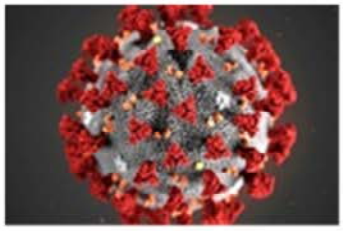
Association for Molecular Pathology
SARS-CoV-2 Molecular Testing

Summary of August SARS-CoV-2 Molecular Testing Survey



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Providing global expertise in molecular testing that drives patient care.

AMP members continue to be on the front lines of clinical laboratory response to and diagnosis of emerging infectious agents using molecular diagnostics, with multiple educational, clinical practice, and advocacy efforts occurring in collaboration with many of our organization partners who are participating today. We will continue those efforts in the days to come and welcome additional opportunities to work together to both resolve today's problems and establish future best practices to improve pandemic response. The preliminary information contained in this report is the result of a joint data collection effort by AMP clinical practice and advocacy regarding our members' experience as they work to respond to the COVID-19 pandemic.

AMP's 2,500+ international membership includes professionals from academic and community medical centers, government, and industry functionally involved in educational, medical, scientific, economic, and regulatory aspects of molecular diagnostics, including but not limited to pathologists and doctoral scientist laboratory directors, basic and translational scientists, technologists, and trainees.

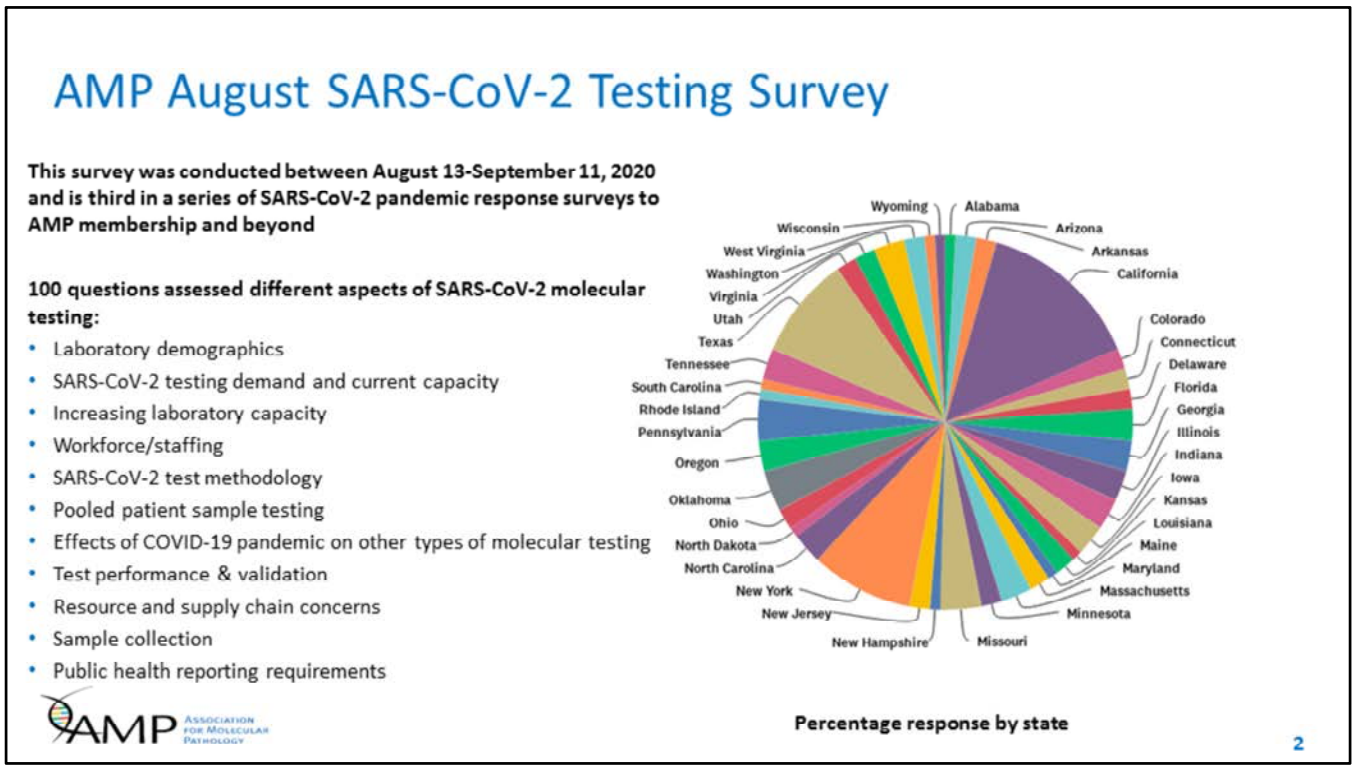
Survey Background and Purpose:

Purpose: In order to better understand the contribution our laboratories are making and the challenges they are facing during the COVID-19 pandemic response, AMP created a series of robust surveys to collect and document laboratories' efforts and experiences throughout the course of the pandemic. These surveys allow us to monitor, understand, and collect real-time data on laboratories' efforts and experiences during the COVID-19 pandemic response. The survey results have been instrumental in AMP's advocacy and clinical practice efforts. AMP released a preliminary report of the survey conducted from April 23-May 5, 2020 ("April Survey"). That survey is available here: https://www.amp.org/advocacy/sars-cov-2-survey/. Data from both the April and August surveys are compared and contrasted below.

Survey scope: This survey covers topics related to molecular diagnostic testing only for SARS-CoV-2 and does not address serology or antigen testing. Consistent with the previous AMP SARS-CoV-2 surveys, this survey was anonymous and results were used in aggregate to help inform advocacy and clinical practice programs on this issue.

Target audience for this survey: Laboratory professionals offering a SARS-CoV-2 molecular test.

AMP Program Areas: Joint effort of Advocacy & Clinical Practice. Robyn & Tara wish to thank all of the AMP staff members on our respective teams, and the marketing and communications team for their assistance and support in conducting this survey.



Survey Design & Methodology:

The 100 question survey was anonymous employing multiple choice, select all that apply, and free text question formats. Skip logic was employed to tailor follow-up questions based upon responses. Survey assessed different aspects of SARS-CoV-2 testing including:

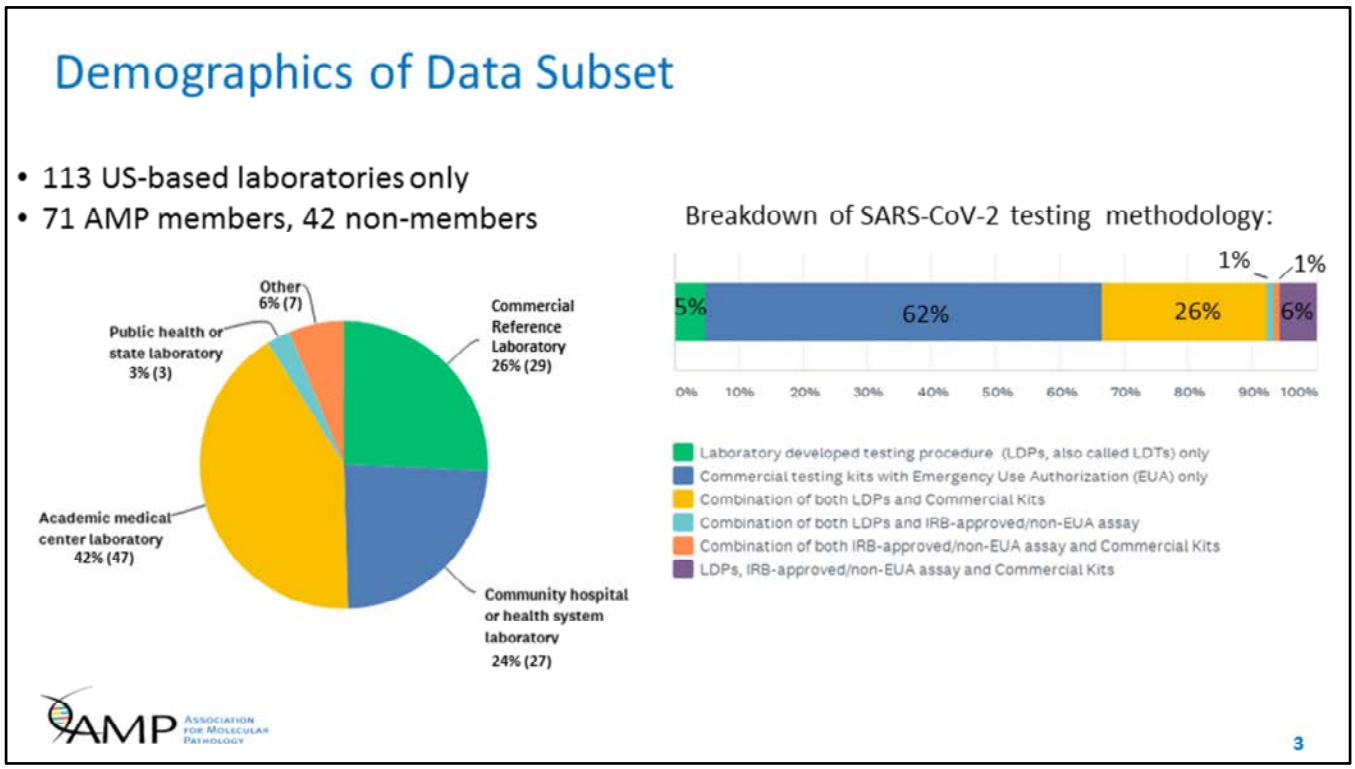
- Laboratory demographics
- SARS-CoV-2 testing demand and current capacity
- Increasing laboratory capacity
- Workforce/staffing
- SARS-CoV-2 test methodology
- Pooled patient sample testing
- Reporting of cycle threshold (Ct) values
- Effects of COVID-19 pandemic on other types of molecular testing
- Test performance
- Test validation
- Resource and supply chain concerns
- Sample collection
- Public health reporting requirements

The survey was open from August 13-September 11, 2020 and was open to all laboratory personnel (AMP members and non-members) who might be conducting COVID19 diagnostic testing. The survey was distributed broadly via email and also on social media.

Summary data results have been initially analyzed using Survey Monkey for summary data. Results were exported into Excel as needed to facilitate comparison of more complex summary responses. Results were gated and analyzed in the following data sets:

- #1 - All laboratory types, US-based, completed surveys only
- #2 – Laboratory type comparison responses US-based, completed surveys only
    - Academic medical centers
    - Community hospital or health system laboratory
    - Commercial reference laboratory (note: this category is inclusive of both referral and reference laboratories)
    - Public health or state laboratory
- #3 - “Near-to-patient“ laboratories versus commercial reference laboratories, US-based, completed surveys only
    - 3A - Academic medical centers and community hospital or health system laboratory combined
    - 3B - Commercial reference laboratory

Results not yet analyzed include all complete responses (combination of US and international laboratories), international laboratories only, and partially completed survey responses.

