



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

6120 Executive Blvd., Suite 700, Rockville, MD 20852

Tel: 301-634-7939 | Fax: 301-634-7995 | amp@amp.org | www.amp.org

June 26, 2020

The Honorable Lamar Alexander
428 Dirksen Senate Office Building
Washington, DC 20510

Sent electronically to pandemicpreparedness@help.senate.gov

Dear Chairman Alexander:

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit comments on your white paper "Preparing for the Next Pandemic." AMP is an international medical and professional association representing approximately 2,500 physicians, doctoral scientists, and medical technologists who perform or are involved with laboratory testing based on knowledge derived from molecular biology, genetics and genomics. Membership includes professionals from the government, academic medicine, private and hospital-based clinical laboratories, and the in vitro diagnostics industry. Now more than ever, in the face of a worldwide pandemic, we appreciate your efforts to improve upon and coordinate infectious disease outbreak response efforts.

As you are aware, molecular laboratory professionals have been at the frontlines of this pandemic working with other essential healthcare professionals to care for patients with COVID-19 and stem the spread of SARS-CoV-2. During this challenging time, AMP is working to support its members and their laboratories in various ways, including by soliciting qualitative and quantitative feedback on the experiences of molecular laboratory professionals during the pandemic with the objectives of creating professional resources and informing policy making. Our most robust effort to collect information to date was through a survey assessing 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 questionnaire was open from April 23, 2020 to May 5, 2020, and we collected 255 total responses, with 118 complete responses from laboratories across the United States. As we provide feedback and answer several of

the questions posed in your white paper, we will be drawing from the findings of this survey.¹ We also plan to resurvey our community in the coming months. To ensure that the follow-up survey gathers the most robust data possible, we will be collaborating with interested partners including the Food and Drug Administration (FDA), and would also welcome questions to assess information that would further support your work. When the survey is complete, we will provide you with additional information about how the experiences of molecular professionals have evolved since late April. We anticipate that in light of states reopening, testing capacity and resources will continue to be affected.

1. Tests, Treatments, and Vaccines – Accelerate Research and Development

The Crucial Roles of Diverse Laboratory Types in a Public Health Emergency

Each laboratory type has its own role in responding to an infectious disease outbreak or pandemic, and AMP strongly encourages Congress to utilize all sectors of the laboratory testing community. In the white paper, you describe the response efforts to the 2009 H1N1 influenza pandemic. During that previous national emergency, AMP drew different conclusions than the Department of Health and Human Services (HHS) made in their report², and in particular, AMP took note of the ways that academic medical center and community laboratories helped to fill testing gaps. During the first month of the pandemic, 62% of the patients screened for H1N1 influenza in Chicago were tested by community molecular diagnostics laboratories with a turnaround time of 24 hours.³ Further, a previously conducted survey of AMP members focused on H1N1 testing revealed that 93% of respondents had a molecular assay that could distinguish between influenza type A and influenza type B with the ability to expand their aggregate testing capacity to 12,000 specimens per day within one month, easily accommodating the testing needs of the entire country during that pandemic outbreak.

During the current pandemic, we similarly find that academic and community molecular diagnostic laboratories, in addition to public health and reference laboratories, have had and continue to have a valuable role.⁴ Certified public health laboratories that work with the Centers for Disease Control and Prevention (CDC) are essential to our collective ability to conduct surveillance and begin testing during an outbreak. However, their limited testing capacity makes it difficult for those laboratories to have a significant clinical diagnostic role. Given their physical location, hospital laboratories and other local community testing sites are on the frontlines providing patient care for the critically ill. Our COVID-19 survey results found that approximately 90% of academic medical centers and community hospital or health system laboratories performing SARS-CoV-2 diagnostic testing reported a turn-around time of less than 24 hours compared to only 57% of commercial laboratories having a turn-around time of less than 24 hours. The fast turn-around times of near-to-patient laboratory testing is especially important because it allows for more rapid decision making as it relates to patient treatment plans, the protection of frontline healthcare workers, curtailment of community transmission, and decisions regarding utilization of scarce personal protective equipment. This is not to discredit the advantages provided by commercial reference laboratories, which often are able to perform a great number of tests; this is an enormous strength when an outbreak is spread across many locations. All of the sectors of the clinical testing landscape need to be supported to ensure a complete laboratory response effort during a pandemic.

