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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

**May 13, 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 6, 2020 include:

### Coronavirus (COVID-19) Updates:

- May 12, 2020: Daily Roundup: FDA actions on treatment acceleration, inspection updates, and more
- May 11, 2020: FDA Takes New Actions to Accelerate Development of Novel Prevention, Treatment Options for COVID-19
- May 11, 2020: FDA updates on surveillance inspections during COVID-19
- May 9, 2020: FDA Authorizes First Antigen Test to Help in the Rapid Detection of the Virus that Causes COVID-19 in Patients
- May 8, 2020: FDA Authorizes First Diagnostic Test Using At-Home Collection of Saliva Specimens

May 7, 2020: FDA Continues to Combat Fraudulent COVID-19 Medical Products

- *Also see the features and Emergency Use Authorization Updates below*

**COVID-19 Updates from FDA**

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## COVID-19 Social Media Toolkit

The FDA Office of Minority Health and Health Equity has published a bilingual social media toolkit, with graphics and information in English and Spanish. (The popular video pictured above, 12 Tips for Grocery Shopping During the Pandemic, is also available in Spanish.)

**View the toolkit**

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## Emergency Use Authorization (EUA) Updates

**Diagnostic test EUAs**
During the COVID-19 pandemic, FDA has worked with more than 500 test developers who have said they will be submitting EUA requests to FDA for tests that detect the virus. To date, 93 tests have been authorized by FDA, including 12 serology tests, and 1 antigen test.

**On May 11, 2020, FDA updated the Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance to include a new section that references the availability**


**of EUA submission templates for molecular, antigen (new), and serology tests.** *Also see: In Vitro Diagnostics EUAs*

**FDA research supports EUA authorizations**

On May 7, 2020, FDA issued an EUA (PDF) for the Duke Decontamination System for use in decontaminating compatible N95 or N95-equivalent respirators for reuse by health care personnel when there are insufficient supplies of these respirators resulting from the COVID-19 pandemic. This is the sixth respirator decontamination system FDA has authorized for emergency use during this pandemic and the second based on public health emergency preparedness research funded by FDA.

**Firsts this week**

On May 6, 2020, FDA issued an EUA (PDF) to Sherlock BioSciences, Inc.'s Sherlock CRISPR SARS-CoV-2 Kit., the first authorized use of CRISPR technology for an infectious disease test. On May 7, 2020, FDA issued an EUA (PDF) for the first diagnostic test with the option of using home-collected saliva samples for COVID-19 testing, and on May 8, 2020, issued an EUA (PDF) for the first antigen test, a new category of tests for use in the ongoing pandemic. Antigen tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs.

**EUA to support certain patients who require mechanical ventilation**

The virus that causes COVID-19 has led to an increased number of people with severe respiratory illness. As a result, there is a shortage of adequate, FDA-approved and available alternative drugs such as propofol that are used for sedation of mechanically ventilated patients. On May 8, 2020, FDA issued an EUA for the Fresenius Propoven 2% Emulsion, authorized to maintain sedation via continuous infusion in patients older than 16 who require mechanical ventilation in an ICU during the COVID-19 public health emergency. Fresenius Propoven 2% Emulsion has important differences in its formulation compared to the FDA-approved propofol drugs; providers should consult the Health Care Provider Fact Sheet (PDF) for more information before administering it.

**Non-NIOSH-approved respirator EUA update**

On May 7, 2020, FDA reissued the EUA (PDF) for non-NIOSH-approved respirators manufactured in China. Read more in the May 7, 2020 Daily Roundup.

**Reminder: FDA Sets up 24/7 Hotline to Help Labs with Diagnostic Test Issues**

FDA's 24/7 hotline (1-888-INFO-FDA, choose option *) is available for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs and media needed for transport and conservation of the samples.

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

**Today! May 13, 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 May.

**Related links:**

- What is an EUA? (video)
- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- EUA Authorized Serology Test Performance
- Emergency Use Authorizations (Devices)
- FDA Combating COVID-19 with Medical Devices (PDF)

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## Information for industry

**Masks: For individuals and organizations who are new to working with the FDA**

If you are interested in manufacturing face masks or surgical masks—or purchasing, importing, or donating these types of masks—FDA has a new web resource that helps answer your questions and provides next steps for action. *(May 11, 2020)*

**Other updates for industry**

- **Food:** FDA issued two documents designed to assist retail food establishments that might have been closed or partially closed during the COVID-19 pandemic in preparing to reopen. The checklist and infographic documents are designed to help businesses that prepare food to serve or sell to the public directly, such as restaurants, bakeries, bars and carry-outs, protect employee and public health as they reopen for business. *(May 8, 2020)*
- **Drugs and biologics guidances:** COVID-19: Developing Drugs and Biological Products for Treatment or Prevention, and General Considerations for Pre-IND Meeting Requests for COVID-19 Related Drugs and Biological Products *(May 11, 2020)*
- 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

- Donate COVID-19 Plasma - If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by donating your plasma.

- 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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