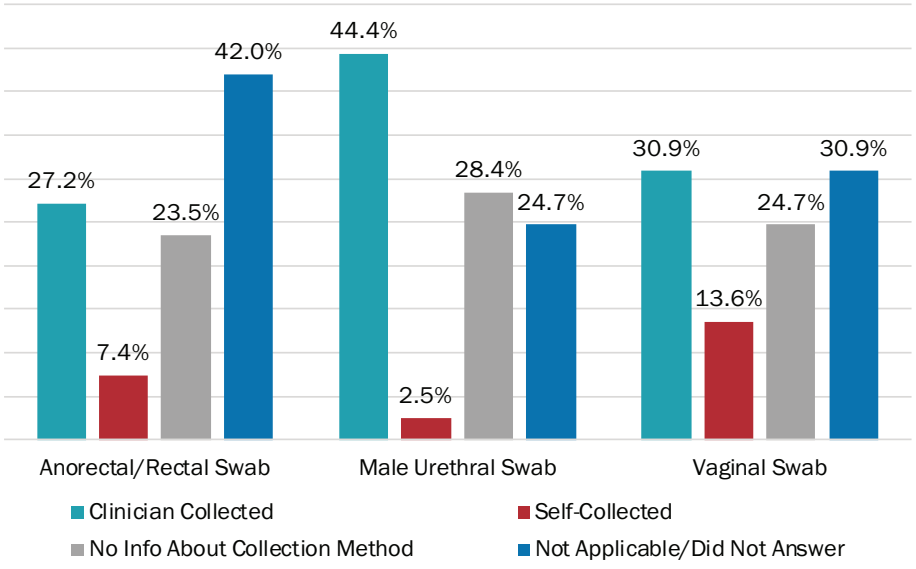
CDC has different specimen type recommendations by gender for CT NAAT testing: first-catch urine as the optimal specimen type for males and vaginal swabs as the optimal specimen type for females.[2] Urine was the most common specimen type received by PHLs for males (n=56, 69.1%) and females (n=44, 54.3%) for CT NAAT testing (Figure 5). While most PHLs were in alignment with CDC recommendations regarding specimen types for male NAAT testing, only 10% reported receiving vaginal swabs for women as their most common type.

Figure 5. Most Common CT Specimen Types Received for CT NAAT (by gender) (N=81)



Of the sample types accepted for CT NAAT testing, most were clinician-collected versus self-collected in a clinical setting, reflecting the current specimen types included in FDA-cleared NAAT assays. PHLs were more likely to receive vaginal swabs that were self-collected (n=11, 13.6%) than anorectal/rectal swabs (n=6, 7.4%) or male urethral swabs (n=2, 2.5%) (Figure 6).

Figure 6. Method of Collection for CT NAAT (by sample type) (N=81)



Lymphogranuloma venereum Testing

Lymphogranuloma venereum (LGV) is a serious infection caused by three serovars of CT. If left untreated, LGV can cause serious adverse health outcomes, including proctitis and irreversible lymphedema. Recent years have seen a significant increase in LGV among high-risk populations, particularly MSM.[3] Testing for LGV is not commonly requested nor performed. Only 12 PHLs (14.8%) reported receiving specimens specifically for LGV testing.

Table 2. Methods of testing for LGV (N=81)

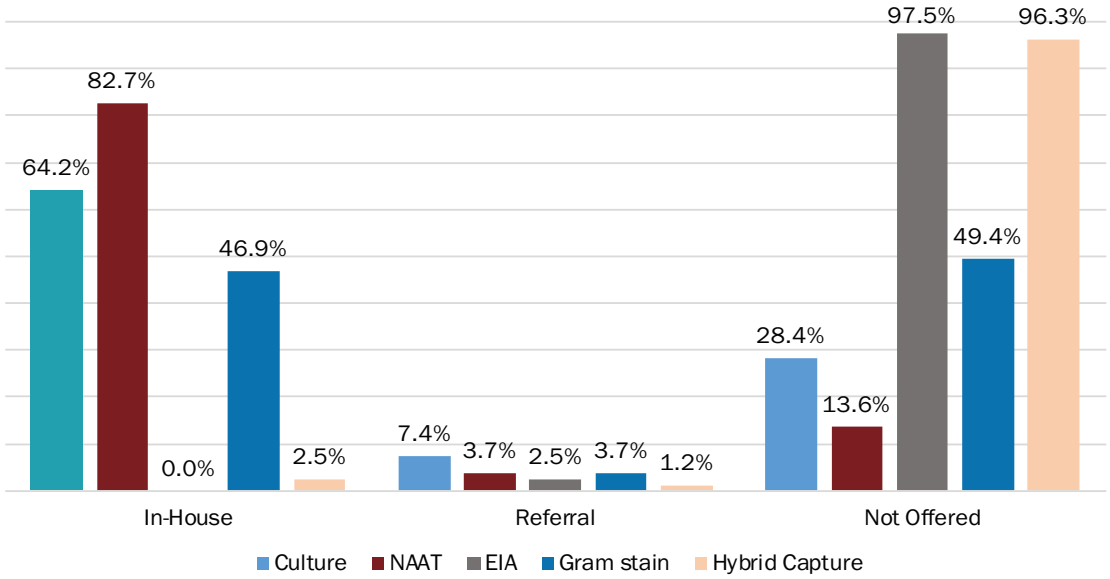
Testing method	N	%
In-house testing by amplification methods for CT	1	1.2%
In-house testing by amplification methods for LGV, specifically	1	1.2%
Referred for testing by amplification methods for CT	1	1.2%
Referred for testing by amplification methods for LGV, specifically	5	6.2%
Referred for testing by culture	1	1.2%
Other	3	3.7%
Testing for LGV is not available	69	85.2%

Neisseria gonorrhoeae Testing

The number of *Neisseria gonorrhoeae* (GC) specimens collected by any method was on average 31,925 with a range of 2 to 209,175 (median: 18,928; interquartile range: 3,570-48,084). The average percent of GC specimens testing positive was 7.8% with a range of 0-100% (median: 3.6%; interquartile range: 2.1-5.5%).

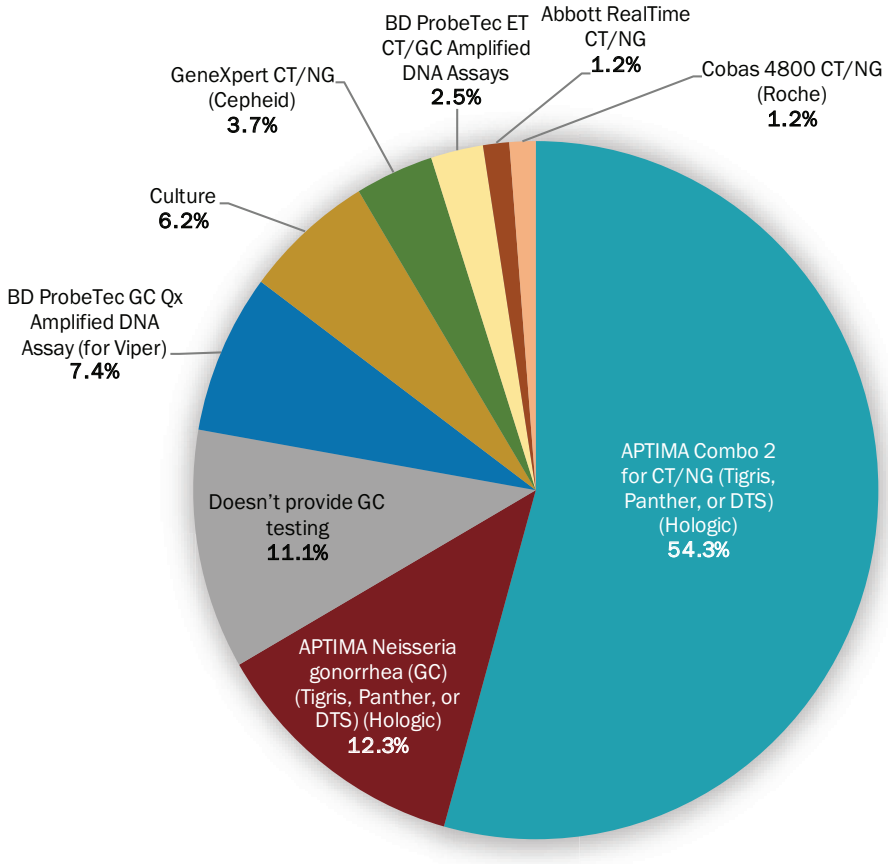
Of the 81 responding clinical laboratories, 67 (82.7%) offered NAAT for GC in-house, 52 (64.2%) offered culture, 38 (46.9%) offered Gram stain, and two (2.5%) offered hybrid capture (Figure 7). Referring testing for GC was uncommon.

