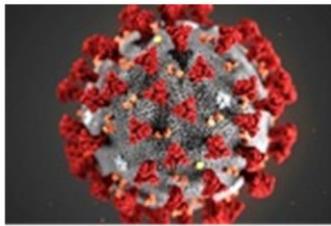


Association for Molecular Pathology SARS-CoV-2 Molecular Testing

Summary of Recent SARS-CoV-2 Molecular Testing Survey



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 we will be sharing today 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 brief but robust survey to collect and document laboratories' efforts and experiences. This survey was anonymous and results were used in aggregate to help inform advocacy and clinical practice programs on this issue.

Survey scope: This survey covers topics related to molecular diagnostic testing only for SARS-CoV-2 and does not address serology or antigen testing.

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

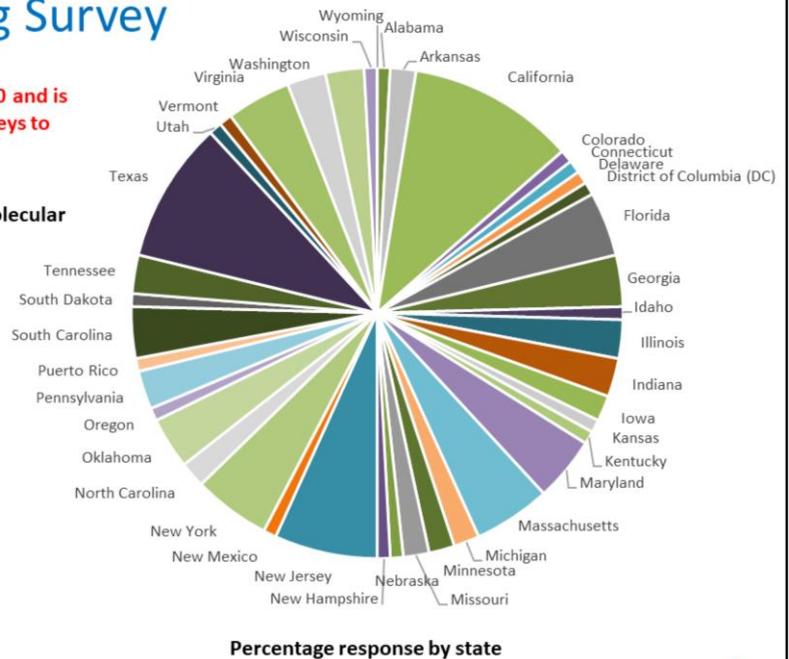
AMP Program Areas: Joint effort of Advocacy & Clinical Practice. Robyn & Tara wish to thank all of the AMP staff members on our respective teams, and the marketing and communications team for their assistance and support in conducting this survey.

AMP SARS-CoV-2 Testing Survey

This survey was conducted between April 23 - May 5, 2020 and is second in a series of SARS-CoV-2 pandemic response surveys to AMP membership and beyond

67 questions assessed different aspects of SARS-CoV-2 molecular testing:

- Laboratory demographics
- SARS-CoV-2 testing demand and current capacity
- Increasing laboratory capacity
- Agency communications regarding laboratory capacity
- SARS-CoV-2 test methodology
- Test performance & validation
- Resource and supply chain concerns
- Sample collection
- Test reimbursement
- Public health reporting requirements



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Survey Design & Methodology:

The 67 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
- Agency communications regarding laboratory capacity
- SARS-CoV-2 test methodology
- Test performance
- Test validation
- Resource and supply chain concerns
- Sample collection
- Test reimbursement
- Public health reporting requirements

The survey was open from April 23-May 5, 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.

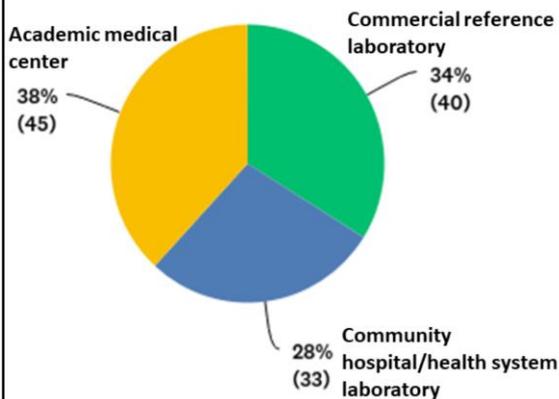
Summary data results have been initially analyzed using Survey Monkey for summary data. Results were exported into Excel as needed to facilitate comparison of more complex summary responses. Results were gated and analyzed in the following data sets:

