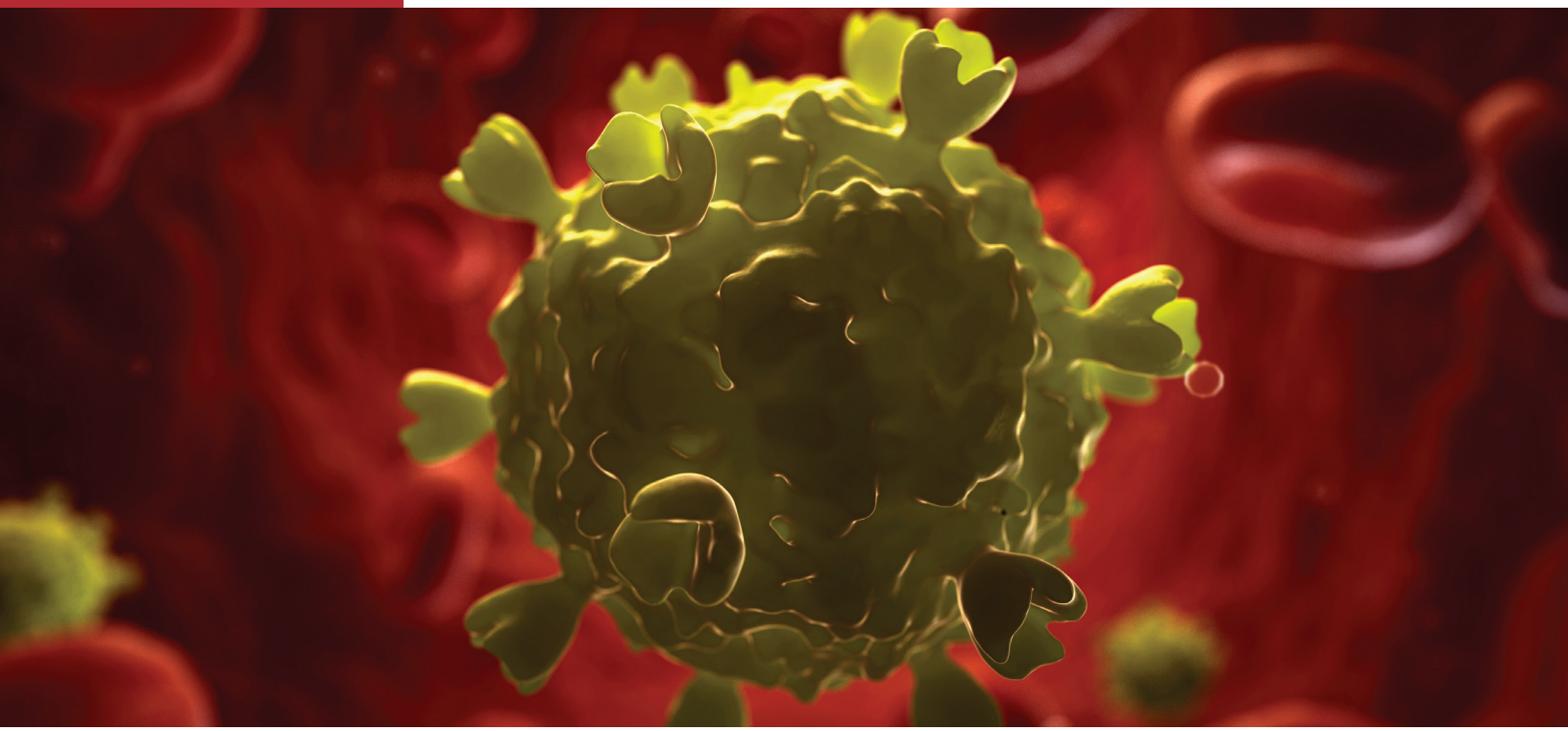
2019–2020 HIV and HCV Diagnostics Survey Report



MARCH 2022

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

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KEY HIGHLIGHTS

- **82% of responding public health laboratories (67 out of 82) offered HIV and/or HCV testing services, with 61% offering both services.**

- **88% of state laboratories (n=42) and 71% of local laboratories (n=24) offered HIV testing services.**
  - 95% of all laboratories (58 out of 61) offering HIV screening in-house assured in-house testing of or referral to supplemental testing and HIV NAT.

- **75% of state laboratories (n=36) and 44% of local laboratories (n=15) offered HCV testing services.**
  - 76% of laboratories that perform HCV screening automatically reflex from screening to RNA testing (either in-house or referral) for HCV Ab-positive specimens.

- **The COVID-19 pandemic significantly impacted public health laboratories' HIV and HCV testing.**
  - Laboratories most commonly reported decreased testing volume, staffing challenges and increased turnaround time.
  - From 2019 to 2020, specimen submissions specimen submissions declined by more than 400,000.
  - The average number of specimens received per laboratory decreased from over 20,000 to under 15,000.

INTRODUCTION

Background

Human immunodeficiency virus (HIV) and hepatitis C virus (HCV) both cause infections of public health importance and have significant clinical impact on those infected. As of 2019, approximately 1.2 million individuals were living with HIV in the US and over 35,000 new cases were diagnosed annually.[1] While incident HIV infections have been declining, HCV infections have been increasing. There were estimated to be 57,500 new HCV infections in 2019 and 2.4 million individuals in the US living with HCV between 2013 and 2016.[2,3]

Two national strategies exist to reduce the number of acute HIV and HCV infections in the US. The US Department of Health and Human Services (HHS) launched Ending the HIV Epidemic (EHE) in 2019 and in 2021 released the updated Viral Hepatitis National Strategic Plans for the United States: A Roadmap to Elimination (2021–2025). EHE seeks to reduce the number of acute HIV infections by 90% by 2030 through improved HIV diagnostics, prevention, treatment and response strategies.[4] Similarly, the Hepatitis Plan seeks to reduce new HCV infections by 90% by 2030 with similar goals to prevent new infections, improve hepatitis-related outcomes, reduce viral hepatitis-related disparities and health inequities, improve surveillance and establish coordinated efforts among partners and stakeholders that address the viral hepatitis epidemics, including collaboration with HIV programmatic partners.[5]

Public health laboratories play a critical role in reaching these national goals by contributing to confirmatory testing, surveillance, genotyping and drug susceptibility testing.

In 2021, the Association of Public Health Laboratories (APHL) fielded a survey to assess HIV and HCV testing capacities, capabilities and practices of member public health laboratories as of 2020. The survey also requested testing data from 2019 in order to evaluate the impacts of the COVID-19 pandemic on HIV and HCV testing capacities and capabilities. The results of the survey will help APHL understand the landscape of HIV and HCV testing in public health laboratories across

the US and will be used to inform education, training and advocacy efforts.

Methods

In May 2021, APHL fielded a 33-question survey to 106 APHL-member public health laboratories, including 59 state and territorial laboratories and 47 local laboratories. The state and territorial laboratories, which will be referred to simply as "state" laboratories throughout the document, include the District of Columbia (DC), Puerto Rico, US Virgin Islands and the US Affiliated Pacific Islands (USAPI). Public health laboratories were asked to report on HIV and HCV testing practices from January 2019 through December 2020. APHL's HIV-Viral Hepatitis (VH) Subcommittee developed the survey with input from the APHL Infectious Disease Committee. The survey was distributed via email to laboratory directors and administered via Qualtrics. Due to unique circumstances, three laboratories submitted responses via PDF and APHL staff manually entered responses. The survey closed June 2021.

Historically, APHL has surveyed member public health laboratories approximately every three years, beginning in 2003. Survey questions requested data on HIV diagnostic practices for a one-year period. To assess the impact of the pandemic on HIV and HCV testing practices, capacities and capabilities, this survey deviated from this tradition and requested data from two years, 2019 and 2020. In 2014, APHL added questions about HCV testing practices to the surveys. Data from the current survey was compared to five previous HIV/HCV surveys conducted by APHL (2005, 2008, 2011, 2014, 2017). The 2003 dataset did not include local public health laboratory responses, is limited in scope and, therefore, was not used for comparisons. In making comparisons across surveys (2005–2017), analysis of testing practices using all survey responses was performed, unless otherwise noted. In order to properly evaluate trends in workforce, testing volume and other testing trends, data were compiled for the subset of public health laboratories (n=25) that completed all prior surveys (2005–2017).

Response Rates and Testing Practices

Overall, 82 public health laboratories (77%, out of 106) completed the survey, including 48 state (59%) and 34 local public health laboratories (41%). State public health laboratories had a higher response rate (81%, n=59) compared to local public health laboratories (72%, n=47). One local public health laboratory submitted an incomplete response, which has been included in these results.

Of the 82 respondents, 82% (n=67) offered HIV and/or HCV testing while 18% (n=15) offered neither (**Table 1**). Nearly 90% of state public health laboratories (n=43) and 71% of local public health laboratories (n=24) offered one or both services. Overall, 66 public health laboratories offered HIV testing services and 51 public health laboratories offered HCV testing services.

Compared to 2017, a greater percentage of laboratories offered HCV testing in 2019–2020, increasing from 54% (44/81) to 62% (51/82). The number of laboratories offering both HIV and HCV testing also increased from 52% (42/81) to 61% (50/82). No change was noted in the percent of laboratories offering HIV testing only.

Table 1. HIV and HCV Testing Services Among Public Health Laboratories in 2019–2020

	State (n=48)	Local (n=34)	Total (n=82)
Offered HIV testing	42 (87.5%)	24 (71%)	66 (80.5%)
Offered HCV testing	36 (75%)	15 (44%)	51 (62%)
Offered HIV and HCV testing	35 (73%)	15 (44%)	50 (61%)
Offered neither HIV nor HCV testing	5 (10%)	10 (29%)	15 (18%)

COVID-19 Impact

Of considerable note, this survey requested data from 2019 and 2020, during which time SARS-CoV-2 (causative agent of COVID-19 infection) emerged. In December 2019, a novel respiratory infection was identified and by mid-March 2020, the World Health Organization (WHO) had declared COVID-19 a pandemic. Widespread shutdowns, stay-at-home orders and overwhelmed hospitals and laboratories followed. COVID-19 mitigation strategies substantially interfered with normal provision of healthcare and public health services. Public health laboratories that offered HIV and/or HCV testing services were asked to indicate which aspects of testing had been impacted by the COVID-19 response (**Table 2**).

