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Medical Countermeasures Initiative Update

June 3, 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 27, 2020 include:

### Coronavirus (COVID-19) Updates:

- June 2, 2020: [Daily Roundup](#): FDA actions on food safety, guidance on single-member IRBs, an authorized NASA ventilator, and more
- June 2, 2020: [Pandemic Challenges Highlight the Importance of the New Era of Smarter Food Safety](#)
- June 1, 2020: [Remarks by Commissioner Stephen Hahn, M.D. — The COVID-19 Pandemic — Finding Solutions, Applying Lessons Learned](#) (with video)
- June 1, 2020: [FDA Takes Action to Protect Public Health; Increase Supply of Alcohol-Based Hand Sanitizer](#)

- [May 29, 2020: Bringing a Cancer Doctor's Perspective to FDA's Response to the COVID-19 Pandemic](#), by Stephen M. Hahn, M.D., Commissioner of Food and Drugs
- [May 29, 2020: FDA Takes Steps to Streamline Development of Tests With At-Home Sample Collection](#)
- [May 27, 2020: FDA Provides New Tool to Aid Development and Evaluation of Diagnostic Tests That Detect SARS-CoV-2 Infection](#)
- *Also see the features and Emergency Use Authorization Updates below*

## COVID-19 Updates from FDA



## Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19

There's a lot of confusion about which medical products might work to prevent or treat coronavirus disease 2019 (COVID-19). Scientists are working hard to develop a number of potential drugs for the prevention or treatment of coronavirus, but none are currently approved by the FDA for these purposes.

The language used to describe potential therapies can be confusing, and there's public interest around the FDA's work to ensure access to potentially life-saving treatments. Here's what those terms mean.

[Read the Consumer Update](#)

## Using COVID MyStudies for eConsent...

FDA

Easy as 1 2 3

1

Contact FDA at  
[CDERMedicalPolicy-RealWorldEvidence@fda.gov](mailto:CDERMedicalPolicy-RealWorldEvidence@fda.gov)

2

Coordinate with the  
COVID MyStudies app team  
(managed by a trusted 3rd party)

3

Use the app to send informed consent  
documents to patients or their legally  
authorized representatives

Investigators and patients or their  
representatives receive copies of  
completed digital informed  
consent documents

### COVID MyStudies App

FDA is making its previously developed FDA MyStudies app available to investigators as a free platform to securely obtain patients' informed consent for eligible clinical trials when face-to-face contact is not possible or practical due to COVID-19 control measures. FDA MyStudies is now referred to as **COVID MyStudies** in the Apple App and Google Play stores.

### Emergency Use Authorization (EUA) Updates

#### FDA makes reference panel available to test developers

On May 27, 2020, the FDA further supported its effort to evaluate diagnostic tests of COVID-19 by [providing a SARS-CoV-2 reference panel](#). This panel is an independent performance validation step for diagnostic tests of SARS-CoV-2 infection that are being used for clinical, not research, purposes.

The FDA panel is available to commercial and laboratory developers who are interacting with the FDA through the [pre-EUA process](#) or whose tests have been issued an EUA. The FDA will provide the reference panel to developers at the appropriate stage in the process. There is no need for these test developers to take additional action in order to receive the reference panel.

#### New template

On May 29, 2020, FDA took steps to further support the development of [COVID-19 tests for at-home self-collection](#) by providing on its website a [template](#) that may be used to facilitate submission of EUA requests for at-home sample collection kits.



### **Additional respirator decontamination system authorized**

On May 27, 2020, FDA [issued an EUA](#) (PDF) for the Stryker Sustainability Solutions (SSS) VHP N95 Respirator Decontamination System (RDS). This product uses vapor hydrogen peroxide (VHP) to decontaminate compatible N95 respirators that are, or potentially are, contaminated with SARS-CoV-2 or other pathogenic microorganisms for multiple-user reuse by healthcare personnel to prevent exposure to pathogenic biological airborne particulates when there are insufficient supplies of face-filtering respirators (FFRs) resulting from the COVID-19 pandemic. Read more in the [May 28, 2020 Daily Roundup](#).

### **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](#) 119 tests under EUAs, which include 103 molecular tests, 15 antibody tests, and 1 antigen test.

### **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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## **Events**

- **Today! June 3, 2020:** [Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus \(COVID-19\) Diagnostic Tests](#) - 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.
  - **Last chance!** 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.
  - **June 9, 2020 webinar:** [FDA Drug Topics: CURE ID: Capturing Clinician's Experiences Repurposing Drugs to Inform Future Studies in the Era of COVID-19](#), 1:00 p.m. ET - This webinar will demonstrate [CURE ID](#) – a mobile app and web platform developed by FDA and NCATS/NIH, that gives the global clinical community the opportunity to report novel uses of existing drugs for patients with difficult-to-treat infectious diseases, including COVID-19. [Register](#) in advance.
  - **June 9-10, 2020 webcast:** [Regulatory Education for Industry \(REdI\): Pharmacovigilance and Risk Management Conference – New Approaches, Tools, and Technologies](#) - [Register](#) in advance.
  - **June 11, 2020 FDA Grand Rounds webcast:** [A Pandemic and a Call to Action for One Health: The FDA One Health Initiative](#) - 12:00 - 1:00 p.m., ET, CE credit available. [Register](#) in advance.
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## Information for industry

- **Devices:**
  - FDA issued a [letter to health care providers](#) to remind reprocessing staff in health care facilities to use the correct sterilization cycle associated with certain models of the Advanced Sterilization Products (ASP) STERRAD Sterilization Systems and to only decontaminate compatible N95 or N95-equivalent respirators for reuse during the COVID-19 pandemic. These sterilization systems help increase the availability of respirators by allowing decontaminated compatible respirators to be reused so health care workers on the front lines can be better protected when providing care to patients with COVID-19. (May 27, 2020)
  - FDA issued two guidance documents (one new guidance and one revised guidance) for industry to help address potential shortages of face masks, surgical masks, respirators, and face shields for use during the COVID-19 public health emergency: [Recommendations for Sponsors Requesting EUAs for Decontamination and Bioburden Reduction Systems for Face Masks and Respirators During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency and Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease \(COVID-19\) Public Health Emergency \(Revised\)](#) (May 27, 2020)
- **Drugs and biologics:**
  - [Effects of the COVID-19 Public Health Emergency on Formal Meetings and User Fee Applications — Questions and Answers](#) (May 26, 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 50 COVID-19-related guidances to date.

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

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## In case you missed it

- **Medical Gloves for COVID-19** - FDA has released a comprehensive resource about medical gloves during the COVID-19 public health emergency. Check this resource to get answers to questions about glove shortages, manufacturing and importing gloves, purchasing gloves, and more.
- New web page: [Coronavirus Disease 2019 \(COVID-19\) Resources for Health Professionals](#)
- Check out FDA's [COVID-19 YouTube playlist](#) for short videos for consumers on coronavirus topics.
- From HHS - The [National Advisory Committee on Children and Disasters](#) is accepting applications for new members until **June 27, 2020**. Related: [YouTube video about applying](#)



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