Figure 7. Percent of Labs Offering Different Types of GC Tests (N=81)



The APTIMA Combo 2® for CT/NG (Tigris, Panther, or DTS) (Hologic) was most commonly reported as the primary test used to detect GC (n=44, 54.3%) (Figure 8).

Figure 8. Primary Testing Method Used for GC (N=81)



GC NAAT Testing

As is the case for positive CT NAATs, CDC no longer recommends repeat testing for positive GC NAAT results unless nongonococcal *Neisseria* species are detected.[2] For specimens collected from anatomical sites typically colonized by these organisms (e.g. oropharyngeal specimens), the CDC recommends consideration be given to retest these specimens with an alternate target assay. Of the 67 PHLs that conduct GC NAAT testing, the majority (n=46, 68.7%) did not perform repeat testing on specimens that tested positive for GC, 20.9% (n=14) reported occasionally performing repeat testing on specimens that tested positive, and 10.4% (n=7) reported routinely performing repeat testing.

Since some assays are available in individual and combined form, to better understand testing practices PHLs were also asked how CT and GC NAATs are ordered. When asked if laboratories offered CT-only, GC-only or CT/GC NAAT, the majority (67.9%) responded that testing can only be ordered in combination (Table 3).

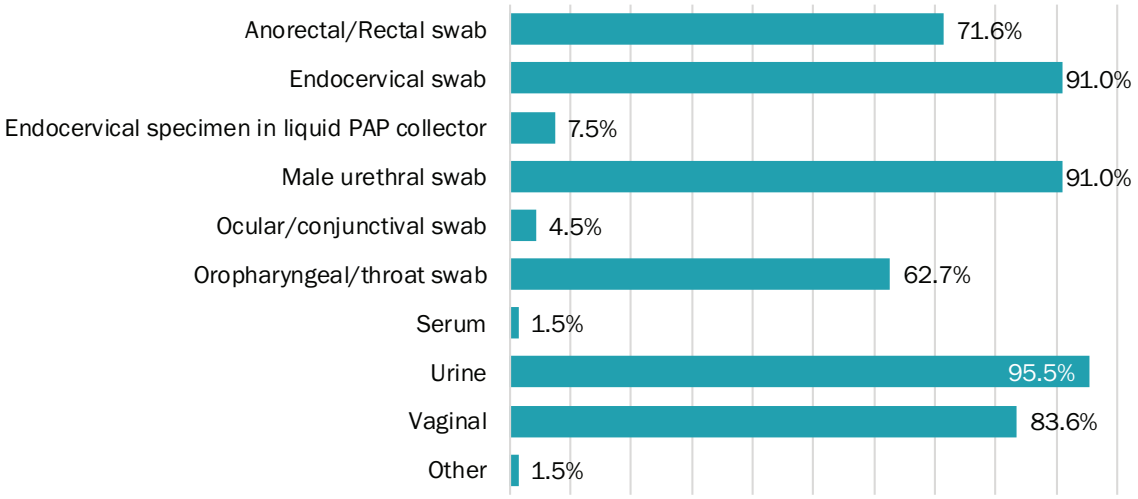
Table 3. Number of laboratories that provide CT and/or GC NAAT (N=81)

Answer	N	%
CT and GC can be ordered individually	11	13.6%
CT/GC can only be ordered in combination	55	67.9%
Did not answer	15	18.5%

When NAAT assays were new and not as widely used, specimens were pooled to reduce the higher material costs associated with the use of NAATs.[2] However, as NAAT testing has become more available and less costly, pooling specimens has become less common. The majority of labs (92.6%) said that they did not pool multiple specimens for NAAT. Only six labs reported pooling both CT and GC for NAAT.

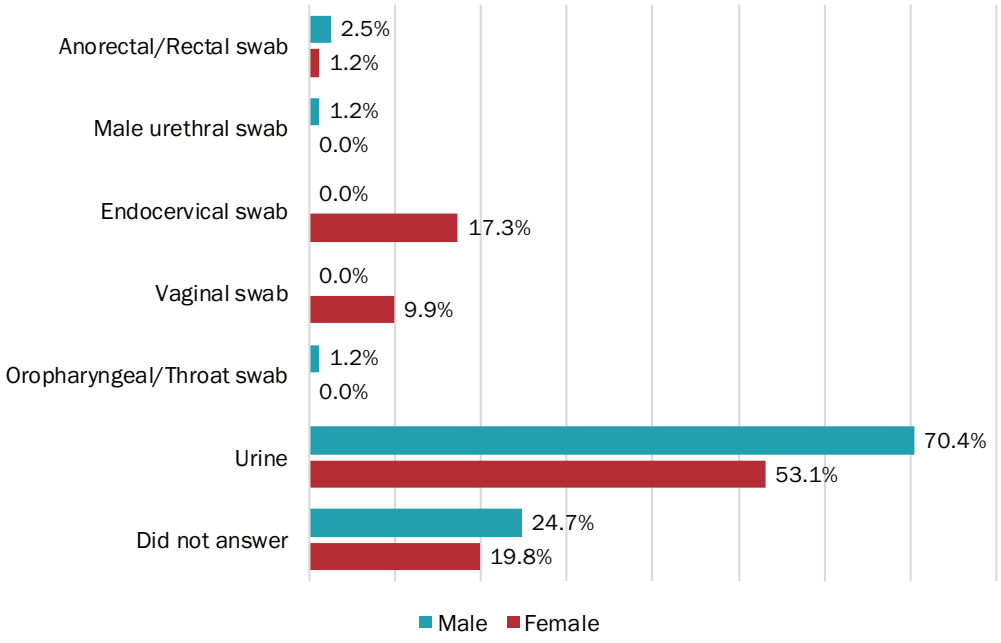
Of the 67 PHLs that tested for GC using NAAT, 95.5% (n=64) accepted urine, 91.0% (n=61) endocervical swabs, 91.0% (n=61) male urethral swabs, 83.6% (n=56) vaginal swabs, 71.6% (n=48) rectal swabs, and 62.7% (n=42) oropharyngeal/throat swabs for GC testing (Figure 9).

Figure 9. Percentage of Labs That Accept Specimens for GC NAAT (N=67)



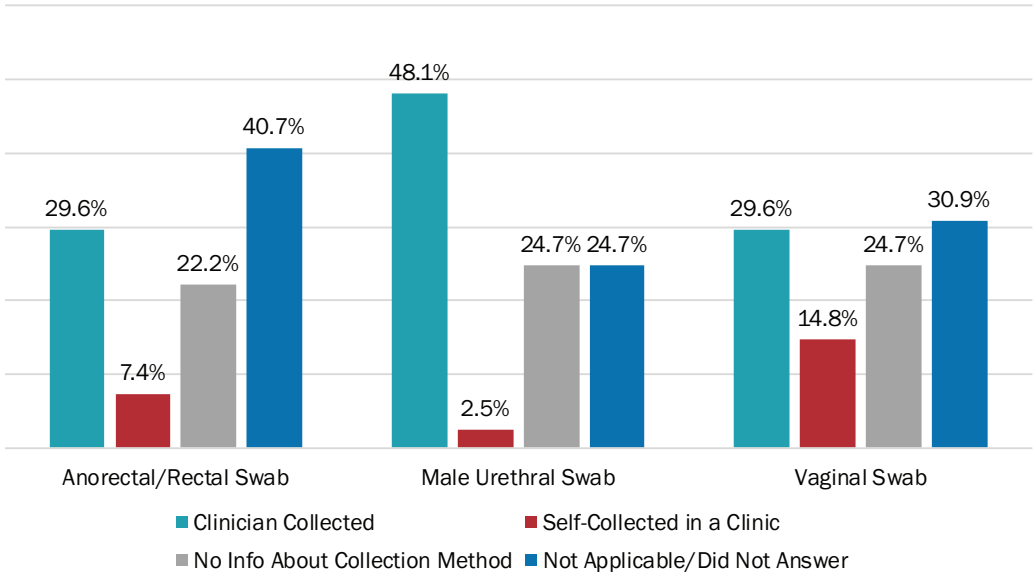
CDC has different specimen type recommendations by gender for GC NAAT testing: first-catch urine as the optimal specimen type for males and vaginal swabs as the optimal specimen type for females.[2] Urine was the most common GC specimen type received from males (n=57, 70.4%) and females (n=43, 53.1%) for GC NAAT testing (Figure 10). While most PHLs were in alignment with CDC recommendations regarding specimen types for male NAAT testing, only 10% reported receiving vaginal swabs for women as their most common type.