- #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)
- #3 - “Near-to-patient “ laboratories versus reference laboratories, US-based, completed surveys only
 - 3A - Academic medical centers and community hospital or health system laboratory combined
 - 3B - Commercial reference laboratory

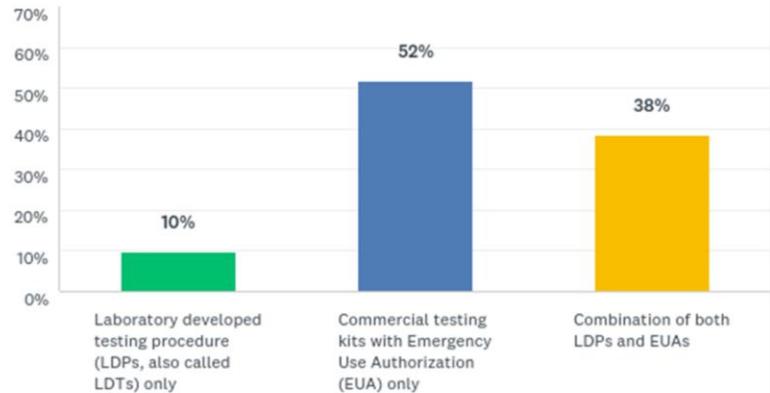
Results not yet analyzed include all complete responses (combination of US and international laboratories), international laboratories only, and partially completed survey responses.

Demographics of Data Subset

- 118 US-based laboratories only
- 95 AMP members, 23 non-members



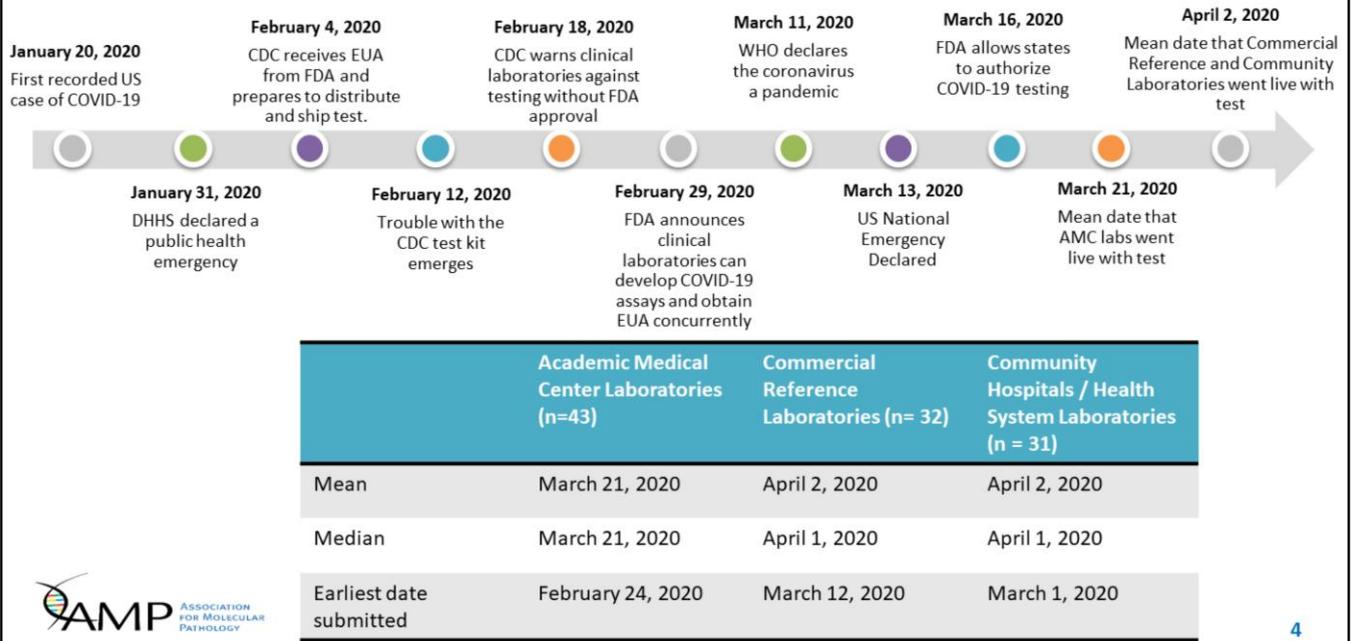
Breakdown of SARS-CoV-2 testing methodology:



