

# Congress of the United States

## House of Representatives

COMMITTEE ON OVERSIGHT AND REFORM

2157 RAYBURN HOUSE OFFICE BUILDING

WASHINGTON, DC 20515-6143

MAJORITY (202) 225-5051  
MINORITY (202) 225-5074  
<http://oversight.house.gov>

April 9, 2020

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

Dr. Robert R. Redfield  
Director  
Centers for Disease Control and Prevention  
1600 Clifton Road  
Atlanta, GA 30329

Dear Commissioner Hahn and Director Redfield:

The Subcommittee on Economic and Consumer Policy seeks information about the regulation and review of coronavirus tests by the Food and Drug Administration (FDA) and the policies regarding coronavirus blood tests issued by the Centers for Disease Control and Prevention (CDC).

Blood tests called “serology tests” identify antibodies in the blood, which can be useful in determining if someone has recovered from coronavirus infection, but they are not as useful in determining if someone currently has the disease. The Subcommittee is concerned that FDA’s decision to permit labs and commercial manufacturers to develop blood-based serology tests without any FDA review may lead to ineffective tests entering the market and the potential unauthorized marketing of these tests for home use. Since antibody tests eventually may be an important part of later phases of our response to the coronavirus crisis, the Subcommittee also would like to hear from CDC about its guidance on the use of serology tests.

Under FDA’s March 16, 2020, policy on diagnostic tests for coronavirus, FDA is allowing companies to use tests while they are preparing Emergency Use Authorizations (EUA) and during FDA’s subsequent review. However, with serology tests, FDA has announced that its approval will not be necessary. Instead, FDA will allow clinical laboratories and commercial manufacturers to develop and distribute serology tests, provided that the manufacturer represents that the test has been validated, FDA is notified, and certain caveats about the use of serology tests are provided with the tests. FDA is not requiring an EUA submission for serology tests

unless they are intended as “the sole basis to diagnose or inform infection status.” FDA’s policy does not authorize any at-home testing or in-home sample collection.<sup>1</sup>

On March 20, 2020, FDA announced that it “is actively and aggressively monitoring the market” and “beginning to see unauthorized fraudulent test kits that are being marketed to test for COVID-19 in the home.”<sup>2</sup> As of April 6, 2020, FDA listed on its website more than 50 commercial manufacturers and laboratories that had notified FDA of a validated serology test, noting that they “will not be pursuing EUAs.”<sup>3</sup>

Pursuant to FDA’s policy, manufacturers have begun taking orders for serology test kits, claiming that point-of-care serological “rapid tests” are a “game changer” and “can help alleviate the burden on the laboratories that are doing testing right now.”<sup>4</sup> Companies have also marketed or prepared to sell serology test kits directly to consumers, stating that they can be performed in the home, a practice which would violate FDA policy.<sup>5</sup> Other companies, such as Scanwell, have sought EUA for at-home serology tests.<sup>6</sup> At least one company has received EUA for a serology test intended for use by medical professionals.<sup>7</sup>

Public health professionals, however, have raised concerns that the tests that have gone on the market, many of which are manufactured in China, pose risks of inaccuracy and a false sense of security that “could be quite dangerous.”<sup>8</sup>

---

<sup>1</sup> Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 During the Public Health Emergency* (Mar. 16, 2020) (online at [www.fda.gov/media/135659/download](http://www.fda.gov/media/135659/download)).

<sup>2</sup> Food and Drug Administration, *Coronavirus (COVID-19) Update: FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits* (Mar. 20, 2020) (online at [www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits](http://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits)).

<sup>3</sup> Food and Drug Administration, *FAQs on Diagnostic Testing for SARS-CoV-2* (online at [www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2](http://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2)) (accessed on Apr. 6, 2020).

<sup>4</sup> *North Carolina Startup Gets Approval for COVID-19 Test That Works in 15 Minutes*, ABC 11, WTVD-TV Raleigh-Durham (Mar. 24, 2020) (online at <https://abc11.com/6046726/>).

<sup>5</sup> STOPCORONA28, *CoronaCide COVID-19 IgM / IgG Rapid Test* (online at [www.stopcorona28.com/](http://www.stopcorona28.com/)) (accessed Mar. 27, 2020); *In-Home COVID-19 Testing Kits Available to Buy on Wednesday in Hays County*, KVUE ABC (Mar. 30, 2020) (online at [www.kvue.com/article/news/health/coronavirus/at-home-coronavirus-testing-kits-at-heb-in-hays-county/269-8fe7d2ec-749c-4d87-a76e-aa864a4fbd9e](http://www.kvue.com/article/news/health/coronavirus/at-home-coronavirus-testing-kits-at-heb-in-hays-county/269-8fe7d2ec-749c-4d87-a76e-aa864a4fbd9e)).