Figure 10. Most Common GC Specimen Types Received for GC NAAT (by gender) (N=81)



Of the sample types collected for GC NAAT testing, most were clinician-collected versus self-collected in a clinical setting. Vaginal swabs (n=12, 14.8%) were more commonly self-collected than anorectal/rectal swabs (n=6, 7.4%), and male urethral swabs (n=2, 2.5%) for GC NAAT testing (Figure 11).

Figure 11. Method of Collection for GC NAAT by Sample Type (N=81)



GC Culture

About half of PHLs reported being able to culture the following specimen types for GC: male urethral swab (n=44, 54.3%), endocervical swab (n=42, 51.9%), rectal swab (n=41, 50.6%), oropharyngeal/throat swab (n=41, 50.6%), and vaginal swabs (n=39, 48.1%) (Figure 12). Thirty laboratories (37%) reported being able to culture ocular/conjunctival swabs for GC.

Figure 12. Types of Specimens Lab is Able to Culture for GC (N=81)

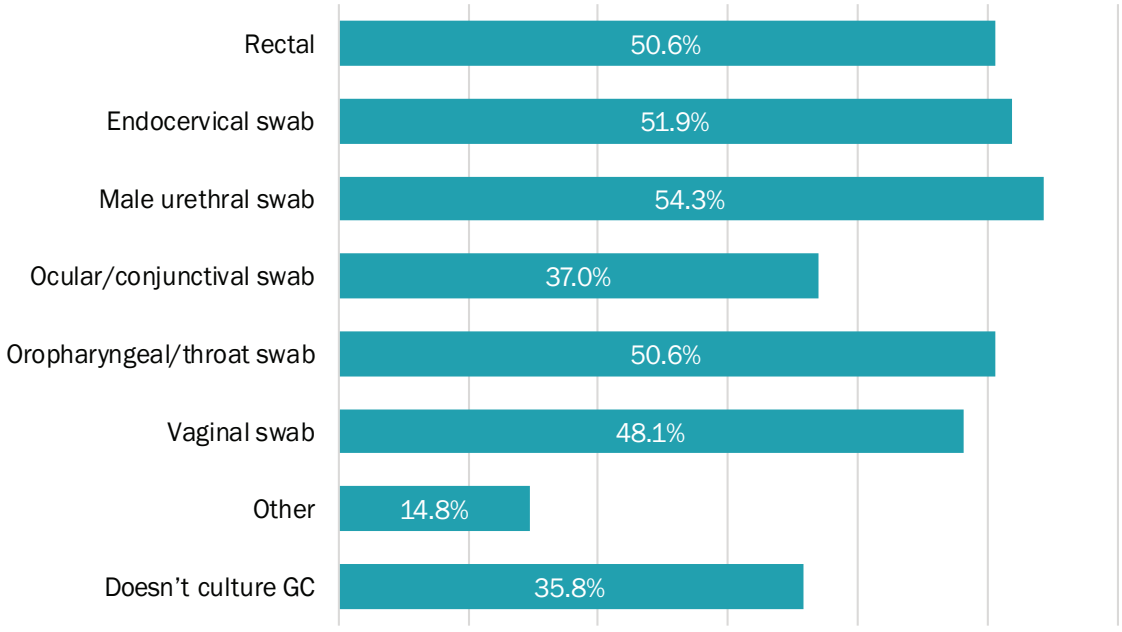


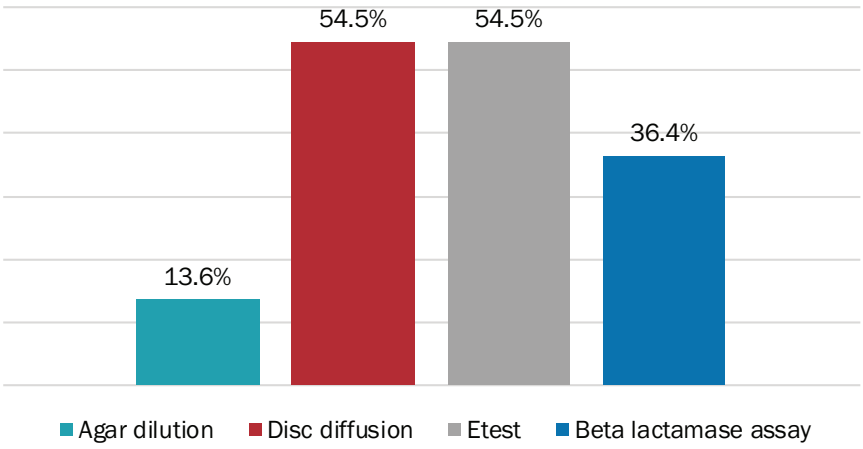
Table 4 below shows the GC culture volume from 2016 by specimen type.

Table 4. GC Volume From 2016 by Specimen Type

Specimen Type	Statistical Measure	Statistic
Body Fluid (n=17)	Mean	8.53
	Median	0
	Range	0-100
	Interquartile Range	0-2
Endocervical swab (n=27)	Mean	3117.26
	Median	2
	Range	0-42,874
	Interquartile Range	0-841
Ocular/conjunctival swab (n=20)	Mean	9.95
	Median	0
	Range	0-100
	Interquartile Range	0-1.75
Male urethral swab (n=30)	Mean	340.07
	Median	35.50
	Range	0-5000
	Interquartile Range	1-259.25
Rectal swab (n=26)	Mean	243.58
	Median	19
	Range	0-3700
	Interquartile Range	0.75-373
Oropharyngeal/throat swab (n=26)	Mean	775.92
	Median	11
	Range	0-15,000
	Interquartile Range	0.75-373
Vaginal swab (n=25)	Mean	222.48
	Median	5
	Range	0-3,000
	Interquartile Range	0-172
Other (n=11)	Mean	452.00
	Median	5
	Range	0-4784
	Interquartile Range	1-14

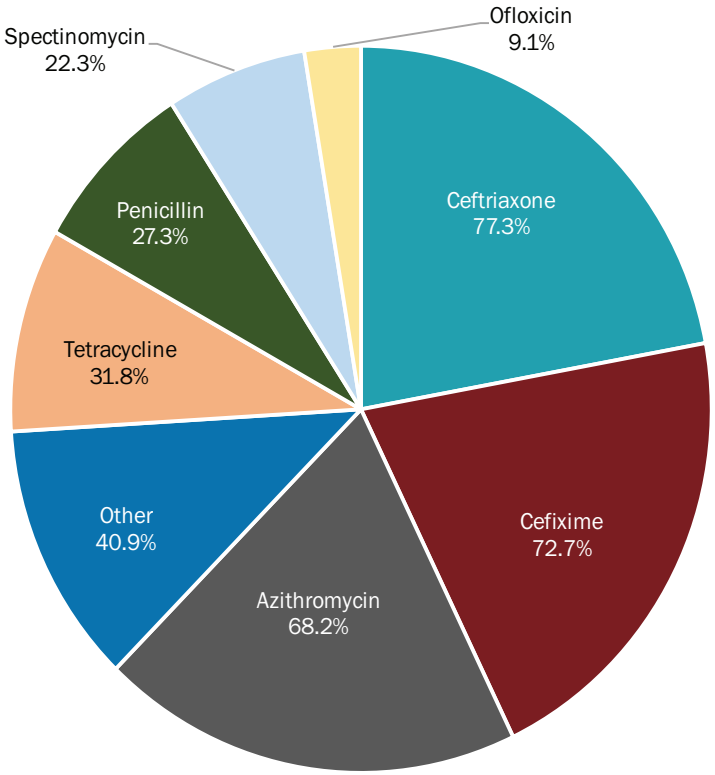
Drug resistance to GC treatment regimens is a growing problem in the US and worldwide and the ability to test for GC drug resistance is of increasing importance.[4] Of the 22 laboratories (27.2%) that reported performing drug susceptibility testing for GC, over half (n=12, 54.5%) reported using disc diffusion or ETEST® to test for GC drug susceptibility (Figure 13).

