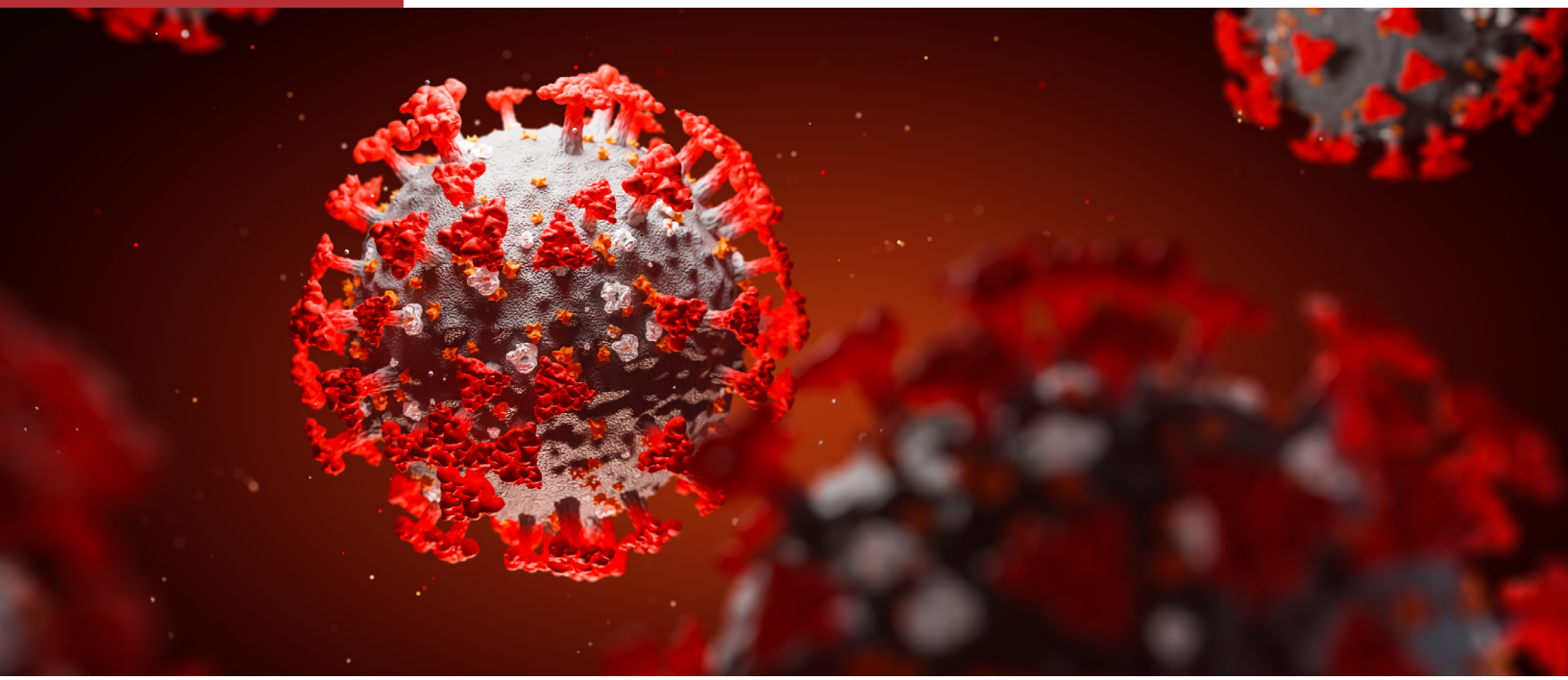
APHL SARS-CoV-2 Capability and Capacity Questionnaire Survey

Summary Report (April 2020 – May 2021)



JANUARY 2022

APHL ASSOCIATION OF PUBLIC HEALTH LABORATORIES®

CONTENTS

BACKGROUND

In December 2019 a cluster of atypical pneumonia cases emerged in Hubei Province, China. A novel coronavirus, SARS Coronavirus 2 (SARS-CoV-2), was isolated and determined to be the cause of a new disease, later named COVID-19. By March 2020 the World Health Organization (WHO) declared COVID-19 a pandemic. In response, the Association of Public Health Laboratories (APHL) launched a weekly survey to assess SARS-CoV-2 testing needs among APHL-member public health laboratories. The survey collected data regarding laboratories' current and projected capabilities and capacities for testing and responding to the pandemic. APHL worked closely with the US Department of Health and Human Services (HHS) and used these data to communicate and respond to laboratory needs, supply chain challenges, gaps in testing and more.

SURVEY, COLLECTION AND NUMBER OF RESPONDENTS

APHL launched the APHL SARS-CoV-2 Capability and Capacity Questionnaire Survey (APHL COVID-19 Survey) on April 13, 2020 to 100 member public health laboratories using Qualtrics®. Surveys were emailed each Monday to laboratory points of contact (POCs), and POCs self-reported laboratory data. Most POCs opted to complete the survey digitally; however, POCs were given the option to complete the survey via telephone with APHL staff recording responses. Though laboratories were given five to seven days to return the survey, back-reported data was accepted and is included in this report.

The weekly APHL COVID-19 Survey closed on June 30, 2021; 59 weeks of data were collected. Ninety-nine public health laboratories responded at least once. This included 40 local laboratories and 59 state and territorial laboratories, including Washington, DC. For the purposes of this report, these state and territorial public health laboratories will be referred to as "state" laboratories. Over these 59 weeks, the participation rate ranged from 65% to 91%, with an average weekly response rate of 80%. Response rates tended to decline during weeks surrounding holidays. A breakdown of the survey weeks and their respective collection periods can be found in the appendix on page 16.

The survey comprised several standing questions asked each week and ad hoc questions that were cycled in and out of the survey over its duration. This report examines the results and trends of 11 standing questions. The first section of this report examines challenges associated with laboratory capacity and capabilities, and the second section examines the equipment, tests and expansion of laboratory capacity and capabilities over the course of the pandemic.

KEY HIGHLIGHTS

Testing Volume

Public health laboratories tested approximately 13,197,600 SARS-CoV-2 specimens.

- State public health laboratories tested 11,228,906 specimens over 59 weeks with an average 3,990 tests per week per laboratory.
- Local public health laboratories tested 1,968,692 specimens over 59 weeks and with an average 1,044 tests per week per laboratory.

Challenges

Public health laboratories most frequently reported challenges—such as backlogs, inability to meet testing demands, low inventories—during the weeks of April 13, July 13, July 20, July 27, November 23, November 30, and December 7, 2020.

Meeting Demand

Over the course of the survey, despite numerous challenges and barriers, 91.5% of public health laboratories were able to meet testing demand on average and less than 5% of public health laboratories experienced backlogs on average.

Extraction Platforms

- QIAGEN QIAcube, Roche MagNA Pure Compact and QIAGEN EZ1 Advanced XL were the most commonly owned extraction platforms. QIAGEN EZ1 Advanced XL, Thermo Scientific Kingfisher Flex and Roche MagNA Pure Compact were the most commonly validated extraction platforms for SARS-CoV-2 testing.
- Public health laboratories gradually increased the total number of extraction platforms owned, on average, from 5.4 to 8.3.

Thermo Cyclers

- ABI 7500 Fast Dx was the most commonly owned and validated thermal cycler.
- Public health laboratories gradually increased the total number of thermal cyclers owned, on average, from 6.4 to 8.1.

Molecular Platforms

- Hologic Panther, Abbott ID Now and Cepheid GeneXpert were the most commonly owned and validated commercial molecular platforms.
- Public health laboratories gradually increased the total number of molecular platforms owned, on average, from 8.6 to 11.2.

SARS-CoV-2 Tests

The CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel was the most commonly-verified SARS-CoV-2 test.

CAPACITY AND CAPABILITY CHALLENGES EXAMINED

One goal of the APHL COVID-19 Survey was to collect data to understand and respond to laboratory needs, supply chain challenges, gaps in testing and laboratories' capacities. The following questions were designed to assess these:

- Are you able to meet the current [testing] demand?
- Within the next week, do you anticipate running out of any reagents or supplies?
  - If you anticipate running out of reagents or supplies, select all that apply.
- Do you currently have a backlog of specimens?
  - If yes, approximately how large is the backlog?
  - If yes, approximately how many days will it take to test all of the backlogged specimens?