Volume of testing, staffing and turnaround time (TAT) were most commonly reported as impacted for both HIV and HCV testing. Laboratories reported that testing volume declined significantly due to clinic closures and testing stoppages that resulted in fewer specimens submitted to public health laboratories. Due to decreased specimen submissions, some laboratories began batching samples, ultimately increasing TAT. During this time, staff turnover was high, and staff were also frequently reassigned to assist in the pandemic response, diverting their workload from their typical HIV or HCV responsibilities. Additionally, shortages strained resources and supplies in laboratories. For example, a plastic shortage beginning in mid-to-late 2020 led to shortages in test tubes, pipette tips and test kits. "Other" impacts described the types of testing that were impacted, such as viral load testing and HCV genotyping.

Throughout the COVID-19 pandemic, calls for reliable and high-quality 'self-testing' opportunities heightened. Public health laboratories were asked whether they had been approached by their health department about implementing testing to support 'self-testing' strategies for HIV or HCV and, if so, in what capacity.

The majority of public health laboratories (87%, 71/82) had neither implemented nor been approached regarding implementing HIV testing to support 'self-testing' strategies. However, 10 public health laboratories (12%, out of 82) indicated that they had been approached by their health department and were in the planning phases of how to address their needs; one public health laboratory was planning to validate alternative specimen types for HIV testing.

The majority of public health laboratories (90%, 74/82) had also neither implemented nor been approached by their health department regarding implementing HCV testing to support 'self-testing' strategies. However, six public health laboratories (7%, out of 82) indicated that they had been approached by their health department and were in the planning phases of how to address their needs; two public health laboratories were planning to validate alternative specimen types for HCV testing.

HIV TESTING

HIV Testing Practices

Sixty-six public health laboratories (42 state, 24 local) that offered HIV testing were asked to indicate which tests they performed in-house and/or made available through referral in 2019–2020 (**Table 3**). Among these 66 laboratories, the most commonly provided in-house tests were HIV immunoassays for screening (n= 61, 92%) and HIV antibody differentiation assays (n=59, 89%), which comprise the first two steps of the HIV laboratory laboratory diagnostic testing algorithm (**Figure 1**).

In 2019–2020, 33% of public health laboratories (22/66) offered in-house HIV-1 NAT (qualitative or quantitative), which was consistent with the 2017 survey results. Approximately one-quarter of all laboratories (17/66) offered qualitative HIV-1 NAT in-house; 45% (30/66) referred specimens to other laboratories.

Fewer than 25% of laboratories (n=66) offered or referred the following HIV test methods (**Table 3**): HIV-2 enzyme immunoassay (EIA) (12%), HIV-1 genotyping assay (21%), CLIA-waived point-of-care (POC) tests (11%), HIV-1 Western blot (11%) and HIV-1 immunofluorescence assay (IFA) (5%).

Of the other HIV testing services examined, nearly one-third of public health laboratories offered cadaveric testing (34%) and diagnostic testing of exposed infants (29%); one-quarter offered PrEP initiation and/or monitoring (25%) (**Table 4**). However, the majority of public health laboratories did not offer the testing services listed in **Table 4**. Fewer than 12% of

public health laboratories offered pooled NAT testing, recency testing and sequencing for cluster identification/molecular surveillance. Of the two public health laboratories that selected that they performed "Other" testing services, one public health laboratory offered quantitative HIV-2 NAT viral load testing and one public health laboratory provided test counseling and treatment follow-up/referral.

All public health laboratories that performed clinical HIV testing (n=66) were asked to identify specimen types accepted by their laboratories and the associated tests offered (**Table 5**). Serum and/or plasma were the most frequently accepted specimen types.

Table 2. Areas of HIV and HCV Testing Reported by Laboratories to be Most Impacted During the COVID-19 Response

Impact on HIV testing	State (n=42)	Local (n=24)	Total (n=66)
Volume of testing	37 (88%)	21 (88%)	58 (88%)
Staffing	25 (60%)	11 (46%)	36 (55%)
Increased TAT	13 (31%)	6 (25%)	19 (29%)
Resources	10 (24%)	3 (13%)	13 (20%)
Reagents/Supplies	7 (17%)	4 (17%)	11 (17%)
Equipment	2 (5%)	1 (4%)	3 (4.5%)
Decreased TAT	2 (5%)	1 (4%)	3 (4.5%)
Other	2 (5%)	0 (0%)	2 (3%)
Impact on HCV testing	**State (n=36)**	**Local (n=15)**	**Total (n=51)**
Volume of Testing	29 (81%)	11 (73%)	40 (78%)
Staffing	19 (53%)	5 (33%)	24 (47%)
Increased TAT	14 (%)	3 (20%)	17 (33%)
Resources	8 (39%)	1 (7%)	9 (18%)
Reagents/Supplies	7 (19%)	3 (20%)	10 (20%)
Equipment	3 (8%)	1 (7%)	4 (8%)
Decreased TAT	2 (6%)	0 (0%)	2 (4%)
Other	1 (3%)	0 (0%)	1 (2%)

Table 3. HIV Testing Performed or Available through Referral at Laboratories Offering HIV Testing (n=66)

Test Method Performed	In-House	Referral
HIV Immunoassay for Screening (e.g., HIV Ab or HIV Ag/Ab)	61 (92%)	3 (5%)
HIV Antibody Differentiation Assay (e.g., Geenius)	59 (89%)	6 (9%)
CLIA-Waived Point-of-Care Test/Rapid Diagnostic Test	7 (11%)	0 (0%)
Qualitative HIV-1 NAT	17 (26%)	30 (46%)
Quantitative HIV-1 NAT (viral load)	14 (21%)	11 (17%)
HIV-1 Genotyping Assay	8 (12%)	6 (9%)
HIV-1 IFA	0 (0%)	3 (5%)
HIV-1 Western Blot	4 (6%)	3 (5%)
Qualitative HIV-2 NAT	5 (8%)	22 (33%)
HIV-2 EIA	6 (9%)	2 (3%)

Table 4. Other HIV Testing Services Performed by Laboratories Offering HIV Testing (n=65)

Test Method/Service Performed	In-House	Referral
Cadaveric testing	22 (34%)	1 (2%)
Diagnostic testing of exposed infants	19 (29%)	2 (3%)
Pooled NAT testing	3 (5%)	2 (3%)
PrEP initiation and/or monitoring	16 (25%)	1 (2%)
Recency testing	4 (6%)	3 (5%)
Sequencing for cluster identification/molecular surveillance (Sanger or Next Generation)	4 (6%)	3 (5%)
Other	1 (2%)	1 (2%)

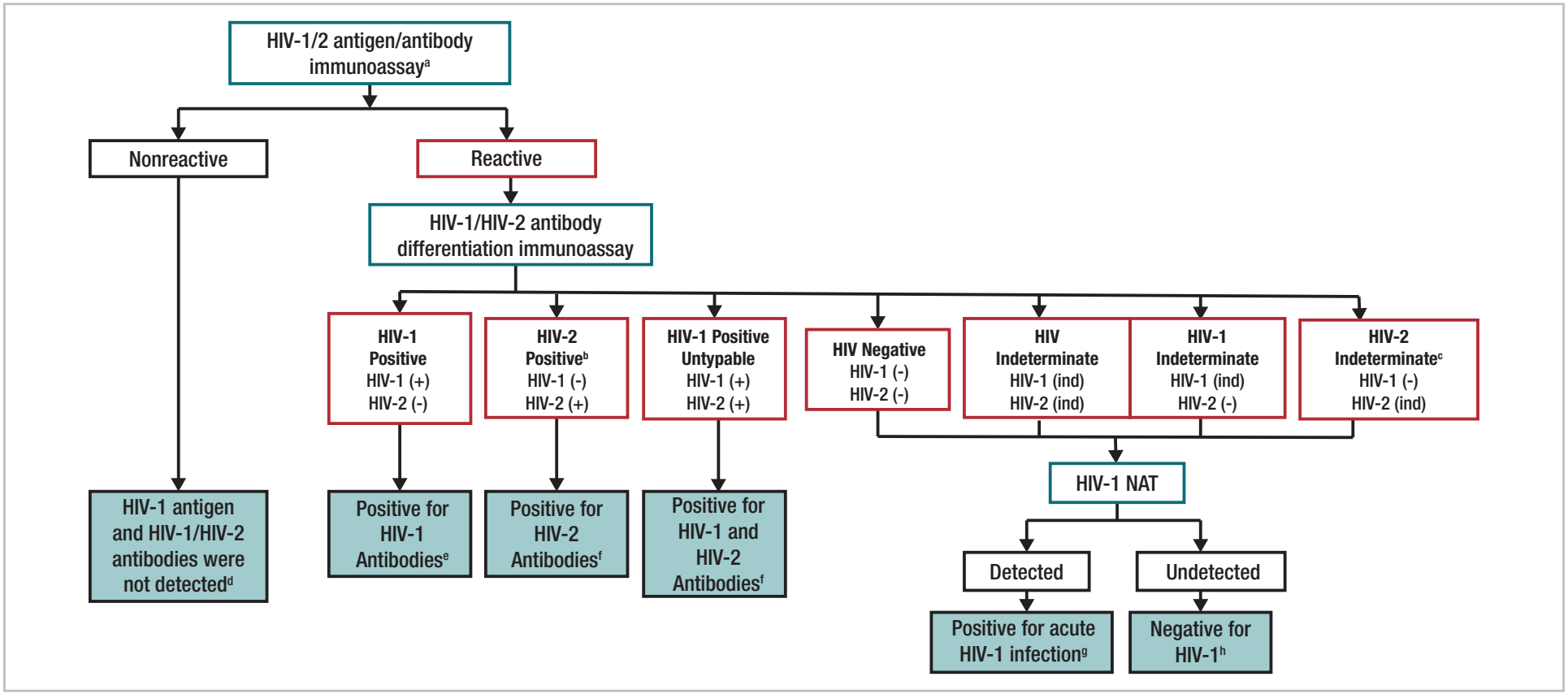
Table 5. Specimen Types Accepted and Testing Performed by Laboratories Offering HIV Testing (n=66)

	State	Local	Total
Serum and/or plasma to perform the entire HIV laboratory diagnostic algorithm	39	20	59 (89%)
Serum and/or plasma that was reactive on a screening assay at an-other clinical laboratory for completion of the diagnostic testing algorithm	21	8	29 (44%)
Any sample type to confirm preliminary positive CLIA-waived point-of-care (single-use) tests	15	5	20 (30%)
Any sample type for PrEP initiation or monitoring	7	9	16 (24%)
Other, please specify	3	5	8 (12%)
Dried blood spot (DBS) to perform the diagnostic testing algorithm	2	0	2 (3%)
Oral fluid to perform the diagnostic testing algorithm	1	1	2 (3%)

HIV Assay Utilization

The HIV laboratory testing diagnostic algorithm is a multi-step and, occasionally, complex process (**Figure 1**).