Figure 13. Method of Testing for GC Drug Susceptibility (N=22)



In 2007, emergence of fluoroquinolone-resistant GC in the US prompted the CDC to cease recommending fluoroquinolones for treatment of GC, leaving only cephalosporins as the only remaining class of antimicrobials available for treatment of gonorrhea in the US.[4] In 2006-2011, studies suggested that the effectiveness of cefixime might be waning, thus, CDC no longer recommends the routine use of cefixime as a first-line treatment regimen for GC. Currently only one regimen, dual treatment with ceftriaxone and azithromycin, is recommended for the treatment of GC in the US.[4] Of the 22 labs that had the capacity to test for GC susceptibility, 77.3% (n=17) could test for resistance to ceftriaxone, 72.7% (n=16) to cefixime, and 68.2% (n=15) to azithromycin (Figure 14).

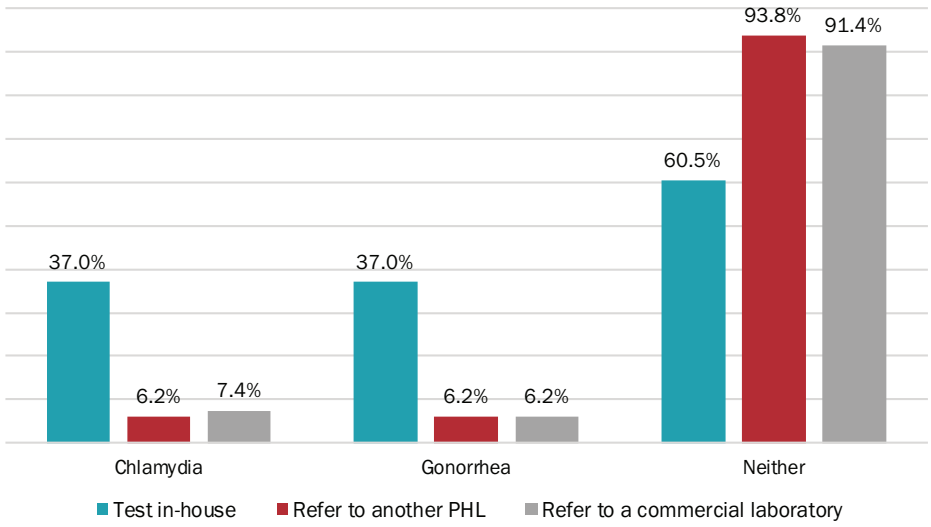
Figure 14. Antimicrobials Included in GC Susceptibility Testing



Medical-Legal Testing for CT and GC

In addition to diagnostic testing, over a third of PHLs (37.0%) reported performing medical-legal testing for CT and GC in-house (Figure 15).

Figure 15. Number of Labs Providing or Referring Medical-legal Testing for CT/GC (N=81)



The types of testing used for medical-legal testing for CT and GC are listed in Table 5. NAAT tests were the most common tests reported for CT (n=26, 32.1%) and GC (n=25, 30.9%).

Table 5. Type of Testing for CT Medical-legal Testing

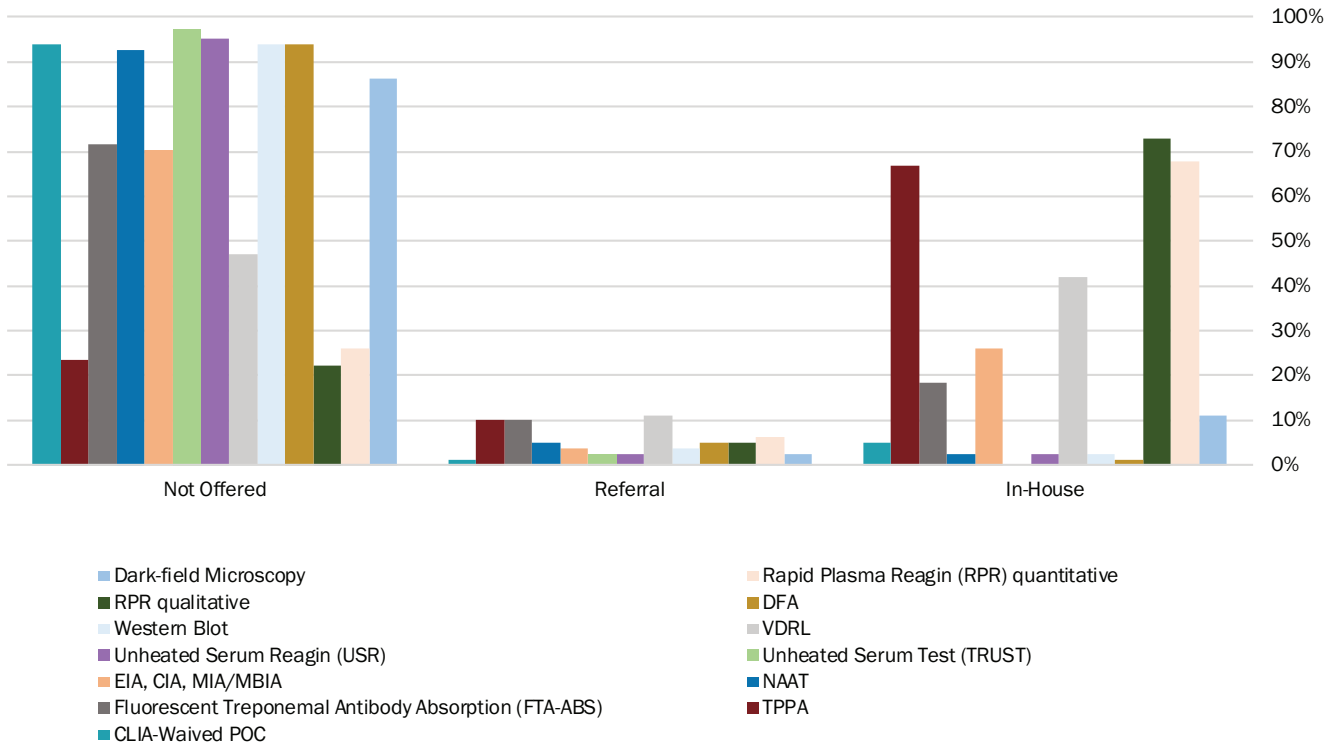
Type of Test	Chlamydia N (%)	Gonorrhea N (%)
Culture	9 (11.1%)	16 (19.8%)
NAAT	26 (32.1%)	25 (30.9%)
Other	0 (0.0%)	2 (2.5%)
Not applicable	2 (2.5%)	2 (2.5%)

Treponema pallidum (Syphilis) Testing

The average number of syphilis specimens received for testing in a PHL was 16,918 with a range of 1 to 149,023 (median: 6,663; interquartile range: 2,083-21,933). On average, 9.9% of specimens tested positive for syphilis with a range of 0-53.5% (median: 5.5%; interquartile range: 3.2%-11.8%).

Of the 81 PHL laboratories, 73 (90.1%) reported conducting at least one syphilis test method in-house. The majority of laboratories (n=59, 72.8%) reported conducting rapid plasma regain (RPR) qualitative testing for syphilis in-house, followed by 67.9% (n=55) offering RPR quantitative testing, 66.7% (n=54) offering *Treponema pallidum* Particle Agglutination (TPPA), and 42.0% (n=34) offering Venereal Disease Research Laboratory (VDRL) testing (Figure 16).