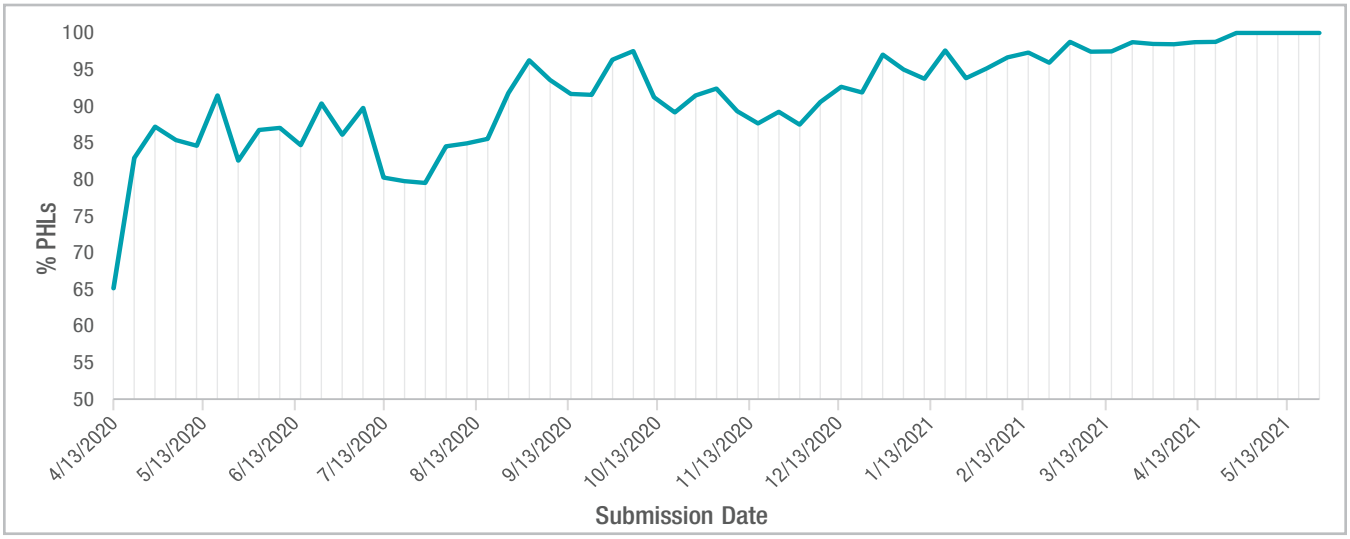
Meeting Demand

Each week public health laboratories were asked to indicate if they were able or not able to meet testing demand.

The highest percentage (35%) of laboratories unable to meet demand occurred in the first week of survey distribution (April 13-19, 2020). Ability to meet demand rose sharply the next week; however, the percentage of laboratories (20%) unable to meet demand spiked again in late July 2020. Of note, local laboratories experienced more pronounced week-to-week variability during the first 15 weeks than state/territorial laboratories. This trend faded in later weeks. Despite another minor spike from November 16 through the week of November 30 where roughly 12% of laboratories reported challenges meeting demand, public health laboratories were increasingly able to meet demand through the end of the survey. From February 8 through May 2021, greater than 95% of laboratories reported being able to meet testing demands (**Figure 1**). Public health laboratories that did not submit data or that submitted data but did not respond to this question were excluded from calculations.

When asked to describe what impacted laboratories' ability to meet demand, public health laboratories indicated numerous limitations and ongoing needs related to high-throughput instrumentation, laboratory personnel, personal protective equipment (PPE), reagents, supplies and kits, backlogs/large surges of specimens and increasingly high demand.

Figure 1. Meeting Testing Demand (n=99)



Reagents and/or Supply Challenges

Each week public health laboratories were asked to indicate if they anticipated running out of reagents and/or supplies within the next week (**Figure 2**). Public health laboratories that did not submit their weekly survey or that submitted their survey but did not respond to this question were excluded from calculations.

Local and state public health laboratories followed similar trends; however, state laboratories displayed a more pronounced peak during the first few weeks, indicating a higher need and/or lower inventory of reagents and supplies. State laboratories also reported running out of reagents and supplies more frequently than local laboratories; for 42 out of 59 weeks (71%) a higher proportion of state laboratories reported running out of reagents and supplies as compared to local laboratories.

The percent of public health laboratories running out of reagents and supplies peaked during the first few weeks and once again in late November-mid December.

From April 13 through May 10, 2020, 30%-42% of public health laboratories reported imminently running out of supplies and reagents, with the greatest number of laboratories reporting these challenges during the first week. After a steady decline for over 20 weeks (and a low of 11% of labs reporting imminent shortages during the week of October 12), in late November 2020 a plastic shortage in conjunction with the ongoing demand for testing caused backorders and shortages to surge across the country. Thirty-one percent of laboratories reported expecting running out of supplies and/or reagents within a week. After several weeks, laboratories' inventories stabilized.

Despite a downward trend, an average of 20% of public health laboratories reported running out of reagents and/or supplies over the course of this survey. Shortages and backorders continue to impact public health laboratories at the conclusion of this survey's distribution; by the end of May, approximately 9% of public health laboratories still reported anticipating running out of reagents and/or supplies.

Starting November 2, Public health laboratories were asked to detail which supplies and reagents were running low in their laboratories (**Figure 3**). Test kits, consumables and "Other" supplies and reagents were most frequently cited as running low. Among the "Other" supplies and reagents, pipette tips were most frequently reported as running low.

Figure 2. Reagent and/or Supply Challenges (n=99)

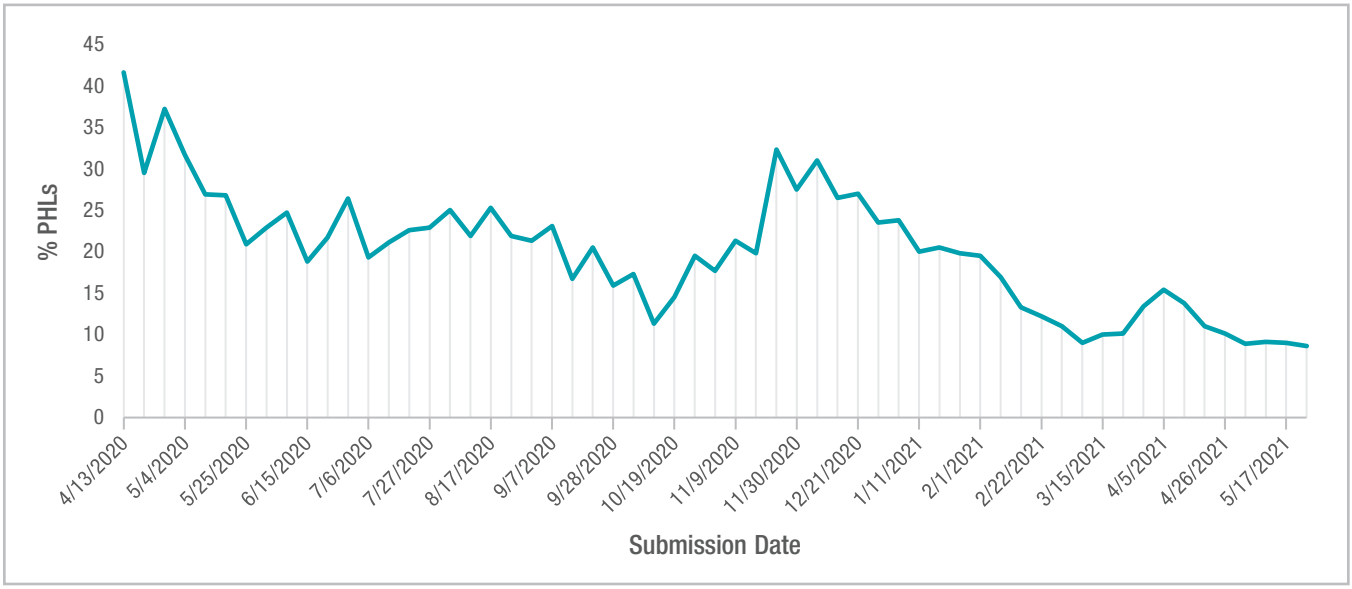
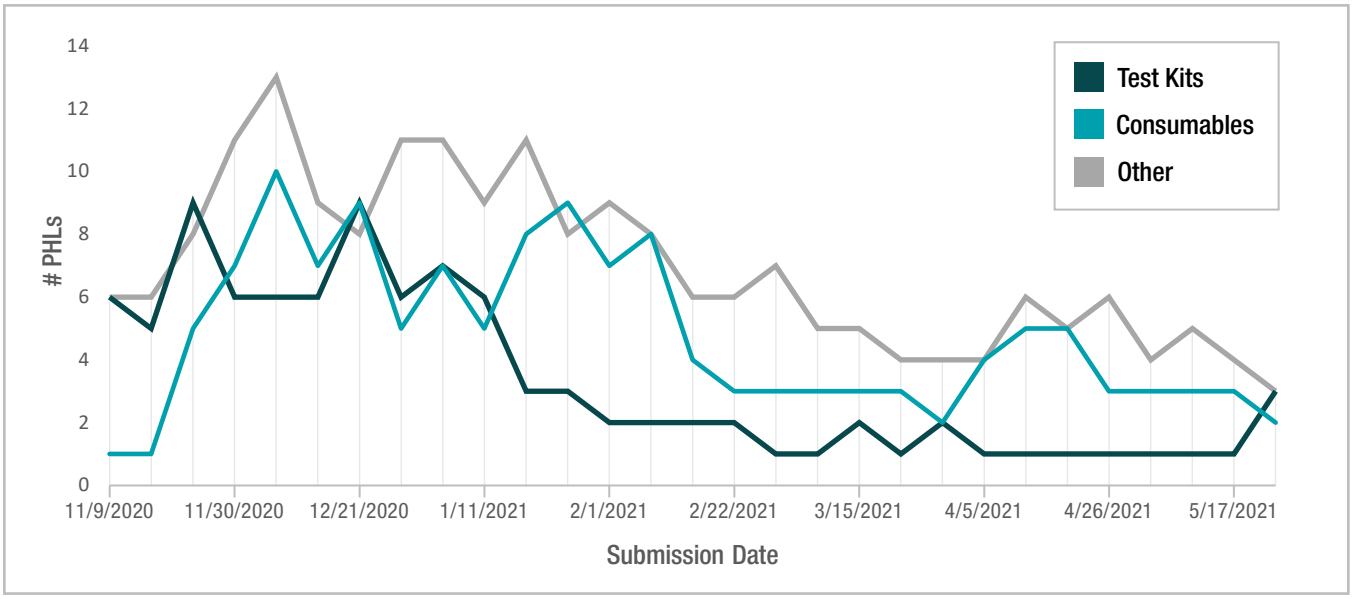