Figure 1. HIV Laboratory Diagnostic Testing Algorithm



[a] APHL and CDC continue to recommend that laboratories use an FDA-approved instrumented HIV-1/HIV-2 antigen/antibody immunoassays as the initial assay the initial assay in the laboratory HIV testing algorithm for serum or plasma due to their superior sensitivity for detecting acute HIV infection. However, the FDAapproved single-use rapid HIV-1/HIV-2 antigen/antibody immunoassay may be used as the initial assay the initial assay in the laboratory HIV testing algorithm for serum or plasma if an instrumented assay is not available.

[b] This includes specimens reported as HIV-2 positive with HIV-1 cross reactivity.

[c] Per the Geenius Package Insert, specimens with this final assay interpretation should be retested with a new cartridge. If the final assay interpretation is again HIV-2 indeterminate, it should be reported as such and followed with an HIV-1 NAT.

[d] If recent HIV exposure is suspected or reported, conduct HIV-1 NAT or request a new specimen and repeat the algorithm according to CDC Guidance.

[e] Link patient to HIV medical care and provide appropriate prevention counseling.

[f] link patient to HIV medical care and provide appropriate prevention counseling. Provider may consider additional testing.

[g] Link patient to HIV medical care and provide appropriate prevention counseling immediately to expedite prevention practices.

[h] A negative HIV-1 NAT result and repeatedly HIV-2 indeterminate or HIV indeterminate antibody differentiation immunoassay result should be referred for testing with a different validated supplemental HIV-2 test (antibody test or NAT) if available. Alternatively, redraw and repeat algorithm in 2–4 weeks to assess HIV-2 infection.

Screening Immunoassay

Public health laboratories were asked to select which HIV immunoassay (IA) their laboratory used for initial screening of serum/plasma specimens (**Table 6**). One public health laboratory indicated two IAs.

In 2019–2020, 92% of public health laboratories (61/66) performing HIV testing offered in-house HIV screening. Three public health laboratories referred specimens to other laboratories for screening; however, two of these laboratories usually offered in-house testing, but testing was suspended and/or diverted temporarily as a result of the COVID-19 pandemic. Two public health laboratories neither performed in-house screening nor referred specimens for screening; however, both laboratories are associated with clinics that perform CLIA-waived POC testing.

Including the two public health laboratories that suspended testing, 63 public health laboratories listed an immunoassay used for initial screening. Overall, 95% of public health laboratories (60/63) utilized an antigen/antibody IA. Six percent of public health laboratories (4/63) utilized a laboratory-based antibody only IA. The Abbott ARCHITECT HIV Ag/Ab Combo (n=26, 41%) and the Bio-Rad GS HIV Combo Ag/Ab EIA (n=21, 33%) were the most common IAs. The BioPlex 2200 HIV was also indicated by 11 public health laboratories (17%), which was an increase from 8% of laboratories offering Bioplex in 2017. One laboratory switched screening assays in 2020 from the Abbott ARCHITECT HIV Ag/Ab Combo to the Abbott Alinity i HIV Ag/Ab Combo.

Supplemental Antibody Assay

In 2019–2020, 59 out of 66 public health laboratories (89%) offered supplemental antibody testing. Of the laboratories that also offered in-house screening, 97% (59/61) performed supplemental assays in-house on serum/plasma. All public health laboratories that offered supplemental testing utilized the Bio-Rad Geenius HIV-1/2 Supplemental Assay. Six public health laboratories (9%) referred testing to another laboratory, one of which indicated referrals were temporary and that the laboratory had suspended testing due to COVID-19. When supplemental testing was not suspended, this public health laboratory also utilized the Bio-Rad Geenius HIV-1/2 Supplemental Assay. One public health laboratory (2%) did not perform nor refer specimens for supplemental testing in 2019–2020, and one public health laboratory switched assays from the Western blot to the Bio-Rad Geenius HIV-1/2 Supplemental Assay.

Table 6. HIV Immunoassays Used for Initial Laboratory Screening of Serum/Plasma Specimens

Type of Assay	Name of Immunoassay	2005 (n=60)	2008 (n=52)	2011 (n=60)	2014 (n=70)	2017 (n=63)	2020 (n=63)
Laboratory-based Ag/Ab IA	Abbott ARCHITECT® HIV Ag/Ab Combo			9 (15%)	17 (24%)	26 (41%)	26 (41%)
	Abbott Alinity i HIV Ag/Ab						1 (2%)
	Alere Determine™ HIV-1/2 Ag/Ab Combo (Rapid)				1 (1%)	3 (5%)	1 (2%
	Bio-Rad GS HIV Combo Ag/Ab EIA			4 (7%)	28 (40%)	25 (40%)	21 (33%)
	Bio-Rad BioPlex® 2200 HIV Ag-Ab					5 (8%)	11 (17%)
Subtotal		**n/a**	**n/a**	**13 (21.6%)**	**46 (66%)**	**59 (94%)**	**60 (95%)**
Laboratory-based Ab IA	Bio-Rad GS HIV-1/HIV-2 Plus O EIA	9 (15%)	39 (75%)	36 (60%)	15 (21%)	2 (3%)	4 (6%)
	Abbott HIV AB HIV 1/2	7 (12%)	2 (4%)	1 (2%)			
	ADVIA Centaur® HIV 1/O/2 Enhanced		3 (6%)	3 (5%)	3 (4%)	1 (2%)	0 (0%)
	Ortho VITROS® Anti-HIV 1+2 Immunoassay			2 (3%)	2 (3%)		
	Bio-Rad Plus rLAV EIA	7 (12%)	5 (10%)			3 (4%)	
	Avioq HIV-1 Microelisa			4 (7%)	3 (4%)		
Subtotal		**60 (100%)**	**49 (94%)**	**46 (76.6%)**	**23 (33%)**	**3 (5%)**	**4 (6%)**
Rapid Ab IA	Uni-Gold™ Recombigen HIV			1 (2%)		1 (2%)	
	Clearview® STAT PAK Assay		2 (4%)		1 (1%)		
	OraQuick ADVANCE®		1 (2%)				
Subtotal		**0 (0%)**	**3 (6%)**	**1 (2%)**	**1 (2%)**	**1 (2%)**	**0 (0%)**

Supplemental HIV-1 Nucleic Acid Test

Laboratories were asked to describe which NAT services they offered or referred, which specimens were accepted for NAT and for what purposes NAT was utilized (**Table 7**). Of the 66 public health laboratories that provided HIV testing services, 33% (n=22) performed qualitative or quantitative NAT in-house (consistent with the rate (32%) observed in 2017) and 65% (n=43) referred specimens to other laboratories. Three laboratories provided both in-house NAT for viral load and clinical management purposes and referred for NAT as part of the diagnostic algorithm. Thus, 62 out of 66 laboratories (94%) ensured HIV NAT was accessible through in-house testing or referral. One public health laboratory removed HIV-1 NAT from their test menu in 2019 due to low requests and three public health laboratories neither provided nor referred for NAT for the duration of 2019–2020. Approximately 6% of public health laboratories neither performed nor referred specimens to the third step of the laboratory diagnostic testing algorithm.

Laboratories were also asked to describe which NAT methods they offered and for what purpose (**Table 8**). Of the 22 public health laboratories that offered NAT in-house, most (95.5%, n=21) provided NAT for diagnosis/detection of acute infection. APTIMA HIV-1 RNA Qualitative assay (54.5%, n=12) was the most commonly used method followed by laboratory developed tests (LDTs) (18%, n=4). Over half (59%, n=13) offered NAT for clinical management/viral load testing and just over one-third (n=8, 36%) offered NAT for supplemental testing for HIV-1 p24 Ag positive samples. The APTIMA HIV-1 Quant Assay and Realtime HIV-1 Amplification kit, m2000 were the most frequently used methods for clinical management/viral load testing. The APTIMA HIV-1 RNA Qualitative assay was also the most commonly used assay for supplemental testing for HIV-1 p24 Ag positive samples. Three laboratories also used NAT for "Other" purposes, including HIV-1 pooling, a research project and exposed infant diagnoses.

Serum (64%, n=14) and plasma (73%, n=16) were the most commonly accepted specimen types. Only five public health laboratories accepted whole blood and one accepted dried blood spots.

Table 7. HIV-1 NAT in Public Health Laboratories

	Number of public health laboratories
Is HIV-1 NAT performed in-house? (n=66*)	
Yes, we perform testing in-house	22 (33%)
No, we refer out specimens	43 (65%)
No, NAT is neither performed not referred	3 (6%)
Other	1 (1%)
What specimen types are accepted for HIV-1 NAT? (n=22)	
Serum	14 (64%)
Plasma	16 (73%)
Whole Blood	5 (23%)
Dried Blood Spot	1 (5%)
Where does your lab refer HIV-1 NAT? (n=43)**	
APHL HIV NAT Reference Center Laboratory	30 (70%)
Another public health laboratory	9 (21%)
A commercial laboratory	2 (5%)
Clinical or hospital laboratory in your jurisdiction	1 (2%)

*Three laboratories performed HIV-1 NAT in house and also referred specimens out.
**43 laboratories refer specimens; however, one laboratory did not provide a response to indicate where specimens were referred to for HIV-1 NAT.