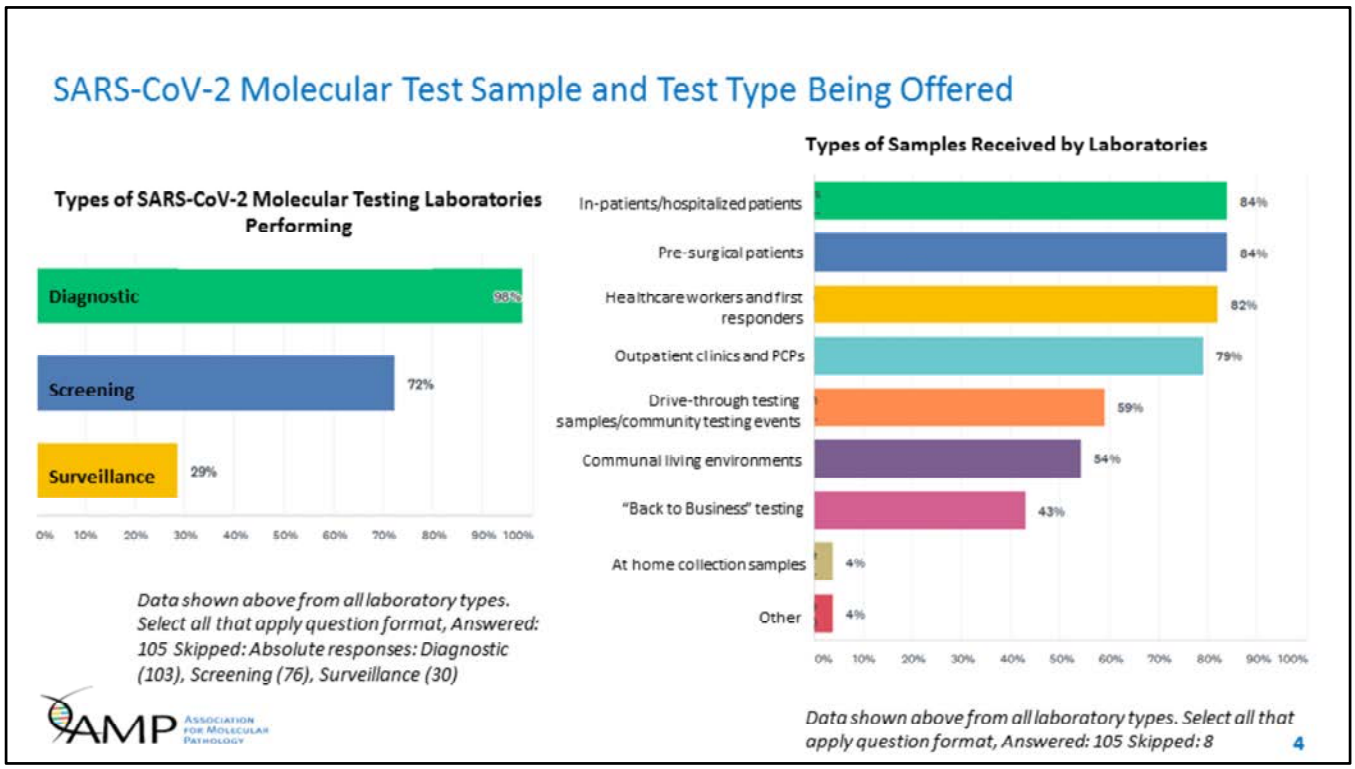


Demographics for Dataset #1 (All laboratory types, US-based, completed surveys only):

- 249 total responses, with 113 complete responses from US laboratories. Of the 113 complete responses, 71 were AMP members, 42 were non-members. Approximately 42% of respondents categorized their laboratory as academic medical center laboratory (n=47), 26% as commercial reference laboratory (n=29), 24% as community hospital or health system laboratory (n=27), 3% as public or state laboratory (n=3), and 6% from other settings (e.g., Indian health service or federal government laboratory; n=7). The survey had broad participation from across the U.S.
- Ninety-one percent of respondents are currently offering a SARS-CoV-2 test(s) to patients, with approximately 12% in the process of validating a test, less than 5% do not plan to offer a test and less than 4% are interested in offering and preparing a SARS-CoV-2 molecular test but have either stopped preparing a test or have not yet begun the process. Survey takers were allowed to choose all that apply to account for the likelihood that laboratories could have one or more SARS-CoV-2 test live but could also be in the process of getting other tests validated and ready to be offered.
- Results indicate that 62% of laboratories are solely using commercial testing kits with FDA emergency use authorization (EUA), 5% are using laboratory developed testing procedures only, 26% are using a combination of both LDPs and EUAs, and 6% are using LDPs, IRB-approved/non-EUA assay and Commercial Kits. Less than 1% reported using either a combination of both LDPs and IRB-approved/non-EUA assay or a combination of both IRB-approved/non-EUA assay and Commercial Kits. One noticeable difference in these results from the April survey is that more laboratories are using commercial testing kits with EUA (62% in August survey vs. 50% in April survey). This is likely due to

both an increased number of commercially-available testing kits being marketed and FDA easing its EUA requirements since the Spring.

NOTE – Graph on right: Data shown from all laboratory types. 105 respondents, absolute # responses: Laboratory developed testing procedure (LDPs, also called LDTs) only (5), Commercial testing kits with Emergency Use Authorization (EUA) only (65), Combination of both LDPs and Commercial Kits (27), Combination of both LDPs and IRB-approved/non-EUA assay (1), Combination of both IRB-approved/non-EUA assay and Commercial Kits (1), LDPs, IRB-approved/non-EUA assay and Commercial Kits (6)



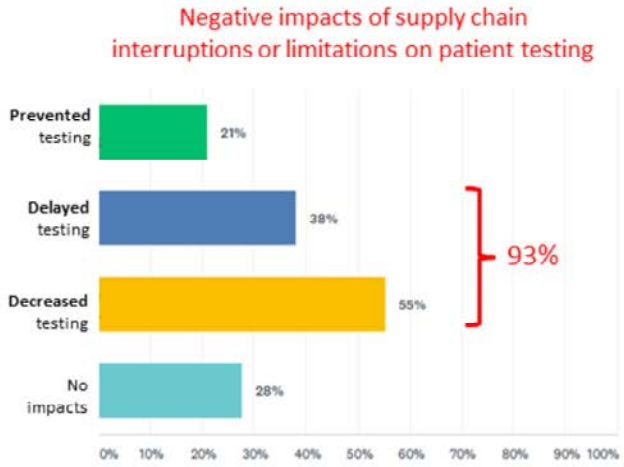
The purposes of SARS-CoV-2 molecular testing (e.g., diagnostic, screening, surveillance) have expanded since April and for the August survey, and AMP wanted to understand how these tests were being used in the community. With the option to choose all that apply to their laboratory, 98% (103) of respondents reported that they are running SARS-CoV-2 diagnostic testing, 72% (76) performing screening testing, and 29% (30) performing surveillance testing. Samples originating from in-patients / hospitalized patients, pre-surgical patients, healthcare workers and first responders, outpatient clinics and primary care physicians are being tested by ~80% of respondents.

NOTE – Graph on right: Data shown from all laboratory types, select all that apply format. 105 respondents, absolute # responses: In-patients/hospitalized patients (88), Pre-surgical patients (88), Outpatient clinics and PCPs (83), Drive-through testing samples / community testing events (62), At home collection samples (4), Communal Living Environments (e.g., long-term nursing facilities, homeless shelters, and prisons)(57), Healthcare workers and first responders (86), "Back to Business" testing (e.g. testing for schools and businesses to reopen/operate)(45), Other (4)

Supply chain issues continue to negatively impact laboratories providing SARS-CoV-2 testing

Type of Supply Chain Limitation	Currently experiencing	Previously experienced, but resolved for now	Have not experienced
Sample extraction / processing platforms *(n=69)*	17%	36%	46%
Testing platforms *(n=70)*	39%	36%	26%
Commercially-available testing kits *(n=74)*	76%	19%	5%
General laboratory reagents (e.g., buffers) *(n=69)*	23%	35%	42%
Reagents for LDPs (e.g., RNA extraction kits, buffers) *(n=67)*	7%	31%	61%
Reagents required for commercially-available testing kits (e.g., buffers not included in kit) *(n=69)*	22%	33%	45%
Swabs *(n=72)*	21%	67%	13%
Transport media (UTM/VTM) *(n=73)*	29%	62%	10%
Platform-specific laboratory consumables (e.g., pipette tips, Eppendorf tubes) *(n=73)*	53%	27%	19%
General laboratory consumables (e.g., pipette tips, Eppendorf tubes) *(n=72)*	38%	33%	29%
Personal protective equipment (PPE) *(n=69)*	29%	35%	36%

Data shown above from all laboratory types. Select all that apply question format, Answered: 75, Skipped: 31



Data shown above from all laboratory types. Select all that apply question format, 105 respondents, absolute # responses: Prevented (22), Delayed (40), Decreased (58), No impacts (29)

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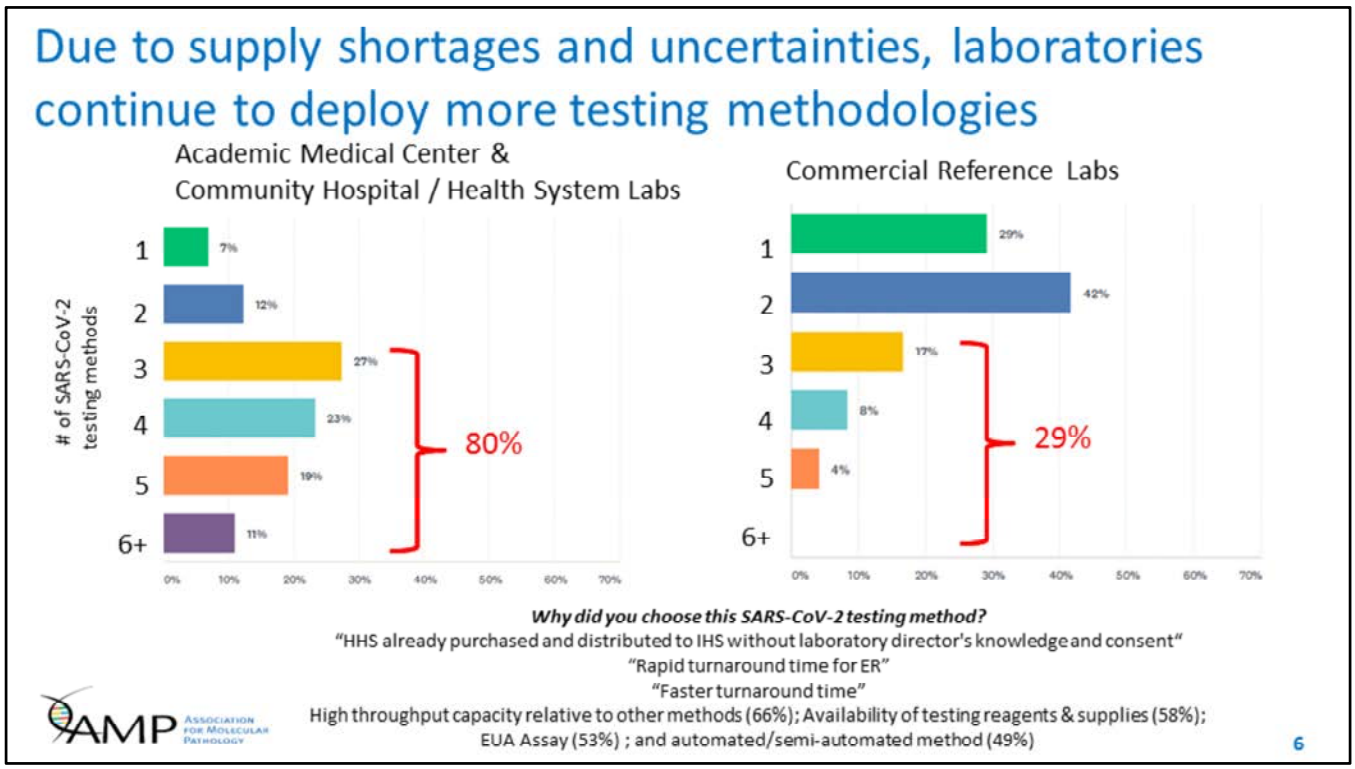
In April, laboratories reported that supply chain interruptions had a significant impact on their testing capacity. In the August survey, respondents report that supply chain interruption continues to have a significant impact, with over 90% reporting that interruptions have delayed and/or decreased testing. Similar responses across all laboratory types indicate additional resources are needed to implement and/or maintain testing, with commercially-available testing kits and platform-specific laboratory consumables identified as the most needed items. Testing platforms and general laboratory consumables were also identified as in short supply for laboratories. The types of supply chain interruptions were similar across laboratory types.

In the April survey, the types of supply chain interruptions that laboratories experienced were vast and include testing platforms, testing kits, reagents, swabs, viral transport media (VTM), laboratory consumables, and PPE, with swabs being the biggest limitation across laboratories. The August data show similar results with the exception of swabs and viral transport media. While respondents noted they were experiencing significant shortages of these materials previously (67% for swabs and 62% for transport media), only 21% and 29% of laboratories respectively report that they are currently experiencing shortages of these items.



In April, AMP reported that laboratories have deployed multiple testing methodologies to provide testing continuously as supply chain shortages prevented or delayed testing. Commercial reference laboratories reported using predominantly one or two methods in their laboratory, while academic medical centers and community hospital laboratories reported predominantly running three, four, or more methods.

