U.S. FOOD & DRUG ADMINISTRATION

FDA COVID-19 Response

At-A-Glance Summary *as of March 26, 2021*

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

- As of March 23, 343 tests and sample collection devices are authorized by the FDA under **Emergency Use Authorizations (EUAs)**; these include 255 molecular tests and sample collection devices, 73 antibody and other immune response tests, and 15 antigen tests. There are 41 molecular authorizations that can be used with home-collected samples. There is one molecular prescription at-home test, two antigen prescription at-home tests, one over-the-counter (OTC) at-home antigen test, and one OTC molecular test.
- 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

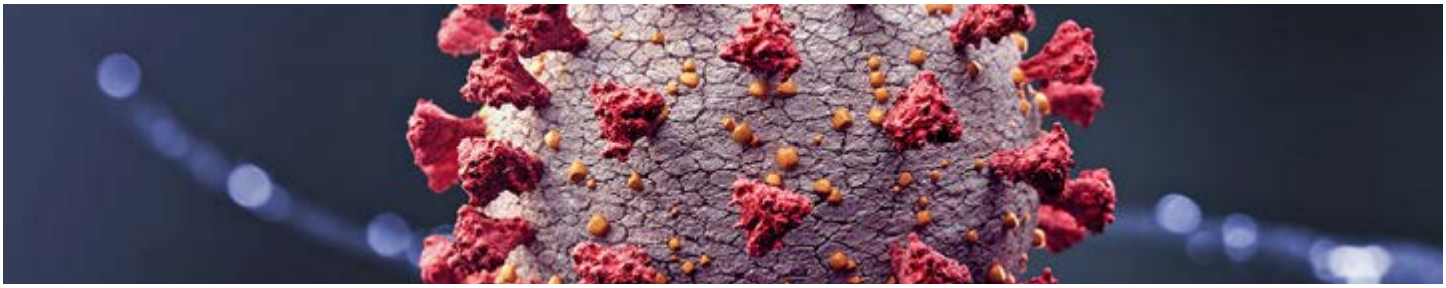
- The FDA added more than 100 **ventilators** and accessories for emergency use to the ventilator EUA and **issued EUAs** for other equipment to treat patients during COVID-19.
- The agency has issued EUAs and policies to help increase the availability of personal protective equipment, such as respirators, gowns, surgical masks, and more.
- **There are now more than 600 drug development programs in planning stages and** nine EUAs for COVID-19 treatments are currently authorized for emergency use. One treatment is currently approved by the FDA for use in COVID-19.

Facilitating the Development of COVID-19 Vaccines

- There are **three COVID-19 vaccines authorized for emergency use**.

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

- As of March 25, the FDA has received more than 1354 reports of fraudulent 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 **170 warning letters** to sellers, more than 297 reports sent to online marketplaces, and more than 288 abuse complaints sent to domain registrars to date.



Recent Actions

- In a March 24 Consumer Update entitled **Learn More About COVID-19 Vaccines from the FDA**, the agency answers questions such as: who approves COVID-19 vaccines and why should I get a COVID-19 vaccine?
- In a March 22 Consumer Update, the FDA provides an update on simple steps to help slow the spread of coronavirus disease to protect ourselves, our families, and our communities. Read more: **Help Stop the Spread of Coronavirus and Protect Your Family**.
- On March 19, the FDA issued an **EUA** to Tiger Tech Solutions, Inc. for the first machine learning-based COVID-19 non-diagnostic screening device that identifies certain biomarkers that are indicative of some types of conditions, such as hypercoagulation (a condition causing blood to clot more easily than normal).
- In a March 18 FDA Voices entitled **FDA's Ongoing Use of Inspectional Tools for Ensuring Access to Safe, Quality Food and Medical Products During the COVID-19 Pandemic**, FDA leaders explain that over the past year, the agency's approach to foreign and domestic inspections for food and medical products has been both risk-based and deliberate. The COVID-19 pandemic required us to rework our business operations so that we could carry out our public health mission while protecting our workforce, and the workforces of those we regulate.
- On March 18, the FDA **authorized revised fact sheets** for health care providers to include additional information on susceptibility of SARS-CoV-2 variants to each monoclonal antibody (mAb) therapy that is available through an **Emergency Use Authorization for COVID-19 treatment**. The fact sheets contain details regarding specific variants and potential resistance that may make the authorized mAb therapies less effective.
- On March 17, the FDA posted **two templates for serology tests** with recommendations on what to include in EUA requests or Pre-EUA submissions: Template for Test Developers of Serology Tests that Detect or Correlate to Neutralizing Antibodies (New) and Serology Template for Test Developers (Update).
- On March 18, the FDA's Dr. Peter Marks participated in a hearing titled: **Examining Our COVID-19 Response: An Update from Federal Officials**, before the U.S. Senate Health, Education, Labor, and Pensions Committee
- On March 17, the FDA granted BioFire Diagnostics LLC marketing authorization for its **BioFire Respiratory Panel 2.1 diagnostic test**. The grant of this De Novo request marks an important step in the FDA's response to the COVID-19 pandemic because it is the first SARS-CoV-2 diagnostic test that will be permitted to be marketed beyond the public health emergency.
- On March 17, the FDA's Dr. Peter Marks participated in the U.S. House Subcommittee on Oversight and Investigations hearing entitled, **Leading the Way Forward: Biden Administration Actions to Increase COVID-19 Vaccinations**.
- On March 16, the FDA posted a new web page: **Screening for COVID-19: Deciding Which Test to Use When Establishing Testing Programs**. This resource is intended for schools, workplaces, communities and others looking to establish testing programs to screen people without symptoms and with no known or suspected exposure to COVID-19. The FDA also posted a **new template** for test developers to help facilitate submission of an emergency use authorization (EUA) request for certain COVID-19 tests for screening using a serial testing approach.
- On March 15, the FDA launched the **COVID-19 EUA FDA Adverse Events Reporting System (FAERS) Public Dashboard** providing weekly updates of adverse event reports submitted to FAERS for drugs and therapeutic biological products used under an EUA during the COVID-19 public health emergency.

