U.S. FOOD & DRUG ADMINISTRATION

FDA COVID-19 Response

At-A-Glance Summary *as of August 14, 2020*

The U.S. Food and Drug Administration, along with other federal, state, and local agencies and public health officials across the country, continues critical work to protect public health during the pandemic of COVID-19. Major focus areas of the FDA's response include increasing the availability of tests, therapeutics, and other devices such as ventilators and personal protective equipment, and many other important items necessary for the response. The FDA is also monitoring the human and animal food supply and taking swift action on fraudulent COVID-19 products.

Highlights of FDA Activities

Ensuring Timely Availability to Accurate and Reliable Tests

- To date, the FDA has currently authorized 212 tests under **Emergency Use Authorizations (EUAs)**; these include 173 molecular tests, 37 antibody tests and 2 antigen tests.
- The FDA continues to monitor authorized tests and emerging scientific evidence and may revise or revoke an EUA, when appropriate, including when a test's benefits no longer outweigh its risks.The **FDA provides continuous updates** to make clear which tests have been **issued EUAs** by the agency, and which **tests should not be used**.

Accelerating Availability of Medical Equipment and Products for Treatment

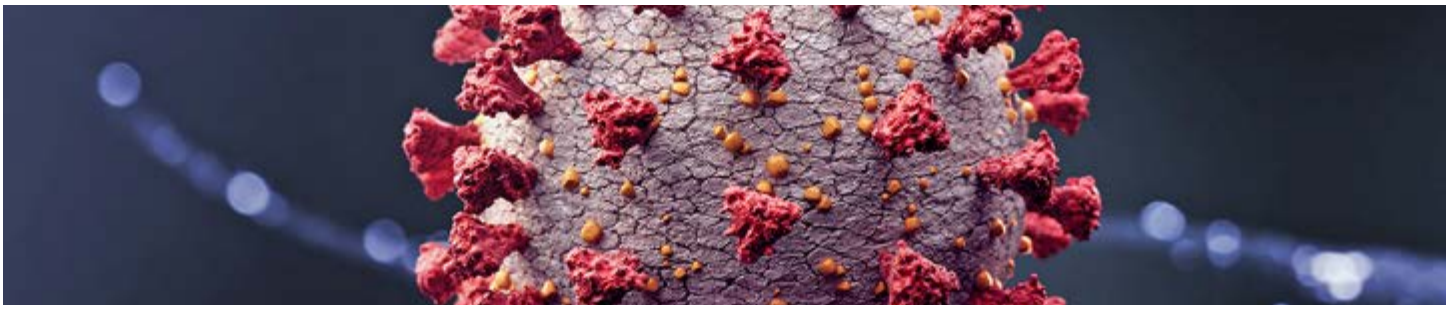
- The FDA added more than 90 **ventilators** and accessories for emergency use to the ventilator EUA and **issued EUAs** for other equipment to treat patients during COVID-19.
- The agency has issued EUAs and policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical masks, and more.
- **There are now more than 570 drug development programs in planning stages and as of the end of July, the agency has reviewed more than 270 trials** of **potential therapies** for COVID-19.

Actively Monitoring the Medical Product and Food Supply Chains to Address Imbalances

- Continue to screen and monitor millions of domestic and international products in the medical supply chain to help ensure COVID-19-related supplies coming into the U.S. are safe and distributed appropriately.

Halting the Sale of Products with Fraudulent Claims Related to COVID-19

- As of July 2020, the FDA has **identified more than 1000 fraudulent and unproven medical products** related to COVID-19.
- To proactively identify and neutralize threats to consumers, the FDA launched Operation Quack Hack in March 2020. The Operation Quack Hack team has reviewed thousands of websites, social media posts, and online marketplace listings, resulting in over **100 warning letters** to sellers, more than 215 reports sent to online marketplaces, and more than 266 abuse complaints sent to domain registrars to date.



