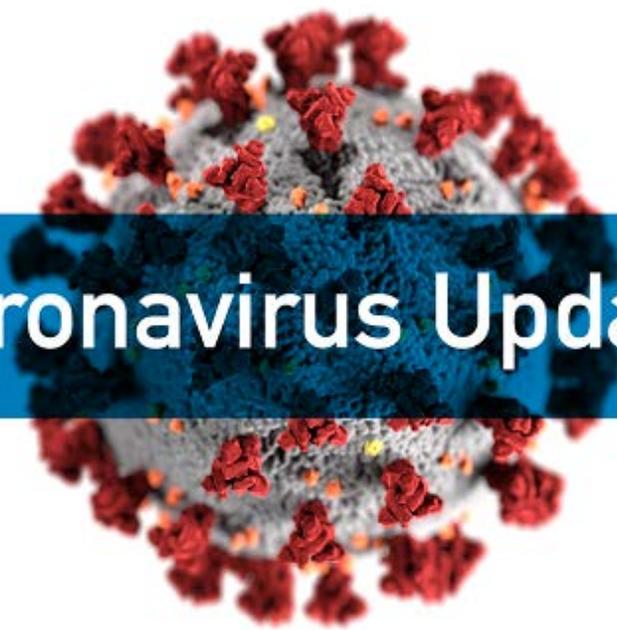


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Medical Countermeasures Initiative Update

April 8, 2020

A detailed 3D rendering of a coronavirus particle, showing its characteristic spherical shape with a grey outer shell and red, spike-like protrusions. The particle is centered in the background of the main content area.

Coronavirus Update

A smaller version of the FDA logo, consisting of the letters "FDA" in white on a blue square background.

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 1, 2020 include:

Coronavirus (COVID-19) Updates:

- Daily Roundups (Monday - Friday) - Go to www.fda.gov/coronavirus, and select Daily Roundup (Type of Information) under [Latest COVID-19 Information From the FDA](#)
- April 7, 2020 - [Serological Tests](#)
- April 3, 2020 - [FDA Coordinates National Effort to Develop Blood-Related Therapies for COVID-19](#)
- April 2, 2020 - [FDA Provides Updated Guidance to Address the Urgent Need for Blood During the Pandemic](#)



FDA Commissioned Corps Officers on the Front Line of COVID-19 Response

Almost 400 FDA Commissioned Corps officers deployed to aid in response to the coronavirus public health emergency

USPHS Commissioned Corps officers are highly-trained public health professionals who work nationally and internationally in careers such as medicine, veterinary sciences, dentistry, nursing, epidemiology and biomedical research to serve underserved and vulnerable communities. During the President's [30 Days to Slow the Spread](#) (PDF) nationwide effort and beyond, the Commissioned Corps officers are focused on helping the most vulnerable among us. *(April 2, 2020)*

[Read more](#)

Emergency Use Authorization (EUA) Updates

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.

30 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, 30 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 65 laboratories.

New FAQ on KN95s

On April 3, 2020, the FDA [posted a new FAQ](#) on KN95s: Can respirators approved under standards used in other countries, such as KN95, be used in the US during the COVID-19 pandemic? Short answer: Yes, if in accordance with certain criteria.

New Respirator EUA

On April 3, 2020, the FDA [issued a new EUA](#) specifically for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators Manufactured in China. Under this EUA, authorized respirators listed in Appendix A are authorized for use in healthcare settings by healthcare personnel when used in accordance with CDC recommendations to prevent wearer exposure to pathogenic biological airborne particulates during FFR shortages resulting from the COVID-19 outbreak.

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

Today! April 8, 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 15, 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) - new April 5, 2020, updated frequently
- [Information for Laboratories Implementing IVD Tests Under EUA](#)
- [FDA Issues New Policy to Help Expedite Availability of Diagnostics](#) (February 29, 2020)

Information for industry

- [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*)
- [Enforcement Policy for Face Masks and Respirators \(Revised\)](#) - On April 2, 2020, the FDA revised an immediately in effect guidance to provide a policy to help expand the availability of general use face masks for the general public and particulate filtering facepiece respirators (including N95 and KN95 respirators) for health care professionals during this pandemic. This guidance updates the previous version of the guidance published on March 25, 2020. This update provides recommendations regarding face shields, surgical masks, and alternatives, which may include KN95 respirators, when FDA-cleared or NIOSH-approved N95 respirators are not available.
- 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](#)

In case you missed it

- [Coronavirus Disease 2019 \(COVID-19\) Frequently Asked Questions](#) (www.fda.gov/coronavirusFAQ)
- [Fraudulent Coronavirus Disease 2019 \(COVID-19\) Products](#) - FDA is actively monitoring for any firms marketing products with fraudulent COVID-19 prevention and treatment claims.
- [Food Safety and Availability During the Coronavirus Pandemic](#) - FDA is working in many ways to help keep people safe while the nation is coping with the coronavirus pandemic (COVID-19). Food availability and food safety are vitally important to our well-being, and the FDA is working hard to help ensure the foods you, your family, and your pets eat are safe and available. (Includes a short, new video for consumers.)
- [FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19](#) – An FDA Voices perspective from Deputy Commissioner for Food Policy and Response Frank Yiannas. (*April 2, 2020*)
- [What You Need to Know: Food and COVID-19 PSA with Frank Yiannas](#) (30-second video - download and share!)
- [Importing COVID-19 Supplies](#) - new web page

- New web pages with [COVID-19 information from the FDA Centers for Drug Evaluation and Research \(CDER\)](#), including:
 - [Clinical trial conduct](#)
 - [Drug shortage response](#)
 - [Hand sanitizers](#)
 - [Manufacturing and supply chain](#)
 - [Import of drugs for potential COVID-19 treatment](#)
 - [Registration and listing assistance for non-traditional manufacturers or hand sanitizer and related COVID-19 drugs](#)
- [FDA Efforts to Connect Manufacturers and Health Care Entities: COVID-19 Response Public-Private Partnership](#) - FDA entered a Memorandum of Understanding (MoU) with the Department of Veterans Affairs (VA) Innovation Ecosystem and the National Institutes of Health (NIH) 3D Print Exchange, to share data, and coordinate on open-source medical products for the COVID-19 response with other stakeholders such as America Makes (*March 25, 2020*)
- [HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus](#) (*March 6, 2020*)

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