This trend continued in the August survey with laboratories continuing to add testing methods; the data shows the number of laboratories only using one method declined from 29% to 11% since April. Specifically, 80% of academic medical center and community hospital/health system laboratories reporting using three or more methods, an increase by more than 20% since April. And, 29% of commercial reference laboratories now report using three or more methods. In comparison, in April the majority of commercial reference laboratories reported using primarily one method, now almost half of commercial laboratories are using two methods.

NOTE – Graph on left: Data shown from Academic Medical Center and Community Hospital / Health System Laboratory types. 73 respondents, absolute # responses: One (5), Two (9), Three (20), Four (17), Five (14), Six or more (8). Graph on right: Data shown from Commercial Reference Laboratory types. 24 respondents, absolute # responses: One (7), Two (10), Three (4), Four (2), Five (1), Six or more (0).

All US-based labs: top 10 primary testing methods

SARS-COV-2 Molecular Testing Methods	Primary* (n=100)	Secondary (n=90)	Tertiary (n=65)
Roche cobas SARS-CoV-2	17%	7%	5%
Laboratory Developed Testing Procedure (LDP/LDT) with EUA Submission	12%	2%	6%
Abbott RealTime SARS-CoV-2 Assay	10%	8%	2%
Hologic Aptima SARS-CoV-2 Assay	10%	9%	2%
Thermo Fisher Scientific TaqPath COVID-19 Combo Kit	9%	7%	2%
Cepheid Xpert Xpress SARS-CoV-2 Test	6%	19%	28%
Abbott Alinity M SARS-CoV-2 Assay	5%	1%	2%
CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	4%	8%	3%
Hologic Panther Fusion SARS-CoV-2 Assay	4%	1%	0%
PerkinElmer New Coronavirus Nucleic Acid Detection Kit	4%	1%	0%

** Data sorted by the primary testing method from largest to smallest*

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A breakdown of the top 10 primary testing methods utilized by the laboratories surveyed shows that laboratories are using a spectrum of methods. General trends are similar to the April survey, with many of the same testing methods still present in the top ten.

Note: Data presented here provide a breakdown of the top 10 primary testing methods utilized by the laboratories surveyed; all laboratory types. Data here are sorted by the primary testing method from largest to smallest, with the percentage of respondents rounded to the nearest whole number for the purpose of presentation.

Top 3 primary testing methods by laboratory type

Academic Medical Centers (n=47)	Community Hospitals / Medical Centers (n=26)	Commercial Reference Laboratories (n=24)
Roche Molecular Systems cobas SARS-CoV-2 (9)	Roche Molecular Systems cobas SARS-CoV-2 (6)	Laboratory developed testing procedure (LDP / LDT) with EUA submission (4)
Laboratory developed testing procedure (LDP / LDT) with EUA submission (8)	Cepheid - Xpert Xpress SARS-CoV-2 Test (5) *OR* Hologic Aptima SARS-CoV-2 Assay (5)	Hologic Aptima SARS-CoV-2 Assay (3) *OR* PerkinElmer New Coronavirus Nucleic Acid Detection Kit (3) *OR* Thermo Fisher Scientific TaqPath COVID-19 Combo Kit (3)
Abbott RealTime SARS-CoV-2 Assay (6)	Abbott ID NOW COVID-19 (3)	Abbott RealTime SARS-CoV-2 Assay (2) *OR* CDC 2019-NCOV Real-Time RT-PCR Diagnostic Panel *OR* Roche cobas SARS-CoV-2 (2)

Top reasons for selecting their primary SARS-CoV-2 molecular testing method?

- High throughput capacity relative to other methods available was #1 reason for Academic Medical Center
- High throughput capacity relative to other methods available and EUA assay were tied for the top reason for Commercial Reference Laboratories
- Availability of testing reagents & supplies was the top reasons for Community Hospital / Health System Labs

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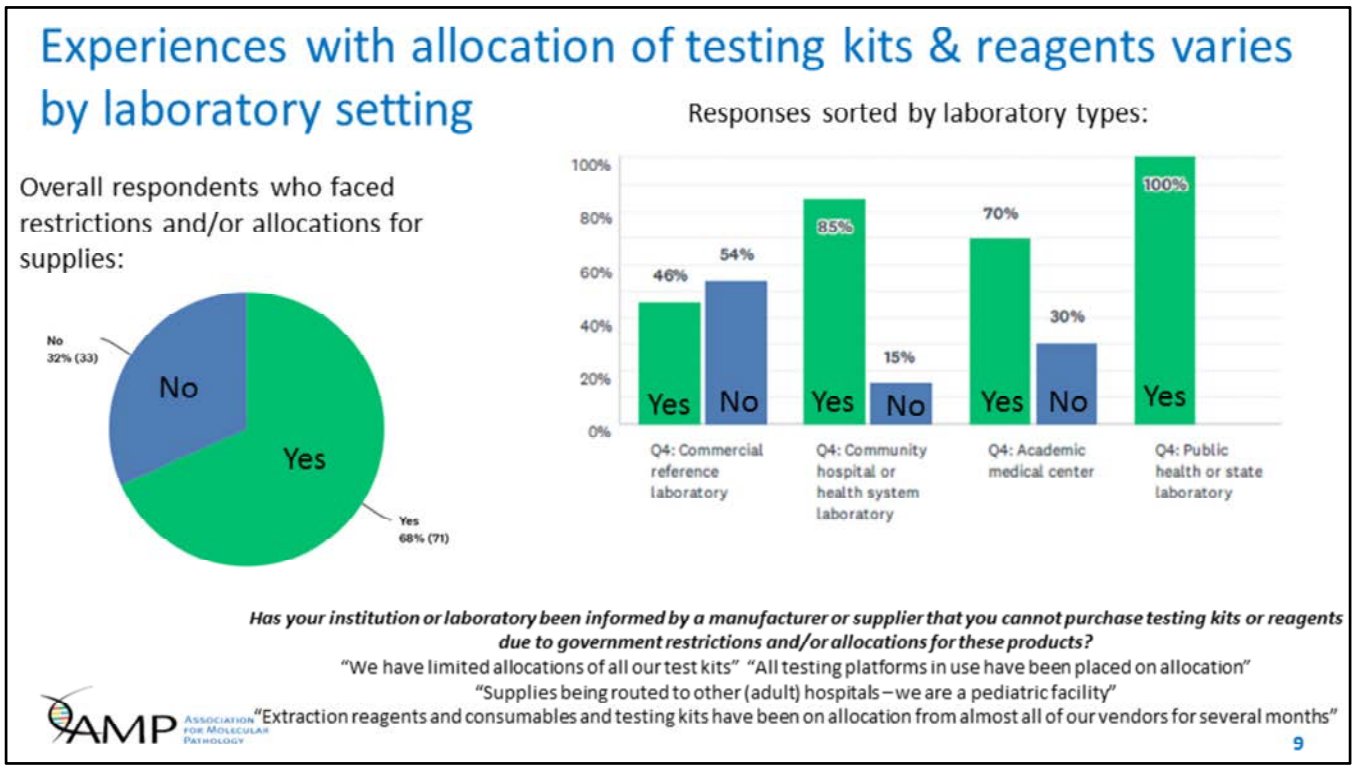
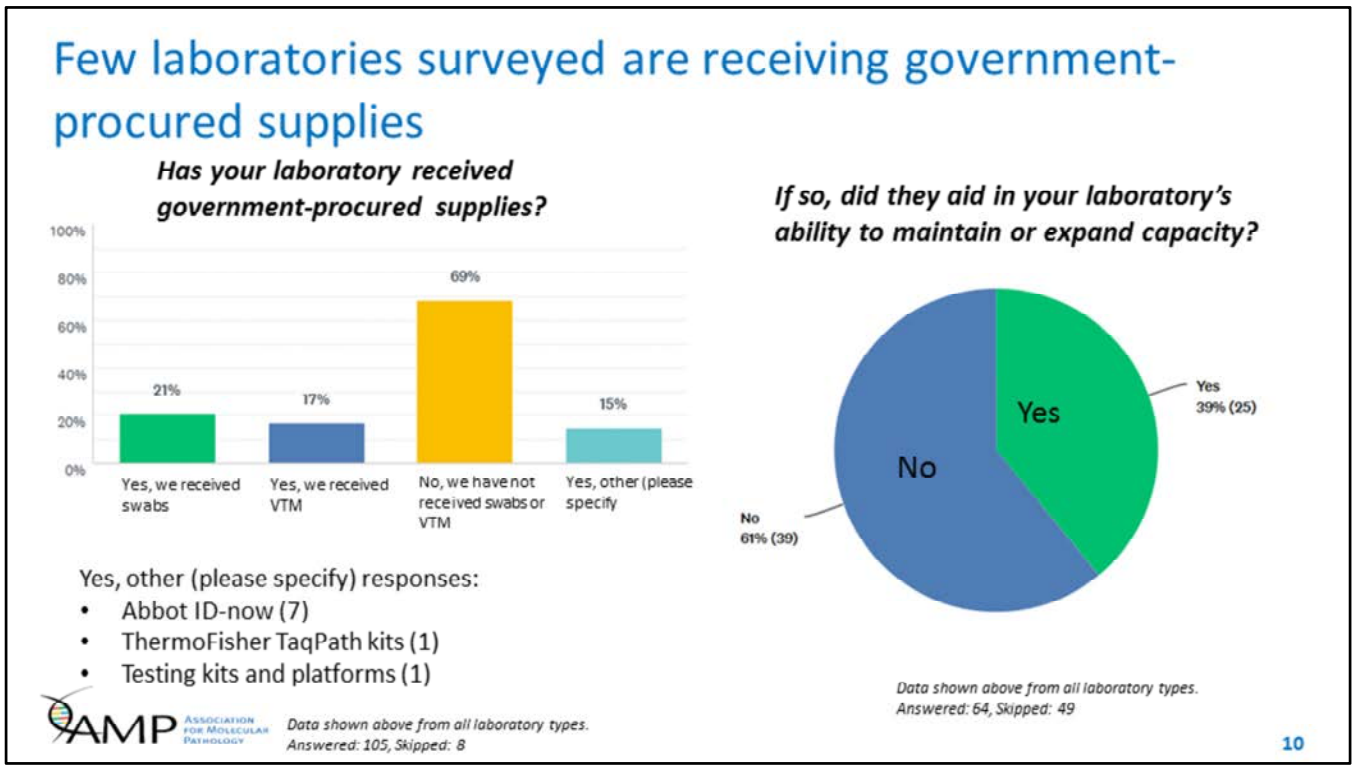
The top three primary testing methods vary depending on laboratory type. High throughput capacity platforms relative to other testing methods available was the top reason for both academic medical center and commercial reference laboratories to select a platform. Commercial reference laboratories also listed using an EUA assay as an important reason.



