



ASSOCIATION FOR MOLECULAR PATHOLOGY

Providing global expertise in molecular testing that drives patient care

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The Honorable Diana DeGette
U.S. House of Representatives
2111 Rayburn House Office Building
Washington, DC 20515

The Honorable Fred Upton
U.S. House of Representatives
2183 Rayburn House Office Building
Washington, DC 20515

Sent electronically to cures2@mail.house.gov

Dear Congresswoman DeGette and Congressman Upton,

On behalf of the Association for Molecular Pathology (AMP), thank you for the opportunity to submit comments on the Cures 2.0 concept paper. 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 safely and efficiently modernize the delivery of health care.

Outlined in detail below, AMP has provided a response to the *National Testing and Response Strategy for Current and Future Pandemics* and the *Pandemic Preparedness Program for Patients* you have identified in the Cures 2.0 concept paper, as they relate to molecular diagnostic testing. As you develop future legislation, we kindly request that you consider our recommendations below. Please note that AMP will be submitting additional comments on the other sections of the Cures 2.0 concept paper in the coming weeks.

I. National Testing and Response Strategy for Current and Future Pandemics

The Impact of Regulatory Policy on SARS-CoV-2 Testing

AMP greatly appreciates the inclusion of policy that would require national testing strategies for the COVID-19 pandemic and future pandemics. As you are aware, the declaration of the public health emergency (PHE) effective January 31, 2020 required that all tests for SARS-CoV-2, regardless of whether they are boxed and shipped testing kits or laboratory developed testing procedures, obtain emergency use authorization (EUA) from the Food and Drug Administration (FDA) prior to being used on patients. Laboratory-developed testing procedures (LDPs), which are developed, validated, and performed within the same laboratory, are regulated as part of medical practice under the Clinical Laboratory Improvement Amendments (CLIA), thus upon initiation of a PHE, laboratories are forced to

bring testing for the emergency through FDA, restricting laboratories from developing and quickly offering LDPs.

On February 4, 2020, FDA granted EUA for the Centers for Disease Control and Prevention's (CDC) 2019-Novel Coronavirus (2019-nCoV) Real-Time Reverse Transcriptase (RT)-PCR Diagnostic Panel.¹ As is well documented, the public health laboratories encountered challenges during the three-step validation procedures for this molecular diagnostic test making it impossible to establish the test for use in their laboratories, resulting in a recall of the test kit and subsequent weeks of delays in diagnosis and the inability to conduct testing and surveillance for COVID-19.² Meanwhile, had FDA regulations allowed so during that time, our members and their laboratories were ready, willing, and able to step up and support the efforts of the public health laboratories to screen, diagnose, and respond to the outbreak from its outset.

FDA's policy has been changed several times since its initial release, as the agency and other stakeholders understood that current policies were negatively affecting the ability of laboratories and developers to offer SARS-CoV-2 testing, thereby preventing access to patient testing.³ We appreciate that FDA has since provided more flexibility to help get these tests to patients in need, such as allowing laboratories to offer validated LDPs for COVID-19 diagnosis as soon as they notify FDA. Additionally, manufacturers of boxed and shipped in vitro diagnostic (IVD) kits have also been provided some flexibility for COVID-19 diagnostic tests. Once regulatory policy changed, dozens of laboratories were able to develop SARS-CoV-2 tests more rapidly to meet the country's testing capacity needs. 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 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 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.

Supply Chain Issues Continue to Prevent Adequate Testing

While laboratories are more readily able to ramp up testing from a 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. AMP recently found through a survey of 118 professionals from US laboratories (conducted between April 23 - May 5, 2020) that testing supply distribution continues to be a limiting factor, with over 80% of laboratories reporting that supply interruptions have delayed or decreased testing⁴. The types of supply chain interruptions that laboratories have experienced are vast and include shortages of testing platforms, testing kits,

¹ <https://www.fda.gov/media/134919/download>

² <https://www.washingtonpost.com/health/2020/02/25/cdc-coronavirus-test/>

³ <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised>

⁴ <https://www.amp.org/advocacy/sars-cov-2-survey/>

reagents, swabs, viral transport medium, laboratory consumables, and personal protective equipment. Swabs were reported as being the biggest limitation across laboratories, with 60% of survey respondents reporting that their laboratories had limited swab supplies at the time they took the survey.