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

- 255 total responses, with 118 complete responses from US laboratories. Of the 118 complete responses, 95 were AMP members, 23 were non-members. Approximately 40% laboratories categorized as academic medical center (AMC), 35% commercial reference laboratory (CRL), and 30% community hospital or health system laboratory (CH/HS). The survey had broad participation from across the US.
- 85% survey takers are currently offering SARS-CoV-2 tests to patients, with approx. 10% in the process of validating a test, and less than 5% do not plan to offer a test.
- Results indicate that 50% of laboratories are solely using commercial testing kits with emergency use authorization (EUA), 10% are using laboratory developed testing procedures only, and 40% are using a combination of both LDPs and EUAs
- Laboratories report that more than 60% of those surveyed are running a full staffing, 7 days a week to perform SARS-CoV-2 testing

Laboratories were quickly able to offer tests...



Once laboratories were able to develop SARS-CoV-2 tests they responded rapidly. Academic Medical Center laboratories reported an average go-live date of March 21, 2020 for their first test, but the earliest lab went live on February 24, 2020. Most Community Hospitals / Health System Laboratories and Commercial Reference Laboratories were launching their SARS-CoV-2 testing approximately 2 weeks later, on average.

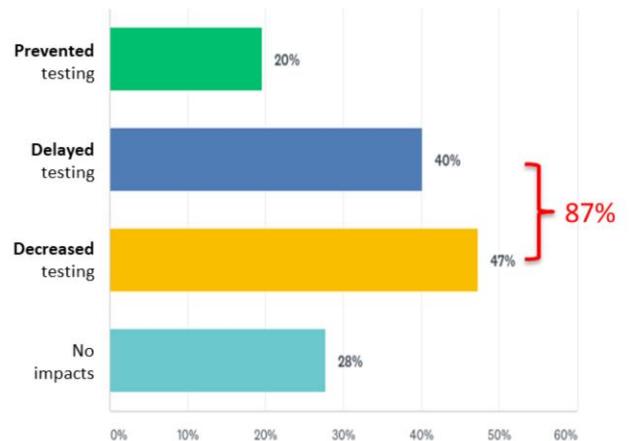
...However, supply chain issues continue to negatively impact laboratories providing SARS-CoV-2 testing

TYPE OF SUPPLY CHAIN LIMITATION	CURRENTLY LIMITED	PREVIOUSLY LIMITED	NEVER LIMITED
Testing platforms (n=73)	32%	33%	36%
Testing kits (n=73)	34%	45%	21%
Reagents (RNA extraction kits, buffers, etc.; n=75)	33%	48%	19%
Swabs (n=77)	60%	31%	9%
Transport media (UTM/VTM; n=75)	53%	35%	12%
Laboratory consumables (tips, tubes, etc.; n=75)	19%	31%	51%
Personal protective equipment (n=74)	27%	31%	42%

Data shown above from all laboratory types. Select all that apply question format, Answered: 81, Skipped: 37



Negative impacts of supply chain interruptions or limitations on patient testing



Data shown above from all laboratory types. Select all that apply question format, 112 respondents, absolute # responses: Prevented (22), Delayed (45), Decreased (53), No impacts (31)