Figure 16. Percent of Labs Offering Different Types of Syphilis Tests (N=81)



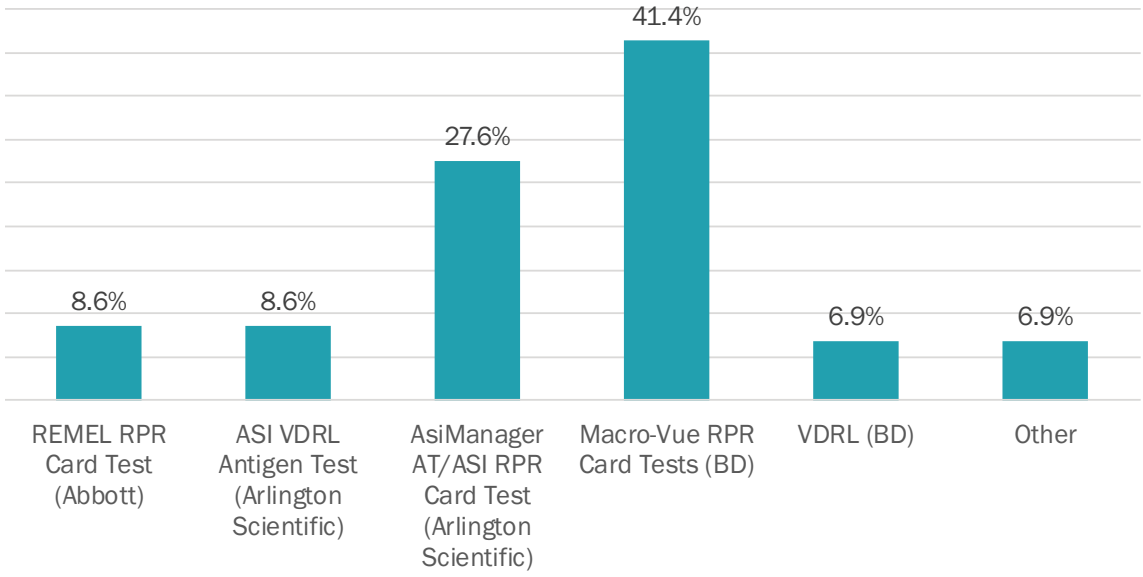
Thirty-four PHLs reported performing VDRL testing and were asked why they performed VDRL. The majority of PHLs (n=29, 85.3%) indicated that they used VDRL as it was the only test still recommended for cerebral spinal fluid testing (Table 6). For those 29 PHLs, we did not confirm which specimen types were tested with VDRL.

Table 6. Reasons Why Laboratories Perform VDRL Testing for Syphilis (N=34)

Reason	N	%
Only test still recommended for cerebral spinal fluid	29	85.3%
Time consuming and costly to perform verification studies to bring different methods on board	5	14.7%
Costly to have more than one nontreponemal assay on testing menu	6	17.6%
Other	4	11.8%

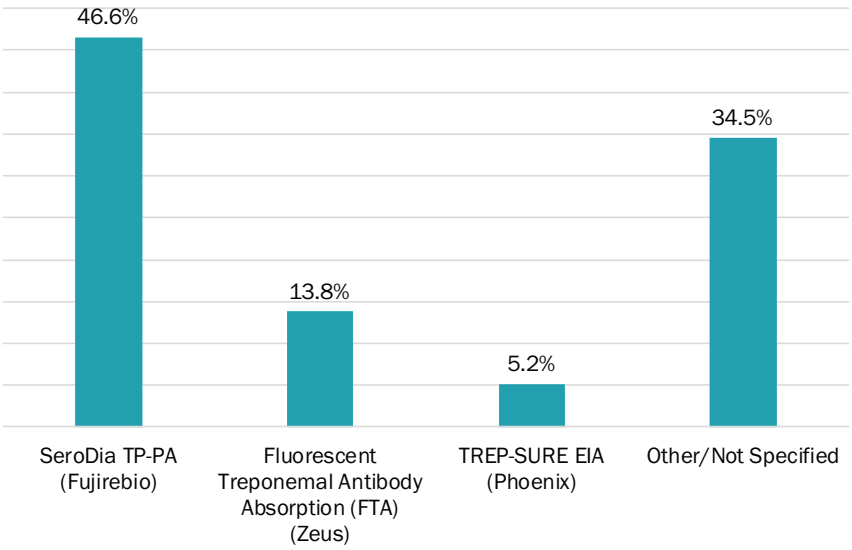
The 73 PHLs that performed at least one syphilis method in-house were asked to report on their testing algorithms for serum/plasma/whole blood samples. The majority (n=58, 79.5%) reported using a traditional algorithm (i.e. starting with a nontreponemal assay as the first test in the testing algorithm). The nontreponemal assays used by PHLs following the traditional algorithm are displayed in Figure 17. Over 40% (n=24) used the Macro-Vue™ RPR Card Test (BD) and over 25% (n=16) used the AsiManager-AT™/ASI RPR Card Test (Arlington Scientific).

Figure 17. Traditional Algorithm: Nontreponemal Assay (N=58)



PHLs following the traditional algorithm reported using the following treponemal tests as their second test in the algorithm (Figure 18). Over 45% (n=27) used the SeroDia® TP-PA (Fujirebio) assay and nearly 15% (n=8) used the Fluorescent Treponemal Antibody Absorption (FTA-ABS) (Zeus) assay.

Figure 18. Traditional Algorithm: Treponemal Test (N=58)



Of the 15 PHLs (20.5%) that reported following the reverse algorithm (i.e. starting with a treponemal assay as the first test in the testing algorithm), 46.7% (n=7) used the Trinity CAPTIA™ Syphilis-G assay, 20.0% (n=3) used the Bio-Rad BioPlex® 2200 Syphilis IgG assay, 13.3% (n=2) used the DiaSorin LIAISON® Treponema assay, and 20.0% (n=3) used other assays. PHLs also reported the nontreponemal test they used as the second step in the reverse algorithm: 10 (66.7%) used the Macro-Vue™ RPR Card Test (BD), two (13.3%) used the AsiManager-AT™/ASI RPR Card Test (Arlington Scientific), and three (20%) used other assays. Of the 15 PHLs that used a non-traditional testing algorithm, 86.7% (n=13) used a third test. All 13 reported using a treponemal assay for the third test. Of these, 11 used a Fujirebio SerioDia® TP-PA test and two used a Zeus FTA-ABS test.

Of the laboratories that test for syphilis, only a little over a third (n=26, 35.6%) reported having an alternative protocol for samples with a past history of syphilis. Over a third (36.2%, n=21) of PHLs using traditional algorithms had an alternative protocol and 33.3% (n=5) of PHLs using a reverse algorithm had an alternative protocol. Seventeen PHLs (23.3%) reported having been asked to test a sample to determine if the cause of a chancre was syphilis or herpes.

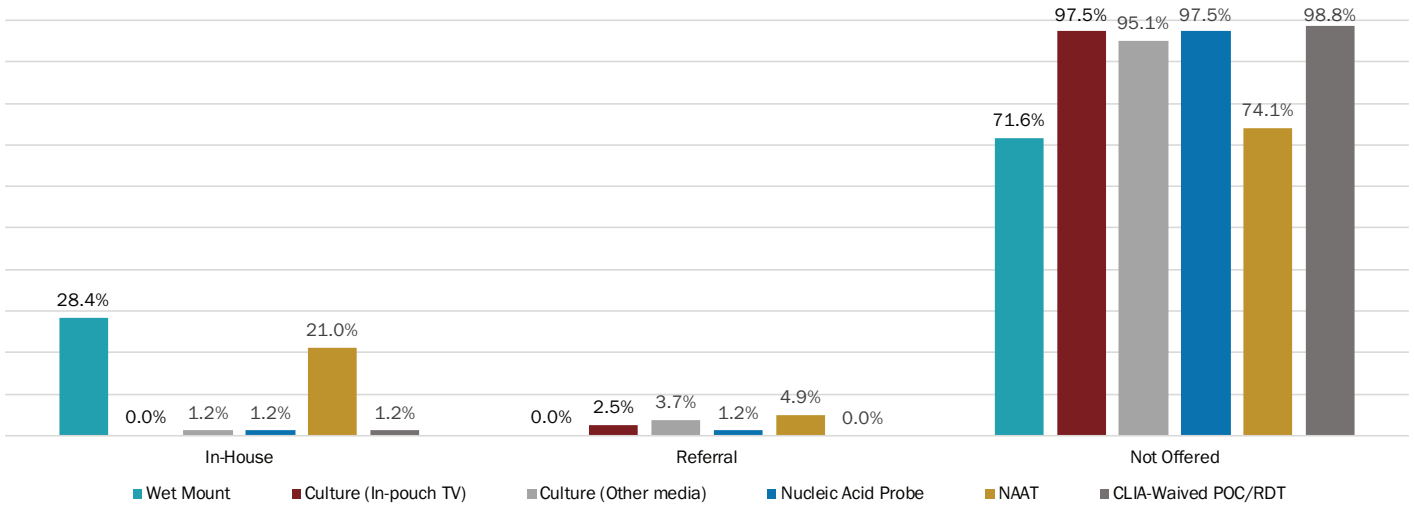
Trichomonas vaginalis Testing

On average, 5,223 specimens were collected for *Trichomonas vaginalis* (TV) testing with a range of 0-97,709 (median: 679; interquartile range: 119-3,135). An average of 10.8% of specimens tested positive for TV with a range of 0-60% testing positive (median: 8.7%; interquartile range: 4.3%-14.8%).