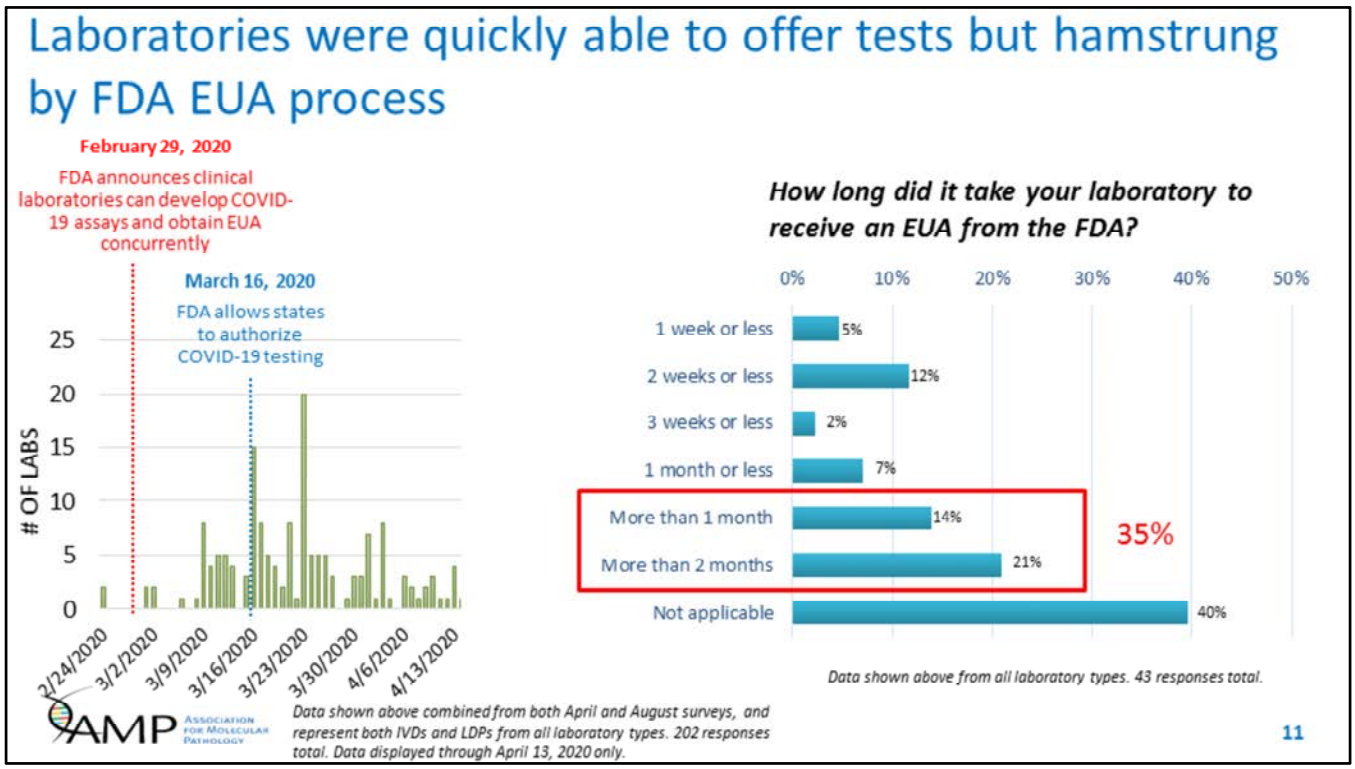
Almost 70% of laboratories surveyed reported that they have been informed by a manufacturer or supplier that they cannot purchase testing kits or reagents due to government restrictions and/or allocations for these products. When looking at the data across laboratory types, approximately 70% of academic medical center and 85% of community hospital/health system laboratories reported that they have been informed by a manufacturer or supplier that they cannot purchase testing kits or reagents due to government restrictions and/or allocations for these products, while only about 45% of commercial reference laboratories reported this fact. Three public health or state laboratories participating in the survey also reported that they have been informed by a manufacturer or supplier that they cannot purchase testing kits or reagents due to government restrictions and/or allocations for these products.

NOTE – Graph on the right: 99 total respondents, absolute # respondents: Commercial reference laboratory (24), Community hospital or health system laboratory (26), Academic medical center (46), Public health or state laboratory (3)



In May, the Federal government worked to distribute swabs and viral transport media to states to help with combating testing reagent shortages. However, when respondents were asked if their laboratory had received government-procured VTM or swabs, only 20% and 17% of laboratories respectively had received these items through government channels. Of those who did receive government-procured supplies, only about 40% felt that these supplies aided their laboratory's ability to maintain or expand testing capacity indicating it wasn't enough support.

NOTE – Graph on the left: 105 total respondents, absolute # respondents: Yes, we received swabs (22), Yes, we received VTM (18), No we have not received any government procured supplies (72), Yes, other (please specify)(16)



Once laboratories were able to develop SARS-CoV-2 tests they responded rapidly. Laboratories reported an average go-live date of March 16, 2020 for their first test, approximately two weeks after FDA announced that clinical laboratories can develop COVID-19 assays and obtain FDA emergency use authorization (EUA) concurrently.

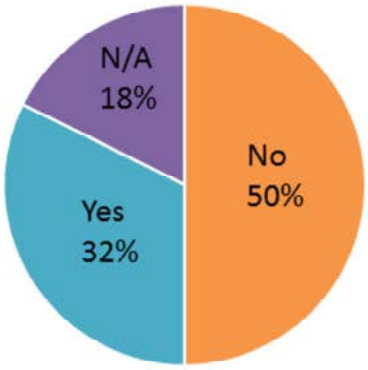
Approximately 35% of respondents noted that it took more than a month for their laboratory to receive an EUA. Some submitted answers to "How long did it take your laboratory to receive an EUA from the FDA?"

- We have not received approval yet after 4 months
- Still in process (since April 2020)
- still in validation
- The FDA review was silent for 6 weeks, then they started asking questions that could have been asked up front.
- Submitted April 7, still waiting as of August 18
- Still waiting on FDA EUA review ongoing

NOTE – Graph on the left: 43 total respondents, absolute # respondents: 1 week or less (2), 2 weeks or less (5), 3 weeks or less (1), 1 month or less (3), More than 1 month (6), More than 2 months (9), Not applicable (17)

Laboratories continue to encounter problems with FDA EUA process

Did you or are you experiencing hurdles in completing an EUA from the FDA?



Data shown above from all laboratory types. 34 responses total.

Comments from respondents:

- *"The FDA was not familiar with the technology in the EUA submission. The EUA review by the FDA took 2 months for completion. "*
- *"I am on round 5 or 6 in responding to FDA questions…Although we made very minor modifications to CDC and ThermoFisher assays (lack of approved PCR instrument) we were required to repeat all aspects of CDC and ThermoFisher FDA EUA submissions."*
- *"We submitted for EUA back in early April. We never heard a thing…[In June, FDA was] helpful regarding the requests but they were asking for information based upon the recent guidelines not based upon the guidelines at the time of submission ."*

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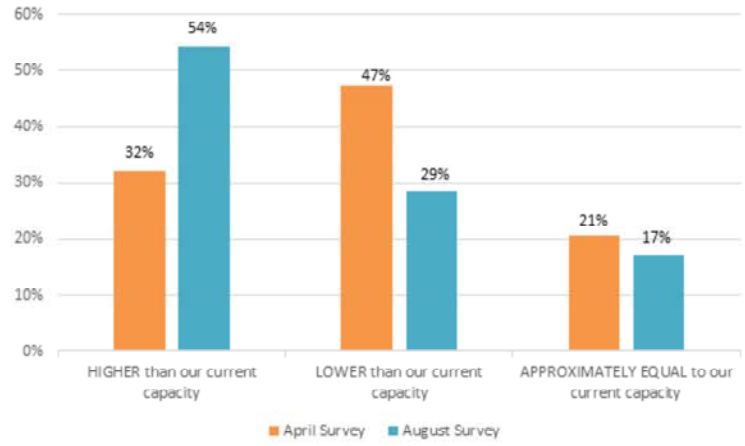
Thirty-two percent of respondents stated that they either are or did experience hurdles in completing the FDA EUA process.

NOTE: Data shown from all laboratory types. 34 total respondents, absolute # respondents: No (17), Yes (11), Not applicable (6)

Demand for SARS-CoV-2 molecular testing has shifted dramatically since April



Respondents experiencing new demands for testing

"Increase as more surveillance testing is needed."

"Increasing demand outstripping capacity"

"Anticipating increase during Fall/Winter season."

"Increase due to back to work testing needs"

Data shown above from all laboratory types. April data: 112 respondents, absolute # responses: Higher (36), Lower (53), Approximately equal (23), August data: 115 respondents, absolute # responses: Higher (57), Lower (30), Approximately equal (18)

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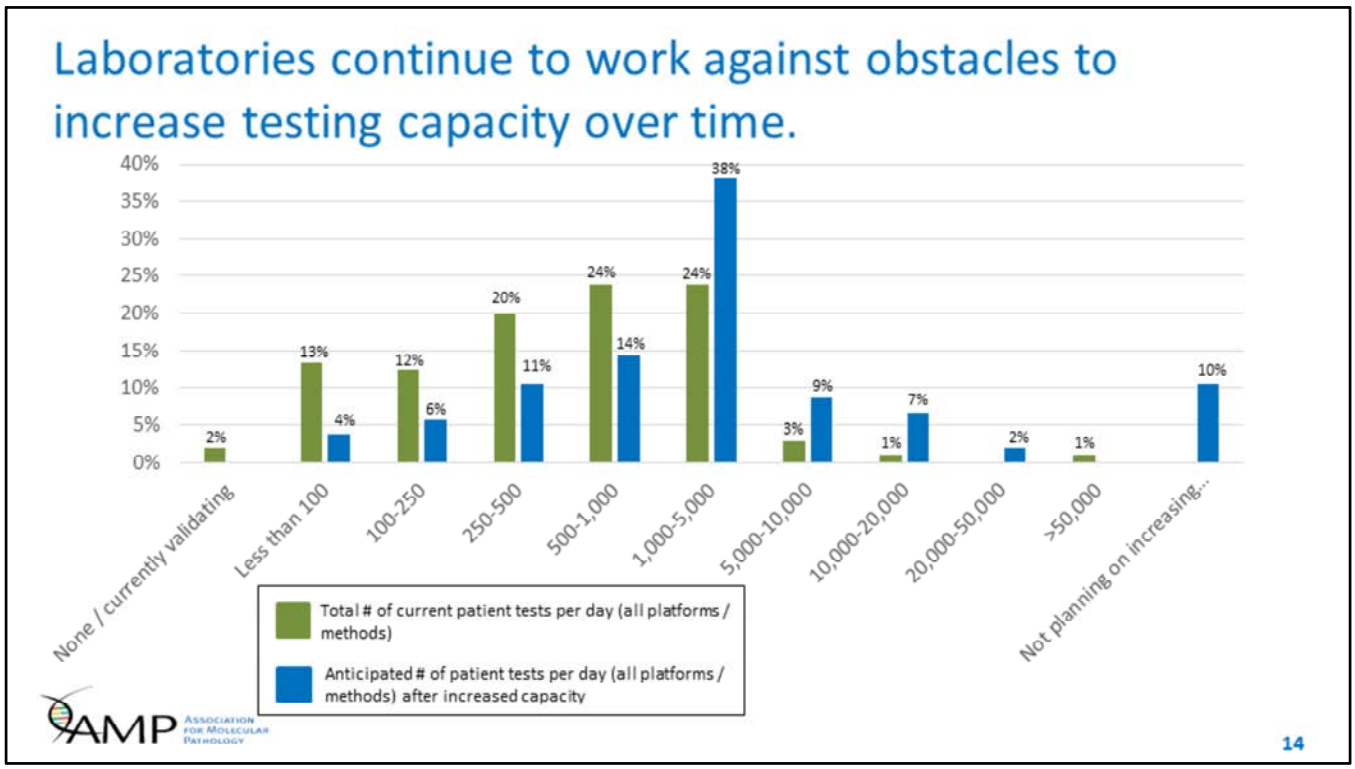
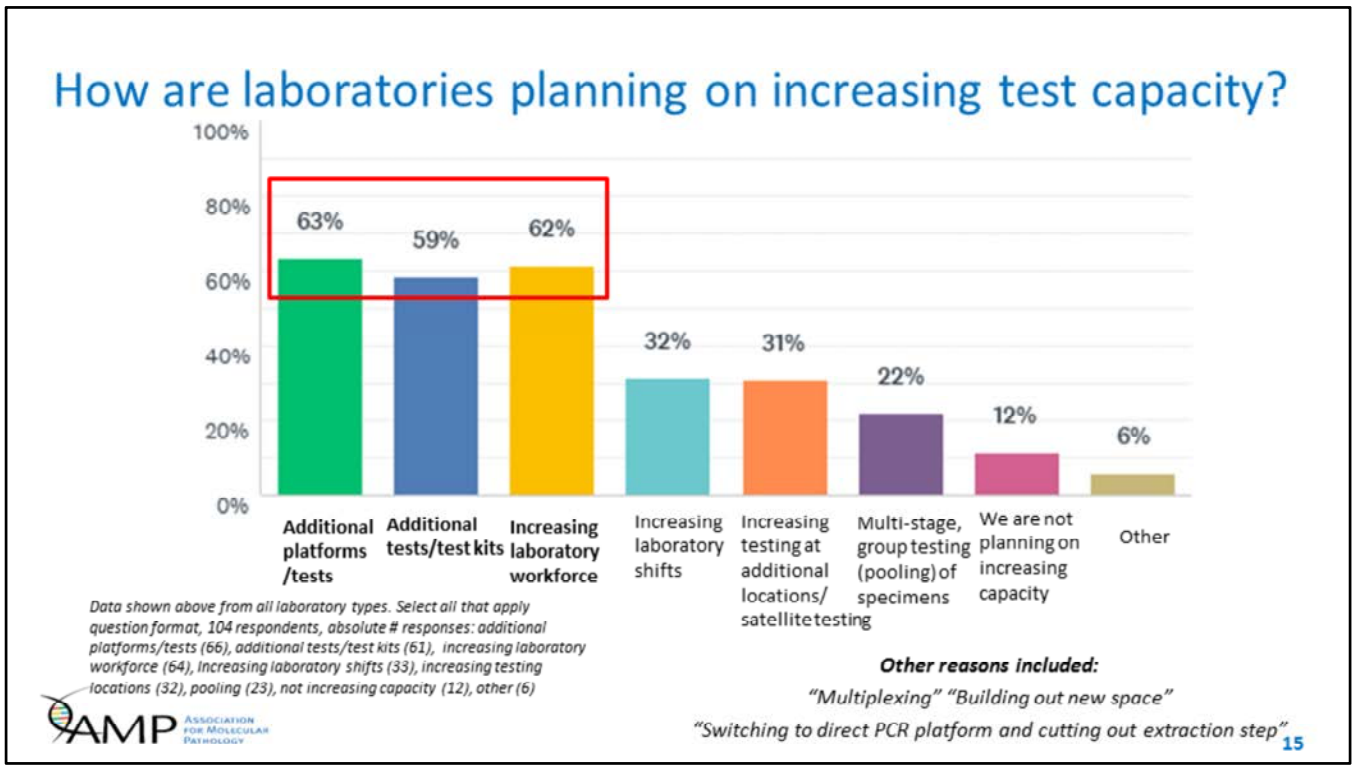
Demand for SARS-CoV-2 molecular testing has shifted dramatically since the April survey. In April, only 32% of respondents indicated demand was higher than the current capacity, while in August, that number increased to 54%. Respondents indicated in April that they anticipated increased demand for testing as reopening activities, to include back to school and back to work activities, would occur and the data present in the August results reflect those predictions. Respondents indicate they anticipate even further increases in testing demand, to include more surveillance and screening testing needs, impacts of fall and winter influenza season, and continuing reopening activities.