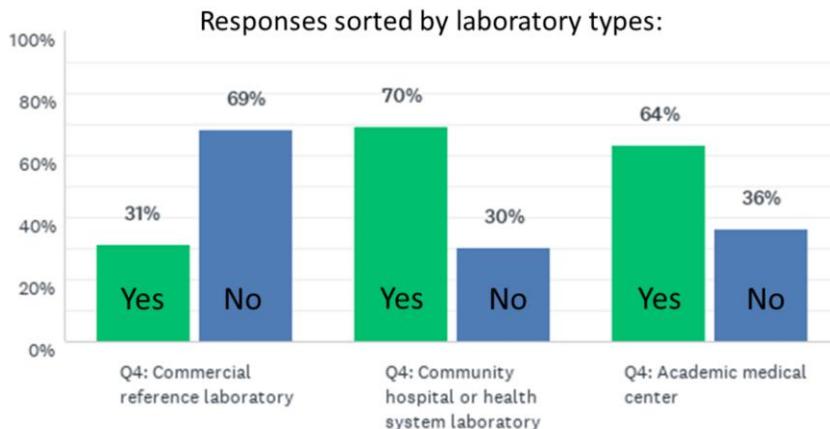
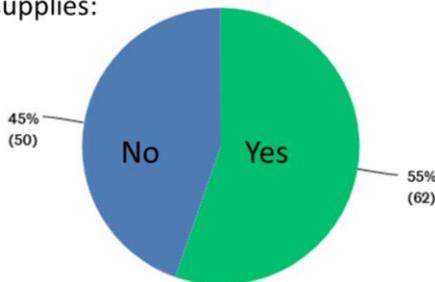
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The first takeaway from our data is the negative impact that supply chain disruptions have had – and are continuing to have – on providing SARS-CoV-2 diagnostic testing. Laboratories report that supply chain interruptions have had a significant impact on their testing capacity, with over 85% 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 specimen collection materials identified as the most needed. While all laboratories are reporting many barriers or limiting factors exist to increasing testing, academic medical center and community hospital laboratories reported more significant barriers to increasing testing than commercial reference laboratories, including limited supply of testing kits and reagents.

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 types of supply chain interruptions were similar across laboratory types with the exception of testing kits. Over 40% of academic medical center and community laboratories report currently experiencing testing kits supply interruptions, with only 13% of commercial laboratories currently experiencing this issue.

Experiences with allocation of testing kits & reagents varies by laboratory setting

Overall respondents who faced restrictions and/or allocations for supplies:



Has your institution or laboratory been informed by a manufacturer or supplier that you cannot purchase testing kits or reagents due to government restrictions and/or allocations for these products?

"We have limited allocations of all our test kits" (n=25)

"We have been unable to receive any testing kits from another vendor due to their allocation process even though we have the instrument in use to perform other testing"

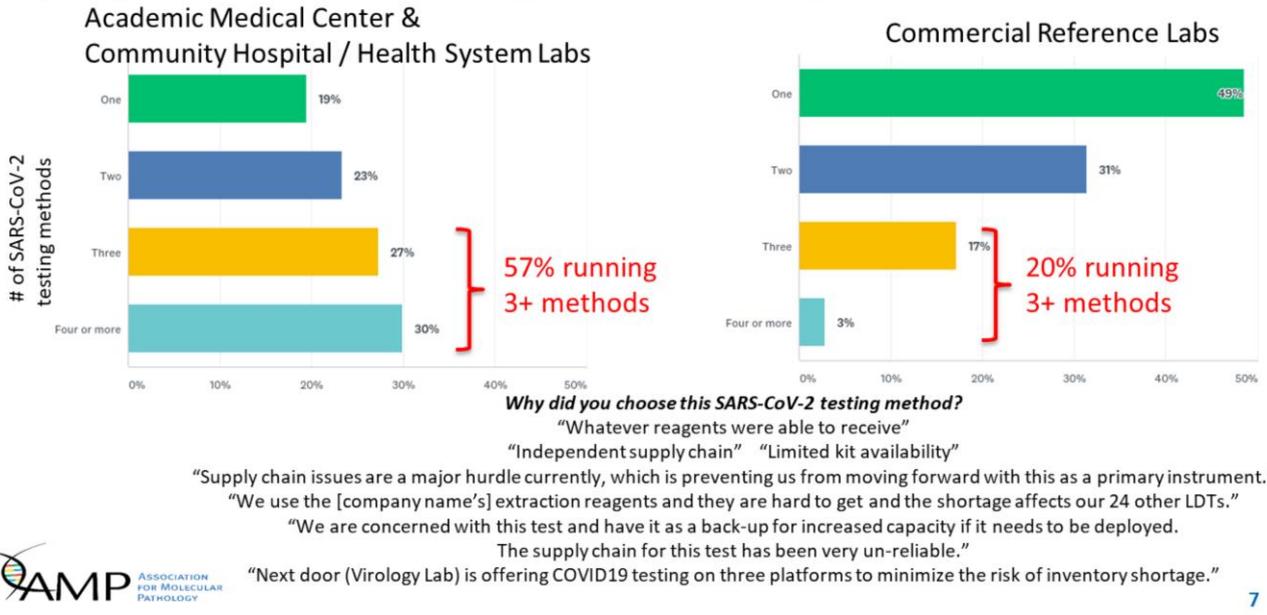
"No, but what we have experienced is that because we are a pediatric hospital, many vendors/manufacturers are telling us that they have to reserve their supply for adult hospitals who have more patients (and bigger purchasing requests)" (n=2)