<sup>6</sup> LEMONAID x Scanwell, *Frequently Asked Questions* (online at [www.lemonxscan.com/](http://www.lemonxscan.com/)) (accessed Mar. 31, 2020).

<sup>7</sup> *FDA Authorizes New Two-Minute Serological Test Kit to Detect Novel Coronavirus*, Business Wire (Mar. 31, 2020) (online at [www.businesswire.com/news/home/20200331005420/en/FDA-Authorizes-New-Two-Minute-Serological-Test-Kit](http://www.businesswire.com/news/home/20200331005420/en/FDA-Authorizes-New-Two-Minute-Serological-Test-Kit)).

<sup>8</sup> *‘Crappy’ Tests to Check for Past Coronavirus Infection Are Flooding the US, Lab Association Says*, CNN (Apr. 5, 2020) (online at [www.cnn.com/2020/04/05/health/coronavirus-infection-tests/index.html](http://www.cnn.com/2020/04/05/health/coronavirus-infection-tests/index.html)).

Serology tests can be performed in a matter of minutes at the point of care, such as in a doctor's office or potentially at home. However, serology tests may not be as sensitive as the "gold standard" polymerase chain reaction (PCR) tests, especially during the initial stages of an infection when the body has not yet fully built up its antibody response.<sup>9</sup>

CDC states that it is developing a serology test "to assist with efforts to determine how much of the U.S. population has been exposed to" coronavirus.<sup>10</sup> CDC's current published guidance for state and local health departments and clinicians on criteria and priorities for testing patients with suspected coronavirus infection does not mention serology tests.<sup>11</sup> As of March 4, 2020, CDC reportedly had begun performing antibody tests to determine how widespread the coronavirus infection was among select populations.<sup>12</sup>

To assist the Subcommittee in its oversight of the government's response to coronavirus, we request that FDA and CDC provide a briefing to our staff on the agencies' efforts to protect consumers against fraudulent serological tests and ensure that serological tests are used effectively to combat the coronavirus, including each of the following topics:

1. The status of CDC's development of a serology test;
2. Serology tests currently being performed by CDC, including steps to ensure accuracy and source of manufacture of tests;
3. How serology tests can and should be used to support clinical diagnosis and surveillance testing, including the feasibility and utility of at-home testing;
4. FDA's review of EUAs for diagnostic tests, including the number of tests authorized for distribution under FDA's policy, the length of time from test validation to EUA submission, and the length of time for FDA's review;
5. Problems with diagnostic tests identified during FDA's EUA review and actions taken in response, including any recalls;
6. Efforts to review the reliability of serology tests distributed pursuant to FDA policy;

---

<sup>9</sup> *Fast, Portable Tests Come Online to Curb Coronavirus Pandemic*, Nature Biotechnology (Mar. 23, 2020) (online at [www.nature.com/articles/d41587-020-00010-2](http://www.nature.com/articles/d41587-020-00010-2)).

<sup>10</sup> Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Testing* (online at [www.cdc.gov/coronavirus/2019-ncov/about/testing.html](http://www.cdc.gov/coronavirus/2019-ncov/about/testing.html)) (accessed Mar. 27, 2020).

<sup>11</sup> Centers for Disease Control and Prevention, *Coronavirus Disease 2019 (COVID-19): Evaluating and Testing PUI* (online at [www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html](http://www.cdc.gov/coronavirus/2019-nCoV/hcp/clinical-criteria.html)) (accessed Mar. 27, 2020).

<sup>12</sup> *CDC Begins Blood Tests to Find Undetected Coronavirus Cases*, Politico (Apr. 4, 2020) (online at [www.politico.com/news/2020/04/04/cdc-coronavirus-blood-tests-165116](http://www.politico.com/news/2020/04/04/cdc-coronavirus-blood-tests-165116)).

The Honorable Dr. Stephen M. Hahn

Dr. Robert R. Redfield

Page 4

7. Efforts to ensure compliance with FDA's policy for serology tests, including requirements that tests not be provided for at-home testing and that test reports include required information;
8. Efforts to monitor for, and remove from the market, serology tests that are fraudulent or not in compliance with FDA policy, such as those being distributed for at-home testing or without required information; and
9. Efforts to inform healthcare providers and consumers about recommended uses for serology tests and to warn consumers about non-compliant or fraudulent serology tests.

Please contact Subcommittee staff by April 14, 2020, to confirm your agency's participation in a briefing to take place by April 17, 2020.

The Committee on Oversight and Reform is the principal oversight committee of the House of Representatives and has broad authority to investigate "any matter" at "any time" under House Rule X. If you have any questions regarding this request, please contact Subcommittee staff at (202) 225-5051.

Sincerely,



---

Raja Krishnamoorthi

Chairman

Subcommittee on Economic and Consumer Policy

cc: The Honorable Michael Cloud, Ranking Member  
Subcommittee on Economic and Consumer Policy