In order to understand the supply barriers in our current system, data from the survey was analyzed by comparing responses from those in academic medical center laboratories, community hospital or health system laboratories, and commercial reference laboratories. In the laboratory industry, academic medical centers and community hospitals generally have their own on-site, CLIA-certified laboratories to conduct general and time-sensitive testing for the patients within their healthcare system (particularly hospitalized patients), whereas less time-sensitive testing is shipped to often out-of-state or cross-country commercial reference laboratories. In our survey, over 40% of those at academic medical center and community hospital laboratories at the time of the survey were currently experiencing testing kits supply interruptions, with only 13% of commercial laboratories currently experiencing this issue.

Moreover, we found that not all categories of laboratories are being supported to the same degree regardless of their ability to contribute significantly to testing demands. 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. Of those reporting this barrier, approximately 60% were academic medical center and community hospital laboratories compared to only 30% of commercial reference laboratories.

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 reference laboratories reported that they have only needed to establish one or two testing approaches in their laboratories.

From the survey results and further feedback provided by our members, we conclude that the disparate application of policy and attention that has been given to different types of laboratories has significantly contributed to the barriers to meeting testing needs in the United States. AMP agrees that a national testing strategy is needed, however, we also urge you to ensure that a testing strategy makes use of and supports the variety of clinical laboratories that have the expertise and capability to test for SARS-CoV-2 and other pathogenic agents. Additionally, national coordination of the supply chains will be crucial in the coming months, and in any future pandemic, to manage the many competing interests for resources and testing (clinical testing, public health testing, epidemiology studies, workplace safety, etc.)

The 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. Essential to our collective ability to conduct surveillance and begin testing during an outbreak are certified public health laboratories working with the Centers for Disease Control and Prevention (CDC). However, their limited testing capacity makes it difficult for those laboratories to have a significant clinical diagnostic role. Hospital laboratories and other local community testing sites are on the frontlines providing patient care for the critically ill. Especially important is their ability to provide faster turnaround times as compared to other laboratories, which allows for more rapid decision making as it relates to patient treatment plans, the protection of frontline healthcare workers, and decisions regarding utilization of scarce personal protective equipment. Commercial reference laboratories provide an innate ability to perform a great number of tests; this is an enormous strength when an outbreak is spread across many locations, but testing is done remotely outside of the original health system and requires additional time for shipping. Thus, reference laboratories are better suited for testing of mildly ill outpatients when turnaround time is less critical. The survey results found that approximately 90% of academic medical centers and community hospital or health system laboratories had a turn-around time of less than 24 hours, while only 57% of commercial laboratories had a turn-around time of less than 24 hours.

Moreover, part of the United States' adaptability comes from the fact that a variety of both IVD kits and LDPs are available for use. As mentioned above, we found that most laboratories are using more than one of the multiple assays that are currently available. Most reference laboratories reported using an in-house LDP as the primary means of diagnostic testing, while academic medical center laboratories reported using LDPs most often as a secondary testing approach. However, even commercially available IVD kits require time and expertise for validation. Frequently overlooked is the crucial role that trained, qualified laboratory staff play in launching and overseeing an IVD testing kit that is performed in their CLIA-approved laboratory. For example, a recent publication provided recommendations for steps that laboratories must take in order to successfully launch and validate an IVD kit for SARS-CoV-2 testing.⁵

As of March 26, 2020, FDA has authorized the use of three point-of-care molecular tests that can be used in a CLIA-waived setting. While there was a great deal of excitement generated in the media when point-of-care testing came online, this has not diminished the need for high-throughput testing so that laboratories can process thousands of samples with high sensitivity within a 24-hour span. This is especially true for highly impacted areas as we strive to meet the critical demand for a high volume of testing. Additionally, testing needs will only continue to increase when public establishments are opened due to requirements for testing patients prior to scheduled non-emergent care, contact tracing for employment-based outbreaks, repeated testing for "back to work" clearance, and an anticipated increase in the spread of SARS-CoV-2 as people come into increased contact. Furthermore, increased serology testing for SARS-CoV-2 antibodies will help us understand the extent of those that have been previously infected and may have some level of immunity. For these reasons, any national testing

⁵ Mitchell SL, St George K, Rhoads DD, et al. Understanding, verifying and implementing Emergency Use Authorization molecular diagnostics for the detection of SARS-CoV-2 RNA. *J Clin Microbiol.* May 2020. doi:10.1128/JCM.00796-20

strategy must encourage involvement from all types of laboratories practicing in the US and support the use of all types of laboratory tests.

