February 24, 2020

Stephen M. Hahn, MD
Commissioner of Food and Drugs
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Commissioner Hahn,

On behalf of our nation's state and local public health laboratories (PHLs), we are writing to urge you to consider enforcement discretion to allow this select group of governmental laboratories the ability to create and implement a laboratory developed test (LDT) for the detection of SARS-CoV-2 (COVID-19). We recognize the gravity of the current COVID-19 situation across the globe and wish to have greater diagnostic capability for both surveillance and for patient diagnosis across the United States, hence this extraordinary and rare request.

While we appreciate the many efforts underway at CDC to provide a diagnostic assay to our member labs under the Emergency Use Authorization (EUA), this has proven challenging and we find ourselves in a situation that requires a quicker local response. We are now many weeks into the response with still no diagnostic or surveillance test available outside of CDC for the vast majority of our member laboratories. While we understand that the EUA process is open to PHLs, we believe a more expeditious route is needed at this time.

To the extent possible, public health laboratories could work together to:

- Utilize a standard protocol or use a limited set of protocols
- Purchase reagents including primers and probes from a common source
- Utilize a standard validation panel
- Recommend a minimum standard validation approach
- Enable confirmation at another PHL while cases remain sporadic. It is also possible to consider the use of LRN advanced labs to serve as a confirmatory lab if resources are available to do so.

We recognize that not all PHL's will develop and implement an LDT. If PHL's decided against the use of an LDT for whatever reason, they could: 1) wait for the availability of the new CDC replacement kit, 2) coordinate with a PHL that has developed an LDT (this is not uncommon for PHLs to work together), or 3) use a commercially available assay once approved by FDA under an EUA.

We look forward to discussing this request with you and your staff as soon as possible. If you have questions, please contact Scott Becker at 301-526-5704 or via email at scott.becker@aphl.org.

Sincerely,

Grace Kubin

Scott J. Becker

Grace Kubin, Ph.D.
Director, Laboratory Services Section
Texas Department of State Health Services

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories

cc: Robert Redfield, MD, Director, Centers for Disease Control and Prevention