¹ <https://www.amp.org/advocacy/sars-cov-2-survey/>

² <https://www.phe.gov/Preparedness/mcm/h1n1-retrospective/Documents/h1n1-retrospective.pdf>

³ Nowak, Jan and Karen Kaul, “The Role of Community Molecular Diagnostics Laboratories in the H1N1 Pandemic”, *Journal of Molecular Diagnostics*, Vol. 11, No. 5, September 2009.

⁴ Kaul, Karen L. (2020). “Laboratories and Pandemic Preparedness: A Framework for Collaboration and Oversight”. *Journal of Molecular Diagnostics*, Vol. 22, No. 7, Advance online publication. <https://doi.org/10.1016/j.jmoldx.2020.05.002>

Yet, all of these sectors were not immediately allowed to contribute when the public health emergency was declared in response to the spread of SARS-CoV-2.⁵ As you note, CDC had communicated to laboratories that any tests for SARS-CoV-2, including laboratory-developed testing procedures (LDPs), are required to be cleared or authorized by the FDA for emergency use once a public health emergency is declared, requirements that are additional to the requirements that laboratories already meet and that also necessitated many laboratories to interact with FDA for the first time. This was a time-consuming process⁶ that prevented a number of laboratories that had developed tests from being able to offer them to the public in a timely manner. However, once FDA policy under a public health emergency was relaxed as described below, laboratories that developed SARS-CoV-2 tests were finally allowed to respond rapidly. Academic medical center laboratories reported an average launch date of March 21, 2020 for their first test, with the earliest laboratory offering their test for clinical use on February 24, 2020. In contrast, most community hospitals / health system laboratories and commercial reference laboratories launched their SARS-CoV-2 testing approximately 2 weeks later, on average. This highlights the importance of academic medical center clinical laboratories in rapidly responding to testing needs in the US.

Unfortunately, now almost five months after the first case of COVID-19 was confirmed in the United States, the government is still not taking full advantage of each sector of the laboratory testing system. AMP found that a larger percentage of academic medical center laboratories (57%) and community hospital laboratories (45%) reported that demand for testing was lower than their current capacity versus only 37% of commercial laboratories, indicating that the capacity of localized testing (i.e., testing that is performed in the same region that a patient is cared for) is currently available and expanding rapidly, but is underutilized. Unfortunately, our survey findings also indicate that academic medical centers and community health laboratories are being deprioritized with regards to accessing limited testing supplies. We found that over 40% of academic medical center and community hospital laboratories at the time of the survey were currently experiencing testing kit supply interruptions, while only 13% of commercial laboratories were currently experiencing this issue. Interestingly, approximately half of all laboratories surveyed reported that they have been informed by a manufacturer or supplier that they cannot purchase the needed testing kits or reagents due to government restrictions and/or allocations for these products. However, of those reporting this barrier, approximately 60% were academic medical center and community hospital laboratories compared to only 30% of commercial reference laboratories.

Based on this experience, AMP strongly supports Recommendation 1.4, Engage and partner with the private sector early to develop diagnostic tests, ensure flexibility to develop and use laboratory-developed tests in a public health emergency, and ensure that the stockpile is better prepared to address diagnostic needs. In response to Question 8 (How can the United States better leverage public-private partnerships, industry, and academic institutions?), we strongly recommend that any policies developed in response to a public health emergency effectively leverage and consider the role of each type of laboratory. Furthermore, efforts should be made to provide real-time coordination amongst laboratories in order to better utilize 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 that samples get processed as quickly as possible.