The diversity in our system 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 Infection⁶,” 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.⁷ 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, 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.⁸ We only come to understand these differences when we have two or more tests to compare.

When multiple testing approaches were deployed, this became the strength of our system allowing us to innovate and adapt rather than be crippled by missteps. For example, innovation has brought about methods that allow patients to safely and effectively collect their own specimens, thus circumventing the need for scarce PPE, validated 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 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.⁹ This continued push towards testing diversity will help us to overcome the significant impacts of supply shortages experienced during the COVID-19 pandemic.

We should take advantage of the diversity and potential capacity in our current US clinical laboratory testing system by building, strengthening, and supporting it through a national testing strategy. **AMP recommends that any national testing strategy should:**

1. **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.
2. **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

⁶ <https://educate.amp.org/local/catalog/view/product.php?productid=183>

⁷ <https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html>

⁸ Sethuraman N, Jeremiah SS, Ryo A. Interpreting Diagnostic Tests for SARS-CoV-2. JAMA. May 2020. doi:10.1001/jama.2020.8259

⁹ <https://www.nih.gov/news-events/news-releases/nih-mobilizes-national-innovation-initiative-covid-19-diagnostics>

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.

- 3. 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 resource availability and reagent and supply quantities.
- 4. Provide 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.

Coverage and Pricing of Tests During a Public Health Crisis

To ensure that we are prepared for future pandemics, it is important to streamline the Centers for Medicare and Medicaid Services' (CMS) coverage and payment policies to ensure that there is adequate testing and that providers are not harmed by unnecessary regulatory burden or inadequate reimbursement. We recognize that CMS has been flexible throughout this crisis to help quickly develop and price codes for SARS-CoV-2 testing. However, this process resulted in a number of slightly different codes for these tests and has created additional confusion amongst laboratories and payers. As reported in AMP's survey, a significant portion of respondents did not know how these diagnostic tests were being coded or priced. We also witnessed a level of confusion at the start of the PHE as testing capacity was increasing that undermined getting tests to patients quickly. **AMP recommends that:**

- 5. Congress should make revisions to the regulatory process to ensure that diagnostic tests developed in response to a pandemic have a clear and transparent pathway to coding, coverage and reimbursement by CMS.**

Additionally, CMS quickly priced these codes in a manner that was not transparent and did not include any feedback from stakeholders. This created additional confusion among laboratories and organizations. Transparency in the pricing process, and involving stakeholders to gain reliable data on the real-world costs of running a test during a pandemic situation, will help to create accurate pricing from the outset. **AMP recommends that:**

- 6. CMS be directed to implement coding and payment policies quickly and transparently in a manner that accounts for the actual cost of testing, including swabs, reagents, and workforce capacity required to run the tests, and communicate this information clearly to laboratory stakeholders.**

Agency Reporting During a Pandemic Needs to be Streamlined

Lastly, 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. 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. 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, AMP also recommends that any national testing strategy:**

7. **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
 - a. Define minimal required data elements for supporting public health contact tracing.
 - b. Establish standardized reporting format that electronic health records (HER) / laboratory information system (LIS) vendors could adopt.
 - c. Establish a standardized reporting agency / process that minimizes delays in return of results and eliminates need for laboratories to duplicate reporting to multiple agencies.
 - d. Provide logistical support for laboratories to provide reportable infectious disease data electronically.

II. Pandemic Preparedness Program for Patients

AMP appreciates that Congress made corrections to the Families First Coronavirus Response Act by amending language with the Coronavirus Aid, Relief, and Economic Security (CARES) Act to ensure that all types of tests for COVID-19 are covered by insurers with no cost sharing for the patient. Originally, the provision left thousands of patients without insurance coverage for essential testing necessary to stem the tide of transmission because it only provided coverage for tests with an FDA EUA. On February 29th, the FDA updated its policy on COVID-19 EUA requirements to allow laboratories to provide LDPs for patients in most instances without immediately needing an EUA. The CARES Act language aligned the coverage policy with the regulatory policy for COVID-19 tests, ensuring that more patients have access to testing. **Moving forward, AMP recommends that any preparedness program should include free access to diagnostic testing, with appropriate reimbursement for laboratories, for all types of tests being utilized in response efforts, regardless of under which regulatory policy they were validated.**

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