Figure 3. Supplies and Reagents Most Frequently Indicated as Running Low (n=99)

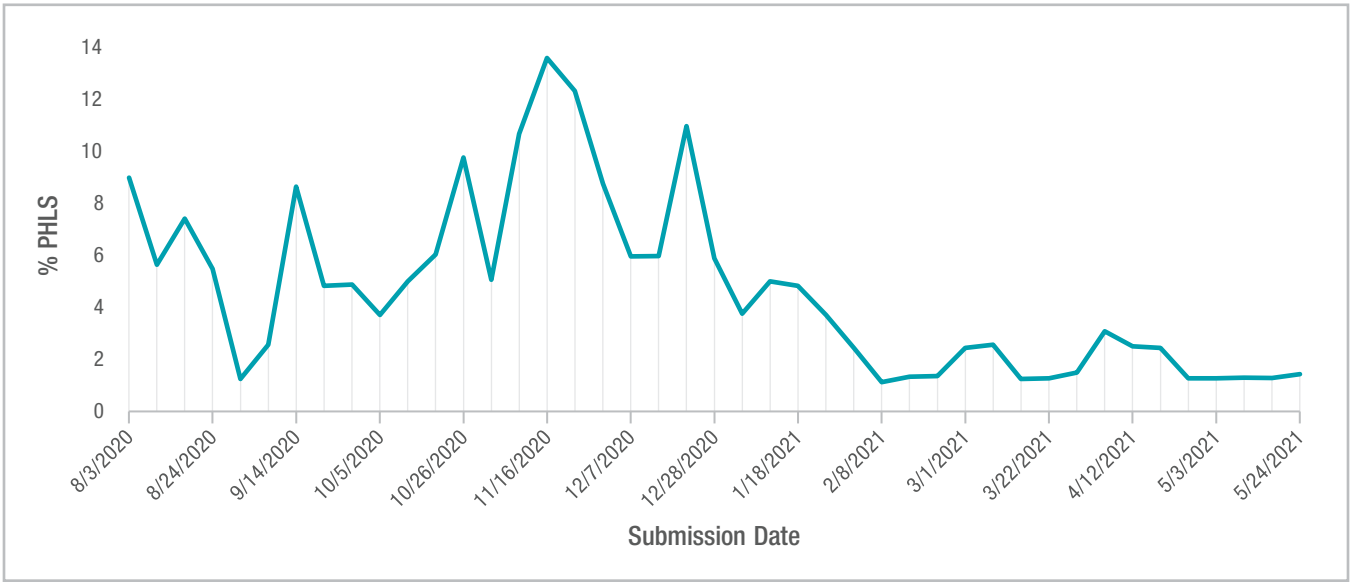


Backlogs

Starting August 3, 2020, public health laboratories were asked to indicate if their laboratory had a backlog of specimens awaiting testing (**Figure 4**). Backlogs ranged from three specimens up to 7,000 specimens and the percentage of public health laboratories reporting a backlog ranged from 1.1% to 13.6%. Public health laboratories estimated that backlogs would take anywhere from less than one day and up to 10 days to clear.

While the average percent of public health laboratories reporting backlogs from August 2020 through May 2021 was 4.7%, this average nearly doubled (9.2%) between late October and mid-December 2020. Congruent with reports of low reagent/supply inventory, a prominent spike in backlogs occurred in mid-November.

Figure 4. Specimen Testing Backlogs (n=96)



EQUIPMENT, TESTS AND PANDEMIC RESPONSE

Another goal of this survey was to gain situational awareness of laboratories' testing capacities and capabilities, including tracking adaptations made by public health laboratories in response to growing testing needs.This section of the report examines the equipment utilized, tests performed and expansion of laboratory capacity and capabilities over the course of the pandemic. The following questions were designed to assess these concepts:

- What are the current extraction platforms, thermal cyclers and molecular platforms your laboratory is using? How many of each instrument do you have?
- Which SARS-CoV-2 tests are you using?
  - Are you performing the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (CDC)?
  - Are you performing any of the following SARS-CoV-2 tests? (Options provided)
  - Has your laboratory completed implementation of the CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay?
- How many specimens have you tested during the previous week with molecular methods?
- Is your laboratory currently performing serology tests?
  - Please specify the type of serology test you currently perform.
  - What serology tests are you currently performing or validating?
- Where are antigen tests being used in your jurisdiction? Which antigen tests are in use in your jurisdiction?
- Are you currently performing next generation sequencing (NGS) on SARS-CoV-2 specimens? What are primary barriers to performing SARS-CoV-2 sequencing?

Extraction Platforms

Each week public health laboratories were asked to identify which extraction platforms their laboratories owned and verified as well as the quantities of each type of platform in their laboratories (**Table 1**). Ninety-nine Public health laboratories reported on extraction platforms in their laboratories.

Throughout the pandemic, public health laboratories utilized various, and often multiple, extraction platforms in their workflow. The greatest number of public health laboratories owned QIAGEN QIAcube, Roche MagNA Pure Compact and QIAGEN EZ1 Advanced XL, with over 62% of all public health laboratories owning one or more of these instruments. However, the greatest number of public health laboratories verified QIAGEN EZ1 Advanced XL, Thermo Scientific Kingfisher Flex and Roche MagNA Pure Compact; 45% 57% of all public health laboratories verified one of these instruments. **Figure 5** shows the total number of public health laboratories that owned and verified various extraction platforms over 59 weeks.