"We have had multiple shipments of reagents diverted to hotspots or larger laboratories" (n=4)



Approximately half of all 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 60% of academic medical center and community hospital 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 30% of commercial reference laboratories reported this fact.

Due to supply shortages and uncertainties, laboratories are deploying multiple testing methodologies



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. Additional survey results not illustrated here also showed that for academic medical centers and community hospitals, a key deciding factor to which testing method is prioritized and used is the availability of testing reagents and supplies. Key deciding factors for commercial reference laboratories include whether the method was high-throughput and/or whether the platform was already available for clinical testing.

All US-based labs: top 10 primary testing methods

SARS-CoV-2 Molecular Testing Methods	Primary* (n=112)	Secondary (n=88)	Tertiary (n=59)
Laboratory developed testing procedure (LDP / LDT) with EUA submission	21%	8%	5%
Roche Molecular Systems cobas SARS-CoV-2	17%	5%	0%
Abbott Molecular RealTime SARS-CoV-2 assay	16%	6%	7%
Cepheid Xpert Xpress SARS-CoV-2 test	8%	19%	25%
Hologic Panther Fusion SARS-CoV-2	6%	1%	0%
Quidel Corporation Lyra SARS-CoV-2 Assay	5%	2%	2%
Thermo Fisher Scientific TaqPath COVID-19 Combo Kit	5%	3%	7%
CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel	4%	9%	7%
DiaSorin Molecular Simplexa COVID-19 Direct assay	4%	13%	9%
Abbott Diagnostics ID NOW COVID-19	3%	2%	9%

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



Data presented here provide a breakdown of the top 10 primary testing methods utilized by the laboratories surveyed. 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=44)	Community Hospitals / Medical Centers (n=33)	Commercial Reference Laboratories (n=35)
Abbott Molecular RealTime SARS-CoV-2 assay (11)	Cepheid Xpert Xpress SARS-CoV-2 test (7) <i>OR</i> Roche Molecular Systems cobas SARS-CoV-2 (7)	Laboratory developed testing procedure (LDP / LDT) with EUA submission (12)
Laboratory developed testing procedure (LDP / LDT) with EUA submission (9)	Abbott Molecular RealTime SARS-CoV-2 assay (6)	Roche Molecular Systems cobas SARS-CoV-2 (4)
Roche Molecular Systems cobas SARS-CoV-2 (8)	Hologic Panther Fusion SARS-CoV-2 (3)	CDC 2019-nCoV Real-Time RT-PCR Diagnostic Panel (3) <i>OR</i> Thermo Fisher Scientific TaqPath COVID-19 Combo Kit (3)

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

- Availability of testing reagents & supplies was #1 for Academic Medical Center & Community Hospital / Health System Labs, and #3 for Commercial Reference Labs
- Platform was already available for clinical testing was #2 for Academic Medical Center & Community Hospital / Health System Labs, and #1 for Commercial Reference Labs



The top three primary testing methods vary depending on laboratory type. When respondents were asked their top reasons for selection their primary SARS-CoV-2 molecular testing method, the availability of testing reagents & supplies was the number one reason for academic medical center and community hospital / health system laboratories, and reason number three for commercial reference laboratories. Whether a specific platform was already available for clinical testing was the second reason for academic medical center and community hospital / health system laboratories, and the top reason for commercial reference laboratories.

