ASSOCIATION FOR MOLECULAR PATHOLOGY
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Association for Molecular Pathology Releases Preliminary Results to Second 2020 Nationwide SARS-CoV-2 Molecular Testing Survey

Demand for COVID-19 diagnostic testing continues to rise as clinical laboratories face significant staffing shortages and persistent supply chain issues

ROCKVILLE, Md. – Oct. 8, 2020 – The Association for Molecular Pathology (AMP), the premier global, molecular diagnostic professional society, today released the preliminary results of its August 2020 SARS-CoV-2 Testing Survey for clinical laboratories. The anonymous survey was created and administered to monitor, understand, and collect real-time data on laboratories' efforts and experiences during the COVID-19 pandemic response. Compared to the previous April 2020 survey, respondents are experiencing continued supply chain interruptions and are now also facing significant staffing shortages, all while demand for molecular diagnostic testing continues to increase. Survey results are being used to help inform AMP's advocacy and clinical practice programs related to improving future pandemic responses.

AMP's 100-question survey assessed many important aspects of SARS-CoV-2 molecular diagnostic testing, including sample types, patient populations, methodologies, validation, performance, supply chain, public health reporting, laboratory workforce, and reimbursement. The preliminary results included feedback from 113 representatives from US-based academic medical centers, commercial reference laboratories, public health laboratories, and community hospitals. Overall, 54% of the respondents indicated testing demand was currently higher than capacity due to the reopening of local businesses and schools across the country. These laboratories are also anticipating further increases in SARS-CoV-2 testing demand over the next few months with the fall and winter influenza season, as well as the need for more surveillance and screening testing.

Staffing shortages and SARS-CoV-2 molecular testing also continue to negatively impact molecular tests for other infectious diseases, cancer and inherited conditions. In fact, 55% of respondents reported that volumes for other tests provided by their laboratory had either decreased slightly or significantly during the pandemic. Most significantly, 85% of respondents have experienced shortages in staff, with 66% noting shortages in qualified clinical laboratory technologists/scientists and 53% experiencing shortages in clinical laboratory technicians.

"Clinical laboratories across the country are on the frontlines of this pandemic, doing their best to keep up with the ever-increasing demand for molecular diagnostic testing despite multiple supply chain and personnel shortages," said Karen E. Weck, MD, AMP President and Professor of Pathology and Laboratory Medicine, Professor of Genetics and Director of Molecular Genetics and Pharmacogenomics at University of North Carolina Chapel Hill. "AMP will continue to review the impacts of the COVID-19 pandemic on clinical practice, regulatory policy and reimbursement. These survey results will be fundamental to informing potential legislation and other initiatives that could significantly improve response to the current and future pandemics."

Based on the common themes found in results from both the April and August surveys, AMP is making two new recommendations and reaffirming the previous five recommendations to federal, state and local governments:

New August 2020 Recommendations

1. **Ensure that regulatory requirements for clinical laboratories are not duplicative or burdensome, especially during a pandemic:** Maintain the Centers for Medicare & Medicaid Services (CMS) via the

Clinical Laboratory Improvement Amendments (CLIA) program as the regulatory agency responsible for oversight of laboratory developed testing procedures in order to ensure that the US can rapidly develop and deploy the testing needed during a public health emergency.

2. **Support the clinical laboratory workforce that is essential to providing an effective medical and public health pandemic response:** Promote better collaboration and communication between the public health and clinical laboratories and relevant government agencies in order to better understand challenges and more effectively leverage capacities and capabilities to support testing needs. Laboratory personnel need to have workforce support and access to career development, training and ongoing educational programs to prepare for future public health emergencies.

Reaffirmed April 2020 Recommendations

3. **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.
4. **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.
5. **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 resource availability and reagent and supply quantities in real-time.
6. **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.
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.

AMP will continue to review and analyze the results of the survey as part of its ongoing commitment to share expertise, assess laboratory needs, engage key stakeholders and provide recommendations for improving future pandemic responses and ensuring more patients have access to high-quality testing procedures.

AMP COVID-19 Virtual Town Hall Webinar

AMP will present the preliminary results and key findings from the August 2020 SARS-CoV-2 Testing Survey during a webinar on Tuesday, Oct. 27, 2020 at 2:00 pm ET. Dr. Weck will be joined by:

- Karen L. Kaul, MD, PhD, former AMP President and Chairman of Department of Pathology at NorthShore University Hospital
- Frederick S. Nolte, PhD, Chair of AMP Infectious Diseases Subdivision and Director of Clinical Laboratories at Medical University of South Carolina
- Jordan Laser, MD, Chair of AMP Professional Relations Committee and Medical Director of Long Island Jewish Medical Center – Pathology and Laboratory Medicine

To register, please visit https://educate.amp.org/local/catalog/view/product.php?productid=223.

To read the full AMP report on the August 2020 SARS-CoV-2 Testing Survey, please visit: https://www.amp.org/advocacy/sars-cov-2-survey/

ABOUT AMP

The Association for Molecular Pathology (AMP) was founded in 1995 to provide structure and leadership to the emerging field of molecular diagnostics. AMP's 2,500+ members practice various disciplines of molecular

diagnostics, including bioinformatics, infectious diseases, inherited conditions, and oncology. Our members are pathologists, clinical laboratory directors, basic and translational scientists, technologists, and trainees that practice in a variety of settings, including academic and community medical centers, government, and industry. Through the efforts of its Board of Directors, Committees, Working Groups, and Members, AMP is the primary resource for expertise, education, and collaboration in one of the fastest growing fields in healthcare. AMP members influence policy and regulation on the national and international levels, ultimately serving to advance innovation in the field and protect patient access to high quality, appropriate testing. For more information, visit www.amp.org and follow AMP on Twitter: @AMPath.

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