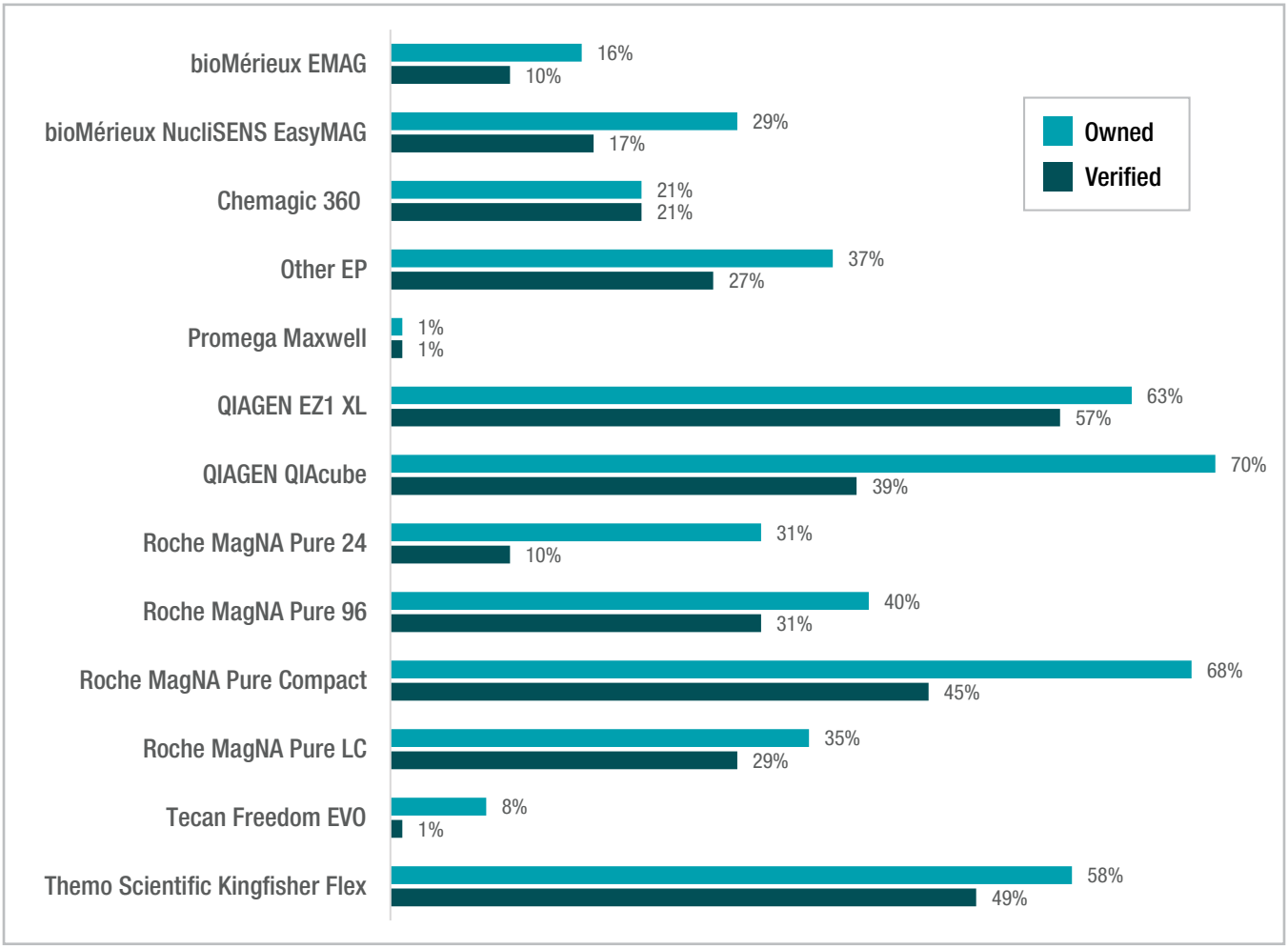
Table 1. Extraction Platforms Owned and Verified by Public Health Laboratories

Extraction Platform	Owned (n)	Verified (n)
bioMérieux EMAG	16	10
bioMérieux NucliSENS EasyMag	29	17
Chemagic 360	21	21
"Other" extraction platforms	37	37
Promega Maxwell	1	1
QIAGEN EZ1 Advanced XL	62	56
QIAGEN QIAcube	69	39
Roche MagNA Pure 24	31	10
Roche MagNA Pure 96	40	31
Roche MagNA Pure Compact	67	45
Roche MagNA Pure LC	35	29
Tecan Freedom EVO	8	1
Thermo Scientific KingFisher Flex	57	49

Over 59 weeks, public health laboratories gradually increased the total number of extraction platforms owned by approximately three instruments per laboratory. During the first five weeks of the survey, Public health laboratories owned, on average, 5.4 extraction platforms. During the last five weeks of the survey, public health laboratories owned, on average, 8.3 extraction platforms.

The greatest number of laboratories acquired Thermo Scientific Kingfisher Flex (n=25), "Other" extraction platforms not listed (n=22) and QIAGEN QIAcube (n=20).

Figure 5. Owned and/or Verified Extraction Platforms (n=99)



Thermal Cyclers

Each week laboratories were asked to identify which thermal cyclers their laboratory owned and verified and the quantities of each type of thermal cycler in their laboratories. **Table 2** lists the thermal cyclers and the total number of Public health laboratories that owned and verified each instrument. Ninety-nine public health laboratories reported on thermal cyclers in their laboratories.

Table 2. Thermal Cyclers Owned and Verified by Public Health Laboratories

Thermal Cycler	Owned (n)	Verified (n)
Applied Biosystems (ABI) 7500 Fast	27	17
Applied Biosystems (ABI) 7500 Fast DX	95	95
Luminex MAGPIX	15	0
"Other" thermal cyclers	18	13
QIAGEN Rotor-Gene Q	4	0
QuantStudio Dx	69	31

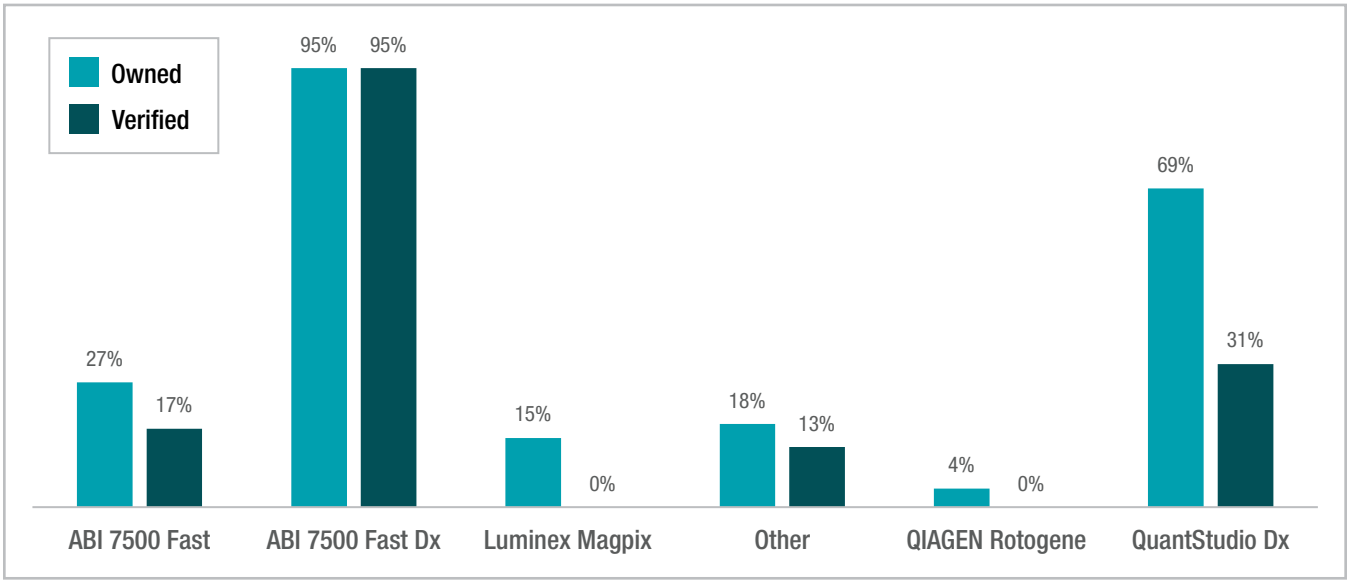
ABI 7500 Fast Dx and QuantStudio Dx were the most commonly owned (96%) and verified (70%) thermal cyclers by public health laboratories.

Figure 6 displays the distribution of various thermal cyclers among public health laboratories.

Over 59 weeks public health laboratories gradually increased the total number of thermal cyclers owned by nearly two instruments per laboratory. During the first five weeks of the survey, public health laboratories owned, on average, 6.4 thermal cyclers. During the last five weeks of the survey, public health laboratories owned, on average, 8.1 thermal cyclers.

The greatest number of laboratories acquired "Other" thermal cyclers not listed (n=14), QuantStudio DX (n=11) and ABI Fast (n=8). Commonly reported "Other" instruments included thermal cyclers from Perkin Elmer, Analytik Jena and Eppendorf.