Laboratories are working against the obstacles to increase testing capacity over time

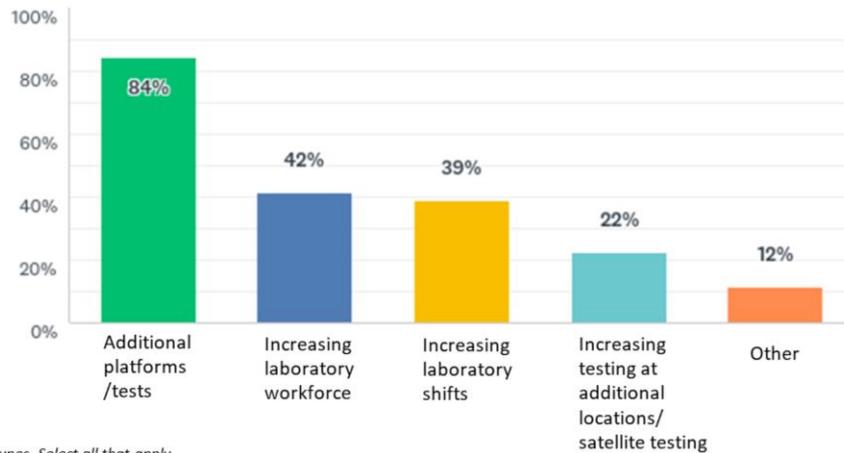
Total # of current patient tests per day (all platforms / methods)

Anticipated # of patient tests per day (all platforms / methods) after increased capacity



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. Additionally, 34% of commercial reference laboratories reported a current capacity greater than 500 tests a day. 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 increases significantly across laboratory types, with academic medical center laboratories reporting that almost 80% plan to have a capacity of over 500 tests a day.

How are laboratories planning on increasing test capacity?



Data shown above from all laboratory types. Select all that apply question format, 103 respondents, absolute # responses: additional platforms/tests (87), increasing laboratory workforce (43), Increasing laboratory shifts (40), increasing testing locations (23), other (12)

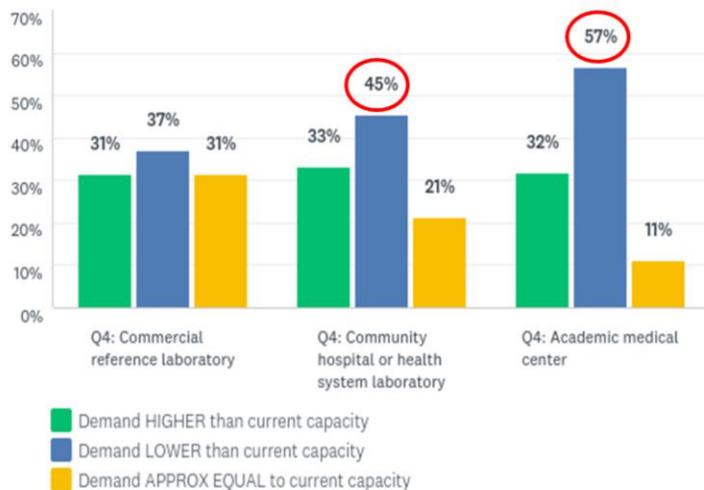
Other reasons included:

“developing collection teams and sites to bring in samples”

“partnering with another laboratory to increase sample intake and return of results capacities”

When laboratories were asked how they plan on increasing their laboratory or hospital system’s capacity, over 80% 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 and/or increasing laboratory shifts.

Near-to-patient testing capacity is currently available & expanding rapidly, but underutilized & under-resourced

