AACC Better health through laboratory medicine.

April 30, 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 April 20, 2020, the Food and Drug Administration (FDA) authorized the first home test collection kit for COVID-19. The agency's decision permits the sale of the kit to consumers, with a physician's order, who suspect they may have been exposed to SARS-CoV-2. Kit purchasers will use a swab to collect a specimen from their nasal passage, place the swab in an insulated package, and mail it back to the laboratory for testing.

We share the FDA's goal of expanding consumer access to COVID-19 testing and are confident in Lab Corp's ability to obtain *analytically* correct results from the test. However, serious *preanalytical* concerns associated with home specimen collection kits exist that must be taken into consideration before deploying these kits widely and allowing physicians to make clinical decisions based on results gained from this home collection approach for obtaining the sample.

While home sample collection kits are designed to be simple, problems commonly occur with self-collection that can affect the quality of the sample and, therefore, the subsequent test result. The patient must swipe the appropriate site of the nasopharyngeal passage, collect enough volume of nasal secretion, and handle the swab so the sample is not contaminated (e.g., patient touching the swab, placing it on an unclean surface) to ensure the accuracy of the test. Lab Corp describes the experiments they conducted to obtain this authorization, which showed stability of the live virus that was spiked onto the swabs. But no experiments were publicly shared that demonstrate equivalence between specimens collected by healthcare professionals and specimens collected by the patients themselves at home.

Studies show that home test collection kits that utilize nasal swabs, as with the FDA authorized kit, have a high rate of false negatives compared to the use of nasopharyngeal swabs (these are the type of swabs recommended for use for COVID-19 testing and generally used in healthcare settings). We are concerned that individuals using this form of nasal swab sample collection will be incorrectly told they do not have COVID-19 and thus fail to be treated properly and take appropriate actions to prevent the spread of the disease.

AACC recommends that the FDA recognize these critical preanalytical concerns with this type of home collection and consider issuing a warning related to their use for COVID-19 testing. Consumers may pay a lot of money for a non-covered test that does not definitively tell them whether they are infected. Further, inaccurate test results may further hinder public efforts to contain the current outbreak.

AACC is a global scientific and medical professional organization dedicated to clinical laboratory science and its application to healthcare. AACC brings together more than 50,000 clinical laboratory professionals, physicians, research scientists, and business leaders from around the world focused on clinical chemistry, molecular diagnostics, mass spectrometry, translational medicine, lab management, and other areas of laboratory science to advance healthcare collaboration, knowledge, expertise, and innovation.

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,

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