Figure 6. Thermal Cyclers Owned and/or Verified by Public Health Laboratories (n=99)



Molecular Platforms

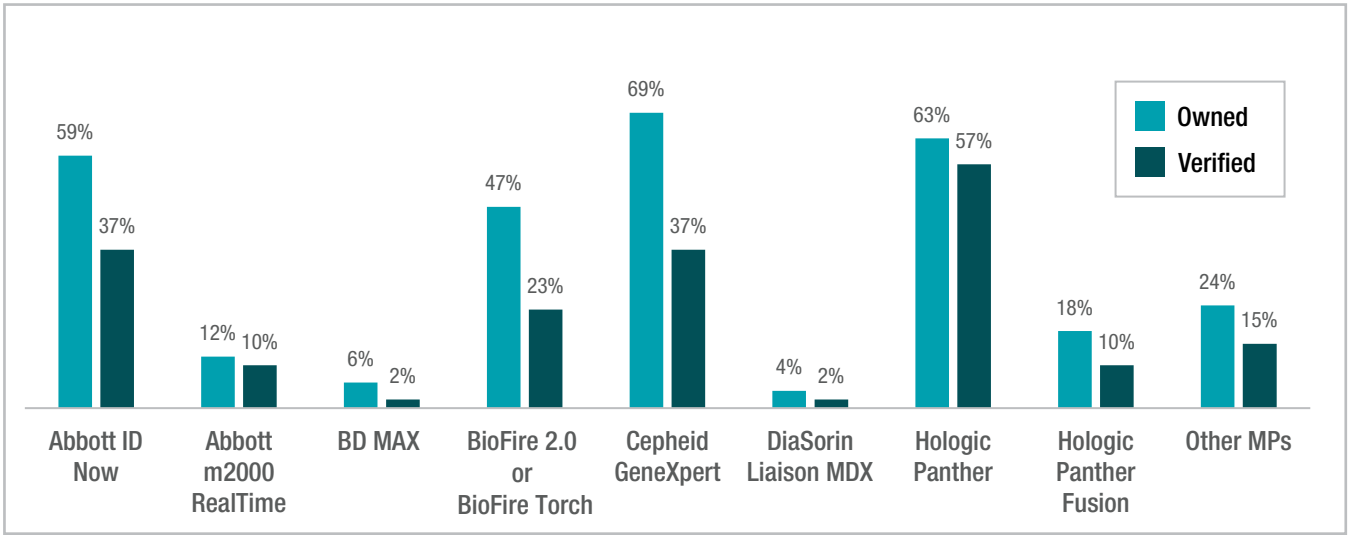
Starting April 20, 2020, laboratories were asked to identify which molecular platforms their laboratories owned and verified, and the quantities of each in their laboratories (**Table 3**). Ninety-nine public health laboratories reported on molecular platforms in their laboratories.

Hologic Panther, Abbott ID NOW and Cepheid GeneXpert Systems were the most frequently owned and verified molecular platforms. Sixty percent of laboratories reported owning at least one of these platforms; 37% of laboratories verified the Abbott ID NOW and/or the Cepheid GeneXpert while approximately 58% of laboratories verified the Hologic Panther Fusion for SARS-CoV-2. **Figure 7** displays the distribution of various molecular platforms among public health laboratories.

Table 3. Molecular Platforms Owned and Verified

Molecular Platform	Owned (n)	Verified (n)
Abbott ID NOW	59	37
Abbott m2000 RealTime System	12	10
BD MAX System	6	2
BioFire 2.0 or BioFire Torch Systems	47	23
Cepheid GeneXpert Systems	69	37
DiaSorin LIAISON MDX	4	2
Hologic Panther System	63	57
Hologic Panther Fusion System	18	10
"Other" Molecular Platforms	24	15

Figure 7. Owned and/or Verified Molecular Platforms (n=99)



Over 59 weeks, public health laboratories increased the total number of thermal cyclers owned by greater than two instruments per laboratory. During the first five weeks of the survey, Public health laboratories owned, on average, 8.6 molecular platforms. During the last five weeks of the survey, public health laboratories owned, on average, 11.2 extraction platforms.

The greatest number of laboratories verified Hologic Panther Systems (n=57), Cepheid GeneXpert Systems (n=25), BioFire 2.0 or BioFire Torch Systems (n=22) and Abbott ID NOW (n=17).

SARS-CoV-2 Tests

For the duration of the survey, laboratories were asked to identify which SARS-CoV-2 tests they performed (**Table 4**). Ninety-nine public health laboratories reported on SARS-CoV-2 tests in their laboratories.

In February 2020, the US Food and Drug Administration (FDA) granted the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel an Emergency Use Authorization (EUA). The 2019-nCoV was the first assay approved for SARS-CoV-2 diagnostic testing. Thus, as expected, early on this panel was used among a high percentage of public health laboratories (approximately 95%). However, by May 2020 there were dozens of other FDA-authorized assays to test for SARS-CoV-2 that public health laboratories adopted. Approximately 70% of laboratories reported using the 2019-nCoV panel during the last few weeks of the survey. Despite this approximately 25% drop, this panel was still the most commonly implemented SARS-CoV-2 test.

Laboratories reported verifying at least 24 unique SARS-CoV-2 tests. The Panther Aptima TMA SARS-CoV-2 assay and the TaqPath COVID-19 Combo Kit were the next most commonly implemented assays, utilized by ~56% and 50% of public health laboratories respectively. **Figure 8** shows the percentage of laboratories that verified various SARS-CoV-2 tests over the duration of the survey.

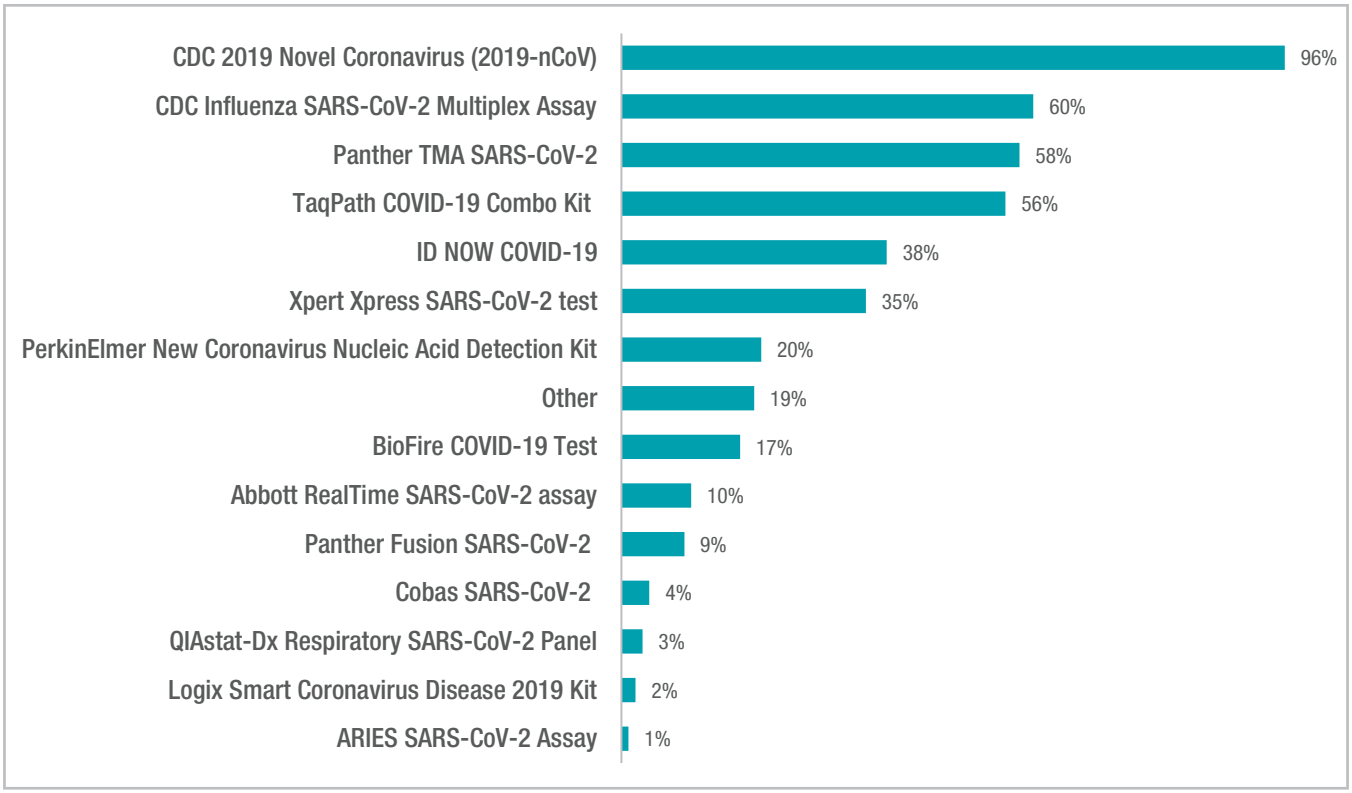
During the week of August 31, when laboratories were first asked about implementing the new CDC Influenza SARS-CoV-2 (Flu SC2) Multiplex Assay, four out of 76 responding laboratories (5%) had implemented it. By May 2021, 68% of public health laboratories had implemented this assay.

