



*Better health through
laboratory medicine.*

May 20, 2020

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

Dear Commissioner Hahn,

On May 16, 2020, the Food and Drug Administration (FDA) used its expedited emergency use authorization (EUA) authority to permit a company to sell its COVID-19 Test Home Collection Kit. The agency's use of its EUA power during the pandemic allows it to circumvent the normal regulatory review process and expedite public access to COVID-19 tests. In this case, the approach resulted in the introduction of an unproven product into the market.

AACC is concerned that the May 16th EUA does not provide adequate information for determining the quality of this kit. This lack of evidence is particularly disconcerting since the company distributing the device did not develop it. A review of the FDA's EUA to this company does not indicate that adequate clinical studies were performed to validate the kit or that good manufacturing practices were followed to develop it. Further, the company selling the kit is not a laboratory.

We urge the FDA to withdraw its approval of this EUA or release the underlying clinical information that served as the basis for its expedited review. Authorization for this test kit should not be granted until the FDA has received and assessed the missing information and has released these data to the public.

AACC supports giving the FDA greater latitude to address public health emergencies, but we believe it is essential that the agency review and publish the underlying scientific evidence that serves as the basis for its decisions. We raised these concerns in an earlier [letter](#). Without this transparency, the healthcare community will be unable to accurately assess the quality of the product.

We understand that increasing the availability of home use collection kits can expand our nation's ability to more quickly diagnose and care for patients with COVID-19. However, physicians and public health officials need accurate test results. Inaccurate results can lead to faulty clinical or public health decisions that could have lasting negative effects in the nation's response to and recovery from the pandemic. Shortcuts, for the sake of increasing test capacity, can do more harm than good.

Commissioner Hahn

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We look forward to working with you on these most important issues of clinical laboratory testing and the quality of the results. To facilitate these interactions, or if you have any questions, please email Vince Stine, PhD, AACC's Senior Director of Government and Global Affairs, at vstine@aacc.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Carmen L. Wiley". The signature is fluid and cursive, with a large, sweeping flourish at the end.

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