Recent Actions

- On Aug. 11, the FDA posted a new webpage with FAQs on **importing medical devices during the COVID-19 pandemic**. The FAQs provide information on importing devices that have been issued EUAs and devices for which an enforcement-discretion policy has been published in a guidance document and includes content on importing respirators, face masks, and PPE, donating medical devices, importing other medical devices, monitoring import status, and identifying contacts for import questions.
- **Remarks given on Aug. 10 by FDA Commissioner Stephen M. Hahn. M.D.** provide thoughts on the critical role of health care professionals during the COVID-19 pandemic.
- To help answer technical questions about the development and validation of tests for SARS-CoV-2, the agency continued a **virtual town hall** series, providing information about the Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests in the Aug. 5 town hall.
- As part of a series, on Aug. 3, a webinar titled **FDA's Regulation of Face Masks and Surgical Masks During the COVID-19 Pandemic**, was held to share information and answer questions related to face masks and surgical masks.
- In an Aug. 3 FDA Voices titled **Investing in Advanced Manufacturing to Support Public Health Preparedness**, agency leaders provided insight into how advanced manufacturing provides an approach for protecting our supply chain and improving our response capacity during crisis situations.
- On July 31, **the FDA authorized the first two COVID-19 serology tests that display an estimated quantity of antibodies present in the individual's blood**. Both tests from Siemens, the ADVIA Centaur COV2G and Atellica IM COV2G, are what are known as "semi-quantitative" tests, meaning that they do not display a precise measurement, but estimate the quantity of a patient's antibodies produced against infection with the virus that causes COVID-19.
- On July 29, the FDA posted **frequently asked questions for patients and consumers about COVID-19 antibody (serology) testing.** A COVID-19 antibody test, also known as a serology test, is a blood test that can detect if a person has antibodies to SARS-CoV-2, the virus that causes COVID-19. COVID-19 antibody tests can help identify people who may have been infected with the SARS-CoV-2 virus or have recovered from the COVID-19 infection.
- On July 29, the FDA **posted a new template** for commercial developers to help them develop and submit EUA requests for COVID-19 diagnostic tests that can be performed entirely at home or in other settings besides a lab, such as offices or schools, and that could be available without a prescription.
- A July 28 **"FDA Insight"** podcast, **Vaccines for COVID-19, Part 2**, provides a discussion on vaccines as they relate to COVID-19. It follows the recent **Vaccines for COVID-19, Part 1** podcast.
- On July 27, the FDA **reiterated a warning not to use certain alcohol-based hand sanitizers** due to the dangerous presence of methanol, or wood alcohol – a substance often used to create fuel and antifreeze that can be toxic when absorbed through the skin as well as life-threatening when ingested. The agency has also taken additional action to help prevent certain hand sanitizers from entering the United States by placing them on an **import alert**. The agency continues to **update the list of hand sanitizers consumer should not use**.
- On July 24, the **FDA reissued the LabCorp COVID-19 RT-PCR Test EUA** to include two new indications for use: testing for people who do not have COVID-19 symptoms or who have no reason to suspect COVID-19

infection, and to allow pooled sample testing. Specifically, the FDA reissued the LabCorp COVID-19 RT-PCR Test EUA to expand use of the test to anyone after the company provided scientific data showing the test's ability to detect SARS-CoV-2 in a general, asymptomatic population. Additionally, the reissuance also includes authorization for LabCorp to test pooled samples containing up to five individual swab specimens collected under observation. In general, sample pooling allows for fewer tests to be conducted overall, conserving resources and potentially allowing more tests to be evaluated more quickly.

RESOURCES

- The FDA has made information available to the public in both English and **Spanish** on our **COVID-19 website**. This includes regularly updating our **Frequently Asked Questions**, issuing **Consumer Updates**, **MedWatch alerts**, **FDA Voices**, stakeholder updates, webinars, and other resources for patients, caregivers and health care providers. The FDA has issued more than 175 **news announcements on COVID-19 topics** since January. In late March, the agency began to issue "Daily Roundups" to capture its ongoing response efforts each weekday.
- **Innovation to Respond to COVID-19** provides an overview of the FDA's work to facilitate and accelerate the development of COVID-19 medical products and ways the agency is exercising regulatory flexibility through guidance to industry. **Educational Resources** provides links to FDA-produced COVID-19-related resources that help explain the agency's work.
- **COVID-19 Resources for Health Professionals** provides quick and easy access to FDA information for health care professionals.
- Coronavirus Disease 2019 (COVID-19) **Emergency Use Authorizations for Medical Devices** provides information on the EUAs for medical devices that the FDA has issued related to COVID-19.
- For information about the different types of tests and the steps involved in processing samples, see **Coronavirus Testing Basics** explainer and **video**. If you think you have COVID-19 and need a test, contact your health care provider immediately.
- To learn more about keeping your pets safe during the coronavirus (COVID-19) pandemic, **watch this video**.
- The FDA has issued more than 55 **guidance documents** to provide updated policies, transparency, and regulatory flexibility to address the vital medical products and public health issues facing the U.S. during this pandemic. These guidances are on diagnostics, personal protective equipment, other medical devices, investigational treatment with convalescent plasma, conduct of clinical trials of medical products, blood supply, hand sanitizers, food safety and supply, telemedicine and other topics.
- The FDA has provided a retail food re-opening checklist for previously closed retail food establishments or those that have been open with limited service related to the COVID-19 pandemic, see **Best Practices for Re-Opening Retail Food Establishments During the COVID-19 Pandemic**.
- If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by **donating your plasma**.
- For updated fact sheets for the Emergency Use Authorizations the FDA has issued, see **therapeutics** and **devices**.
- For updated information about COVID-19 clinical trials underway in the U.S. and internationally, see **clinicaltrials.gov**.
- **Subscribe** to receive updated COVID-19-related information from the FDA.