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

September 21, 2020

LCDR Natalie Gibson
200 Independence Avenue SW
Washington, DC 20201

Delivered electronically via COVID19TestSupplies@hhs.gov

Subject: RFI RESPONSE

Ms. Gibson:

On behalf of the Association for Molecular Pathology (AMP), I want to express our appreciation for your request for information on the ability of CLIA-certified or accredited commercial, academic, medical center and public health laboratories to feasibly provide additional testing capability. We understand that the Office of the Assistant Secretary for Health (OASH) is seeking laboratory-specific information, and as such, we have disseminated information about this request for information (RFI) broadly to AMP members. AMP appreciates your efforts to assist laboratory professionals in their testing efforts and hopes that you receive promising RFI responses that result in enhanced SARS-CoV-2 testing capacity. We also wanted to take this opportunity to share relevant COVID-19 testing insights gleaned as a result of AMP's most recent survey of laboratorians providing COVID-19 diagnostic testing across the country.

I. Do you represent a CLIA-certified or accredited laboratory?

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, who have served 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.

AMP has and continues to work to support our members during this pandemic in part by gathering data to inform government decision-making. We received highly positive feedback from both federal agency staff and congressional offices following a survey of laboratory experiences and information related to SARS-CoV-2 molecular diagnostic testing in April (our findings are summarized here and our presentation during the June 15th CDC Clinical Laboratory COVID-19 Response Call can be found here).

As a follow up to the April survey, AMP recently completed another survey of 113 professionals from US laboratories across 38 states. Survey responses were obtained August 13 through September 11, 2020. The questions were developed by incorporating feedback from staff from the Food and Drug Administration COVID-

19 Response Team on In Vitro Diagnostics Shortages and interested congressional offices on the April survey findings. Respondents were laboratory professionals from various laboratory settings:

- 42% of respondents were from academic medical centers,
- 26% of respondents were from commercial laboratories (category is inclusive of both referral and reference laboratories),
- 24% of respondents were from community hospital or health system laboratories, and
- 3% from were from public health or state laboratories.

II. What is your current laboratory testing capacity (e.g., installed base of platforms, throughput, level of personnel, etc.)?

In the recent survey, we asked laboratory professionals about their laboratory's testing capacity. Fifty-four percent (54%) of respondents reported that their institution's demand for testing was HIGHER than their capacity, indicating that a great number of laboratories could benefit from additional resources to meet demand. Additionally, the majority of respondents reported that their laboratory had a capacity of either:

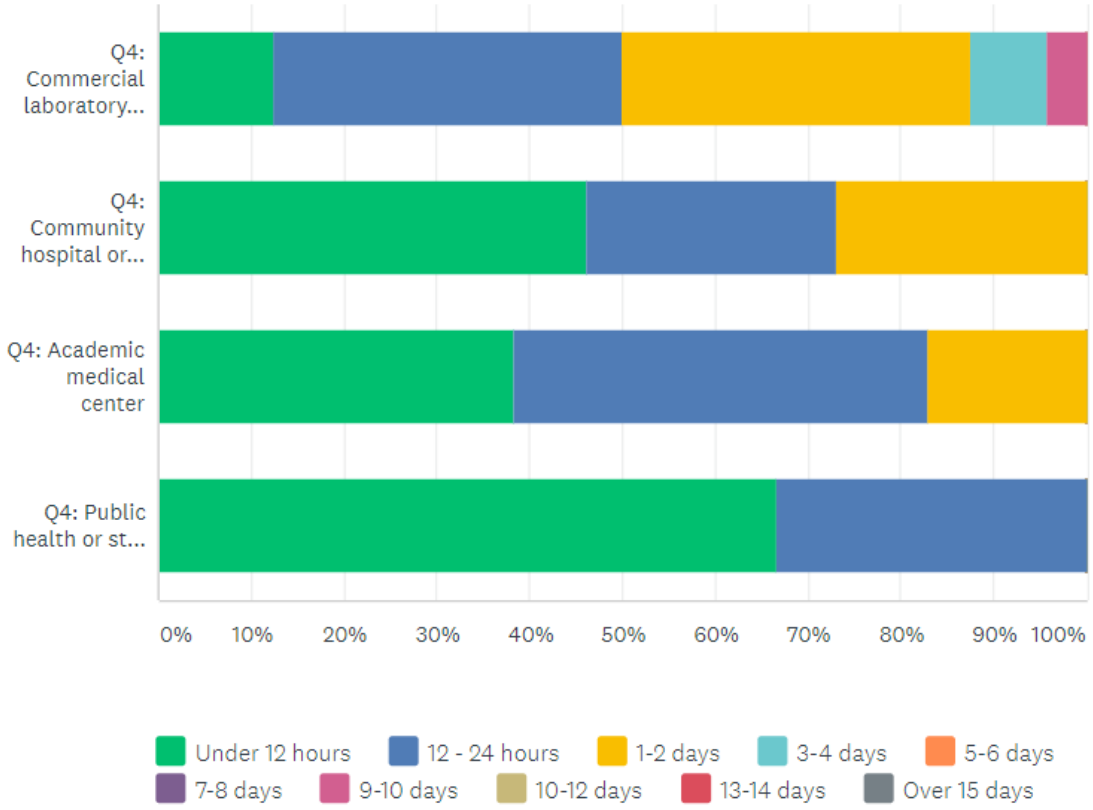
- 250-500 specimens per day (20%),
- 500-1,000 specimens per day (24%), or
- 1,000-5,000 specimens per day (24%).