⁵ Nolte, Frederick S et al. "Responding to the Challenges of SARS-CoV-2: Perspectives from the Association for Molecular Pathology (AMP) Infectious Disease Subdivision Leadership". The Journal of Molecular Diagnostics, Advance online publication. <https://doi.org/10.1016/j.jmoldx.2020.06.003>

⁶ Lefferts, Joel A et al. "Implementation of an Emergency Use Authorization Test During an Impending National Crisis." The Journal of Molecular Diagnostics, Vol. 22, Num. 7, 14 May. 2020,

The Roles of Diverse Test Types in a Public Health Emergency

FDA's policy changed several times since its initial release as the agency and other stakeholders gained an understanding of how these policies were negatively affecting the ability of laboratories and developers to offer SARS-CoV-2 tests to meet a surging clinical need for patient testing. We appreciate that FDA has since provided more flexibility in its guidance, such as allowing laboratories to offer validated LDPs for COVID-19 diagnosis as soon as they notify FDA, but it is important to note that under non-emergency circumstances, laboratories accredited by the Clinical Laboratory Improvement Amendments (CLIA) under the Centers for Medicare and Medicaid Services (CMS) using LDPs would have been allowed to develop, validate, and offer LDPs for clinical care without notifying FDA or seeking review by the Agency. Our survey results indicate that 50% of laboratories are using an LDP (10% are using laboratory developed testing procedures only, and 40% are using a combination of both LDPs and commercial IVD test kits with an emergency use authorization). Meeting the requirements developed for device manufacturers was a significant challenge for laboratories that are not familiar with FDA's procedures, and these newly imposed FDA requirements greatly delayed the ability of laboratories to provide tests to patients.

Additionally, while the policies became more relaxed over time to address the public health needs in this crisis, in many cases the frequent policy changes have themselves created barriers to bringing tests through the regulatory system. For example, a laboratory that began a test submission to the FDA in March has had to make repeated changes to their application throughout the approval process as the changing standards meant their application was frequently out of date and that the laboratory had to re-do validation testing, an exercise that has cost enormous time and resources. We remain concerned about the time lost when laboratories could have been providing tests to their patients and want to ensure that such delay is prevented in the future.

In order to provide laboratories with the flexibility to use LDPs in a public health emergency as you describe in Recommendation 1.4, policy should be changed so that LDPs are not treated as medical devices that require Emergency Use Authorizations (EUAs). Instead, regarding Question 3 (*What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?*) and Question 9 (*What the lessons learned from the current fast tracking of tests, treatments, and vaccines to make them available even more rapidly?*), AMP encourages you to make use of the successful regulatory system under CMS developed in response to the CLIA, which oversees laboratory examinations and processes including LDPs. Specifically, with regards to Question 7 (*How can Congress and HHS make sure CDC and FDA are working more closely with the private sector on diagnostic tests to detect emerging diseases?*), CMS's role should be factored into a national response system in addition to FDA and the CDC.

Additionally, AMP urges you to consider the recently introduced legislation, Verified Innovative Testing in American Laboratories (VITAL) Act of 2020 (S. 3512). This bill would clarify that federal regulatory authority over LDPs should rest within CMS, even during a public health emergency. Additionally, it would direct the HHS Secretary to report to the Senate HELP Committee and House Energy and Commerce Committee on recommendations for updating CLIA as well as provide an assessment of the availability and utilization of LDPs during the 2020 COVID-19 pandemic response. This law is needed now more than ever to provide regulatory certainty and allow the laboratory community to better serve patients, both amidst this pandemic and in all future clinical needs for diagnostic testing services.