Table 4. SARS-CoV-2 Tests (n=99)

Test	Number of Laboratories (n)
Abbott RealTime SARS-CoV-2 Assay (Abbott Molecular)	10
ARIES SARS-CoV-2 Assay (Luminex Corporation)	1
BioFire COVID-19 Test (BioFire Defense LLC)	17
CDC 2019 Novel Coronavirus (2019-nCoV)	95
CDC Influenza SARS-CoV-2 Multiplex Assay (Flu-SC2)*	59
Cobas SARS-CoV-2 Test (Roche Molecular System Inc)	4
ID NOW COVID-19 Assay Abbott Diagnostics Scarborough Inc)	38
Logix Smart Coronavirus Disease 2019 (COVID-19) Test Kit (Co-Diagnostics Inc)	2
"Other" SARS-CoV-2 tests	19
Panther Fusion SARS-CoV-2 Assay (Hologic Inc)	9
Panther Aptima TMA SARS-CoV-2 Assay (Hologic Inc)	57
PerkinElmer New Coronavirus Nucleic Acid Detection Kit	20
QIAstat-Dx Respiratory SARS-CoV-2 Panel (QIAGEN GmbH)	3
TaqPath COVID-19 Combo Kit (Thermo Fisher Scientific Inc)	55
Xpert Xpress SARS-CoV-2 test (Cepheid)	35

* Only 92 Public health laboratories reported data for the CDC Flu-SC2 assay.

Figure 8. SARS-CoV-2 Tests Verified by Public Health Laboratories (n=99)



Specimens Tested Each Week

Public health laboratories were asked to report the number of specimens tested via molecular methods during the week prior to the survey. From April 13, 2020 to May 30, 2021 Public health laboratories had tested approximately 13,197,600 specimens to date via molecular methods.

Between April and November 2020, the number of specimens tested each week steadily climbed. From the first week through early August 2020, the total number of specimens tested increased by over six times. Despite a small testing decline shortly thereafter, testing continued to climb and peaked again in Mid-November, with 81 laboratories testing 371,934 specimens in one week. Following this major peak, with occasional variation, testing gradually declined through the end of the survey. **Figure 9** shows the total number of specimens tested per week for the duration of the survey.

Over the entire survey, each public health laboratory tested 2,809 specimens on average; however, from July 13 through November 29, 2020, when laboratories averaged the highest number of tests per lab, a single public health laboratory averaged 3,815 tests per week.

A stark discrepancy in testing numbers can be noted between state and local public health laboratories. State Public health laboratories tested 11,228,906 specimens over 59 weeks and a single state public health laboratory averaged 3,990 tests per week. Local Public health laboratories tested 1,968,692 specimens over 59 weeks and a single local public health laboratory averaged 1,044 tests per week. Part of this nine million specimen difference is attributable to the number of reporting laboratories; 59 state and territorial laboratories participated while 40 local laboratories participated in the APHL COVID-19 Survey. However, on average, state public health laboratories tested nearly four times as many SARS-CoV-2 specimens per week. **Figure 10** shows the average number of specimens tested per week and highlights the proportion of specimens processed by state versus local laboratories.

Figure 9. Molecular Testing: Total Number of Specimens Tested (n=99)

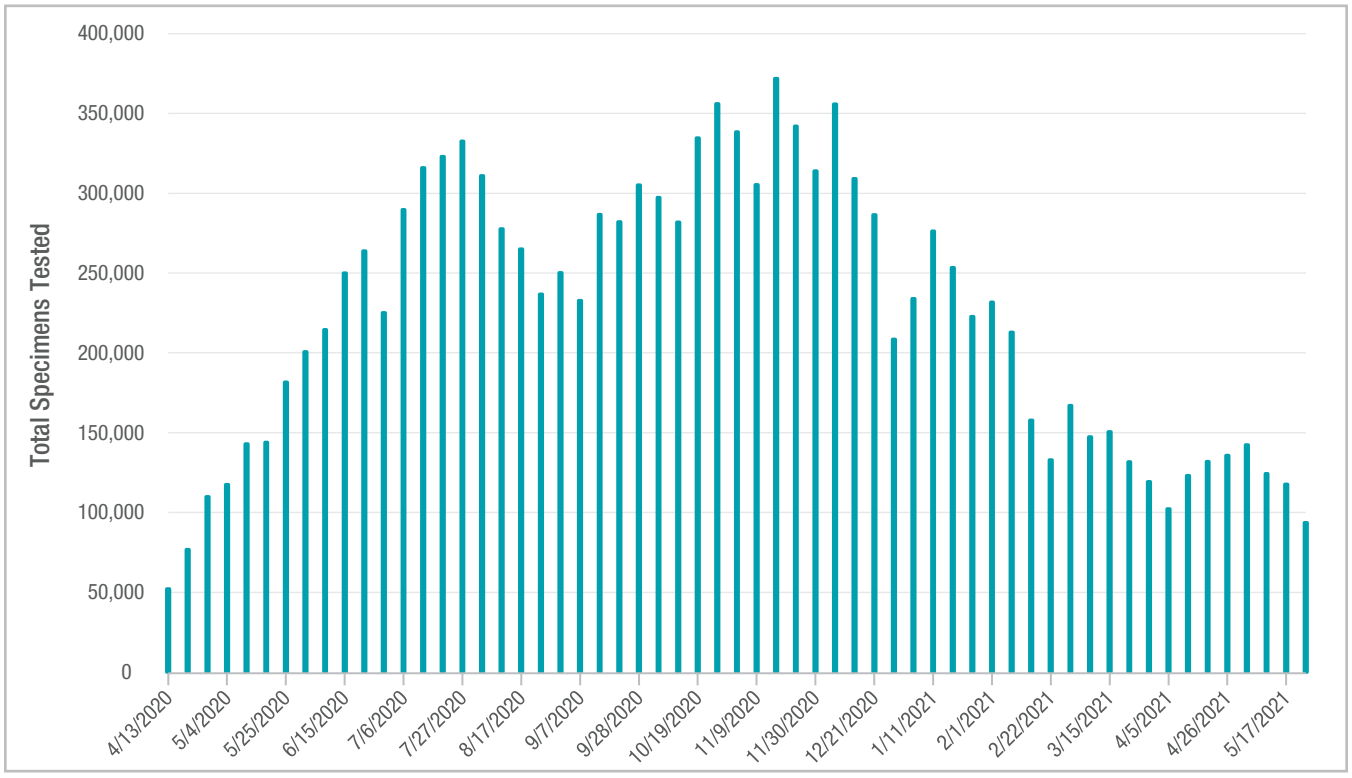
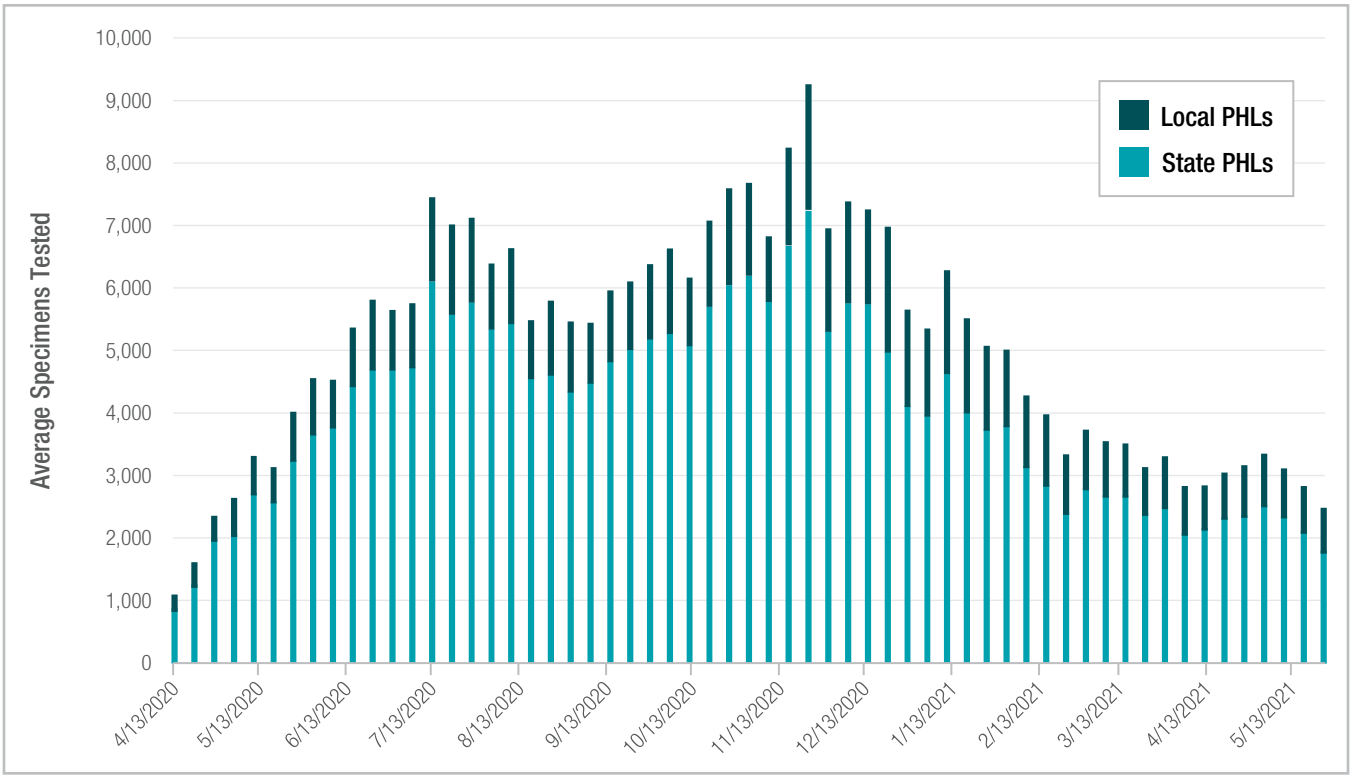