Of the 81 responding PHLs, 34 (42.0%) offered TV testing. TV testing was more likely to be offered by local PHLs than by state PHLs. Seventy-three percent (n=22) of all local PHLs offered TV testing, while only 23.5% (n=12) of state PHLs offered testing, likely reflecting a closer connection to patient care. The most common types of TV tests used for in-house testing were Wet Mount (n=23, 28.4%) and NAAT (n=17, 21.0%) (Figure 19). Few laboratories made referrals for any type of TV testing.

Of the 17 laboratories that offered TV NAAT testing, 10 (58.8%) said that TV NAAT can be ordered as an individual test and 7 (41.2%) said that TV NAAT can only be ordered in combination with CT/GC NAAT.

Figure 19. Types of TV Tests Offered by Location (N=81)

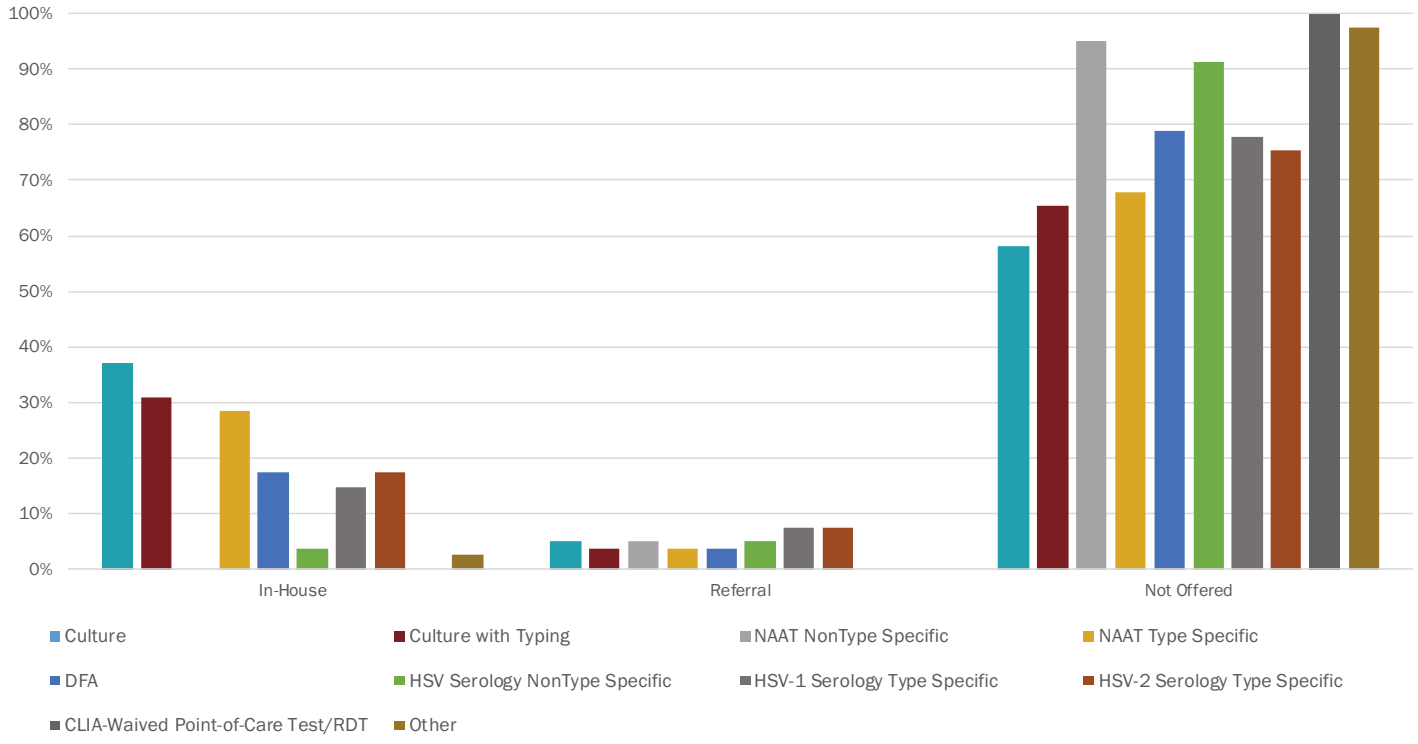


Herpes Simplex Virus Testing

The average number of Herpes Simplex Virus (HSV) specimens collected were 863 with a range of 18-9,926 (median: 402; interquartile range: 200-851). An average of 37.62% of specimens tested positive for HSV with a range of 8.7%-63.0% (median: 38.6%; interquartile range: 28.5%-46.6%).

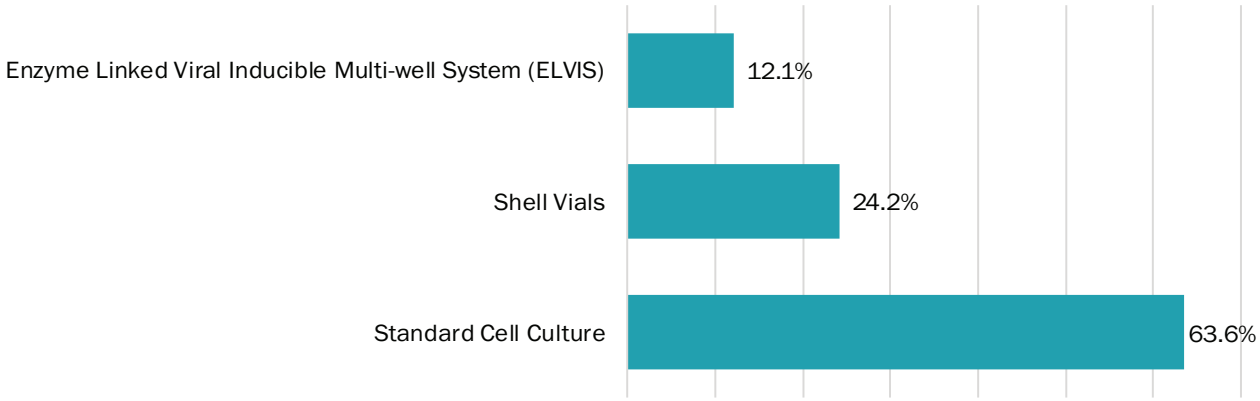
Of the 81 PHLs, 43 (53.1%) reported offering any type of HSV testing in-house. Fifty percent (n=15) of all local PHLs offered HSV testing and 54.9% (n=28) of state PHLs offered HSV testing. Types of HSV testing offered by laboratories are displayed in greater detail in Figure 20. Over a third of laboratories (n=30, 37.0%) reported offering culture for HSV testing, 30.9% (n=25) offered culture with typing, 28.4% (n=23) offered NAAT Type Specific testing, 17.3% (n=14) offered DFA, 17.3% (n=14) offered HSV-2 type serology, 14.8% (n=12) offered HSV-1 type specific serology, 3.7% (n=3) offered non-type specific HSV serology, and 2.5% (n=2) offered other tests.