HIV NAT is a critical third step in the HIV laboratory diagnostic testing algorithm, but for many laboratories in-house HIV-1 NAT may be cost prohibitive. Many laboratories do not receive enough specimens that qualify for NAT (i.e., positive screening assay and negative or indeterminate supplemental assay) to justify the cost of bringing NAT in-house. As a result, APHL in coordination with CDC, established two HIV Nucleic Acid Testing Reference Centers in 2012. This shared service model allows laboratories that participate in the program to submit qualifying samples to one of two designated reference centers for HIV NAT. Among the 43 laboratories that referred specimens out for HIV NAT in 2019–2020, the majority of laboratories (70%, n=30) referred specimens to one of the two APHL HIV NAT Reference Center Laboratories (**Table 7**). Just over 20% (n=9) referred specimens to another public health laboratory, such as a state public health laboratory or a CDC laboratory. Two public health laboratories referred specimens to commercial laboratories, (i.e., Quest or LabCorp); one public health laboratory referred specimens to a clinical and/or hospital laboratory. One laboratory did not provide a response.

Testing Volume and Specimen Types

APHL asked public health laboratories to report the total number of specimens their laboratories received and further break down this number by the types of specimens received. These numbers excluded proficiency testing specimens or specimens submitted solely for patient management. While 66 public health laboratories provided responses, three laboratories were excluded because the number of specimens tested and total number of specimens by type were incongruent by more than 100 specimens. Minor discrepancies between number of specimens processed and number of specimen types were attributable to challenges with estimations within LIMS among other factors.

In 2019, nearly 1.3 million specimens were received, averaging 20,580 specimens per laboratory. Specimens received per public health laboratory ranged from 0 to 255,920, with a median of 6,618 specimens.

In 2020, the number of specimens received declined by more than 400,000; fewer than 900,000 specimens were received. The average number of specimens received per public health laboratory decreased by over 6,400 and laboratories tested on average 14,416 specimens. Specimens received per public health laboratory ranged from 0 to 222,280, with a median of 4,153 specimens.

While specimens submitted to public health laboratories has been declining since this survey was first fielded in 2005, the sharp decline between 2019 and 2020 is primarily attributable to the COVID-19 pandemic. Numerous factors impacted testing volume. For example, clinics closed and/or suspended testing and patients were likely hesitant to seek testing.

The most common specimen types were serum (54% in 2019, 49% in 2020) and serum/plasma (unable to distinguish) (32% in 2019, 36% in 2020), which is consistent with previous years (**Figures 2** and **3**). However, in 2017, 69% of specimens were serum and 15% were serum/plasma (unable to distinguish), displaying a dramatic drop in serum submissions (30%) and increase (>130%) in serum/plasma (unable to distinguish) specimens in three years. This drop in serum submissions may be balanced by the increase in specimens identified as serum/plasma (unable to distinguish). Some shift is likely also attributable to different laboratories responding to the 2017 and 2019–2020 surveys. The drop could also be attributable to educational efforts by public health laboratories to expand knowledge of testing opportunities available using plasma. For example, baseline viral load is possible using plasma.

Whole blood was also commonly submitted in both 2019 and 2020, making up 11–12.5% of all submissions each year. This was a slight increase from the 9% of public health laboratories that received whole blood in 2017. Plasma (2%), oral fluid (1%) and dried blood spots (<1%) were the least common specimen types received for diagnostic testing.

Table 8. HIV NAT Methods and Purpose (n=22)

	Diagnosis/ detect acute infection	Supplemental test for HIV-1 p24 Ag positive samples*	Clinical management/ Viral load	Other purpose
APTIMA HIV-1 RNA Qualitative Assay (Hologic)	12	4	0	1
APTIMA HIV-1 Quant Assay-Panther (Hologic)	2	2	7	0
COBAS Ampli-Prep/COBAS TaqMan HIV-1 Test on 48/96 (Roche)	1	2	2	0
Cobas HIV-1 on 6800/8800 (Roche)	1	1	1	0
RealTime HIV-1 Amplification Kit, m2000 (Abbott)	2	0	4	1
Other Quantitative HIV-1 RNA Assay	1	1	1	0
Laboratory Developed or Modified FDA Approved NAT, Qualitative	4	1	0	1
Laboratory Developed or Modified FDA Approved NAT, Quantitative	1	0	0	0
Total	**18** (82%)	**8** (36%)	**13** (59%)	**2** (9%)

* Following BioPlex 2200 HIV Ag-Ab or Alere Determine HIV-1 Ag only results

Figure 2. HIV Specimen Types Received for HIV Diagnostic Testing in 2019 (percentage) (n=1,296,550)

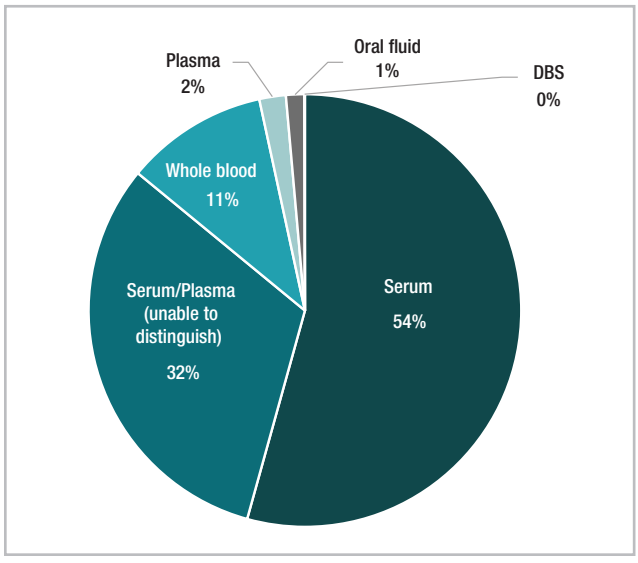
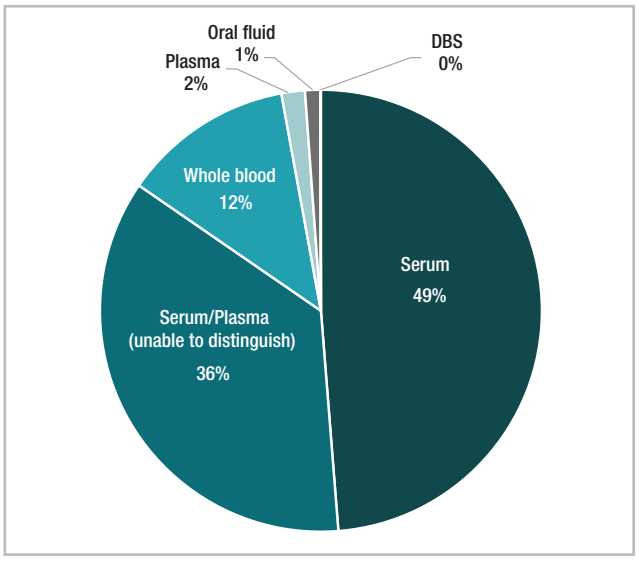


Figure 3. HIV Specimen Types Received for HIV Diagnostic Testing in 2020 (percentage) (n=894,546)



Trends in Oral Fluid Testing

In the 2017 APHL HIV-HCV Diagnostics Survey, 16 out of 65 public health laboratories (25%) accepted and screened oral fluid specimens. However, 10 public health laboratories planned to discontinue oral fluid testing and one public health laboratory planned to move to a rapid/rapid algorithm. This trend toward discontinuation of oral fluid testing was observed in the 2021 survey. In 2019–2020, 95% of public health laboratories (n=63) did not screen oral fluid for HIV. Only two public health laboratories (3%) accepted oral fluid specimens by the end of 2020 as one public health laboratory that previously accepted oral fluid specimens suspended HIV testing due to the pandemic response. Both laboratories used the Avioq HIV-1 Microelisa. Because there are no FDA-approved methods for confirmation of HIV in oral fluid specimens, these public health laboratories were asked to describe how they handled HIV confirmation. Both public health laboratories performed an in-house validation of the Bio-Rad Geenius HIV-1/2 Supplemental Assay.

Testing Volume Trends

Based on analyses of 25 public health laboratories (24 state, 1 local) that have submitted HIV testing data from 2005 through 2020 (six surveys), testing volume has progressively declined since 2005, during which time testing volume peaked at 1.19 million specimens (**Figure 4**). By 2019, overall testing volume declined by nearly 50%. By 2020, testing volumes declined by two-thirds. However, this dramatic decline seen between 2019 and 2020 is largely attributable to numerous factors associated with the COVID-19 pandemic.

Figure 4. Samples Received for HIV Testing – Volume Trends for Public Health Laboratory System, 2005–2020 (n=25)

