

Congress of the United States
Washington, DC 20515

April 29, 2020

Dr. Stephen Hahn
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Dear Commissioner Hahn,

While we have yet to receive any response to our April 9th request for information about COVID-19 diagnostic testing, we write again to express great concern about the free-for-all that the FDA is permitting for COVID-19 serology tests. We strongly urge prompt revision of FDA policy. As you and other experts have noted, accurate tests are critical to “flatten the curve” in order to phase out costly “social distancing” strategies. By relinquishing its regulatory authority and failing to validate serology tests, the FDA has permitted the market to be flooded with tests, a number of which are potentially fraudulent. This endangers our Nation by allowing consumers to be duped by aggressive marketers and creating a false sense of security that a “yes or no” test on the presence of antibodies assures immunity.

On March 16th, the FDA issued guidance allowing manufacturers to develop and market serology tests without any FDA review or even submitting an Emergency Use Authorization (EUA) request. The only apparent limitations placed on them under “Pathway D,” is not falsely claiming FDA authorization, and that they self-attest to the FDA self-validation of the test. The FDA has since acknowledged that it is requiring submission of neither any data to demonstrate test validation, nor packaging and marketing materials. We strongly urge you to immediately require the submission of validation data, packaging and marketing materials, and test kits in order to begin prompt validation review by the FDA.

To date, the FDA has not issued any guidance for manufacturers on the design of an accurate serology test or specificity and sensitivity targets that must be met for validation. Other countries have released such guidance, including France, where tests must have 98% specificity and 90-95% sensitivity to be marketed.¹ We strongly urge the FDA to immediately establish such guidance for manufacturers and take action to remove tests from the market that do not meet the specificity and sensitivity goals the FDA requires.

We also request an update on the current status of any information regarding the accuracy of COVID-19 serology tests, which the FDA has received. Please provide the following information by May 8, 2020 in writing and make it publicly available on the FDA’s website:

1. A list of manufacturers who have submitted a completed EUA application for a serology test, which applications have been approved, and a timeline for the review of the remaining applications.

¹ https://www.has-sante.fr/jcms/p_3179992/en/cahier-des-charges-definissant-les-modalites-d-evaluation-des-performances-des-tests-serologiques-detectant-les-anticorps-diriges-contre-le-sars-cov-2

2. The FDA's current policy to validate a serology test under an EUA application, including the sensitivity and specificity targets the test must meet to receive authorization.
3. A list of manufacturers that have voluntarily submitted performance data to the FDA in terms of sensitivity and specificity about their COVID-19 serology tests.
4. A list of manufacturers that have voluntarily submitted their tests under the newly established validation initiative between the FDA, NIH, and CDC. Please include which tests have been fully reviewed, including the name of the test and manufacturer, the results of that review, and a timeline for review of the remaining tests.
5. The FDA's current policy for actions it will take for tests that do not meet sensitivity and/or specificity targets under the validation initiative, or are otherwise found to be faulty or fraudulent.
6. A list of the information the FDA has received from non-manufacturer sources regarding the specificity and sensitivity of COVID-19 serology tests, or any concerns regarding the accuracy of the tests. Please include the name of the manufacturer, the specific test, and the claim and data concerning the test.
7. A list of actions that the FDA has taken in response to performance data submitted by the manufacturer or other sources that demonstrates a test does not meet specificity and/or sensitivity targets, or is otherwise faulty or fraudulent. Please include the name of the manufacturer, the specific test, and the date and reason for the specified action.
8. The FDA's oversight plan to identify any false marketing claims and a list of actions that the FDA has already taken in response to false marketing claims. Please include the name of the manufacturer, the specific test, and the reason for the specified action.
9. The FDA's current and planned education efforts to inform researchers, health care providers, and the public on the accuracy of serology tests, and for what purposes the test results may be used, as well as their limitations.
10. A description and any results of research currently being conducted by the FDA into the number of antibodies needed to likely achieve immunity, and the duration of immunity. Please include the names of agencies and researchers with whom the FDA is collaborating.

The FDA's current guidance fails to provide much-needed information that is crucial for U.S. policymakers and health care providers to protect the health of Americans. Accurate tests are essential to track the prevalence of disease, and eventually to allow individuals to determine their likelihood of immunity. Firm policy, effective enforcement, and data transparency are necessary to help us overcome this pandemic.

We appreciate your timely response and shared commitment to protecting the public's health and safety.

Sincerely,



Lloyd Doggett



Rosa DeLauro