- In a March 12 **Letter to Clinical Laboratory Staff, Point-of-Care Facility Staff and Health Care Providers**, the FDA alerted that false positive results can occur with the Roche Molecular Systems, Inc. cobas SARS-CoV-2 & Influenza A/B Nucleic Acid Test for use on the cobas Liat System.
- Patients today have more treatment options in the battle against coronavirus disease. In a March 11 Consumer Update, the FDA provides a closer look at some of the available COVID-19 treatments and explains how to get more information about them and others. Read more: **Know Treatment Options for COVID-19**.
- In a March 5 Consumer Update entitled **Why You Should Not Use Ivermectin to Treat or Prevent COVID-19**, the agency highlights the growing interest in a drug called ivermectin to treat humans with COVID-19. Ivermectin is often used in the U.S. to treat or prevent parasites in animals. The FDA has received multiple reports of patients who have required medical support and been hospitalized after self-medicating with ivermectin intended for horses.
- On March 5, the FDA issued an EUA to **Cue Health Inc. for its over-the-counter at-home diagnostic test for COVID-19**. It is a molecular test that can be used completely at home without a prescription by people with or without COVID-19 symptoms. It requires the use of a compatible smartphone and a downloadable app. The app provides testing instructions and works with the Cue Cartridge Reader (provided separately) and the Cue testing cartridge to perform the test.
- On March 5, the FDA issued an EUA to **Adaptive Biotechnologies for its T-Detect COVID Test**. The test analyzes DNA from a patient's T cells (white blood cells) to aid in identifying people with an adaptive T cell immune response to SARS-CoV-2, indicating recent or previous SARS-CoV-2 infection. The test should be used together with a clinical examination and a patient's medical history. Negative results do not rule out acute or current SARS-CoV-2 infection.
- In a March 5 **Health Equity Forum Podcast**, hosted by the FDA's Office of Minority Health & Health Equity, host RADM Richardae Araojo, discusses the FDA's efforts to stop fraudulent products from reaching our markets, especially those claiming to prevent, treat, or cure COVID-19.
- A March 4 Consumer Update, entitled **6 Tip-offs to Rip-offs: Don't Fall for Health Fraud Scams**, provides tips to avoid health fraud scams. Consumers can increase their chances of identifying and avoiding health fraud scams by focusing on being smart, aware and careful when purchasing health care products.
- On March 3, the FDA sent letters to 25 firms that produce and issue "FDA registration certificates" to medical device companies (including manufacturers, distributors and sellers). In the letters, the **FDA is requesting that firms cease producing and issuing such registration certificates**. The registration certificates often have the look of an official government document and many display the FDA logo. The FDA does not issue any type of device establishment registration certificate. Registration and listing with FDA does not denote approval or clearance of the establishment or its devices. Some device manufacturers and distributors have used registration certificates to create the misimpression that the FDA has reviewed, approved, cleared or authorized their products.
- On March 4, the FDA **alerted consumers, health care providers and other users** of thermal imaging systems intended to measure human body temperature—also known as telethermographic systems, infrared thermographs, thermal cameras, and "fever cameras"—that improper use of the systems may provide inaccurate temperature readings due to a variety of factors. Additionally, the FDA issued several warning letters to certain firms offering unapproved, uncleared and unauthorized thermal imaging systems for sale.
- In a March 2 FDA Voices entitled, **National Consumer Protection Week: FDA Is Vigilant in Protecting Consumers Against COVID-19 Vaccine Scams**, the FDA warns about fraudsters seeking to profit from anxiety and fears associated with COVID-19. The FDA is on the lookout for charlatans seeking to profit from the pandemic.
- A March 1 Consumer Update entitled **Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments**, explains that some people and companies are trying to profit from this pandemic by selling unproven and illegally marketed products that make false claims, such as being effective against the coronavirus. The FDA is particularly concerned that these deceptive and misleading products might cause Americans to delay or stop appropriate medical treatment, leading to serious and life-threatening harm.

RESOURCES

- The FDA has made information available to the public in both English and **Spanish** on our **COVID-19 website** in addition to **multilingual COVID-19 resources.** 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 300 **news announcements on COVID-19 topics** since January, 2020.
- **Educational Resources** provides links to FDA-produced COVID-19-related resources that help explain the agency's work.
- The FDA web page, **COVID-19 Vaccines**, provides updates and information about the agency's work to facilitate development of COVID-19 vaccines that meet FDA's rigorous scientific standards.
- 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.
- The FDA has provided information on **COVID-19 treatment options**.
- Before buying or using hand sanitizer, the FDA recommends checking this **list of hand sanitizers consumers should not use**. Bookmark **www.fda.gov/handsanitizerlist** for the latest, and use our **step-by-step search guide** to find out if your product is on the list.
- **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.
- **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.
- The FDA has issued more than 70 **guidance documents** to provide updated policies, transparency, and regulatory flexibility to address the food supply, 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 information about **COVID-19 vaccination and the food and agriculture sector**.
- 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.