Additional information about barriers to expanding testing capacity is provided in Section IV.

III. What is your current ability to accession specimens and report out laboratory results in no less than 24-48 hours?

In the August survey, AMP also asked about information related to turnaround time. Nearly all laboratories encompassed by the survey are able to report out laboratory results in less than or equal to two days (96% of laboratories using their primary test method, 98% for the secondary testing method, and 97% for the tertiary testing method). More than 70% of laboratories are able to report out results within 24 hours (72% of laboratories using their primary test method, 84% for the secondary testing method, and 93% for the tertiary testing method). (Note: AMP's April survey revealed that laboratories often employ more than one platform type/testing method to allow them to adapt to supply shortages and other uncertainties. More information about supply shortages are provided in Section IV.) A greater percentage of respondents from academic medical centers, community hospital/health system laboratories, or public health or state laboratories reported being able to report results within 12 hours compared to respondents from commercial/reference laboratories. Thus, near-to-patient laboratories can more rapidly turn around SARS-CoV-2 test results. See green bars in Figure 1 below.

Figure 1. Turnaround Time for Laboratories' Primary Testing Method by Laboratory Type from August Survey.



IV. What level of additional capacity could your laboratory provide if additional testing instruments were made available?

AMP asked additional questions related to testing capacity and found that testing supply issues were often viewed as a major barrier to expanding their current testing capacity. As an example, 51% of respondents reported that purchasing commercially available testing kits was a major barrier and 30% of respondents reported that purchasing additional platforms and/or equipment for sample testing was a major barrier (see Table 1; testing supply issues are noted with red text).

Table 1. AMP August Survey Results on Barriers to Increasing Testing Capacity.

Barrier Type	Major Barrier	Limiting Factor
Concerns about supply chain interruptions	52%	41%
Unable to purchase additional commercially-available testing kits	51%	27%
Limited supply of specific plastic disposables for testing instruments (e.g., pipette tips)	36%	40%
Unable to increase laboratory workforce	34%	39%
Unable to purchase additional platforms and/or equipment for sample testing	30%	27%
Unable to increase laboratory shifts	22%	29%
Limited supply of sample collection materials (i.e., swabs, VTM)	20%	46%
Unable to purchase additional platforms and/or equipment for sample processing (e.g., liquid handlers, extraction kits)	18%	37%
Validating / increasing testing volumes at additional locations/satellite testing is using up scarce materials within the institution as a whole	11%	29%
Lack of institutional support to expand testing	10%	16%
Unable to increase laboratory administrative support	9%	30%
Limited supply of specific reagents for LDPs	8%	28%
Test reimbursement rates do not support costs	5%	28%

Many laboratories reported that they were planning to increase their testing capacity and were planning to do so through numerous ways. The most commonly cited way was by using additional platforms (64% of respondents). The second most commonly cited way was by adding new tests/test kits into their workflow (59%). Thus, laboratories are already working to find ways to use additional platforms and tests to expand their testing capacity.

AMP's April survey revealed that laboratories are employing more than one platform type/testing method to allow them to adapt to supply shortages and other uncertainties. In the August survey, AMP asked participants about which platforms they considered their primary choice, secondary choice, or tertiary choice within their

laboratory and what factors determined the test platform type/testing method that they prefer. We found the main reasons that respondents preferred one test platform/testing method are as follows:

- The platform allowed for a higher throughput capacity relative to other methods available (66% of respondents);
- Availability of testing reagents and supplies (58%);
- It would allow them to use a test kit with an existing FDA emergency use authorization (53%);
- The platform allowed for automated/semi-automated method (50%);
- The platform was already available in their laboratory for clinical testing (48%);
- Technical staff availability/competency (48%); and,
- Analytical performance (43%).

In general, laboratories are most often making decisions regarding testing platform/testing method based on high throughput capacity and availability of testing reagents and supplies. Based on these results, if laboratories were able to gain access to a platform and had a dependable supply of reagents, then they would likely incorporate them into their workflow.

As our survey results both in April and August show, the unreliable supply chain and opaqueness regarding information about whether supplies are available and how supplies are allocated is the main challenge that laboratories still face in providing COVID-19 diagnostic test results to their patients. In an effort to provide much needed transparency into the supply chain shortages, we encourage OASH to regularly release information on the effort to provide additional testing platforms and reagents to interested laboratories. AMP also encourages transparency into other efforts to address ongoing laboratory supply shortages moving forward.

Note that although testing reagents and supplies are major concerns, other factors are also limiting the ability of laboratories to perform at theoretical maximum capacity. These concerns encompass a wide variety of factors that impact the specialty of laboratory medicine including limitations on the available workforce, limitations on scheduling, lack of administrative support, and reimbursement challenges. These challenges require longer-term solutions that should be systematically addressed going forward.

AMP hopes that these initial findings can be helpful to your efforts. We are working to examine the data in much greater detail and would welcome the opportunity to meet with OASH to provide additional information into our finding. Please do not hesitate to reach out to Tara Burke at tburke@amp.org.

Sincerely,

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