

March 21, 2020

The Honorable Nancy Pelosi
Speaker of the House
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Kevin McCarthy
Minority Leader
U.S. House of Representatives
Washington, D.C. 20515

The Honorable Mitch McConnell
Majority Leader
U.S. Senate
Washington, D.C. 20510

The Honorable Chuck Schumer
Minority Leader
U.S. Senate
Washington, D.C. 20510

Dear Speaker Pelosi, Minority Leader McCarthy, Majority Leader McConnell, and Minority Leader Schumer:

The American Society for Clinical Laboratory Science (ASCLS) writes you on behalf of the tens of thousands of professionals in laboratories tonight trying to keep their fellow Americans safe by skillfully detecting the deadly virus causing this global pandemic. Since clinical laboratories were first notified by the CDC on January 20, 2020, they have been monitoring and preparing as best they could for this worst-case scenario.

ASCLS believes we are unlikely to see the needed SARS-CoV2/COVID-19 testing capacity for at least a month and perhaps more, even under the best of circumstances.

The unfortunate and casual use of the term “test” to describe several complex steps (many of them manual) and components has led to a fundamental misunderstanding by the public and policy makers about the availability of testing and the best ways to ensure the public’s health.

All current SARS-CoV2/COVID-19 testing to date has employed Reverse Transcription Polymerase Chain Reaction (RT-PCR) technology. RT-PCR testing requires a qualified laboratory scientist or technician to manually isolate the coronavirus’s RNA and reverse transcribe it into DNA for analysis in an appropriate instrument. At each step the laboratory professional carefully performs quality control protocols to ensure an accurate and precise result.

References to “tests” in the context of COVID-19 often provide the misleading impression that this is like the strep and influenza Point of Care (POC) tests many of your constituents are familiar with in their physician’s office. The Administration’s March 14 announcement expanding “drive up testing” caused further confusion as it should be more accurately

described as “drive up sample collection.” No testing is performed there. After samples are collected, they are transported to high complexity laboratories where untriaged samples have overwhelmed an already drowning system.

Announcements about the rollout of testing on more platforms are welcome, but sample preparation by laboratory professionals is hampered by shortages or unavailability of reagents, RNA extraction kits, and other consumables. Exacerbating the problem are shortages of Nasopharyngeal (NP) swabs and Oropharyngeal (OP) swabs to collect samples from patients and transport media to get properly collected specimens to the laboratory, and personal protective equipment for healthcare workers collecting the specimens.

Understanding the dual causes of this crisis is critical to solving it.

1. Clinical laboratories are spread thin, under enormous stress, and on the verge of collapse. COVID-19-positive patients, generally require additional diagnostic testing, placing even greater pressure on an already strained laboratory workforce as testing volumes increase.

The number of FDA cleared/approved clinical tests or test systems have increased over 384% since 1993 to more than 62,000 while the laboratory workforce has remained relatively static. Despite ever-growing demand, educational programs at full capacity have produced just 6,300 graduates in 2017; a number that has not grown in the last five years.

The United States has failed to support educational programs producing medical laboratory scientists and technicians. Unlike physicians and nurses and some other health professions, and despite years of warnings from clinical laboratory groups like ASCLS, Congress has failed to enact and appropriate funds for a single program providing needed resources to these educational programs, nor the network of laboratories that support that training by allowing preceptorships that are required of all to graduate.

2. Annual cuts of more than \$1 billion in Medicare reimbursements under the Preserving Access to Medicare Act (PAMA), that are now being matched by cuts from private insurers and state Medicaid programs, have left laboratories unable to invest in current technology. Systematic under-reimbursement to laboratories has resulted in a lack of investment that would have made the system more robust and prepared for just this

occurrence. Even now, hospitals and independent laboratories are unable to justify or access the capital necessary to install the instruments needed for COVID-19 testing.

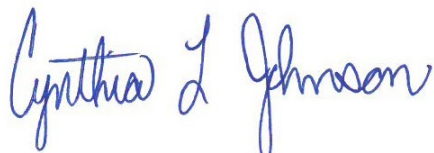
Our healthcare system is built on the foundation of clinical laboratory testing and diagnostics, and this crisis has clearly revealed the cracks in that the foundation. Nearly 14 billion diagnostic tests are performed each year in the United States; the single highest volume medical activity, influencing approximately 70 percent of physician-patient interactions.

Congress must act to immediately reinforce a strained clinical laboratory system. Congress must:

- Fund the American Clinical Laboratory Association's (ACLA) immediate request for an Emergency Laboratory Surge Capacity Fund of \$5 billion for laboratories performing COVID-19 testing.
- Direct that the authorities in Title III of the Defense Production Act (50 U.S.C. § 4531 et seq.) must be used to support laboratories performing COVID-19 testing.
- Enact and fund the Allied Health Personnel Shortage Act (H.R.6302). The Act would bolster the health care workforce by establishing a program of scholarships and loan repayment to alleviate shortages of clinical laboratory scientists and other allied health professionals. The scholarship and loan repayment programs include a period of obligated service for recipients in a designated health professional shortage area.
- Provide funding to the Health Resource and Services Administration for Medical Laboratory Technician and Medical Laboratory Science educational programs to expand the number of students these programs accept in the fall. This funding must be flexible enough to be used to fund laboratory preceptorships as that is a clear chokepoint for graduation.

The American Society for Clinical Laboratory Science (ASCLS), our members and the entire clinical laboratory community will continue to work to protect the health and well-being of our neighbors and stand ready to help build a more robust and effective response to COVID-19.

Sincerely,



Cynthia J. Johnson, MS, MLS(ASCP)^{CM}
President