The diversity in the United States laboratory system and testing offerings is a strength particularly during a pandemic. As an example, it allows for laboratories to continuously assess quality control and understand the limitations of each type of test. As recently reviewed during an AMP webinar called "Sample Collection and

Molecular Diagnosis of SARS-CoV-2 Infection⁷,” many aspects of testing – including swab type, specimen type, the number of days/weeks after the onset of the infection in a patient, etc. – impact test quality and utility. For instance, comparative studies led to the CDC removing its preference for and recommendation of nasopharyngeal swabs.⁸ This was important for addressing swab shortages and opening up sample collection outside of healthcare establishments. Additionally, emerging evidence suggests that the sensitivity of a diagnostic test is lower when viral loads drop below a certain level as infection progresses, i.e., when people are tested at a greater number of days from symptom onset, and that this is particularly problematic for certain testing methods.⁹ We only come to understand these differences when we have two or more tests to compare.

When multiple testing approaches were able to be deployed, laboratories were able to innovate and adapt rather than be crippled by missteps early on when only the CDC test kit was available. Moreover, innovation has brought about methods that allow patients to collect their own specimens, thus circumventing the need for scarce PPE, validated use of saline instead of extremely limited viral transport media, used saliva as a specimen type to alleviate the swab shortage, identified different viral strains, and ensured that testing in a geographic area is sensitive and specific for that particular population. Congress already has demonstrated its understanding of the importance of innovation to overcome testing limitations as evident through its creation and support of the newly launched Rapid Acceleration of Diagnostics (RADx) initiative.¹⁰ This continued push towards testing diversity will help us to overcome the significant impacts of supply shortages experienced during the COVID-19 pandemic which, as you understand, are significant.

Thus, in response to Question 3 (*What could the federal government have done to be better positioned with diagnostics, vaccines, and treatments for COVID-19?*), we also believe that the federal government should assess the type and location of diagnostic testing services needed during each phase and aspect of responding to a pandemic – surveillance, providing acute care, informing contact tracing efforts, safely reopening businesses, etc.

Lastly, AMP supports the involvement of both public and private entities in the development of standard reference materials in order to harmonize testing across technologies and platforms while making use of the benefits associated with a diverse set of testing options. In response to Question 8 (*How can the United States better leverage public-private partnerships, industry, and academic institutions?*), AMP would also encourage the Department of Health and Human Services to take a leading role in involving a diverse group of stakeholders to work together in development, dispersal, and use of those standard reference materials. This would further support research and advancement of knowledge about testing and its appropriate usage.

⁷ <https://educate.amp.org/local/catalog/view/product.php?productid=183>

⁸ <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

⁹ Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. May 2020. doi:10.1001/jama.2020.8259

¹⁰ <https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics>

2. Disease Surveillance – Expand Ability to Detect, Identify, Model, and Track Emerging Infectious Diseases

Agency Reporting During a Pandemic Needs to be Streamlined

Our testing system is only as good as the information we have about it, and the solution to filling knowledge gaps is not as simple as requiring all laboratories offering COVID-19 testing to report to the federal level. Based on data from our COVID-19 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. At the time of the survey, respondents relayed that they are currently reporting to various state or federal agencies or departments. Approximately 75% of respondents reported that their laboratory spends up to two hours 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. Respondents expressed frustration in the notion that reporting is not standardized across the nation, and that information is required to be submitted to multiple locations.

Suffice it to say, complying with multiple agency reporting requirements with variable formats has been burdensome to the clinical laboratories, and still, the information that is being collected is not as meaningful as we need it to be to address public health needs. While AMP agrees with Recommendation 2.1 (*Ensure timely communication between health professionals, states, the CDC, and the public, as appropriate, of case data and information regarding how emerging infectious diseases affect populations, including who is at higher risk for severe disease and death, to help inform state and local response and address any potential disproportionate impact on minority populations.*), there should be a balance to limit onerous reporting requirements that pull laboratory professionals away from their critical work, while still obtaining the necessary data to understand the nature of the pathogen, the pandemic, and the success of our response efforts. Therefore, in response to Question 1 (*What other barriers, in addition to limited testing capacity, and insufficient and outdated technology, make it difficult to detect and conduct public health surveillance of emerging infectious diseases?*), AMP also recommends that any national testing strategy:

Standardize agency reporting format and processes for reportable infectious diseases during a pandemic, including:

1. **Define minimal required data elements for supporting public health contact tracing.**
2. **Establish standardized reporting format that electronic health records (EHR) / laboratory information system (LIS) vendors could adopt.**
3. **Establish a standardized reporting agency / process that minimizes delays in return of results and eliminates need for laboratories to duplicate reporting to multiple agencies.**
4. **Provide logistical support for laboratories to provide reportable infectious disease data electronically.**

3. Stockpiles, Distribution, and Surges – Rebuild and Maintain Federal and State Stockpiles and Improve Medical Supply Surge Capacity and Distribution

Supply Chain Issues Continue to Prevent Adequate Testing

AMP recently found that testing supply distribution continues to be a limiting factor, with over 80% of laboratories reporting that supply interruptions have delayed or decreased testing. The types of supply chain interruptions that laboratories have experienced are vast and include shortages of testing platforms, testing kits, reagents, swabs, viral transport medium, laboratory consumables, and personal protective equipment. Swabs were reported as being the most significant limitation across laboratories, with 60% of survey respondents reporting that their laboratories had limited swab supplies at the time they took the survey. Viral transport media was the second most problematic supply chain limitation with 53% of laboratories reporting they were currently experiencing this issue. Moreover, as previously described, we found that not all categories of laboratories are being supported with access to supplies to the same degree regardless of their ability to contribute significantly to testing demands. While laboratories are more readily able to ramp up testing from an FDA regulatory perspective, we are alarmed that the lack of a coordinated approach to distributing testing supplies is continuing to hamper the ability to meet the testing needs in the United States. When laboratories made efforts to address shortages, approximately half of the laboratory professionals that participated in our COVID-19 survey reported that government was a barrier. Thus, while this section in your white paper often emphasizes the role of states in managing and dispersing supplies, **AMP urges you to ensure that a national testing strategy that better coordinates supplies is created and used for both the current and future pandemics.**

Specifically regarding **Recommendation 3.3** (*Require appropriate levels of personal protective equipment and ancillary medical supplies to be stockpiled and replenished, both at the federal and state level. Additionally, stockpiled supplies and countermeasures should more frequently and consistently utilize the shelf-life extension program to extend the life of a product in reserve or better identify the expiration of such products and plan to use those products before expiration.*) and **Recommendation 3.5** (*Moving forward, state and health system stockpiles must be developed and maintained, with some federal support, to ensure the United States is ready for the next public health emergency. The federal Strategic National Stockpile must also be replenished and expanded to include certain supplies we now know are needed to respond to a pandemic and maintained with more oversight and accountability.*), **AMP recommends that policy limitations and barriers to stockpiling testing supplies, including swabs, collection devices, and transport media, should be explored and resolved.**¹¹

In regards to the maintenance of the federal Strategic National Stockpile, AMP agrees that while it is critical for materials and testing reagents that have a limited shelf-life to be stockpiled so that they are ready to be deployed when an emergency occurs, any mechanism to maintain the supplies within the Stockpile should not be overly burdensome to hospitals, laboratories, or the manufacturers who provide supplies for the Stockpile. For example, a reasonable policy might allow laboratories or hospitals to purchase reagents from the Stockpile during non-emergency times, with these consumables being quickly replaced to maintain the supply. Currently, many hospitals and laboratories have difficulty maintaining a reserve of supplies, due to requirements to keep operations as lean as possible for budgetary reasons. In response to **Question 2** (*How can states and hospitals improve their ability to maintain a reserve of supplies in the future to ensure the Strategic National Stockpile is the backup and not the first source of supplies during emergencies?*), any solution to encourage hospitals to maintain a reserve of supplies in the future would likely require extensive federal support. Moreover,

¹¹ See for examples of barriers: <https://www.genomeweb.com/pcr/coronavirus-sample-collection-tool-shortages-will-be-short-lived-according-suppliers#.XuvSLWhJE2w>

determination of how this would be accomplished should be made with input from all stakeholders, including hospital administrators and clinical laboratory directors.