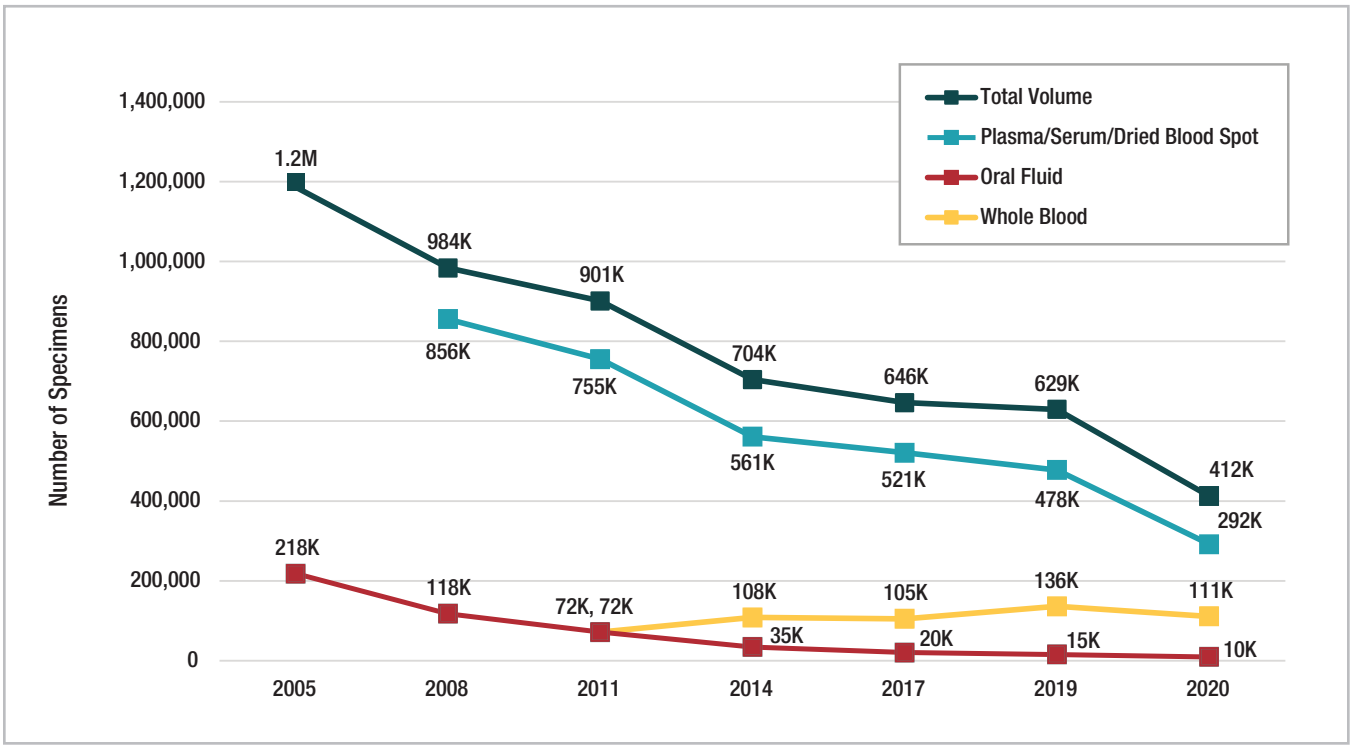


Figure 4: The 2005 survey data cannot be parsed to determine test volume for plasma/serum or whole blood. The 2008 survey data cannot be parsed to determine whole blood volume.

As seen with the total volume of specimens, oral fluid testing also peaked in 2005, with approximately 218,000 specimens submitted, making up 18% of all specimens submitted (**Table 10**). In 2019, 15,488 specimens were received and by 2020, fewer than 10,000 oral fluid specimens were received. Oral fluid specimens submitted declined over 95%. This is congruent with fewer public health laboratories offering oral fluid testing (25 laboratories in 2005 and two laboratories by the end of 2020) as well as trends in the market for oral fluid tests, including the discontinuation of the only FDA-approved supplemental assay for oral fluids.

Additionally, since 2017, at least four laboratories that had completed the testing survey each previous year had discontinued HIV testing services.

Table 10. Testing Volume Change, by Specimen Type and Percent Contribution to Total Volume (n=25)

Specimen Type	Survey Year							Percent Change Between Survey Years		
	2005 (1,551,077)	2008 (1,201,751)	2011 (1,085,714)	2014 (852,118)	2017 (735,134)	2019 (629,344)	2020 (412,195)	2005/8-2020	2017-2019	2019-2020
Proportion of Total Volume										
Oral Fluid	18%	10%	7%	4%	3%	2%	2%	-89%	-3%	0%
Plasma/ Serum/DBS	Not Available	89%	78%	79%	83%	76%	71%	-20%	-8%	-7%
Whole Blood	Not available	Not available	14%	16%	14%	22%	27%	0%	57%	23%

The 2005 survey data cannot be parsed to determine test volume for plasma/serum or whole blood. The 2008 survey data cannot be parsed to determine whole blood volume.

HIV Infections Detected

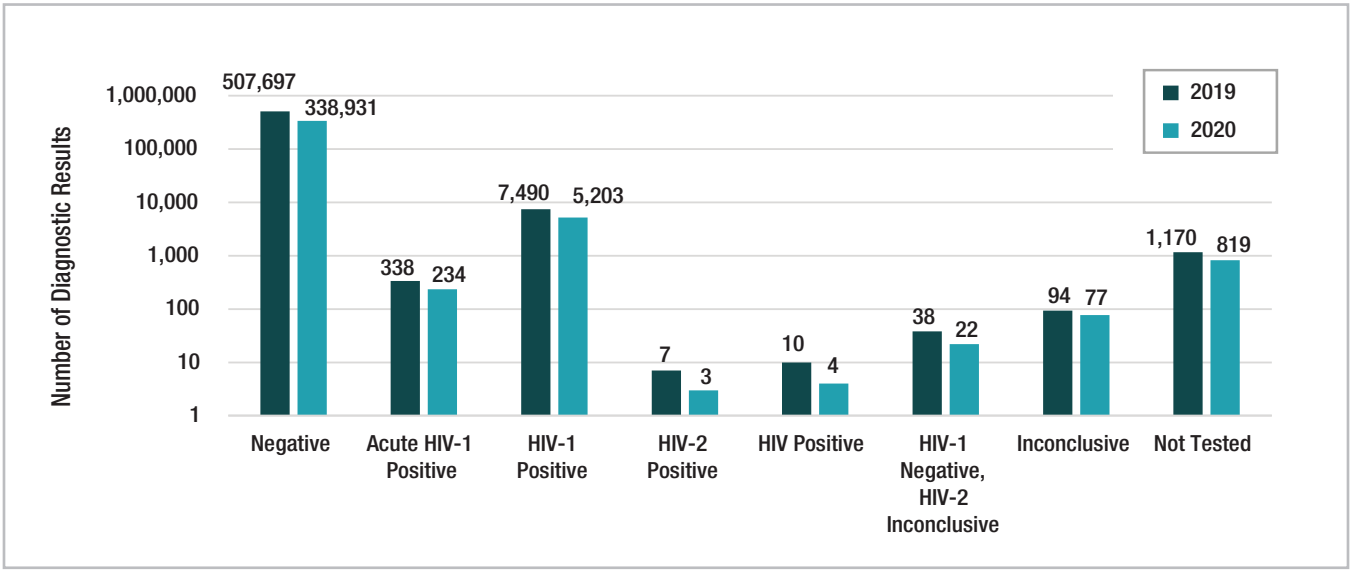
Public health laboratories were asked to report results for serum and/or plasma tests in 2019 and 2020. Due to incomplete reporting, only a subset of the data was suitable for analysis. For public health laboratories to be included in the analysis they had to report testing volumes for serum, plasma and/or serum/plasma (unidentified), and the number of results reported had to be within 100 specimens of their reported number of specimens received.

Results were categorized into one of the following:

- Negative
- Acute HIV-1 Positive
- HIV-1 Positive
- HIV-2 Positive
- HIV Positive
- HIV-1 Negative/HIV-2 Inconclusive
- Inconclusive
- Not Tested

Data on 517,159 specimens from 47 laboratories in 2019 and 345,293 specimens from 49 laboratories in 2020 were analyzed (**Figure 5**). For various reasons, such as sample rejection, approximately 0.2% of specimens were not tested.

Figure 5. Reported HIV Diagnostic Results for Serum/Plasma Specimens (2019, n=47; 2020, n=49)



Each year, public health laboratories reported 98.2% of specimens as negative, a slight increase from 2017. Overall, in 2019 the positivity rate was 1.5%. The positivity rate increased slightly in 2020 to 1.58%. Both years displayed a slight increase from 2017 when 1.3% of specimens from 59 public health laboratories tested positive. **Table 11** displays the HIV test results from 2017, 2019 and 2020. Of note, the proportion of specimens not tested decreased from 1.1% to 0.2% in both 2019 and 2020. This is significant because specimens that are not tested require patients return for additional specimen collection, which may or may not occur, and ultimately extends waiting periods and possibly delays

Table 11. Final HIV Results Reported by Public Health Laboratories as a Percentage of Total HIV Result, By Year

	2017 (n=59)	2019 (n=47)	2020 (n=49)
Negative	97.6%	98.2%	98.2%
HIV-1 Positive	1.2%	1.5%	1.5%
Acute HIV-1 Positive	0.07%	0.07%	0.07%
HIV-2 Positive	0.001%	0.001%	0.001%
HIV Positive	0.012%	0.002%	0.001%
HIV-1 Negative/HIV-2 Inconclusive	0.019%	0.007%	0.006%
Inconclusive	0.026%	0.018%	0.023%
Not Tested	1.1%	0.226%	0.237%

Confirmation of Rapid Reactive Specimens

An important role for public health laboratories is testing specimens from CLIA-waived settings. CLIA-waived settings may use POC rapid tests to screen their patients and subsequently send preliminary positive specimens to public health laboratories to complete the laboratory diagnostic testing algorithm. Different specimen types, such as DBS or oral fluid, that screen positive in a CLIA-waived setting follow different testing algorithms.

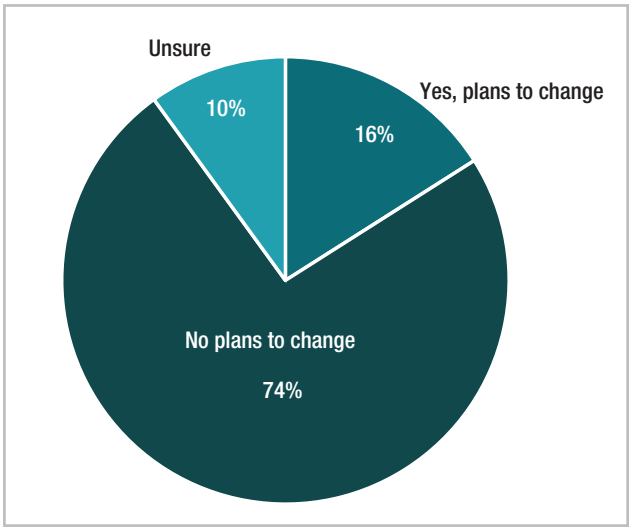
In 2019–2020, 20 laboratories reported accepting specimens for confirmation of preliminary positive POC (single-use) tests performed outside the laboratory in a CLIA-waived setting (**Table 4**). Of these laboratories, 12 (60%) received tests to confirm preliminary positive specimens but were unable to determine which samples received fell into this category. One laboratory did not provide responses to questions asking about specimens received for confirmation of preliminary positive POC tests. The remaining seven laboratories (35%) were able to identify samples from POC tests. HIV Ag/Ab or HIV Ab assays were the most commonly used assays to confirm a preliminary positive. Although seven public health laboratories accept preliminary positive specimens and could identify them as such, only three public health laboratories reported receiving specimens in 2019 and 2020. In 2019, 842 specimens were tested. In 2020, 75 specimens were tested. In these three labs, submissions of preliminary positive specimens tested on POC tests performed outside the laboratory in a CLIA-waived setting decreased by 91%. This decrease could reflect decreases in the CLIA-waived testing due to lack of access to testing services or potentially due to the CLIA-waived setting confirming by another method, such as the rapid-rapid algorithm or sending their specimens to another laboratory.

