AACC | Better health through laboratory medicine.

February 28, 2020

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

Dear Commissioner Hahn,

The American Association for Clinical Chemistry (AACC) requests that the Food and Drug Administration (FDA) exercise enforcement discretion to permit qualified laboratories to build and utilize laboratory developed tests (LDTs) to detect SARS-CoV-2 and diagnose COVID-19. Currently the FDA Emergency Use Authorization (EUA) edict bars these laboratories from developing and utilizing such tests without prior agency approval. This added regulatory burden associated with FDA review is significantly thwarting the ability of America's clinical laboratories to test for this highly contagious disease at a crucial time in the spread of this possible pandemic.

Currently, only one test is available for detecting COVID-19—the Centers for Disease Control (CDC) 2019-Novel Coronavirus Real-Time RT-PCR Diagnostic Panel. The CDC acknowledges that there have been problems with this test. The Association of Public Health Laboratories (APHL), which represents state and local public health laboratories performing this test, has requested an exemption from the EUA requirements so that frontline laboratory professionals can develop more accurate LDTs without the delay that would result from FDA review. AACC supports this request to ensure patients have access to vital, high-quality testing.

AACC is concerned, however, that this approach does not go far enough to protect Americans' health in this global outbreak. While in the US we are still experiencing low numbers of human cases, the World Health Organization has declared a global public health emergency resulting from the widespread human to human transmission of the disease. If the number of COVID-19 cases rapidly increases in this country, as it has in South Korea and Italy, the US public health system may be overwhelmed with testing requests causing a delay in access to testing and a resultant impediment to diagnosis and appropriate care.

While the preferred option for addressing this crisis would be the use of a cleared assay, provided by a trusted vendor in enough quantity to meet anticipated demand, that is not currently an option. Therefore, to prepare for a sharp rise in the demand for testing, AACC recommends that the FDA also exempt the many national and regional clinical laboratories with the expertise and capacity to develop and perform LDTs that can accurately detect SARS-CoV-2 and diagnose COVID-19. Regulated under the Clinical Laboratory Improvement Amendments (CLIA), these clinical laboratories are subject to stringent personnel, quality control, and proficiency testing requirements. These CLIA laboratories already

develop, validate, and perform LDTs for serious public health conditions (e.g., influenza, prescription drug monitoring). Using the expertise of all our laboratory professionals will ensure that American citizens have access to rapid, accurate testing and clinicians will receive test results in a timely fashion to treat their patients.

If you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

Carmen L. Wiley, PhD, DABCC, FAACC
President, AACC