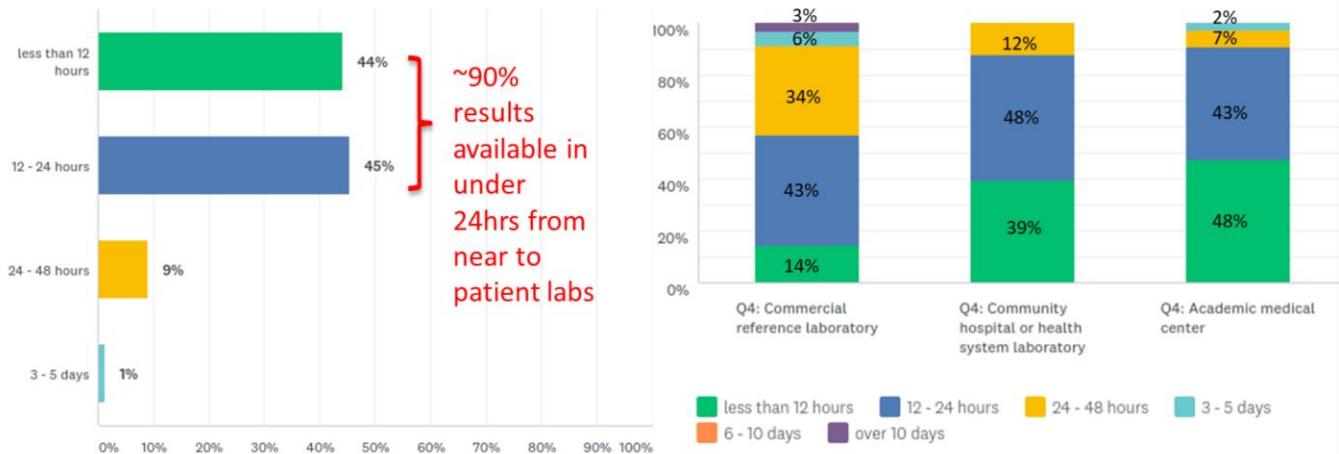


ALL respondents anticipating INCREASES in testing volumes:

- Reopening / "back to work/school"
- Pre-surgical / pre Labor & Delivery testing
- Essential worker / vulnerable population testing
- Widening of CDC's testing recommendations / criteria
- Asymptomatic outpatients / screening

Almost 50% of those surveyed report that their current institutional demand for SARS-CoV-2 testing is LOWER than current capacity, however, many laboratorians reported that they expect demand will increase with phased opening particularly resuming of surgical and additional medical procedures. Approximately 30% of laboratories reported that demand was higher than capacity regardless of laboratory setting. Variability was observed within the laboratory settings (academic, community, and commercial reference laboratories) reporting demand for SARS-CoV-2 testing lower than their testing capacity. A larger percentage of academic medical center laboratories (57%) and community hospital laboratories (45%) reported demand was lower than current capacity versus only 37% of commercial laboratories.

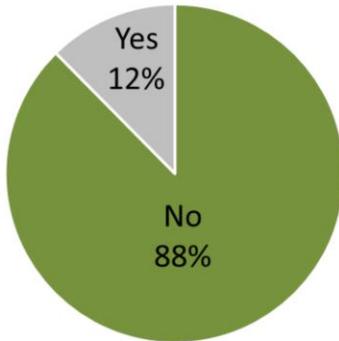
Near-to-patient laboratories report a rapid turnaround time for SARS-CoV-2 test results



Laboratories reported that turnaround time for their primary method of testing is accomplished predominantly between 12-24 hours (43%) or 24-48 hours (34%) with almost half of academic medical centers reporting a turnaround time of less than 12 hours.

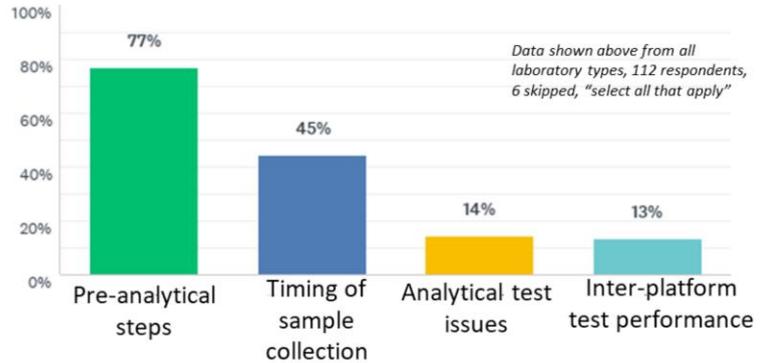
Are laboratories seeing high false negative rates?

Are you experiencing significant numbers of false negatives (across all platforms)?



Data shown above from all laboratory types, 112 respondents, 6 skipped

What have you observed or suspect to be the cause of the majority of your false negative results?



Data shown above from all laboratory types, 112 respondents, 6 skipped, "select all that apply"

Is your laboratory taking additional steps beyond routine quality assurance checks designed to identify or reduce the number of potential false negative results?