Figure 20. Type of HSV Tests Offered by Location (N=81)



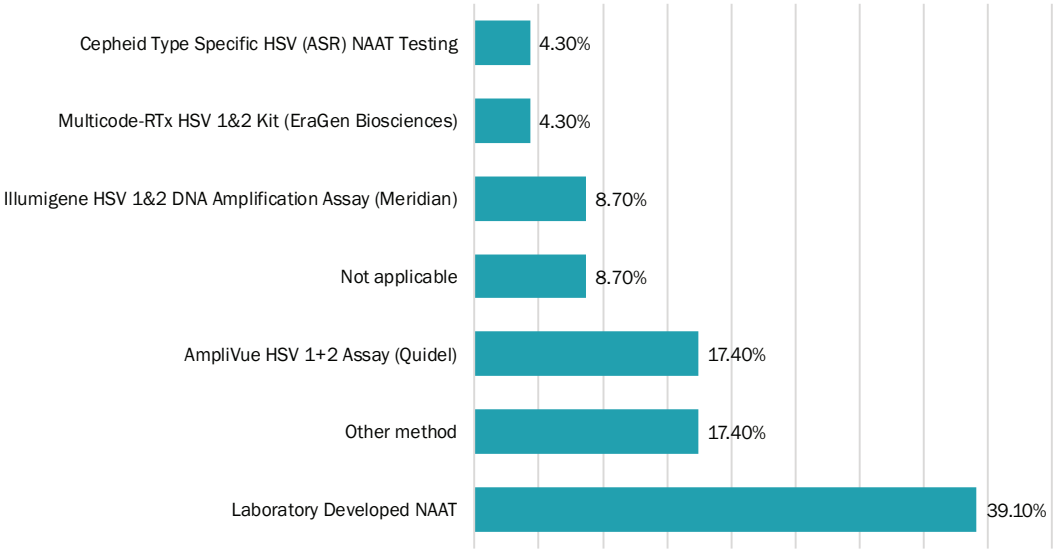
Of the 33 laboratories that reported using culture for HSV, the majority (63.6%) reported using standard cell culture (Figure 21).

Figure 21. Primary Method Used for HSV Culture or Culture with Typing (N=33)



Of the 23 laboratories that used HSV NAAT, 39.1% used a laboratory developed NAAT, followed by 17.4% using the AmpliVue™ HSV 1+2 Assay (Quidel) and 17.4% using another method (Figure 22).

Figure 22. Primary Method Used for HSV NAAT (N=23)



The methods used for HSV Serology testing are listed in Table 7. PHLs could select all HSV Serology methods performed in their laboratory.

Table 7. Methods Used for HSV Serology (N=81)

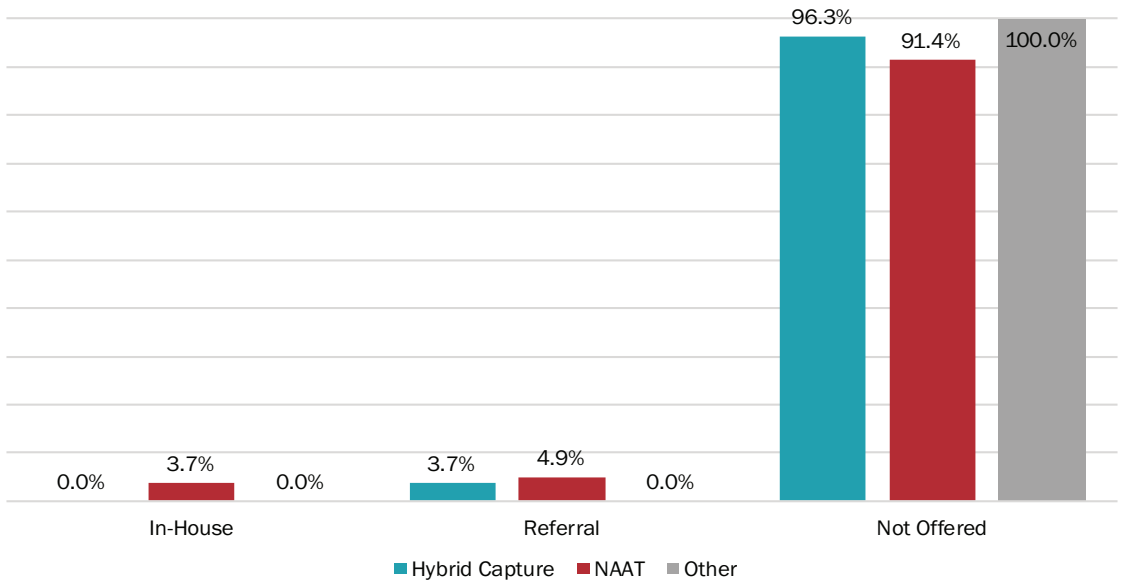
Type of Test	N	%
Artus HSV-1/2 QS-RGQ MDx Kit (Qiagen)	0	0.0%
BioPlex 2200 HSV-1 and HSV-2 IgG (Bio-Rad)	1	1.2%
Captia Herpes Group IgG ELISA (Trinity)	0	0.0%
Captia HSV1 IgG EIA (Trinity)	0	0.0%
Captia HSV2 IgG EIA (Trinity)	0	0.0%
Captia HSV 1 Type Specific IgG EIA (Trinity)	0	0.0%
Captia HSV 2 Type Specific IgG EIA (Trinity)	0	0.0%
Cobas HSV 1 and 2 Test (Roche)	0	0.0%
Elecsys HSV-1 IgG Immunoassay (Roche)	0	0.0%
HerpeSelect 1 and 2 Immunoblot IgG (Focus)	2	2.5%
HerpeSelect 1 ELISA IgG HSV-1 (Focus)	6	7.4%
HerpeSelect 2 ELISA IgG HSV-2 (Focus)	8	9.9%
HSV Type 1 IgG ELISA Test (Gold Standard Diagnostics)	0	0.0%
HSV Type 2 IgG ELISA Test (Gold Standard Diagnostics)	0	0.0%
SeraQuest HSV Type 1 Specific IgG (Quest)	0	0.0%
Sure-Vue HSV-2 (Fisher Scientific/Inova Diagnostics)	0	0.0%
ZEUS ELISA HSV gG-1 IgG Test System (Zeus Scientific)	0	0.0%
ZEUS ELISA HSV gG-2 IgG Test System (Zeus Scientific)	0	0.0%
Other	5	6.2%

Human Papillomavirus Testing

An average of 2,902 human papillomavirus (HPV) specimens were collected with a range of 500-4,372 (median: 3,835; interquartile range: 500-3,835. An average of 17.8% of specimens tested positive for HPV with a range of 10.0%-23.0% (median: 20.2%; interquartile range: 10.0%-23.0%).

Testing for HPV in PHLs is not very common, with only three state PHLs (3.7%) offering any HPV testing method. It may be that few PHLs offer HPV testing because HPV is not a notifiable STD and HPV testing is normally associated with clinical care versus public health. The number of laboratories offering HPV testing in-house or referring for testing are illustrated in Figure 23.

Figure 23. Type of HPV Tests Offered by Location (N=81)



Plans to Add or Drop STD Testing Services

Over a third (34.6%) of laboratories said they planned to add additional testing services within the next 12 months (from summer 2017 when the survey was conducted), 40.7% said they had no plans to add services, and 24.7% said they were unsure. Services that laboratories planned to add are detailed in Table 8.

Table 8. Plans to Add the Following STD Services in 12 Months (N=28)

Type of Test	N	%
Nucleic Acid Amplification (NAAT) for Detection of CT	1	3.6%
Any *Lymphogranuloma venereum* (LGV) testing	1	3.6%
Other Chlamydia testing	2	7.1%
NAAT for Detection of GC	1	3.6%
Gonorrhea culture	1	3.6%
GC antimicrobial susceptibility testing	5	17.9%
Other Gonorrhea testing	3	10.7%
Treponemal Syphilis Assays (e.g., EIA, Rapid)	8	28.6%
Other Syphilis testing	4	14.3%
Any Trichomonas testing	10	35.7%
Any HSV testing	7	25.0%
Any HPV testing	2	7.1%
Any *Mycoplasma genitalium* testing	7	25.0%

Type of Test	N	%
Any Next Generation Sequencing Methods for STDs	1	3.6%
Any other STDs	1	3.6%

Six laboratories (7.4%) said they planned to eliminate STD testing services within the next 12 months, while 70 (86.4%) said they did not plan to eliminate services, and five (6.2%) said they were unsure.

