February 26, 2020

Grace Kubin, Ph.D.
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Texas Department of State Health Services
1100 West 49th Street
Austin, TX 78756

Scott J. Becker, MS
Chief Executive Officer
Association of Public Health Laboratories
8515 Georgia Avenue, Suite 700
Silver Spring, MD 20910

Dear Dr. Kubin and Mr. Becker,

Thank you for your letter to the Food and Drug Administration (FDA or the Agency). FDA appreciates the critical role of state and local public health laboratories in our nation's response to public health emergencies, as well as the severity of the current situation with the 2019 novel coronavirus disease (COVID-19).

In the context of a public health emergency, false diagnostic test results can lead to significant adverse public health consequences—not only serious implications for individual patient care but also serious implications for the analyses of disease progression and for public health decision-making. The Emergency Use Authorization (EUA) statutory provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act) help ensure that FDA has appropriate oversight over the emergency use of certain unapproved products, as well as over unapproved uses of approved products, including diagnostic tests, regardless of who makes them. In certain emergency circumstances, FDA may issue an EUA if it determines, among other things, that the product "may be effective" in the diagnosis, treatment, or prevention of a disease or condition and that the known and potential benefits of the product, when used to diagnose, prevent, or treat the identified disease or condition, outweigh the known and potential risks of the product.

In your letter, you propose developing and implementing a laboratory-developed test for COVID-19 that could be used across multiple public health laboratories with a standard protocol, common sources of reagents, and a standard validation panel and approach. Such a test could be reviewed and, with supporting validation, authorized under a single EUA for use across multiple public health laboratories. In fact, FDA has developed a template to streamline the process to facilitate the protocol that you propose while ensuring FDA's appropriate oversight. Enclosed please find a template to help guide your development and validation of this protocol.

FDA welcomes the review of submissions of diagnostic test information on a rolling basis and is committed to a prompt and interactive review of them. Once you have developed your protocol, the Agency will coordinate closely with the Association of Public Health Laboratories (APHL) to facilitate access to appropriate materials for validation of your test protocol. In past experiences with these rolling reviews, FDA has been able to authorize tests for public health emergencies within as little as 1 day upon receipt of the complete validation. The Agency would be happy to talk with you about options for the timely availability of such tests.

The Agency is currently supporting over 70 developers in the diagnostic space, including some public health laboratories, and FDA looks forward to collaboration with APHL and/or additional member laboratories as well. We welcome dialogue on opportunities to support the development and implementation of validated tests for COVID-19.

Sincerely,

Stephen M. Hahn, M.D.
Commissioner of Food and Drugs

Enclosure