U.S. FOOD & DRUG ADMINISTRATION

FDA COVID-19 Response

At-A-Glance Summary *as of July 23, 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 187 tests under **Emergency Use Authorizations (EUAs)**; these include 154 molecular tests, 31 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 85 **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 510 drug development programs in planning stages and as of mid-July, the agency has reviewed more than 230 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 June 2020, the FDA has **identified more than 700 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 **90 warning letters** to sellers, more than 150 reports sent to online marketplaces, and more than 250 abuse complaints sent to domain registrars to date.

Recent Actions

- A July 21 FDA Voices, titled **FDA's Ongoing Work to Support and Advance COVID-19 Diagnostic Test Accuracy and Availability**, describes how the FDA has been proactive and supportive of test development by all comers — including laboratories, and large and small commercial manufacturers — to speed development and to quickly authorize tests that the science supports. The agency engaged with the lab and commercial manufacturer communities even before any cases of COVID-19 were diagnosed in the U.S., working with over 500 developers since January, and has been working around the clock to authorize over 180 **EUAs for tests**, including molecular, serology, antigen, and tests with at-home specimen collection indications.
- In a July 20 FDA Voices, titled **FDA Protects Patients and Consumers from Fraud During COVID-19**, agency leaders explain that the FDA's consumer protection work is a cornerstone of the agency's mission and a critical component of its pandemic response efforts.
- Agency leaders explain that laboratory safety is of the highest priority in all of the FDA's scientific research and analytical facilities in the FDA Voices issued on July 20, titled **FDA's Continued Commitment to the Safety and Security of Our Laboratories**.
- On July 20, **FDA announced** that it is extending the enforcement discretion policy for certain human cell, tissue, and cellular and tissue-based products (HCT/Ps). As a result of the challenges presented by the COIVD-19 public health emergency, the agency is extending the enforcement discretion policy for an additional six months (through May 2021).
- On July 18, the FDA authorized the first COVID-19 diagnostic test to be authorized for use with pooled samples – the FDA reissued an EUA to **Quest Diagnostics** to authorize its **Quest SARS-CoV-2 rRT-PCR test** for use with pooled samples containing up to four individual swab specimens collected under observation.
- In a July 14, FDA Voices, titled **An Update and Behind the Scenes: FDA's Coronavirus Treatment Acceleration Program**, agency leaders discuss efforts to leverage cross-agency scientific resources and expertise on COVID-19 therapeutic development and review.
- Three new **"FDA Insight" podcasts** include:
  - July 21: **Vaccines for COVID-19, Part 1**
  - July 14: **Clinical Trials and Treatments for COVID-19**
  - July 7: **Food Safety and COVID-19**
- On July 10, the FDA announced preparations to resume **domestic inspections, guided by a new a risk-assessment system**. The **White House Guidelines for Opening Up America Again** are providing FDA a roadmap for optimizing operations and new work arrangements, and CDC guidance is informing efforts related to workplace exposures to COVID-19 in non-healthcare settings. To arm FDA investigators with the most reliable and accurate information, the FDA developed a rating system to assist in determining when and where it is safest to conduct prioritized domestic inspections. The COVID-19 Advisory Rating system (COVID-19 Advisory Level) uses real-time data to qualitatively assess the number of COVID-19 cases in a local area based on state and national data.
- On July 2, the FDA issued an EUA to the CDC for **the third diagnostic test for detection and differentiation of the viruses that cause flu and COVID-19** in

individuals suspected of COVID-19 by their health care provider.

- On July 2, the FDA issued the **second EUA for a COVID-19 antigen test**. An antigen test is a diagnostic test that quickly detects fragments of proteins found on or within the virus by testing samples collected from the patient's nasal cavity using swabs.

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 125 **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 week-day.
- **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.