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Medical Countermeasures Initiative Update

May 27, 2020



## Coronavirus Disease 2019 (COVID-19) Update

FDA is an active partner in the coronavirus disease (COVID-19) response, working closely with our government and public health partners across the U.S. Department of Health and Human Services, and with our international counterparts. Actions by the FDA in our ongoing response to the COVID-19 pandemic since our last MCMi email update on May 20, 2020 include:

### Coronavirus (COVID-19) Updates:

- May 26, 2020: [Daily Roundup](#): FDA actions on antibody testing updates, new abbreviated new drug applications, guidance on medical devices and more
- May 21, 2020: [FDA Provides Promised Transparency for Antibody Tests](#)
- *Also see the features and Emergency Use Authorization Updates below*

[COVID-19 Updates from FDA](#)

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## Emergency Use Authorization (EUA) Updates

### Antibody test transparency

On May 21, 2020, FDA posted a [list of antibody tests](#) that are being removed from the “notification list” of tests being offered under the [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency](#). Antibody tests on this new removal list include those voluntarily withdrawn from the notification list by the test’s commercial manufacturer and those for which there is not a pending EUA request or issued EUA. The FDA expects that the tests on the removal list will not be marketed or distributed. Antibody tests offered by commercial manufacturers as outlined under the policy, which was issued on March 16 and updated on May 4, continue to be located on the notification list pending review of their EUA request.



### Testing FAQ updates

The FDA updated the [FAQs on Testing for SARS-CoV-2](#) to clarify information about at-home self-collection and what tests should no longer be distributed for COVID-19.

### U.S. Army EUA

The FDA [issued an EUA](#) (PDF) to Walter Reed National Military Medical Center for the COVID-19 Airway Management Isolation Chamber (“CAMIC”) to be used by healthcare providers within the U.S. Army and Military Health System as an extra layer of barrier protection, in addition to personal protective equipment, to prevent exposure to pathogenic biological airborne particulates during transport of patients, at the time of definitive airway management, or when performing medical procedures on such patients during the COVID-19 pandemic. The CAMIC system is a barrier device constructed by draping a large clear plastic bag over a box-like frame that is placed over the head, neck, and shoulders of the patient to isolate (i.e., capture and remove) airborne particulates.

### Diagnostic test EUAs

During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus. To date, the FDA has [authorized](#) 104 tests under EUAs, which include 100 molecular tests, 12 antibody tests, and 1 antigen test.

### Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests

**Today! May 27, 2020:** FDA will host a virtual Town Hall for clinical laboratories and commercial manufacturers that are developing or have developed diagnostic tests for SAR-CoV-2, 12:15 p.m. - 1:15 p.m. ET. FDA will host additional town halls in this series on Wednesdays in June.

### Related links:

- [What is an EUA?](#) (video)
- [FAQs on Diagnostic Testing for SARS-CoV-2](#) (frequently updated)
- [EUA Authorized Serology Test Performance](#)

- [FDA Combating COVID-19 with Medical Devices \(PDF\)](#)
  - [Contacts for Medical Devices During the COVID-19 Pandemic](#)
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## Information for industry

- **Food:**
  - The U.S. Department of Agriculture (USDA) and the FDA announced that the agencies signed a [Memorandum of Understanding \(MOU\)](#) to support the U.S. food and agriculture sector so that Americans can continue to have access to a safe and robust food supply. As a next step in carrying out [Executive Order 13917](#), the MOU sets up a process to help prevent interruptions at FDA-regulated food facilities, including fruit and vegetable processing, in which the two agencies can make determinations about circumstances in which the USDA could exercise its authority under the Defense Production Act.
  - The FDA and USDA also released [recommendations](#) to help address shortages of personal protective equipment (PPE), cloth face coverings, disinfectants, and sanitation supplies in the food and agriculture industry during the COVID-19 pandemic.
- The FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid COVID-19 response efforts. FDA has issued more than 40 COVID-19-related guidances to date.

[COVID-19-Related Guidance Documents](#)

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## In case you missed it

- In a new video, [Donate Blood and Plasma to Make a Difference](#), the FDA explains one way you can make a difference is to donate blood or plasma if you are eligible to donate.



- [FDA At-A-Glance COVID-19 Response Summary \(PDF\)](#) - a quick look at facts, figures, and highlights of FDA's response efforts (*updated May 22, 2020*)
- New resource from HHS - [ASPR's Portfolio of COVID-19 Medical Countermeasures under Investigation \(May 21, 2020\)](#)
- [FDA Approves Only Drug in U.S. to Treat Severe Malaria \(May 26, 2020\)](#)
- Register by **June 5, 2020** for the [FDA Training Course: Achieving Data Quality and Integrity in Clinical Trials Involving High-Consequence Pathogens](#), scheduled for July 27-31, 2020 in Omaha, Nebraska. Professionals who have experience with high-consequence pathogen clinical trials are

encouraged to apply to attend.

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