Planned Changes to HIV Testing

Respondents (n=82) were asked to describe any planned changes to current HIV testing practice in their laboratories prior to December 31, 2021, which was approximately 1.5 years after distribution of the survey (**Figure 6**). Nearly three-quarters of public health laboratories (n=61) had no plans to implement changes to their testing practices. Thirteen public health laboratories reported planned changes and eight public health laboratories were unsure of any planned changes.

Only two public health laboratories had plans to eliminate or decrease testing; the remaining 11 public health laboratories planned to replace assays or add new testing services.

Figure 6. Planned Changes to HIV Testing Practices



SCREENING IMMUNOASSAY

Additions or Changes

- Seven public health laboratories planned to replace an existing screening assay with a new screening assay.
- Two public health laboratories planned to modify an existing screening assay.

Eliminate or Decrease

- One public health laboratory planned to eliminate an existing screening assay.

SUPPLEMENTAL ANTIBODY ASSAY

Additions or Changes

- Two public health laboratories planned to modify an existing supplemental antibody assay.

SUPPLEMENTAL HIV-1 NUCLEIC ACID ASSAY

Additions or Changes

- Three public health laboratories planned to add an HIV NAT to be performed on site.
- Two public health laboratories planned to replace an existing HIV NAT performed on site with a new HIV-1 NAT.
- One public health laboratory planned to modify an existing HIV NAT.

OTHER HIV TESTING SERVICES

Additions or Changes

- Three public health laboratories planned to replace current genotyping methods.
- One public health laboratory planned to add HIV sequencing.

Eliminate or Decrease

- One public health laboratory planned to eliminate HIV genotyping (plan to send specimens to another public health laboratory moving forward).

Outreach, Training, Education on the Recommended Laboratory Diagnostic Testing Algorithm

Twenty-seven public health laboratories (33%, n=82) provided outreach, including training, education or consultation, regarding HIV diagnostic testing in 2020. This is a slight decrease from the 40% of public health laboratories (32/80) that provided outreach in 2017. Algorithm interpretation and result interpretation were the most frequently identified topics of outreach, provided by 85% of these laboratories (23/27). **Table 12** displays the most common topics on which public health laboratories provided outreach.

These 27 public health laboratories most frequently provided outreach, training education or consultation to health department HIV prevention programs (n=22), clinicians/providers (n=17) and HIV surveillance programs (n=16). "Other" entities that received consultation included departments of correction, contracted testing sites and local health departments (unspecified programs). The modality by which outreach was provided frequently involved informal consultation via phone, email or other platform (n=23), written guidance/information (n=14) or in-person training (n=8). Of note, in 2017, public health laboratories reported in-person seminars or meetings as the most common modalities (44%, 14/32).

Table 12. Topics on which Public Health Laboratories Provided Outreach; Entities to Whom Public Health Laboratories Provided Outreach; Modalities by which Outreach was Provided (n=27)

Common topics on which public health laboratories provided outreach regarding HIV diagnostic testing	Number of public health laboratories (n=27)
Algorithm Interpretation	23 (85%)
Result Interpretation	23 (85%)
Specimen Handling/Requirements	16 (59%)
Specimen Collection-Traditional Samples and Methods	12 (44%)
Result Reporting	11 (41%)
Implementing recommended laboratory diagnostic testing algorithm (appropriate tests, sequence)	9 (33%)
Supplemental HIV Ab differentiation tests (performance or platforms)	7 (26%)
Testing for PrEP Enrollment or PrEP Maintenance	6 (22%)
HIV-1 NAT/RNA for Diagnosis (performance or platforms)	5 (18.5%)
Rapid Tests (performance and selection of test kit)	5 (18.5%)
Screening Methods: HIV Ag/Ab or HIV Ab Immunoassays (performance or platforms)	5 (18.5%)
Entities to whom public health laboratories provided outreach	
HIV Prevention Program (Health Department)	22 (81%)
Clinicians/Providers	17 (63%)
HIV Surveillance Program (Health Department)	16 (59%)
HIV Patient Care (Health Department)	5 (18.5%)
Other public health laboratories	5 (18.5%)
Other, please specify	4 (15%)
Hospital Laboratories	3 (11%)
CLIA-waived Testing Sites	3 (11%)
Commercial Laboratories	2 (7%)
Modalities for outreach in 2020	
Informal consultation via phone, email, or other	23 (85%)
Written guidance or information (e.g., newsletter, policy update, template procedures)	14 (52%)
In-person training	8 (30%)
Web-based seminar/meeting	6 (22%)
In-person seminar/meeting	6 (22%)
Web-based training	2 (7%)

On the Horizon: New HIV Testing Technology

HIV testing technology is evolving with assays entering and leaving the market regularly. In order to provide the most efficient and effective testing services, public health laboratories must stay current on new and updated technologies. All respondents were provided a list of new technologies and asked to select the technologies they would be most interested in bringing in-house, should the technologies be FDA-approved and/or included in the APHL/CDC laboratory diagnostic testing algorithm (**Table 13**).

Approximately 60% of public health laboratories were interested in HIV-1 NAT with a dual claim and nearly half of respondents were interested in an HIV-1/HIV-2 assay. Public health laboratories also indicated that rapid HIV NAT (37%) and HIV-1 NGS methods (33%) would be of interest.

Table 13. Laboratories Noted Interest in Potential New HIV Testing Technology, Grouped by Whether the Laboratory was Currently Performing HIV Testing or Not.

Potential New HIV Testing Technologies	All Respondents (n=82)	Currently Performing HIV Testing (n=66)	Not Currently Performing HIV Testing (n=16)
HIV-1 NAT with a dual claim (single assay that is FDA approved for diagnosis and viral load monitoring)	38 (46%)	33 (50%)	5 (31%)
HIV-1/HIV-2 NAT	31 (38%)	26 (39%)	5 (31%)
Rapid HIV NAT (HIV-1 and/or HIV-2)	23 (28%)	19 (29%)	4 (25%)
HIV-1 NGS Method	21 (26%)	18 (27%)	3 (19%)
Alternative supplemental HIV-1/2 antibody differentiation assay	16 (20%)	15 (23%)	1 (6%)
Alternative HIV-1/2 Ag/Ab Differentiating Combination Immunoassay	15 (18%)	14 (21%)	1 (6%)
Rapid HIV-1/2 Ag/Ab Combination Immunoassay	11 (13%)	7 (11%)	4 (25%)
HIV-2 NAT	6 (7%)	4 (6%)	2 (13%)
HIV-1 p24 Ag confirmatory assay	11 (13%)	11 (17%)	0 (0%)
Other, please specify	1 (1%)	1 (2%)	0 (0%)
None of the Above	19 (23%)	12 (18%)	7 (%)

HCV TESTING

HCV Testing Services

Of the 82 respondents, 51 public health laboratories (62%) indicated that they offered testing services for the diagnosis or management of HCV during 2019 and 2020. This included 15 local and 36 state laboratories. However, one local public health laboratory discontinued HCV services in 2020 and has not provided additional information regarding services provided prior to discontinuation.

Respondents were asked to identify HCV testing services offered and to describe the HCV antibody tests and HCV RNA methods utilized. The majority of public health laboratories offering HCV services (n=50) provided HCV antibody (92%) and HCV RNA (58%) testing (**Table 14**). Antibody testing is utilized as the first step in diagnosis of HCV infection and used to screen patients before sending samples for confirmation using HCV RNA testing. With over half of all laboratories (46/82) offering HCV testing and nearly one-third of all laboratories (29/82) offering HCV RNA nucleic acid testing, there is a high level of diagnostic HCV testing capacity among public health laboratories.

Fewer than eight public health laboratories offered genotyping and only three public health laboratories offered sequencing services.

Table 14. HCV Testing Services

HCV Testing Service	State (n=36)	Local (n=14)	Total (n=50)
HCV Ab (Anti-HCV); laboratory based or rapid test	34	12	46 (92%)
HCV RNA (quantitative or qualitative)	21	8	29 (58%)
HCV Genotyping	4	3	7 (14%)
HCV Sequencing	3	0	3 (6%)

Laboratories were also asked to identify their HCV laboratory diagnostic testing algorithm (**Table 15**). Currently, the CDC recommends screening of HCV with an HCV Ab (Anti-HCV) assay followed by confirmation with HCV RNA testing. Following a positive screening assay, 19 out of 46 laboratories (41%) that perform screening automatically reflex to in-house RNA testing.

Approximately 76% of laboratories that perform screening utilize testing algorithms that reflex or refer positive specimens to RNA testing. This is a best practice because it helps ensure specimens that screen positive receive the necessary subsequent testing and diagnosis, facilitating timely care and treatment. Eleven laboratories didn't follow this algorithm and may report results following a positive screening test or offer RNA testing upon request. Laboratories may offer this alternative algorithm for many reasons, such as restrictions within their laboratory or state or local agreements with submitting clinicians. However, herein lies a significant opportunity for public health laboratories to further impact HCV elimination. By implementing automatic reflexing, laboratories help ensure that the necessary tests are run in a timely manner and the burden of returning for additional specimen collection does not fall on the patient or provider, thus reducing loss to follow up. Further examination and conversations of barriers may reveal opportunities to implement automatic reflexing.