Figure 10. Molecular Testing: Average Number of Specimens Tested



Serology Testing

Ninety-eight public health laboratories reported on the status of serology testing in their laboratories (**Table 5**). Sixty-one public health laboratories, including 41 state and 20 local labs, offered serology testing by the conclusion of the APHL COVID-19 Survey. Laboratories were most likely to offer IgG (n=38) testing as compared to IgM (n=2) or both IgG and IgM (n=19). Sixteen labs also performed "Other" serology tests, which included also testing for IgA and total antibodies.

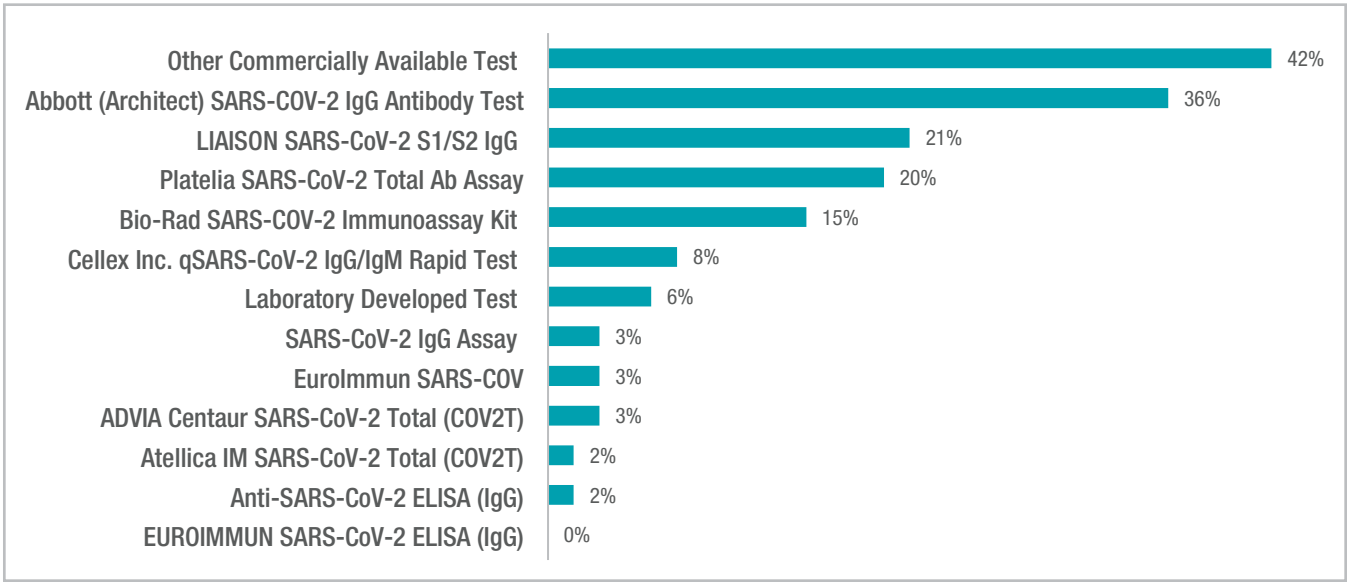
The most common response, selected by 28 public health laboratories, was "Other" commercially available tests. Biomerieux Vidas and Abbott Alinity were two frequently reported "Other" tests. The Abbott ARCHITECT SARS-CoV-2 IgG Antibody Test (n=24) and the DiaSorin LIASON SARS-CoV-2 assay (n=14) were also frequently cited. **Figure 11** shows the percentage of public health laboratories that reported performing each of the serology tests.

Table 5. Serology Tests Offered by Public Health Laboratories (n=61)

Test	Number of Laboratories (n)
Abbott ARCHITECT SARS-COV-2 IgG Antibody Test (Abbott Laboratories)	24
ADVIA Centaur SARS-CoV-2 Total (COV2T) (Siemens Healthcare Diagnostics Inc.)	2
Atellica IM SARS-CoV-2 Total (COV2T) (Siemens Healthcare Diagnostics Inc.)	1
Bio-Rad SARS-COV-2 Immunoassay Kit (Bio-Rad Laboratories Inc.)*	10
Cellex Inc. qSARS-CoV-2 IgG/IgM Rapid Test (Cellex Inc.)	5
EUROIMMUN SARS-CoV-2 (EUROIMMUN US Inc.)*	2
EUROIMMUN Anti-SARS-CoV-2 ELISA (IgG) (EUROIMMUN US Inc.)	1
EUROIMMUN SARS-CoV-2 ELISA (IgG) (EUROIMMUN US Inc.)	0
Laboratory developed test	4
LIAISON SARS-CoV-2 S1/S2 IgG (DiaSorin Inc.)	14
Platelia SARS-CoV-2 Total Ab assay (Bio-Rad Laboratories Inc)	13
SARS-CoV-2 IgG assay (Abbott Laboratories Inc.)	2
"Other" commercially available serology test	28

* Specific serologic testing products available from these manufacturers changed during the months of data collected. Data do not indicate which specific products were implemented.

Figure 11. Serology Tests Performed by Public Health Laboratories (n=61)



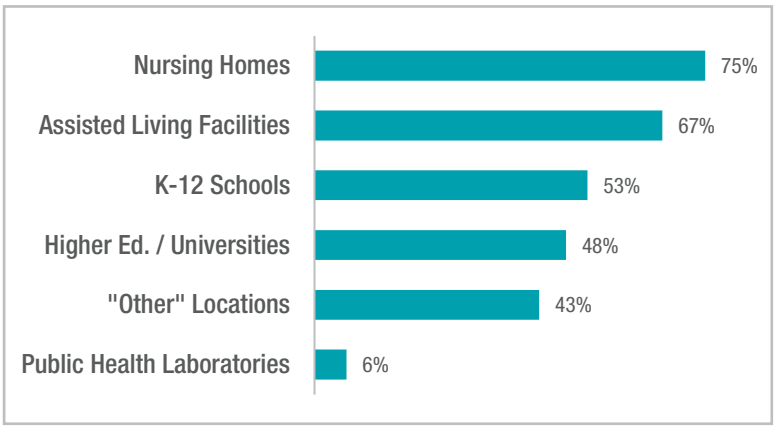
Antigen Tests

Beginning November 9, 2020, public health laboratories were asked to identify where and which antigen tests were being performed in their jurisdictions. Ninety-eight public health laboratories responded and 97 public health laboratories indicated that antigen tests were offered in their jurisdictions (**Figure 12**).

Notably, 73 public health laboratories reported antigen tests being used in local nursing homes and 65 public health laboratories reported antigen tests being used in local assisted living facilities. Although less frequently reported, antigen tests were still relatively commonly performed in K-12 schools (n=51), higher education/universities (n=47) and "other" locations (n=42). Common "other" locations included community testing events, correctional facilities, homeless shelters, clinics and hospitals. Very few public health laboratories (n=6) reported performing antigen tests at their facilities.

Excluding testing at public health laboratories, antigen test usage increased over time at each location. From week to week, antigen tests were consistently and most frequently used in nursing homes, followed closely by assisted living facilities. From the beginning to the end of the survey, there was a 16.7% and 12% increase in public health laboratories reporting testing at these locations respectively. Testing in higher education/universities increased 12.3%; testing in K-12 schools increased 15%; testing in "Other" locations increased 17.9%.

