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Medical Countermeasures Initiative Update

April 15, 2020

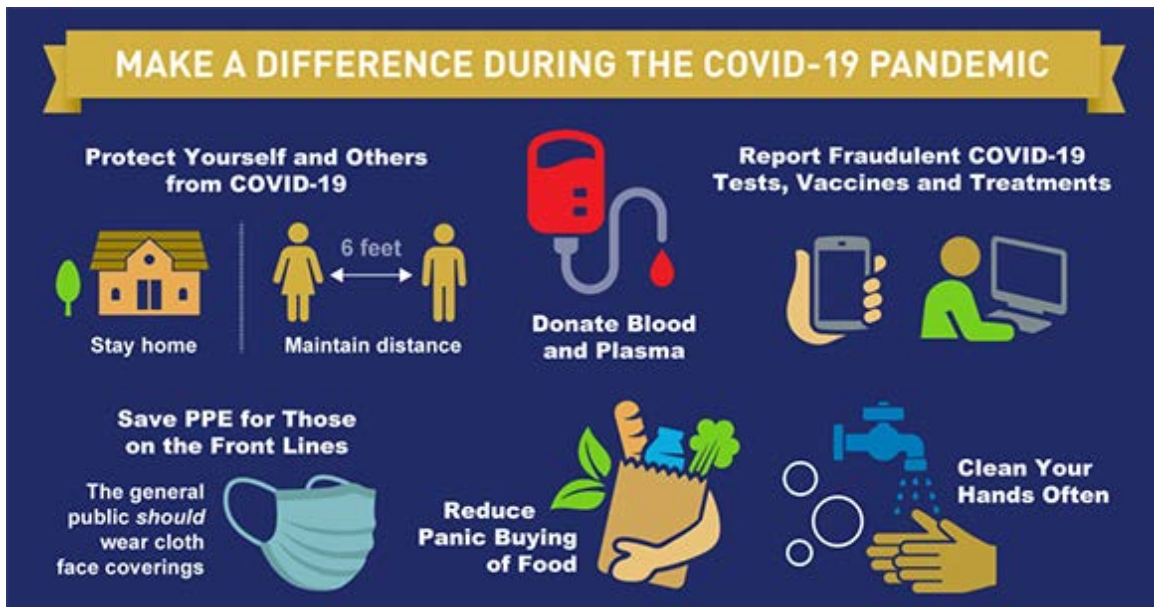


## Coronavirus Disease 2019 (COVID-19) Update

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 April 8, 2020 include:

### Coronavirus (COVID-19) Updates:

- April 14, 2020: [Daily Roundup](#): FDA actions on warning letters, updated consumer information on testing, and more in its ongoing response to the COVID-19 pandemic.
- More Daily Roundups (Monday - Friday) - Go to [www.fda.gov/coronavirus](http://www.fda.gov/coronavirus), and select Daily Roundup (Type of Information) under [Latest COVID-19 Information From the FDA](#)
- April 10, 2020: [A Perspective on the FDA's COVID-19 Response](#)
- April 9, 2020: [FDA Combating COVID-19 with Therapeutics](#) (PDF)
- *Also see [Emergency Use Authorization Updates](#) below*



## How You Can Make a Difference During the Coronavirus Pandemic

The COVID-19 pandemic has created challenges in our everyday lives. As we each do our part to help slow the spread of coronavirus disease, we look to the helpers all around us and wonder if we, too, could do more. Here are some ways you and your family can help.