In April, laboratories reported a wide-spectrum of number of patient tests performed per day, with around 50% of laboratories currently reporting a volume of less than 200 tests a day. Data from the August survey demonstrates 55% of laboratories reported a current capacity greater than 500 tests a day, indicating they have increased capacity in the past few months. However, despite significant barriers, laboratories plan to increase or are in the process of increasing testing capacity in their laboratory, with 90% of U.S. laboratories reporting that they plan to increase testing capacity over the next one to three months. The expected future capacity also increases significantly, with laboratories reporting that 70% plan to have a capacity of over 500 tests a day.

NOTE - Current # patient tests per day: Data shown from all laboratory types. 105 respondents, absolute # responses: None / currently validating (2), Less than 100 (14), 100-250 (13), 250-500 (21), 500-1,000 (25), 1,000-5,000 (25), 5,000-10,000 (3), 10,000-20,000 (1), 20,000-50,000 (0), >50,000 (1)

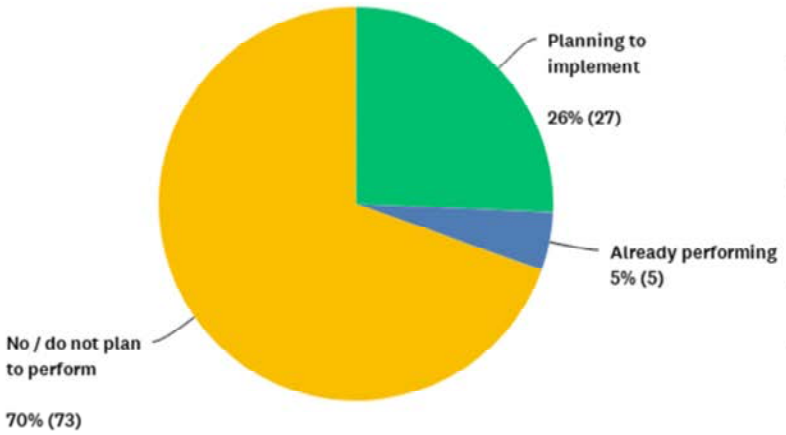
NOTE - Anticipated # patient tests per day: Data shown from all laboratory types. 105 respondents, absolute # responses: Less than 100 (4), 100-250 (6), 250-500 (11), 500-1,000 (15), 1,000-5,000 (40), 5,000-10,000 (9), 10,000-20,000 (7), 20,000-50,000 (2), >50,000 (0), not planning on increasing capacity (11)



When laboratories where asked how they plan on increasing their laboratory or hospital system's capacity, over 60% reported that they plan to add more platforms or tests to reach desired capacity. Additionally, laboratories also reported other avenues to increasing capacity, such as increasing the laboratory workforce (62%) and/or adding additional tests or test kits (59%).

Majority are not currently employing sampling pooling strategies

Are you already performing or planning to implement pooled patient sample testing?



Why have you chosen not to perform pooled sample testing?

- *Not confident the pool approach will lead to satisfactory test sensitivity (multiple)*
- *Technical logistics; operational concerns outweighed advantages (multiple)*
- *Prevalence is currently too high to implement (multiple)*
- *Validating would take up precious resources (tech time/supplies/reagents; multiple)*
- *Too labor intensive; labor is limiting factor (multiple)*
- *Software/LIS support for tracking pools and deconvolution of pools missing (multiple)*
- *Waiting for EUA on the platforms we use (multiple)*

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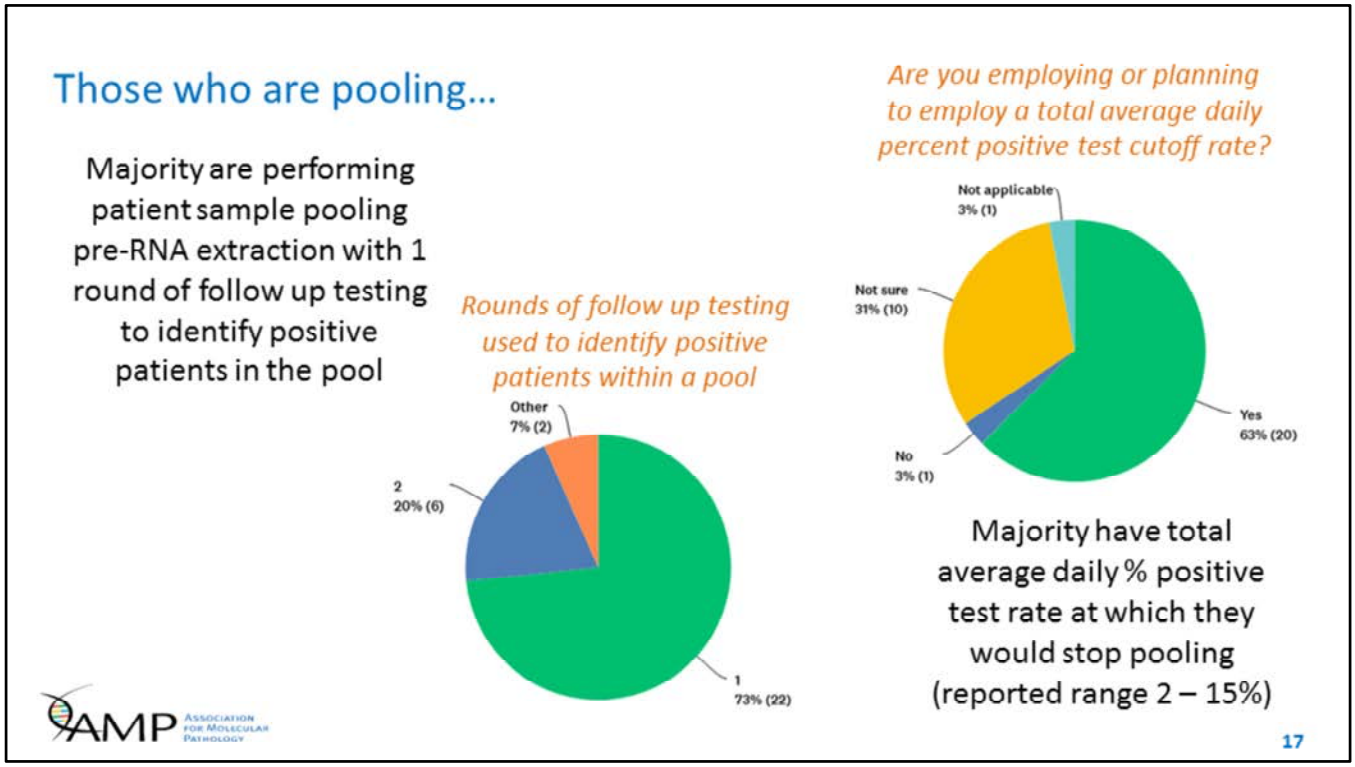
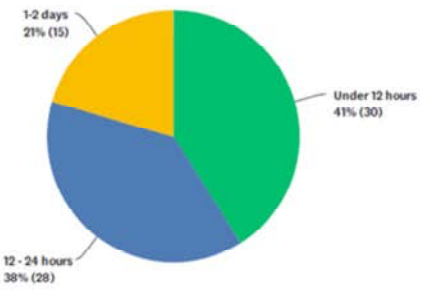
Since the April survey was conducted, clinical laboratories have begun discussing the option of pooled sample testing approaches in order to increase the number of samples that could be tested. 70% of survey respondents indicate they are not currently, or do not plan to, employ sample pooling strategies (Slide 16). When queried as to why they would not perform sample pooling, respondents indicated numerous factors: lack of confidence in the pooling approach would lead to satisfactory test sensitivity, operational concerns that outweigh potential benefits, SARS-CoV-2 prevalence rate in the community being too high to implement, validation of method would divert limited resources, method is to labor intensive, software and laboratory information system limitations, and plans to wait for EUAs for tests on their existing platforms.

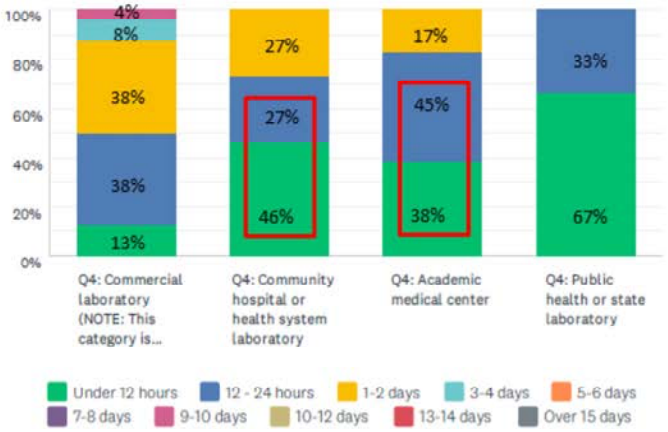


The majority (81%) of laboratories who are currently performing or planning to employ pooled sample patient testing are pooling samples pre-RNA extraction, with the majority (73%) using one round of follow-up testing to identify positive patients in the pool. Seventy-five percent of respondents indicated their ideal pool size was between four and five individual patient samples. Respondents provided a range of potential cutoff values for performing pooled patient testing (reported range 2-15%), with the majority indicating they would stop if a greater than 5% total average daily positive test rate was observed.

Near-to-patient laboratories report a rapid turnaround time for SARS-CoV-2 test results



~80% results available in under 24 hrs from near to patient labs



Data shown above from all laboratory types. 100 respondents, absolute # responses: Commercial reference laboratory (24), Community hospital or health system laboratory (26), academic medical center (47), public health or state laboratory (3)

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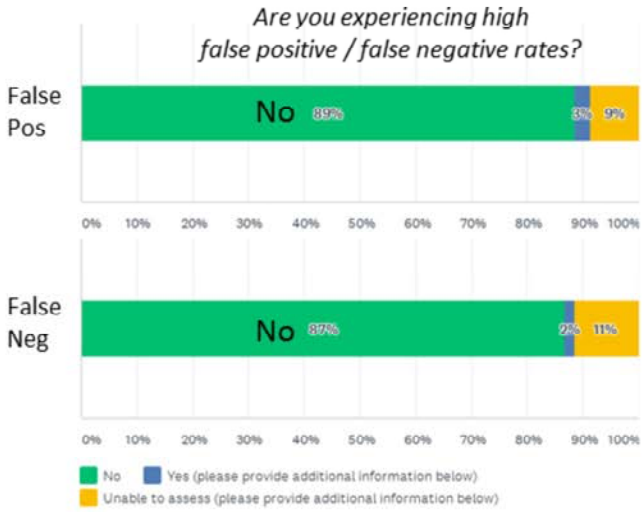
Laboratories reported that turnaround time for their primary method of testing is accomplished predominantly between 12-24 hours (41%) or 24-48 hours (38%). 83% of academic medical centers and 73% of community hospital and health system laboratories reporting a turnaround time of less than 24 hours.