Figure 12. Antigen Testing Sites (n=97)



Sequencing

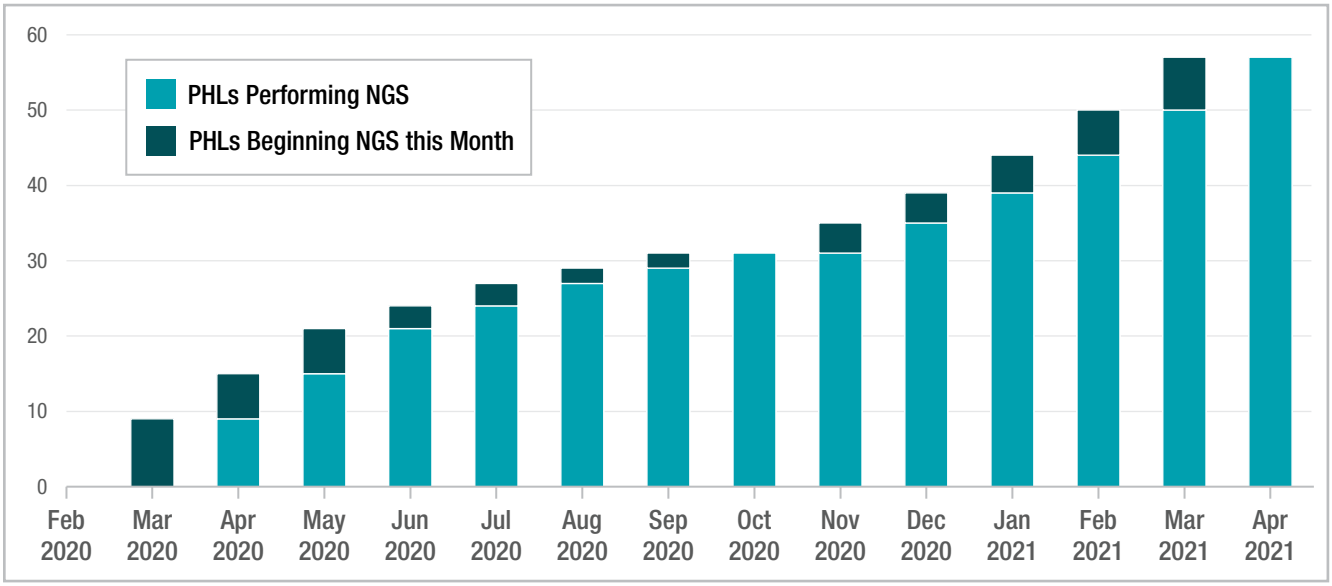
Starting January 11, 2021, public health laboratories were asked to identify whether or not they performed next generation sequencing (NGS) on SARS-CoV-2 specimens. If sequencing was implemented, public health laboratories were asked to identify when sequencing began. If sequencing was not implemented, laboratories were asked to identify barriers to performing sequencing in-house.

By the end of May 2021, 57 out of 96 responding laboratories (59%) performed NGS on SARS-CoV-2 specimens. Not including US territories, 44 state public health laboratories (86%; n=51), including Washington, DC, reported performing NGS by the close of the survey. Additionally, 47 out of 50 Epidemiology and Laboratory Capacity (ELC)-funded laboratories (94%) implemented NGS. In order to ensure consistency of responses, APHL staff confirmed with all public health laboratories who responded positively that wet-lab sequencing was performed in-house. While they are not included in these analyses, several public health laboratories partnered with outside entities, such as universities, to sequence SARS-CoV-2 specimens and upload sequences to national databases.

The greatest numbers of public health laboratories implemented NGS in March–May 2020 (n=21) and January–March 2021 (n=18). Although the number of public health laboratories implementing NGS varied from month-to-month, the number of laboratories ready to sequence steadily grew over the year (**Figure 13**). Two additional laboratories indicated that they implemented sequencing; however, information regarding when NGS was implemented was unavailable.

Common barriers to bringing sequencing in-house were inadequate amounts of laboratory resources, including staff, space and time, as well as a lack of necessary equipment, infrastructure, bioinformatics expertise and funding. Many of these barriers correspond to challenges previously mentioned. Of note, bioinformatics expertise was and continues to be in high demand and short supply as it is a crucial component to implementing and maintaining in-house sequencing.

Figure 13. Implementing and Performing NGS on SARS-CoV-2 Specimens (n=96)



CONCLUSION

Since the emergence of SARS-CoV-2, public health laboratories have faced and continue to face monumental challenges. Numerous factors impacted laboratories' abilities to meet testing demands, maintain critical inventories of supplies and reagents, address testing backlogs, verify and validate new instrumentation, implement novel tests, bring on in-house sequencing and respond efficiently and effectively to extraordinary circumstances.

The onset of the pandemic brought an unprecedented deluge of testing requests for a novel virus that required quick adaptations from public health laboratories, including diverting laboratory staff from separate programs and projects to support the response. public health laboratories encountered numerous supply chain challenges as well as shortages in supplies and reagents. This included a major plastic shortage in fall 2020 that impacted critical pipette tip and test tube inventories. Furthermore, challenges in the pandemic response were exacerbated by limitations in laboratory space, equipment and personnel. Public health laboratories also experienced unprecedented politicization and workforce burnout.

Despite these countless challenges, public health laboratories responded swiftly and efficiently. Between April 2020 and May 2021, on average, 91.5% of public health laboratories met testing demand and reported testing over 13,000,000 SARS-CoV-2 specimens. Public health laboratories expanded their testing capacities rapidly and increased the average number of owned extraction platforms, thermal cyclers and molecular platforms in order to accommodate testing demand. Over the course of the survey, less than 5% of public health laboratories experienced backlogs during a given week. As of May 2021, nearly 60% of public health laboratories had implemented in-house sequencing of SARS-CoV-2 in order to perform surveillance and monitor the circulation of SARS-CoV-2 variants across the US. Since the conclusion of this survey, additional public health laboratories have implemented sequencing and/or partnered with outside institutes to sequence SARS-CoV-2 specimens.

APHL continues to monitor member laboratories' capacities, capabilities and ongoing challenges of the COVID-19 pandemic response.

APPENDIX: DATA COLLECTION PERIODS

Week Number	Start Date	End Date
Week 1	13-Apr-20	19-Apr-20
Week 2	20-Apr-20	26-Apr-20
Week 3	27-Apr-20	3-May-20
Week 4	4-May-20	10-May-20
Week 5	11-May-20	17-May-20
Week 6	18-May-20	24-May-20
Week 7	25-May-20	31-May-20
Week 8	1-Jun-20	7-Jun-20
Week 9	8-Jun-20	14-Jun-20
Week 10	15-Jun-20	21-Jun-20
Week 11	22-Jun-20	28-Jun-20
Week 12	29-Jun-20	5-Jul-20
Week 13	6-Jul-20	12-Jul-20
Week 14	13-Jul-20	19-Jul-20
Week 15	20-Jul-20	26-Jul-20
Week 16	27-Jul-20	2-Aug-20
Week 17	3-Aug-20	9-Aug-20
Week 18	10-Aug-20	16-Aug-20
Week 19	17-Aug-20	23-Aug-20
Week 20	24-Aug-20	30-Aug-20
Week 21	31-Aug-20	6-Sep-20
Week 22	7-Sep-20	13-Sep-20
Week 23	14-Sep-20	20-Sep-20
Week 24	21-Sep-20	27-Sep-20
Week 25	28-Sep-20	4-Oct-20
Week 26	5-Oct-20	11-Oct-20
Week 27	12-Oct-20	18-Oct-20
Week 28	19-Oct-20	25-Oct-20
Week 29	26-Oct-20	1-Nov-20
Week 30	2-Nov-20	8-Nov-20

Week Number	Start Date	End Date
Week 31	9-Nov-20	15-Nov-20
Week 32	16-Nov-20	22-Nov-20
Week 33	23-Nov-20	29-Nov-20
Week 34	30-Nov-20	6-Dec-20
Week 35	7-Dec-20	13-Dec-20
Week 36	14-Dec-20	20-Dec-20
Week 37	21-Dec-20	27-Dec-20
Week 38	28-Dec-20	3-Jan-21
Week 39	4-Jan-21	10-Jan-21
Week 40	11-Jan-21	17-Jan-21
Week 41	18-Jan-21	24-Jan-21
Week 42	25-Jan-21	31-Jan-21
Week 43	1-Feb-21	7-Feb-21
Week 44	8-Feb-21	14-Feb-21
Week 45	15-Feb-21	21-Feb-21
Week 46	22-Feb-21	28-Feb-21
Week 47	1-Mar-21	7-Mar-21
Week 48	8-Mar-21	14-Mar-21
Week 49	15-Mar-21	21-Mar-21
Week 50	22-Mar-21	28-Mar-21
Week 51	29-Mar-21	4-Apr-21
Week 52	5-Apr-21	11-Apr-21
Week 53	12-Apr-21	18-Apr-21
Week 54	19-Apr-21	25-Apr-21
Week 55	26-Apr-21	2-May-21
Week 56	3-May-21	9-May-21
Week 57	10-May-21	16-May-21
Week 58	17-May-21	23-May-21
Week 59	24-May-21	30-May-21

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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