Testing Facilities, Funding and Billing

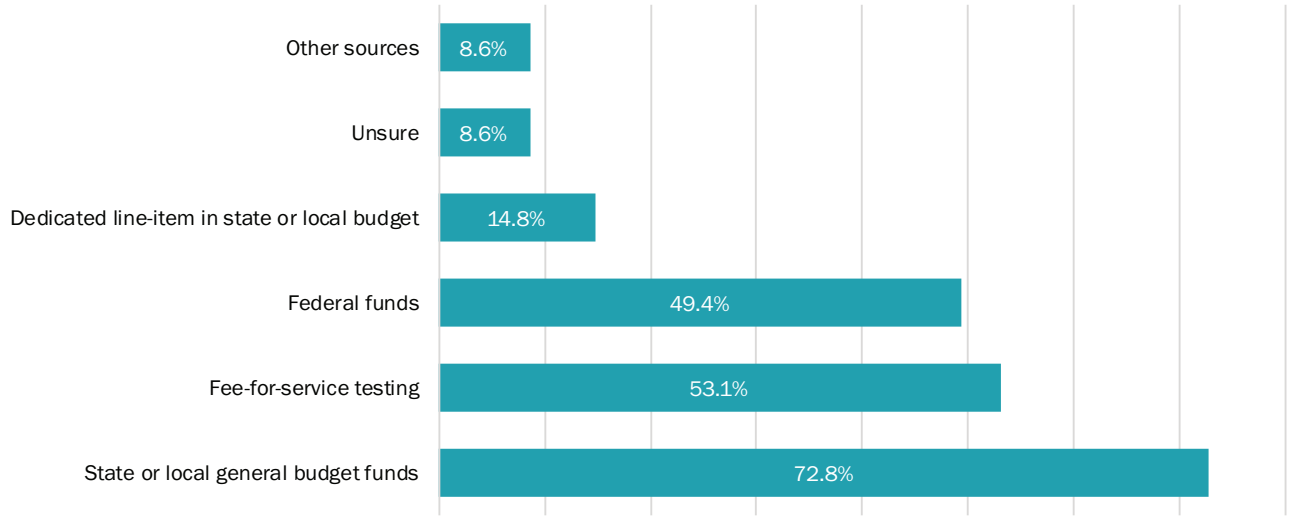
Public health laboratories reported receiving specimens from a variety of facilities for STD testing. The majority reported receiving specimens from public clinics (88.9%) and corrections facilities (67.9%). Types of facilities that submit patient specimens to laboratories for STD testing are listed in Table 9 below and stratified by laboratory type.

Table 9. Types of Facilities Submitting Patient Specimens to Lab for STD Testing by Lab Type (N=81)

Type of Facility	Local PHL (N=30) N (%)	State PHL (N=51) N (%)
Public clinic	28 (93.3%)	44 (86.3%)
Corrections	17 (56.7%)	38 (74.5%)
Other federal, state or local department or agency	4 (13.3%)	25 (49.0%)
Private physician office or clinic	6 (20.0%)	27 (52.9%)
Clinical laboratories in your jurisdiction	9 (30.0%)	31 (60.8%)
Non-profit agencies (e.g., Planned Parenthood)	9 (30.0%)	34 (66.7%)
Other	6 (20.0%)	11 (21.6%)

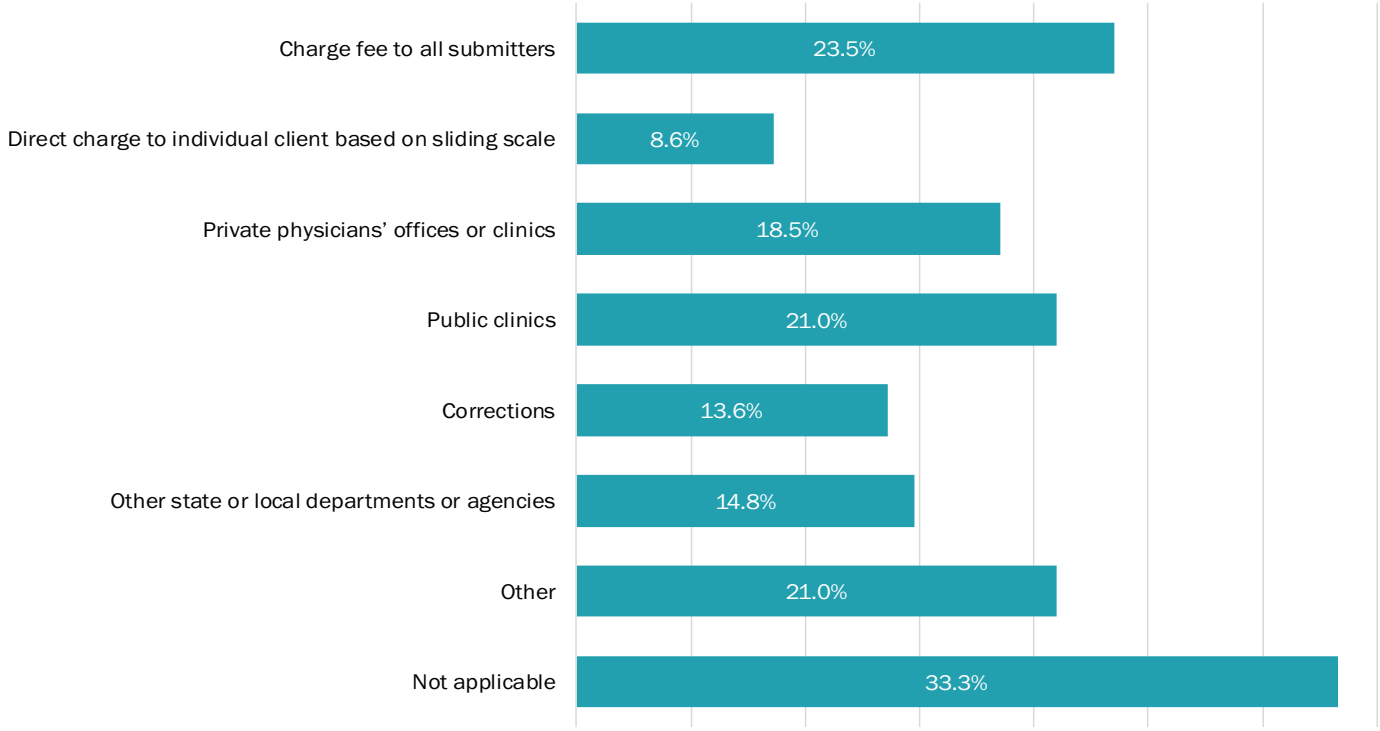
Nearly three-quarters (72.8%) of laboratories received funding from state or local general budget funds for STD testing and roughly half received funding from fee-for-service testing (53.1%) or federal funds (49.4%) (Figure 24).

Figure 24. Lab Funding Sources for STD Testing (N=81)



Public health laboratories had a wide range of submitters they charged fees to for STD testing. Nearly a quarter of PHLs (23.5%) charged fees to all submitters, 18.5% charged private physicians' offices or clinics, 21.0% charged public clinics, 13.6% charged corrections facilities, and 14.8% charged other state or local departments or agencies (Figure 25). Only 8.6% of laboratories directly charged individual clients based on a sliding scale.

Figure 25. Types of Submitters Charged Fees for STD Testing (N=81)



REFERENCES

1. Centers for Disease Control and Prevention. STDs in the United States, 2017.
2. Centers for Disease Control and Prevention. Recommendations for the Laboratory-Based Detection of *Chlamydia trachomatis* and *Neisseria gonorrhoeae* - 2014. Morbidity and Mortality Weekly Report 2014;63:1-18.
3. de Vries H. *Lymphogranuloma venereum* in the Western world, 15 years after its re-emergence: new perspectives and research priorities. Current Opinion in Infectious Diseases 2019;32:43-50.
4. Centers for Disease Control and Prevention. 2015 Sexually Transmitted Diseases Treatment Guidelines: Gonococcal Infections 2015.

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 project was 100% funded with federal funds from a federal program of $289,765.This publication was supported by Cooperative Agreement #NU60OE000103 from 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.

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