Additionally, it is important to note that due to supply shortages and uncertainties, laboratories are building redundancy by deploying multiple testing methodologies so they can continue offering testing to patients. This is not business as usual. These disparate supply chain issues also resulted in differing decisions about testing options offered by laboratories. Laboratory professionals reported supply chain concerns as a significant reason driving them to source, validate, and support multiple SARS-CoV-2 molecular test types simultaneously. Fifty-seven percent (57%) of academic medical centers and community hospital or health system laboratories reported they are running three, four, or more individual methodologies in order to maintain testing capacity when supplies for one platform become scarce. Conversely, 80% of commercial reference laboratories reported that they have only needed to establish one or two testing approaches in their laboratories, highlighting the unequal distribution of testing supplies that has prioritized reference laboratories that are more remote to patient care.

Therefore, we encourage you to build upon Recommendation 3.4 (*The federal government, states, and the private sector must work more effectively together to distribute tests, treatments, and vaccines. Plans should be established in advance for how the federal government, states, and the private sector will coordinate to assess needs and distribute newly developed tests, treatments, or vaccines.*) to ensure that the federal government leads efforts in partnership with states and the laboratory community to:

- 1. 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.
- 2. Increase transparency, communication, and real-time transmission of information between laboratories and suppliers (commercial manufacturers and government):** There is a need for laboratories have real-time access to resource availability and reagent and supply quantities.

4. Public Health Capabilities – Improve State and Local Capacity to Respond

In response to **Question 1** (*What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?*), AMP would like to reiterate that there may be opportunities for laboratories to better coordinate regionally to ensure that moments of excess testing supplies and capacity are leveraged to ensure samples get processed as quickly as possible. However, there may be challenges associated with this approach that need to be addressed as well. For example, hospital systems use a variety of diverse software for their electronic health records, which also frequently handle test ordering and the receiving of patient test results. Due to these diverse electronic systems it is frequently technologically challenging for a healthcare provider to order a test for a patient from a health system that uses a different electronic system. This barrier has prevented healthcare providers from ordering COVID-19 diagnostic tests from laboratories that might have a fast turn-around time and currently be experiencing a lower demand than their maximum test capacity. Additionally, concerns about the interoperability of reporting systems need to be resolved to ensure that laboratories are properly able to report the results of tests they perform for the public health records, in order to both prevent incomplete reports on patients and ensure that cases are not being counted numerous times. The lack of a unified patient identifier also complicates the reporting of results, increasing the complexity of linking results from specific patients to

their medical records across institutions. Finally, the reimbursement system would need to have a system for paying for a test that is partially processed at one location but ultimately performed at another.

5. Who Is on the Flagpole? – Improve Coordination of Federal Agencies During a Public Health Emergency

AMP would like to take the opportunity to thank you for including **Recommendation 5.1** (*Congress must clarify who is in charge and has the ability and authority to keep a continued focus on preparedness for pandemics and other major public health threats when other priorities may seem more pressing, and improve how federal agencies will coordinate during a pandemic. These roles and responsibilities must also be clearly communicated to states and local governments so they can include this information in their own preparedness planning.*). We agree that lack of clarity regarding who is in charge on any particular issue caused inefficiencies in the response effort. In response to **Question 2** (*What specific changes to our public health infrastructure (hospitals, health departments, laboratories, etc.) are needed at the federal, state, and local levels?*), AMP would like to reiterate our recommendations from page 6 intended to streamline laboratory reporting, adding that reporting standards need to be established on a national level through a public process.