"We do repeat testing from same sample with new extractions"

"Added extra controls to test" "Test using another method"

"These decisions are not made by our lab"

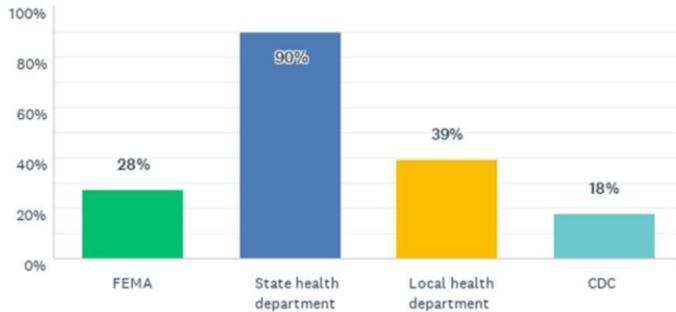
"We are not at PoC, but have disclaimers on all reports going out for specimens not received with proper handling, among other discrepant collection methods"



The majority of survey respondents did not report experiencing significant numbers of false negatives, however academic and community laboratories reported taking significant steps to identify or reduce the number of potential false negative results. These follow up steps are 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-patient testing supporting public health test-trace-isolate measures. This may become more critical during 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.

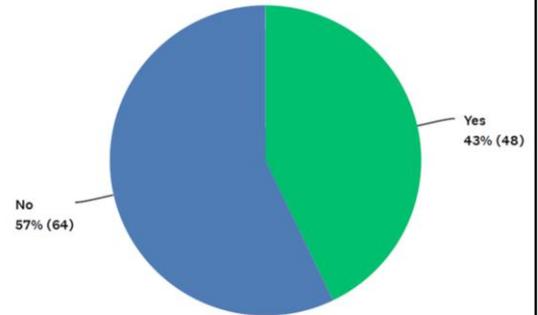
Concerns about Public Health Reporting Processes

To which of government body are you reporting information?



Data shown above from all laboratory types. Select all that apply question format, 112 respondents, absolute # responses: FEMA (31), state health dept. (101), local health dept. (44), CDC (20)

Are multiple public health reporting requirements burdensome?



Why do you find these reporting requirements burdensome?

"The notion that reporting is not standardized across the nation is ridiculous"

"Takes up staff time"

"Additional administrative time. Everyone wants data in a different format"



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Based on data from the survey, discussions within CDC Clinical Laboratory Partners network, and discussions on CDC COVID-19 response calls, there have been challenges with laboratory capability/consistency to provide data to public health agencies that effectively supports contact tracing efforts. At the time of the survey, respondents report they 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. Respondents expressed frustration in the notion that reporting is not standardized across the nation, and the information is required to be submitted to multiple locations.

Recommendations

Based on the survey findings, AMP developed 5 key recommendations. The recommendations aim to effectively leverage America’s large and diverse laboratory network to best respond to both the Coronavirus pandemic and potential future pandemics.

RECOMMENDATION	IMPORTANCE & POTENTIAL SOLUTIONS
<p>1. Reassess type and location of SARS-CoV-2 testing services needed</p>	<p>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 (<i>e.g.</i>, molecular test or serology test) with a different necessary turnaround time:</p> <ul style="list-style-type: none"> • Symptomatic, recovering, and asymptomatic patients • Acutely presenting patients (<i>e.g.</i>, ED, trauma surgery) • Scheduled surgical and labor & delivery patients • Contact tracing for facility outbreaks • “Back to work” clearance testing
<p>2. Reprioritize supply allocations based on clinical testing needs, which could change over time</p>	<p>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.</p>
<p>3. Increase transparency, communication, and real-time transmission of information between laboratories and suppliers (commercial manufacturers and government)</p>	<p>There is a need for laboratories to understand in real-time the resource availability and reagent and supply quantities, to include:</p> <ul style="list-style-type: none"> • Ongoing communication regarding shipment and delivery date • Manufacturer’s anticipated delays and types of delays (<i>e.g.</i>, production, allocation) • Governmental allocation strategies
<p>4. Real-time coordination amongst laboratories to leverage moments of excess capacity</p>	<p>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 (<i>e.g.</i>, a dashboard consisting of laboratories, manufacturers, and government representatives would allow real-time supply chain understanding and help to prevent communication and resource bottlenecks)</p>

<p>5. Standardize agency reporting format and processes for reportable infectious diseases during a pandemic</p>	<p>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:</p> <ul style="list-style-type: none"> • 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
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Next Steps

- Conversations with policy makers and continued conversations with 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 has been invited to present preliminary survey data on an upcoming CDC COVID-19 Response Call
- AMP plans to continue to survey membership and COVID-19 pandemic develops to assess laboratory needs. 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?

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.