

If your email program has trouble displaying this email, [view it as a web page](#).



Medical Countermeasures Initiative Update

March 25, 2020

A 3D rendering of a coronavirus particle, showing its characteristic spherical shape with a grey outer shell and red, spike-like protrusions.

Coronavirus Update

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 March 18, 2020 include:

Coronavirus (COVID-19) Updates:

- March 24, 2020 - [Daily roundup](#) (on a variety of FDA actions)
- March 24, 2020 - [FDA takes action to increase U.S. supplies through instructions for PPE and device manufacturers](#)
- March 24, 2020 - [FDA Helps Facilitate Veterinary Telemedicine During Pandemic](#)
- March 23, 2020 - [Daily roundup](#) (on a variety of FDA actions)
- March 22, 2020 - [FDA provides update on patient access to certain REMS drugs during COVID-19 public health emergency](#)

- [March 22, 2020 - FDA Continues to Facilitate Access to Crucial Medical Products, Including Ventilators](#)
- [March 21, 2020 - FDA Issues first Emergency Use Authorization for Point of Care Diagnostic](#)
- [March 20, 2020 - FDA Alerts Consumers About Unauthorized Fraudulent COVID-19 Test Kits](#)
- [March 20, 2020 - FDA allows expanded use of devices to monitor patients' vital signs remotely](#)
- [March 20, 2020 - FDA provides guidance on production of alcohol-based hand sanitizer to help boost supply, protect public health](#)
- [March 19, 2020 - FDA Continues to Facilitate Development of Treatments](#)
- [March 19, 2020 - Blood Donations](#)
- [March 18, 2020 - FDA Focuses on Safety of Regulated Products While Scaling Back Domestic Inspections](#)
- [March 18, 2020 - FDA Issues Guidance for Conducting Clinical Trials](#)

[COVID-19 Updates from FDA](#)

FDA and EMA Collaborate to Facilitate SARS-CoV-2 Vaccine Development

FDA and the European Medicines Agency (EMA) jointly chaired the first global regulators meeting to discuss regulatory strategies to streamline the development of SARS-CoV-2 vaccines. *(March 23, 2020)*

[Read this FDA Voices](#)

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.

16 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 submitting applications to make tests that detect the virus. To date, 16 EUAs have been issued for nation-wide use--7 in the last week, including the [first point-of-care diagnostic](#). Under our [laboratory developed test policy](#) (PDF) during



COVID-19, the FDA has been notified by more than 65 laboratories.

Today! March 25, 2020, 3:00 - 4:00 p.m. ET

FDA will hold a [Virtual Town Hall for the Immediately in Effect Guidance on Coronavirus \(COVID-19\) Diagnostic Tests](#)

Non-NIOSH Approved Respirator EUA (March 24, 2020)

In response to this evolving public health emergency and continued filtering facepiece respirator (FFR or respirator) shortages, FDA has concluded based on the totality of scientific evidence available that certain imported disposable FFRs that are not NIOSH-approved are appropriate to protect the public health or safety (as described under section II Scope of Authorization) under section 564 of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 360bbb-3). Under this EUA, authorized respirators listed in Exhibit 1 are authorized for use in healthcare settings by healthcare personnel (HCP) 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.

- [Letter of authorization \(PDF\)](#)
- [Non-NIOSH Approved Respirator EUA FAQ](#)

Related links:

- [FAQs on Diagnostic Testing for SARS-CoV-2 \(frequently updated\)](#)
 - [Emergency Use Authorizations \(Devices\)](#)
 - [Information for Laboratories Implementing IVD Tests Under EUA](#)
 - [FDA Issues New Policy to Help Expedite Availability of Diagnostics \(February 29, 2020\)](#)
-

Information for industry

- [Medical Glove Conservation Strategies: Letter to Health Care Providers \(March 20, 2020\)](#) - Also see: [FAQs on Shortages of Medical Gloves](#)
- [Ventilator Supply Mitigation Strategies: Letter to Health Care Providers \(March 22, 2020\)](#) - Also see: [Enforcement Policy for Ventilators and Accessories and Other Respiratory Devices During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#)
- [Final guidance: Postmarketing Adverse Event Reporting for Medical Products and Dietary Supplements During a Pandemic \(March 20, 2020\)](#)
- [Updated Instructions for Submitting Lot Release Samples and Protocols for CBER-regulated Products During the COVID-19 Pandemic \(March 19, 2020\)](#)
- 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](#)

In case you missed it

- [Coronavirus Disease 2019 \(COVID-19\) Frequently Asked Questions](#) (www.fda.gov/coronavirusFAQ)
- [Preguntas más frecuentes acerca de la Enfermedad del Coronavirus 2019 \(COVID-19\) – Coronavirus Disease 2019 \(COVID-19\) Frequently Asked Questions](#) are now available in Spanish
- [Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments](#) (March 24, 2020) - Also see: [Fraudulent Coronavirus Disease 2019 \(COVID-19\) Products](#)
- [FDA Offers Assurance About Food Safety and Supply for People and Animals During COVID-19](#) (March 24, 2020)
- [FDA advises patients on use of non-steroidal anti-inflammatory drugs \(NSAIDs\) for COVID-19](#) (March 19, 2020)
- The FDA Medical Countermeasures initiative (MCMi) published its [FY 2019 program update report](#) (March 18, 2020)
- [HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus](#) (March 6, 2020)

Did someone forward you this email? [Subscribe](#)

(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)



Twitter: [@FDA_MCMi](#)
www.fda.gov/medicalcountermeasures

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)
[Privacy Policy](#) | www.fda.gov