[Read more](#)

## Emergency Use Authorization (EUA) Updates

### More EUAs to decontaminate N95 respirators

FDA **issued an EUA** to decontaminate compatible N95 or N95-equivalent respirators for reuse by health care workers in hospital settings. The FDA issued the EUA to STERIS Corporation for the STERIS V-PRO 1 Plus, maX and maX2 Low Temperature Sterilization Systems using the STERIS N95 Decontamination Cycle (non-lumen cycle), which uses vaporized hydrogen peroxide. This EUA will support decontamination of approximately 750,000 N95 respirators per day in the U.S. (April 10, 2020)

FDA also **issued an EUA** to Advanced Sterilization Products (ASP) for the STERRAD Sterilization Cycles that has the potential to decontaminate approximately 4 million N95 or N95-equivalent respirators per day in the U.S. for single-user reuse by health care



workers in hospital settings. This authorization will help increase the availability of respirators so health care workers on the front lines can be better protected and provide the best care to patients with COVID-19. *(April 11, 2020)*

### **Blood purification system**

FDA [issued an EUA](#) for a blood purification system to treat patients 18 years of age or older with confirmed COVID-19 admitted to the intensive care unit with confirmed or imminent respiratory failure. The FDA issued the EUA to Terumo BCT Inc. and Marker Therapeutics AG for their Spectra Optia Apheresis System and Depuro D2000 Adsorption Cartridge devices. *(April 10, 2020)*

### **33 diagnostic EUAs issued to date**

In the COVID-19 pandemic, the FDA has worked with more than 160 test developers who have said they will be requesting EUAs for tests that detect the virus. To date, 33 EUAs have been [issued for nationwide use](#). Under our [laboratory developed test policy](#) (PDF) during COVID-19, the FDA has been notified by more than 180 laboratories.

### **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! April 15, 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 also plans to hold virtual town halls for clinical laboratories and commercial manufacturers to help answer questions on **April 22 and 29**.

#### **Related links:**

- [FAQs on Diagnostic Testing for SARS-CoV-2](#) (frequently updated)
- [Emergency Use Authorizations](#) (Devices)
- [FDA Combating COVID-19 with Medical Devices](#) (PDF)
- [Information for Laboratories Implementing IVD Tests Under EUA](#)
- [Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency](#) *(updated March 16, 2020)*

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## **Information for industry**

- **Reminder:** [FDA-ARGOS SARS-CoV-2 Reference Grade Sequence Data Now Available](#) - In response to the COVID-19 pandemic, the FDA—in collaboration with the Centers for Disease Control (CDC), the Biodefense and Emerging Infections Research Resources Repository (BEI Resources), the Institute for Genome Sciences at the University of Maryland and the National Center for Biotechnology Information (NCBI)—developed quality-controlled, reference sequence data for the SARS-CoV-2 reference strain for the United States. *(April 1, 2020)*
- [Product-Specific Guidances for Chloroquine Phosphate and Hydroxychloroquine Sulfate](#) *(April 13, 2020)*
- [FDA Letter to Stakeholders: Do Not Use Ivermectin Intended for Animals as Treatment for COVID-19 in Humans](#) *(April 10, 2020)*
- [Temporary Policy Regarding Non-Standard PPE Practices for Sterile Compounding by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency: Guidance for Industry](#) *(April 10, 2020)*
- [Guidance for Industry: Policy for the Temporary Use of Portable Cryogenic Containers Not in Compliance With 21 CFR 211.94\(e\)\(1\) For Oxygen and Nitrogen During the COVID-19 Public Health Emergency](#) *(April 9, 2020)*
- [Investigational COVID-19 Convalescent Plasma: Guidance for Industry](#) *(April 8, 2020)*
- [FAQs on Shortages of Surgical Masks and Gowns](#) *(updated April 9, 2020)*
- The FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid coronavirus disease 2019 (COVID-19) response efforts. Please bookmark our new web page, [COVID-19-Related Guidance Documents for Industry, FDA Staff, and Other Stakeholders](#), for the latest information (button below).

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

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## In case you missed it

- [Coronavirus Disease 2019 \(COVID-19\) Frequently Asked Questions](#)
- [What You Need to Know: Food and COVID-19 PSA with Frank Yiannas](#) (30-second video - download and share!)
- [Importing COVID-19 Supplies](#)
- Web pages with [COVID-19 information from the FDA Centers for Drug Evaluation and Research \(CDER\)](#), including information on clinical trials, drug shortages, hand sanitizers, manufacturing, supply chain, and more.
- [HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus](#) *(March 6, 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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