In response to **Question 5** (*Have well-intended requirements and directives created too much bureaucracy and slowed federal response?*), we would once again like to address the impact of the FDA policy that is set into place when a public health emergency is declared. When the January 27th emergency declaration took effect, suddenly laboratories that were ready to offer SARS-CoV-2 LDPs were required to obtain an EUA before performing clinical testing. This caused significant delays in access to testing and the consequences have been significant and reverberated throughout the entire healthcare system during this crisis. Had the academic, community, and public health laboratories been allowed to use LDPs sooner, the following could have been achieved or prevented:

- Earlier recognition that COVID-19 was in circulation (i.e. community spread) in the United States, which may have allowed earlier transmission prevention measures.
- Potential for testing of vulnerable populations when symptoms appeared, such as nursing home residents.
- Significantly higher testing capacity throughout the United States allowing for improved patient management and resource management in the hospital system, including staff, ECMO, and ventilators.
- Better use of financial resources by hospitals on immediate needs including purchasing protective equipment, hiring staff, etc. instead of diverting funding and time to navigate a regulatory process they are otherwise not subject to during non-emergencies.
- Eliminate the psychological stress due to uncertainty of one's COVID-19 status.
- Greater lead time for supply chain management.
- More immediate understanding of the scope of the outbreak and the impact on the United States which could have allowed for better informed government and policy decisions, including decisions on quarantining and social distancing. Decisions could have been made using data, not suspicions and fear.

Once again, AMP urges you to consider the Verified Innovative Testing in American Laboratories (VITAL) Act of 2020 (S. 3512). AMP is confident that this would further ensure that the United States is equipped with prepared, high quality laboratories that can contribute to patient care both during emergency and non-emergency times.

In response to **Question 6** (*How can federal departments and agencies more effectively work together to respond to public health emergencies?*), we want to emphasize the importance of determining who is going to

reimburse for testing during a pandemic and how we are going to prevent patients from being unduly burdened because of testing needs. As your staff is well aware, inconsistencies between FDA regulatory requirements for LDPs and provisions meant to ensure coverage of COVID-19 testing in the Families First Coronavirus Response Act left thousands of patients without the ability to obtain no-cost testing even though they have healthcare insurance. We appreciate Congress's work to resolve these gaps with the passage of the Coronavirus Aid, Relief, and Economic Security (CARES) Act. However, we note that coverage and reimbursement challenges still exist and there are reports of patients experiencing significant financial burdens when they seek COVID-19 testing, including insurance denials if they are asymptomatic. This problem will only continue to grow as the need for asymptomatic testing increases over the next few months, for example as hospitals provide testing before medical and surgical procedures and states seek to restore their workforce. **During this forward-thinking exercise, we encourage you to explore innovative approaches to ensure that anyone can truly access testing at no cost if they have potentially been exposed, while compensating laboratories appropriately for the work and resources required to provide and maintain timely and appropriate testing throughout the entire public health emergency.**

Lastly, AMP would like to emphasize that where possible, significant improvements and solutions to the testing response effort should be immediately implemented for the current COVID-19 pandemic. Despite the significant barriers described above, laboratories are increasing testing capacity, with 90% of laboratories in the United States reporting that they plan to increase testing capacity over the next one to three months. However, all respondents also anticipated increases in testing volumes in the coming months as public establishments are opened including testing patients prior to scheduled non-emergent care, contract tracing for employment-based outbreaks, repeated testing for "back to work" clearance testing, and generally, an anticipated increase in the spread of SARS-CoV-2 as people come into more contact with each other. It is in the best interest of America not to wait for another pandemic to see the fruits of your labor.

Thank you for your continued leadership and efforts to improve health care delivery as our country faces new and difficult challenges. Should you have any questions or wish to discuss these issues further, please don't hesitate to contact Sarah Thibault-Sennett, PhD, Policy Analyst, at sthibaultsennett@amp.org.

Sincerely,

Karen E. Weck, MD, FCAP
President, Association for Molecular Pathology