Table 15. HCV Testing Algorithms Performed by Public Health Laboratories

Testing Performed and Next Steps	State (n=36)	Local (n=14)	Total (n=50)
Laboratory Performs HCV Ab Screening and HCV RNA Testing	**19**	**6**	**25** (50%)
Automatically reflexes to perform HCV RNA testing in-house (using the same sample)	12	5	17 (34%)
Other, please specify	5	1	6 (12%)
Performs an HCV RNA testing in-house upon request (using the same sample)	1	0	1 (2%)
Requests another sample to perform HCV RNA testing in-house	1	0	1 (2%)
Laboratory performs HCV Ab Screening Only	**15**	**6**	**21** (42%)
Recommends provider submit a specimen for HCV RNA testing to another laboratory	5	3	8 (16%)
Automatically refers to another laboratory for HCV RNA testing (using the same sample)	5	1	6 (12%)
Other, please specify	3	2	6 (12%)
Automatically refers to another laboratory for HCV RNA testing (using an additional sample already submitted)	1	0	1 (2%)
Requests submission of another sample to refer to another laboratory for HCV RNA testing	1	0	1 (2%)
Laboratory Performs HCV RNA Testing Only	**2**	**2**	**4** (8%)

HCV Assay Utilization

Public health laboratories that performed HCV antibody screening, RNA testing or genotyping were asked to indicate which assays they used and for what purpose as of 2020 (**Table 16**).

For HCV screening, 46 out of 50 public health laboratories utilized an HCV Ab (historically referred to as an "Anti-HCV") test: 48% of these laboratories (n=21) utilized the Abbott ARCHITECT Anti-HCV and 33% (n=15) utilized the Ortho HCV Version 3.0 ELISA. Three or fewer public health laboratories utilized other assays.

For HCV RNA, 24 out of 50 (48%) public health laboratories used HCV RNA for diagnosis of current infection and 14 (28%) used HCV RNA for monitoring (viral load). For diagnosis of current infection, the Hologic Aptima HCV RNA Qual and Hologic Hepatitis C Quant Dx Assay were each used by 38% of public health laboratories (9/24). For monitoring, 36% of public health laboratories (5/14) utilized the Hologic Hepatitis C Quant Dx Assay, and 21% (3/14) use the Roche COBAS Ampliprep/COBAS Taqman HCV Test, v2.0 or the Abbott RealTime HCV.

Additionally, seven public health laboratories offered HCV genotyping. Two public health laboratories utilized Abbott Realtime HCV Genotype II and two laboratories utilized Genmark HCV Direct.

Table 16. HCV Assays Offered by Public Health Laboratories as of 2020

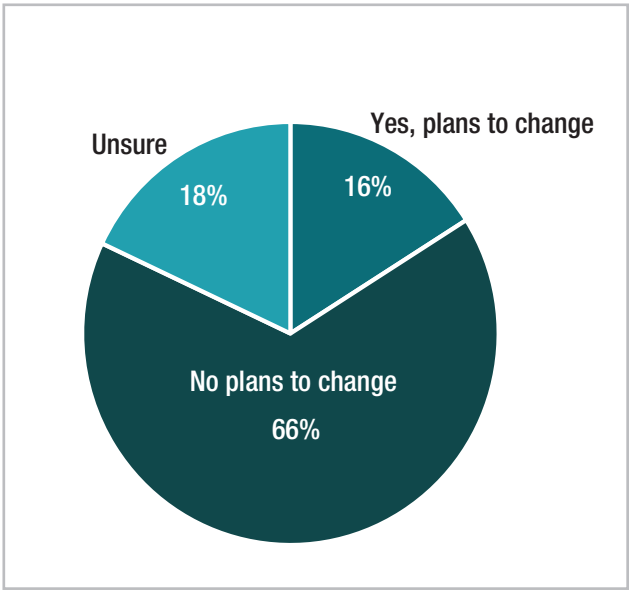
	Assay	Number of public health laboratories (n=46)
HCV Antibody (Anti-HCV) Assay for Screening	ARCHITECT Anti-HCV (Abbott)	21 (46%)
	HCV Version 3.0 ELISA (Ortho)	15 (33%)
	VITROS Anti-HCV (Ortho)	3 (6.5%)
	ADVIA Centaur Anti-HCV (Siemens)	2 (4%)
	Alinity I Anti-HCV (Abbott)	2 (4%)
	OraQuick HCV Rapid Antibody Test (OraSure)	2 (4%)
	Elecsys Anti-HCV (Roche)	1 (2%)
	Assay	**Number of public health laboratories (n=24)**
HCV RNA for Laboratory Diagnosis of Current Infection	APTIMA HCV RNA Qual (Hologic)	9 (37.5%)
	Hepatitis C Quant Dx Assay (Hologic)	9 (37.5%)
	Other HCV RNA Assay, please specify	2 (8%)
	cobas HCV (Roche)	1 (4%)
	COBAS Ampliprep/COBAS Taqman HCV Test, v2.0 (Roche)	1 (4%)
	Assay	**Number of public health laboratories (n=14)**
HCV RNA for Patient Management/ Viral Load for HCV	APTIMA HCV RNA Qual (Hologic)	6 (25%)
	Hepatitis C Quant Dx Assay (Hologic)	3 (21%)
	Other HCV RNA Assay, please specify	3 (21%)
	COBAS Ampliprep/COBAS Taqman HCV Test, v2.0 (Roche)	2 (14%)
	RealTime HCV (Abbott)	0 (0%)
	Assay	**Number of public health laboratories (n=7)**
HCV Genotyping Assay	Realtime HCV Genotype II (Abbott)	2 (29%)
	VERSANT HCV Genotype 2.0 (LiPA) (Siemens)	1 (14%)
	Laboratory Developed-HCV Genotyping Assay	1 (14%)
	Other HCV Genotyping, please specify: Genmark HCV Direct (n=2) Illumina MiSeq (n=1)	3 (43%)

Planned Changes to HCV Testing

Respondents (n=82) were asked to describe any planned changes to current HCV testing practice in their laboratory prior to December 31, 2021, which was approximately 1.5 years after distribution of the survey (**Figure 7**). Approximately two-thirds of public health laboratories (n=54) had no plans to implement changes to their testing practices. Thirteen public health laboratories reported planned changes; all 13 laboratories planned to replace assays or add new testing services. Fifteen public health laboratories were unsure of any planned changes.

No public health laboratories planned to eliminate or decrease testing. Some changes to testing services were attributed to COVID-19 (n=5) and funding or efforts around the US Department of Health and Human Services' Ending the HIV Epidemic initiative (n=2).

Figure 7. Planned Changes to HCV Testing



SCREENING IMMUNOASSAY

Additions or Changes

- Two public health laboratories planned to add a screening assay to be performed on site.
- Two public health laboratories planned to replace an existing screening assay.

HCV RNA

Additions or Changes

- Six public health laboratories planned to add an HCV NAT to be performed on site.
- Three public health laboratories planned to replace an existing HCV NAT performed on site with a new HCV NAT.
- Three public health laboratories planned to modify existing HCV NAT.

OTHER HCV TESTING SERVICES

Additions or Changes

- One public health laboratory planned to evaluate Global Hepatitis Outbreak and Surveillance Technology (GHOST).
- One public health laboratory planned to modify a service.

HIV AND HCV: WORKFORCE, ADDITIONAL RESOURCES, REIMBURSEMENTS

HIV and HCV Workforce

Public health laboratories were asked to indicate the number of full-time equivalents (FTEs) that are currently trained to perform HIV or HCV testing and the number of FTEs routinely assigned to perform this testing (**Table 17**). As a reminder, FTEs trained and assigned to perform HIV and HCV testing are not mutually exclusive and there is likely significant overlap between FTEs performing HIV and HCV testing.

Among 66 public health laboratories that performed HIV testing, laboratories on average had 4.9 FTEs trained to perform HIV testing and 3.3 FTEs routinely assigned to perform HIV testing. The average number of FTEs trained ranged from 1–24 and the number of FTEs routinely assigned ranged from 0–24.

While state and local laboratories both had approximately 5 FTEs trained to perform HIV testing, local laboratories had slightly fewer FTEs (n=2.3) routinely assigned to perform HIV testing as compared to state laboratories (n=3.9). This is possibly attributable to lower HCV testing volume at local laboratories.

Table 17. FTEs Trained to Perform and Routinely Assigned to Perform HIV Testing in Public Health Laboratories

	State (n=42)		Local (n=24)		Total (n=66)	
FTEs trained vs. routinely assigned to perform HIV testing	Trained	Assigned	Trained	Assigned	Trained	Assigned
Sum	211	162	115	56	326	218
Average	5.0	3.9	4.8	3.2	4.9	3.3
Median	4	3	3.5	2	4.0	3

Between 2008 and 2015, workforce trained and dedicated to HIV testing declined, which is consistent with public health laboratories receiving fewer specimens to process. Since 2017 however, there has been a slight increase in FTEs routinely assigned to HIV testing in state laboratories. In 2017, state laboratories averaged 1.9 FTEs. This increase could be attributable to increased NAT testing in-house requiring additional laboratory staff, different laboratories with larger HIV testing programs responding to this survey or select laboratories growing their HIV testing program. For example, the number of FTEs dedicated to HIV testing ranged from 0.15–7 in 2017 and in 2019–2020, this range increased to 1–29.