False positive and false negative rates low, but assessment remains challenging



Comments:

- *Without clinical gold standard this is hard to assess*
- *With multiple platforms with varying LOD we have had discordance between platforms. This is especially difficult to manage when testing asymptomatic patients.*
- *Many false negatives were determined not to be the assay but rather the collection*
- *Chart review of false-negative sample showed they were collected over two weeks after symptom onset for 75% of false negatives*
- *Not confirming test results. Providers have not asked to retest anyone symptomatic.*
- *Some "false negatives" based on lower LOD, use [second] test for confirmation*

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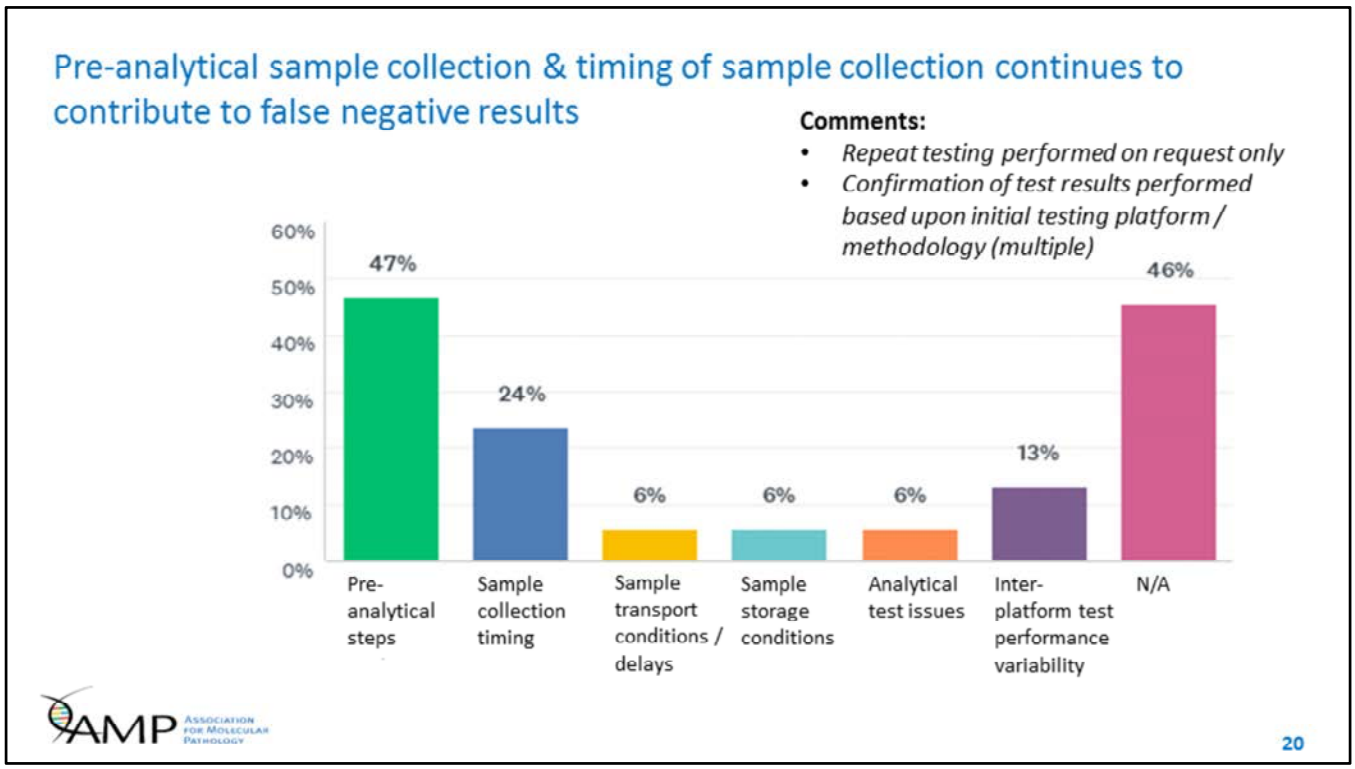
The majority of survey respondents did not report experiencing significant numbers of false negatives (87%) or false positives (89%), however respondents indicated that the absence of a clinical gold standard and variability of testing platforms with regard to limits of detection (LOD) were factors that present analytical challenges.

NOTE – High False Pos Rate Graph: Data shown above from all laboratory types. Select all that apply question format, 105 respondents, absolute # responses: No (93), Yes (3), Unable to assess (9). High False Neg Rate Graph: Data shown above from all laboratory types. Select all that apply question format, 105 respondents, absolute # responses: No (91), Yes (2), Unable to assess (12).



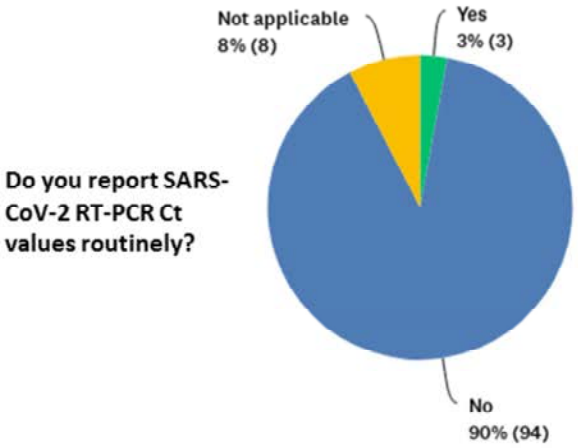
Consistent with April survey data, laboratories reported pre-analytical sample collection and the timing of sample collection continues to contribute to false negative results. Inter-platform variability in test performance, which based upon comments provided at the time of the April survey was suspected to be occurring, was identified by 13% of respondents as a contributing factor in their experience. 60% of respondents indicated that they repeat sample collection based upon clinical suspicion to attend to and resolve a false negative result. This type of follow-up is not atypical for clinical laboratories performing infectious disease diagnostic testing, however, the opportunity for clinicians to work collaboratively with their institution's clinical laboratory professionals and local public health officials provides potential advantages for near-to-patent testing supporting public health test-trace-isolate measures. This may become more critical as we continue the reopening phase, when very rapid responses could help to blunt the impacts of potential future outbreaks, limiting or avoiding the need to return to stricter mitigation methods.

It's also important to point our here that the concern about "false negatives" and the number of compounding variables, discussed above, highlight the vital role laboratory professionals play as part of the collaborative care team. Our members are currently working within their institutions to provide education on the benefits and drawbacks regarding various test strategies and collaborating with their colleagues to ensure that any negative results are truly negatives.

NOTE: Data shown above from all laboratory types. Select all that apply question format, 105 respondents, absolute # responses: Pre-analytical steps (e.g., sample collection,

transport issues, etc.)(49), Timing of sample collection (25), Transport conditions or delays (6), Sample storage conditions (6), (Analytical test issue (e.g., test design)(6), Inter-platform test performance (e.g., limit of detection differences)(14)

Vast majority of respondents do not report SARS-CoV-2 Ct (threshold cycle) values



Comments:

- *EUA is only for qualitative diagnosis, therefore we don't provide Ct # to clinicians, but we follow this data internally and with epidemiology*
- *We do not report the Ct #, however we do respond when clinicians call for the Ct # of their specific patient*
- *Would require another extensive clinical validation*
- *Verbal report only*
- *Pending validation*

Only 4% reported they would report Ct values upon or due to a clinician request
Only 2% reported they would use Ct values to establish criteria for an active infection.

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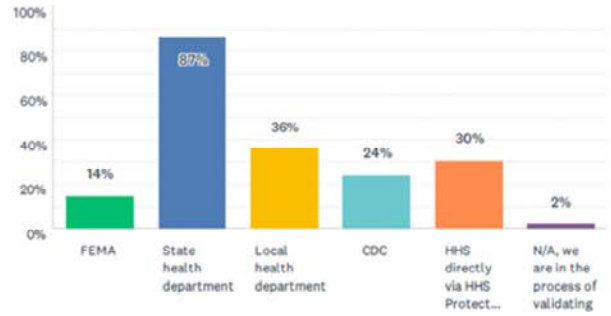
90% of respondents indicated they do not report SARS-CoV-2 Ct values. Comments provided included that current EUAs are only available for qualitative diagnosis and there would need to be additional extensive validation to utilize this information clinically. Only 4% indicated they would report Ct values upon or due to a clinician request, while only 2% reported they would use Ct values to establish criteria for an active infection.

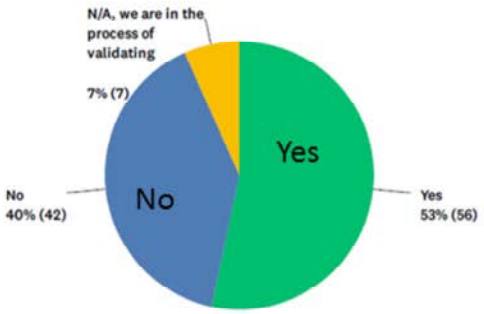
Concerns about Public Health Reporting Processes

To which of government body are you reporting information?



Data shown above from all laboratory types. Select all that apply question format, 105 respondents, absolute # responses: FEMA (15), state health dept. (91), local health dept. (38), CDC (25), HHS portal (32), N/A (2)

Are multiple public health reporting requirements burdensome?



Why do you find these reporting requirements burdensome?

"Data elements required are ridiculous"

"Manual entry into multiple formats"

"We are not staffed for the additional time required for reporting"