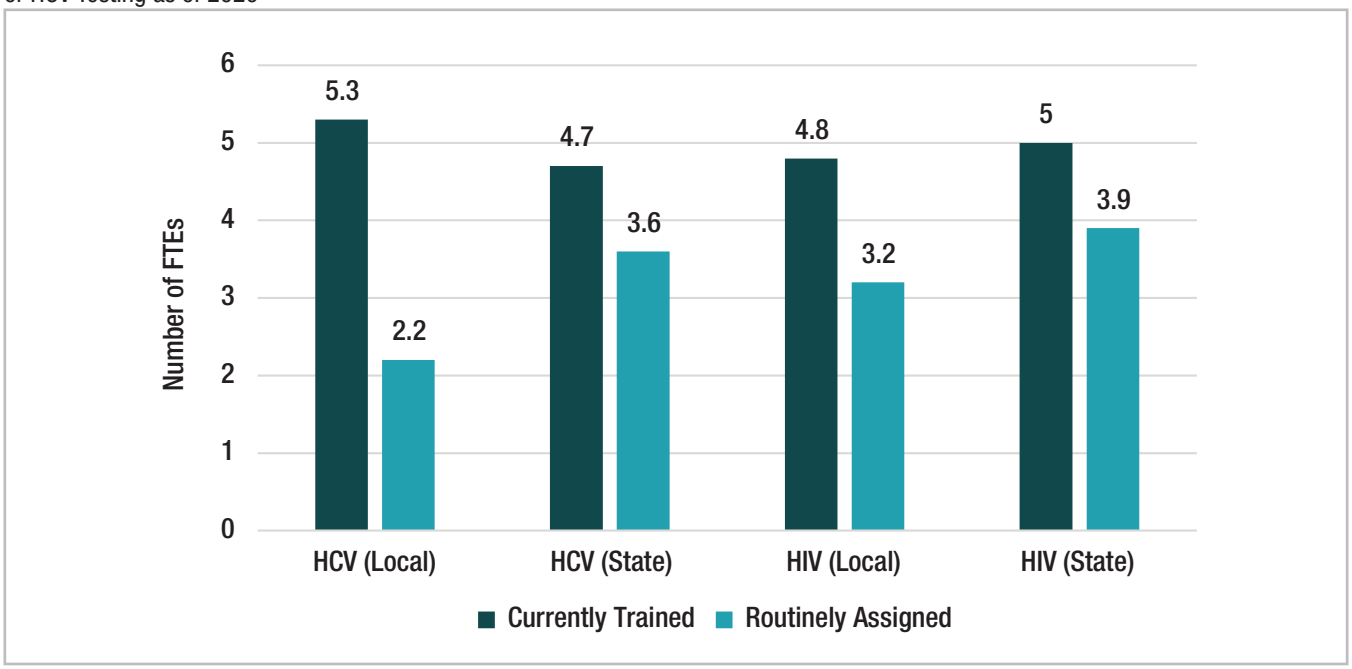
Among 50 public health laboratories that performed HCV testing, laboratories on average had 4.9 FTEs (range: 1–17) currently trained to perform HCV testing and 3.2 FTEs (range: 0–17) routinely assigned to perform HCV testing (**Table 18**). State public health laboratories (n=36), on average, had 4.7 FTE trained to perform HCV testing and had 3.6 FTE routinely assigned. Local public health laboratories (n=14), on average, had 5.3 FTEs trained to perform HCV testing and 13 local public health laboratories had 2.2 FTEs routinely assigned to perform HCV testing. Historical data on the HCV testing workforce is not available as it was not previously collected.

Figure 8 compares the number of FTEs employed by state and local public health laboratories that are trained in HIV and HCV testing and that are routinely assigned to this testing.

Table 18. FTEs Trained to Perform and Routinely Assigned to Perform HCV Testing in Public Health Laboratories

	State (n=36)		Local (n=14)		Total (n=49)	
FTEs Trained vs. Routinely Assigned to Perform HCV Testing	Trained	Assigned	Trained	Assigned	Trained	Assigned
Sum	170	128.5	74	29	244	157.5
Average	4.7	3.6	5.3	2.2	4.9	3.2
Median	4	3	4	2	4	3

Figure 8. Average Number of FTEs at State and Local Public Health Laboratories that are Trained and Routinely Assigned to Perform HIV or HCV Testing as of 2020



Additional Tools/Resources

In order to assess and best address the needs of APHL member laboratories, the survey requested public health laboratories identify HIV and HCV topic areas that would be useful to have additional tools and/or resources in the upcoming year (**Table 19**). More than half of responding public health laboratories (61%) selected additional tools/resources on new/emerging diagnostics technologies for both HIV and HCV. Also of interest were genotype testing (32%), validation of new or modified FDA-approved assays (30.5%), integrated screening for multiple pathogens (27%) and LIMS/informatics infrastructure (21%). "Other" suggestions included the following topics: alternative specimen types and collection devices, public health strategies for Office of the Chief Medical Examiner (OCME) testing of HIV/Viral Hepatitis, whole genome sequencing and updates to the testing algorithm.

Table 19. Additional Tools/Resources that Would be Useful to Public Health Laboratories in the Upcoming Year

	Number of public health laboratories (n=82)	Percent of public health laboratories
New/emerging diagnostic technologies-HIV	50	61%
New/emerging diagnostic technologies-HCV	48	58.5%
Genotype testing	26	32%
Validation of new or modified FDA-approved assays	25	30.5%
Integrated screening for multiple pathogens	22	27%
LIMS/informatics infrastructure	17	21%
Implementing diagnostic algorithm-HCV	16	19.5%
None of the above	16	19.5%
Educating clinical laboratories on diagnostic algorithms	15	18%
Implementing diagnostic algorithm-HIV	11	13%
Development of in-house assays	8	10%
3rd party billing – basics	8	10%
3rd party billing – policy/regulation	8	10%
3rd party billing – contracting with insurers	6	7%
Other – please specify	4	5%
Incidence testing	3	4%

Reimbursement Methods

HIV and HCV programmatic and testing services have been historically underfunded. One opportunity to recuperate costs is to seek reimbursements from third-party payers (e.g., Medicare, Medicaid and other health insurers). In order to continue providing critical diagnostic and prevention services, the ability of health departments to receive third-party reimbursement for HIV and HCV testing services is essential.

Survey respondents were asked to identify from which third-party payers or submitting providers (clinical or "secondary party" payers) their public health laboratories sought reimbursements for HIV and/or HCV diagnostic testing (**Table 20**). Public health laboratories not offering the respective testing services have been excluded from these analyses; one public health laboratory did not provide reimbursement information. While 45% of public health laboratories were currently billing for both HIV and HCV services, 40% of public health laboratories had no plans to implement billing for HIV and 29% had no plans to bill for HCV. Opportunities for laboratories to seek reimbursement should be explored in order to relieve the burden of test costs and continue to provide these essential services. Since 2017, there has been a slight increase (3%) in laboratories billing for HIV services, but a larger increase in laboratories without plans to implement billing for HIV services, an increase from 30% to 40%. Data regarding reimbursement of HCV services was not

previously collected.

Among public health laboratories that billed for HIV services, Medicaid (79%) was the most common third-party payer billed; private insurance (52%), Medicare (41%) and submitting providers (38%) were also commonly billed. For public health laboratories that billed for HCV services, Medicaid (70%) was also the most common third-party payer billed. Private insurance (39%), submitting providers (39%), and Medicare (35%) were each billed by slightly more than one-third of all public health laboratories.

Table 20. Public Health Laboratories' Reimbursement and Billing Practices

Laboratories Seeking Reimbursement for HIV or HCV Testing	HIV (n=65)	HCV (n=49)
Yes, currently billing	29 (45%)	23 (45%)
No plans to implement	26 (40%)	15 (29%)
Don't know, provide additional information	8 (12%)	9 (18%)
No, but plan to implement by 12/31/2021	2 (3%)	2 (4%)
For those currently billing, which payers do you seek reimbursement from?	**HIV (n=29)**	**HCV (n=23)**
Medicaid	23 (79%)	16 (70%)
Private Insurance	15 (52%)	9 (39%)
Medicare	12 (41%)	8 (35%)
Submitting providers (Clinical)	11 (38%)	9 (39%)
Other, please specify	2 (7%)	1 (4%)
Bill clients directly	*1*	*1*
HIV program	*1*	-
Not sure, please provide additional information	1 (3.50%)	2 (9%)

DISCUSSION

As of 2020, 81% of public health laboratories (n=66) offered HIV testing services and 62% of public health laboratories (n=50) offered HCV testing services.

The HIV laboratory diagnostic testing algorithm remained highly utilized by public health laboratories, with 58 out of 61 laboratories that offered in-house HIV screening (95%) also assuring in-house or referral to supplemental testing and HIV NAT. The Abbott ARCHITECT HIV Ag/Ab Combo and Bio-Rad GS HIV Combo Ag/Ab EIA were the most commonly utilized screening IAs and all laboratories performing in-house supplemental testing utilized the Bio-Rad Geenius HIV-1/2 Supplemental Assay. As of 2020, 92% and 89% of laboratories offered screening and supplemental testing, respectively. Since 2017, there was a slight increase in the percentage of laboratories performing qualitative or quantitative HIV NAT in-house, from 32% to 38%.

Despite limitations due to the COVID-19 pandemic, one-third of laboratories provided outreach, training and/or education regarding the HIV laboratory diagnostic testing algorithm.

Among the laboratories that offered HCV testing services, 46 (92%) performed screening and 29 (58%) offered HCV NAT. Congruent with best practice, 76% of laboratories that perform screening automatically reflex from screening to RNA testing for positively screened specimens. For laboratories not reflexing, this provides an opportunity to consult and discuss opportunities to implement this practice.

Consistent with previous years, overall testing volume continued declining, but was also significantly impacted by the COVID-19 pandemic. Between 2019 and 2020, 63 responding laboratories reported receiving over 250,000 fewer specimens. Over 80% of laboratories reported COVID-19 impacting the volume of HIV and HCV testing at their laboratory and approximately 50% of laboratories indicated a negative impact on staffing, including staff being diverted from normal duties and burnout.

Moving forward, there are ample opportunities to continue learning. Nearly 50% of respondents would be interested in educational opportunities regarding HIV-1 NAT with dual claim. Over 25% of respondents also indicated interest in HIV-1/HIV-2 NAT assays, rapid HIV NAT tests and HIV-1 next-generation sequencing methods. Furthermore, laboratories expressed interest in additional tools or resources related to new and emerging HIV and HCV technologies (~60%), genotype testing (32%) and validation of new or modified FDA-approved assays (30.5%).

ACRONYMS

Ab ..... Antibody

Ag ..... Antigen

Ag/Ab ... Antigen/Antibody

APHL ..... Association of Public Health Laboratories

CDC ..... Centers for Disease Control and Prevention

CLIA ..... Clinical laboratory improvement amendments

DBS ..... Dried blood spots

EIA ..... Enzyme immunoassay

FDA ..... US Food and Drug Administration

FTE ..... Full time equivalent

HCV ..... Hepatitis C virus

HIV ..... Human immunodeficiency virus

IA ..... Immunoassay

IFA ..... Immunofluorescence assay

NAT ..... Nucleic acid test

POC ..... Point of care test

PrEP ..... Pre-exposure prophylaxis

TAT ..... Turnaround time

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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.

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