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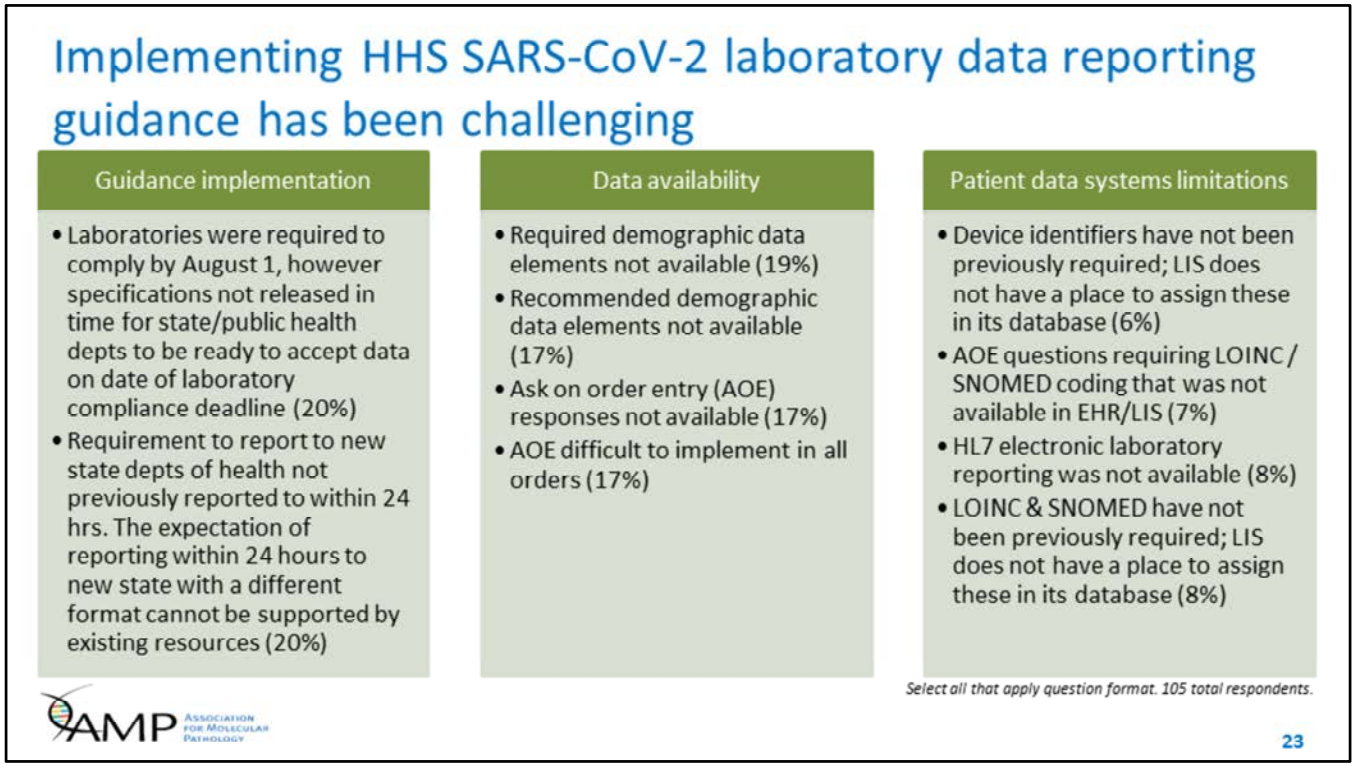
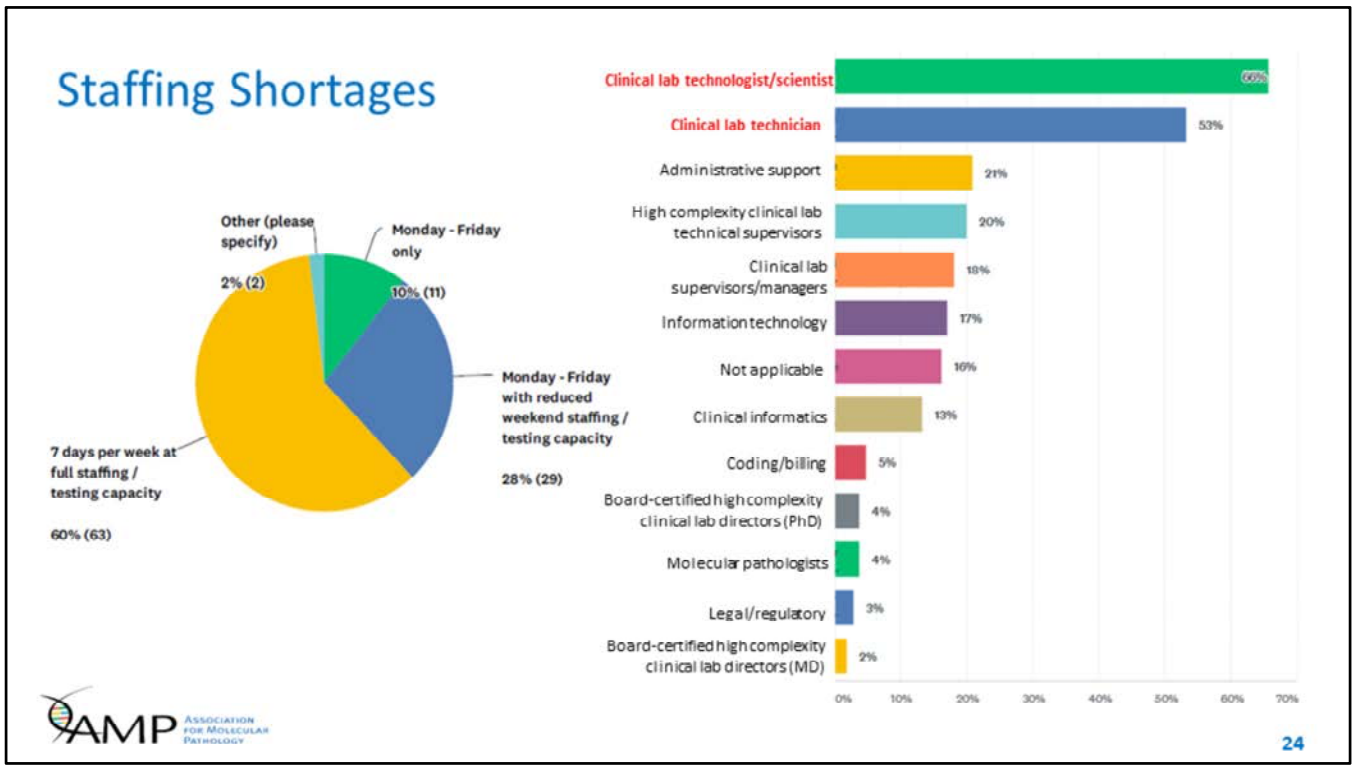
Based on data from the April survey and subsequent discussions with stakeholders, there have been challenges with laboratory capability/consistency to provide the required data to public health agencies that effectively supports contact tracing efforts. Data from both the April and August surveys indicate respondents are currently reporting to various state or federal agencies or departments. Approximately 75% of respondents report that their laboratory spends 2 hours or less per day complying with public health reporting requirements, with almost half of the respondents stating that they found the current multiple public health reporting requirements burdensome to their laboratory's workflow. These findings remain consistent with the data received in April. Respondents continue to express frustration in the notion that reporting is not standardized across the nation, and the information is required to be submitted to multiple locations.

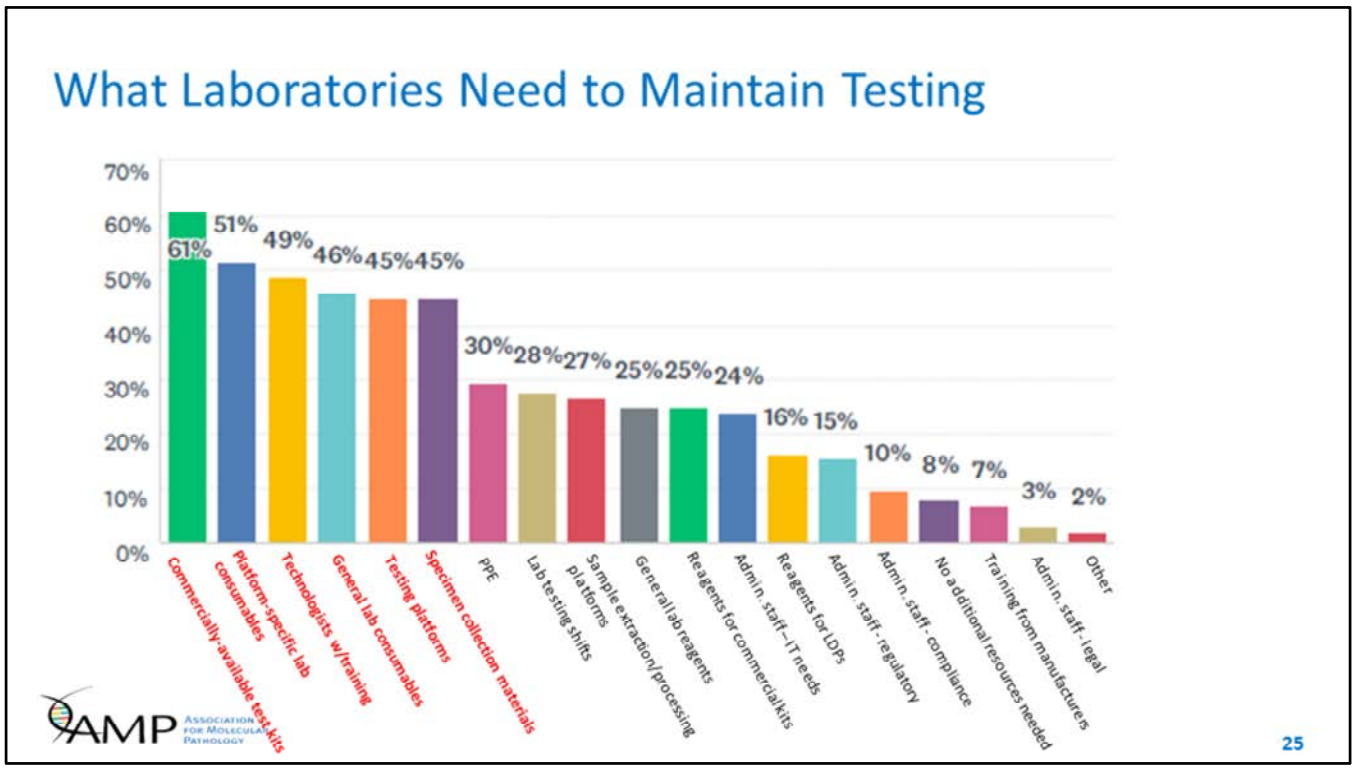


The U.S. Department of Health and Human Services issued SARS-CoV-2 laboratory data reporting guidance that went into effect for laboratories August 1, 2020. Sixty-five percent of respondents reported having one or more difficulties with implementing the new HHS guidance. Challenges in guidance implementation, data availability, and limitations of patient data systems (i.e., electronic health records (EHR) and laboratory information system (LIS)) were identified by respondents as barriers to implementing the guidance.



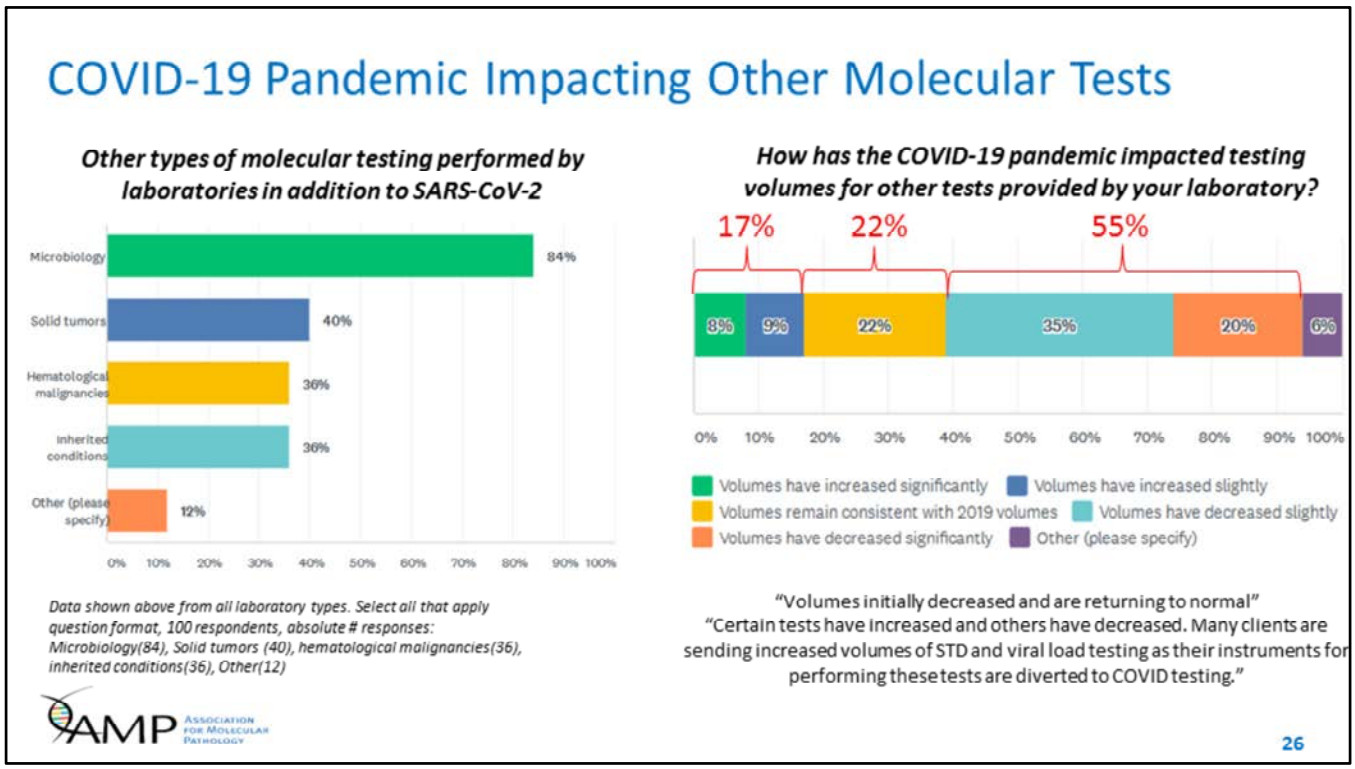
Laboratories report that 60% of those surveyed are running a full staffing, 7 days a week to perform SARS-CoV-2 testing. However, approximately 85% of respondents have experienced shortages in staff, with 66% noting shortages in clinical laboratory technologist/scientists and 53% experiencing shortages in clinical laboratory technicians. However, results show significant shortages in many other positions including administrative support, information technology, clinical informatics, and high-complexity clinical laboratory technical supervisors.

NOTE - Graph on right: Data shown above from all laboratory types. Select all that apply question format, 105 respondents, absolute # responses: Clinical laboratory technologist/scientist (69), Clinical laboratory technician (56), Administrative support (22), High complexity clinical laboratory technical supervisors (21), Clinical laboratory supervisors / managers (19), Information Technology (18), Not applicable (17), Clinical informatics (14), Coding / billing (5), Board-certified high complexity clinical laboratory directors (PhD or equivalent) (4), Molecular pathologists (MD or equivalent) (4), Legal / regulatory (3), Board-certified high complexity clinical laboratory directors (MD or equivalent) (2)



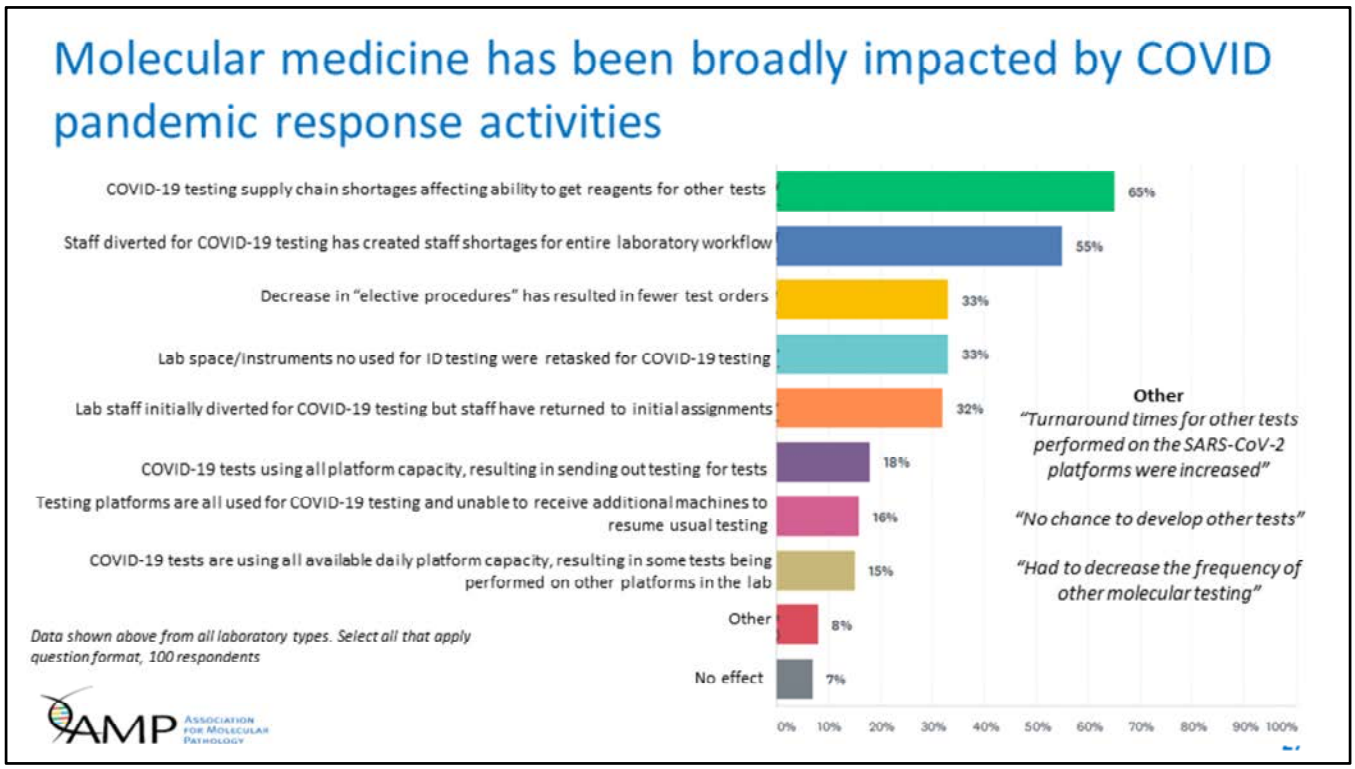
Moreover, when respondents were asked what they needed to maintain testing, almost 50% responded that they need technologists with training.

NOTE: Data shown from all laboratory types. Select all that apply question format, 105 respondents, absolute # responses: Commercially-available testing kits (64), Platform-specific laboratory consumables (54), Technologists with training (51), General laboratory consumables (48), Testing platforms (47), Personal protective equipment (PPE) (31), Laboratory testing shifts (29), Sample extraction / processing platforms (28), General laboratory reagents (26), Reagents for commercially-available testing kits (26), Administrative support staff for IT needs (25), Reagents for LDPs (17), Administrative support staff – regulatory needs (16), Administrative support staff – compliance needs (10), No additional resources needed (8), Training from manufacturers (7), Administrative support staff – legal needs (3), Other (2)



Laboratories performing SARS-CoV-2 molecular testing also perform other types of testing, including not only other microbiology tests, but also molecular tests for cancer and inherited conditions. 55% of respondents reported that volumes for other tests provided by their laboratory had either decreased slightly or significantly, 22% reported that volumes had remained consistent with 2019 test volumes, and 17% reported that volumes had either increased slightly or significantly.

NOTE – graph on left: Data shown from all laboratory types. 100 respondents, absolute # responses: Volumes have increased significantly (8), Volumes have increased slightly (9), Volumes remain consistent with 2019 volumes (22), Volumes have decreased slightly (35), Volumes have decreased significantly (20), Other (6)



Respondents reported molecular testing has been broadly impacted by the COVID-19 pandemic in a number of ways. For example, 65% of respondents reported that COVID-19 testing supply chain shortages were affecting their ability to get reagents for other tests, and 55% reported that staff diverted for COVID-19 testing has created staff shortages for entire laboratory workflow. (Slide 27) AMP is currently surveying laboratories performing molecular testing for cancer to understand in more depth how the COVID-19 pandemic is affecting molecular testing.

NOTE: Data shown from all laboratory types. Select all that apply question format, 100 respondents, absolute # responses: COVID-19 testing supply chain shortages affecting ability to get reagents for other tests (65), Staff diverted for COVID-19 testing has created staff shortages for entire laboratory workflow (55), Decrease in "elective procedures" has resulted in fewer test orders (33), Lab staff initially diverted for COVID-19 testing but staff have returned to initial assignments (32), COVID-19 tests using all platform capacity, resulting in sending out testing for tests (18), Testing platforms are all used for COVID-19 testing and unable to receive additional machines to resume usual testing (16), COVID-19 tests are using all available daily platform capacity, resulting in some tests being performed on other platforms in the lab (15), Other (8), No effect (7)

Recommendations

Based on the common themes found in results from both the April and August surveys, AMP is making two new recommendations and reaffirming the previous five recommendations. These recommendations aim to effectively leverage America's large and diverse laboratory network to best respond to the Coronavirus pandemic.

RECOMMENDATION	IMPORTANCE & POTENTIAL SOLUTIONS
Reassess type and location of SARS-CoV-2 testing services needed	In order to provide acute care, safely reopen businesses and reinvigorate the economy, there should be a reassessment of what type of testing is needed and where. Each one of the situations below could require a different method of testing (*e.g.,* molecular test or serology test) with a different necessary turnaround time: • Symptomatic, recovering, and asymptomatic patients • Acutely presenting patients (*e.g.*, ED, trauma surgery) • Scheduled surgical and labor & delivery patients • Contact tracing for facility outbreaks • "Back to work" clearance testing
Reprioritize supply allocations based on clinical testing needs, which could change over time	Depending upon the prevalence of SARS-CoV-2 in a community, there may be a shift in testing methodology and related supply needs over time. The need for testing supplies designed for acute care, surveillance, high-throughput, and other clinical needs should be monitored widely to provide real-time feedback to agencies to support data-driven supply allocations. Ideally these monitoring systems would be proactively established, rapidly activated following novel pathogen identification, and maintained throughout the course of response.
Increase transparency, communication, and real-time transmission of information between laboratories and suppliers (commercial manufacturers and government)	There is a need for laboratories to understand in real-time the resource availability and reagent and supply quantities, to include: • Ongoing communication regarding shipment and delivery date • Manufacturer's anticipated delays and types of delays (*e.g.*, production, allocation) • Governmental allocation strategies
Real-time coordination amongst laboratories to leverage moments of excess capacity	Based on data regarding testing capacity and demand, there may be an opportunity to coordinate regionally to ensure that any excess test capacity is leveraged to ensure samples get processed as quickly as possible (*e.g.,* a dashboard consisting of laboratories, manufacturers, and government representatives would allow real-time supply chain understanding and help to prevent communication and resource bottlenecks)

Standardize agency reporting format and processes for reportable infectious diseases during a pandemic	Complying with multiple agency reporting requirements with variable formats has been burdensome to the clinical laboratories. To improve future responses, the public health laboratory community, clinical laboratories, and CDC should collaborate to: • Define minimal required data elements for supporting public health contact tracing • Establish standardized reporting format that Electronic Health Records (EHR) / Laboratory Information Systems (LIS) vendors could adopt • Establish a standardized and centralized reporting agency / process that minimizes delays in return of results and eliminates need for laboratories to duplicate reporting to multiple agencies • Provide logistical support for laboratories to provide reportable infectious disease data electronically

Additional data from the August survey has resulted in the following two new recommendations:

RECOMMENDATION	IMPORTANCE & POTENTIAL SOLUTIONS
Ensure that regulatory requirements for clinical laboratories are not duplicative or burdensome, especially during a pandemic	The declaration of the public health emergency effective January 27, 2020 required that all tests for SARS-CoV-2, regardless of whether they are boxed-and-shipped testing kits or laboratory developed testing procedures (LDPs), obtain emergency use authorization (EUA) from the FDA prior to being deployed for patient use, which restricted labs from developing LDPs. Despite FDA policy changes to loosen EUA regulations, laboratories still struggle with the FDA EUA process. • Maintaining the Centers for Medicare & Medicaid Services (CMS) via the Clinical Laboratory Improvement Amendments (CLIA) program as the regulatory agency responsible for oversight of LDPs ensures that the US can rapidly develop and deploy the testing needed during a public health emergency.
Support the clinical laboratory workforce as essential to providing an effective medical and public health pandemic response	• Promote improved and ongoing collaboration and communication between the public health and clinical laboratories and relevant state and Federal agencies to better understand challenges and more effectively leverage capacities and capabilities. • Ensure financial infrastructure to support laboratory staff needs during a public health emergency (e.g., hazard pay programs) • Support providing career pathways, training, and ongoing education to ensure adequate and effective workforce is available to respond to future pandemics.

Next Steps

- Continued conversations with both policy makers and laboratory stakeholder community
    - Provide survey results and recommendations to hill and agency staff.
    - Work collaboratively with laboratory stakeholder groups to mold effective legislation and policies to support AMP members and their laboratories during this pandemic.
- AMP will continue to closely monitor the COVID-19 pandemic and assess the needs of its members. Some key questions to follow over time:
    - Have the supply chain problems been resolved and/or improved?
    - Are labs shifting their primary diagnostic test methodologies?
    - Has testing capacity remained above demand?
    - Have tested patient demographics changed over time?
- As the nation pivots to focus on the public health crisis, diagnosis and care associated with other diseases, especially cancer, are likely to suffer significant reverberations for some time. Molecular testing laboratories that provide testing crucial for diagnosing and managing cancer are not immune from these effects of COVID-19; and, understanding the full extent that COVID-19 has had on these laboratories remains unknown. AMP is currently surveying the laboratory community to understand the effects of the COVID-19 pandemic on molecular testing for cancer. Results will be released in November.

Long term, AMP intends to review impacts to clinical practice, regulatory, & reimbursement and provide recommendations on how to better prepare for the next pandemic. These survey results will be fundamental to determining potential initiatives with significant impacts to improve future pandemic responses.