



FDA COMBATING COVID-19 WITH MEDICAL DEVICES

Since the beginning of the COVID-19 pandemic, FDA has been working to facilitate the development and availability of medical products and equipment for use by patients, physicians and healthcare systems as expeditiously and safely as possible. All of [FDA's latest actions around COVID-19](#) are available on our website.

During public health emergencies, FDA can use emergency authorities, including Emergency Use Authorizations (EUAs), to help make medical products available as quickly as possible by allowing unapproved medical products to reach patients in need when there are no adequate, FDA-approved and available alternatives. These products may include tests to help diagnose diseases, critical medical devices needed by patients or healthcare personnel in the context of a public health crisis, and drugs to be used in an emergency to diagnose, treat, or prevent serious or life-threatening diseases or conditions.

During this pandemic, there have been a number of supply issues that have made it challenging to obtain access to diagnostic tests and test supplies (like swabs), and medical equipment. We are updating [testing FAQs](#) regularly to provide information, including alternative test supplies and ways to conduct testing when necessary. If test developers or labs are having any issues developing or running tests, and for difficulties obtaining medical devices such as personal protective equipment (PPE) and other medical equipment shortages, please see [Contacts for Medical Devices During the COVID-19 Pandemic](#).

Testing is one of the pillars of our nation's response to COVID-19 and the FDA continues to take actions to help make these critical products available, including by issuing EUAs. During this pandemic, FDA has issued EUAs for different types of COVID-19 tests. One type are polymerase chain reaction (PCR) tests, a molecular diagnostic testing technique that detects the genetic material from the virus and can help diagnose an active COVID-19 infection. Another type of authorized COVID-19 tests are antigen diagnostic tests, designed for the rapid detection of proteins from the virus that causes COVID-19. A third type are serological tests which can help identify individuals who have developed an adaptive immune response to the virus, indicating recent or prior infection, by detecting antibodies to SARS-CoV-2 in human blood specimens (serological, or antibody, tests should not be used to diagnose active infection).

In addition to COVID-19 tests, the FDA has issued EUAs for other devices, such as ventilators, respirators, face shields, and decontamination systems to treat COVID-19 patients and to protect healthcare workers. The list below includes the device EUAs that FDA has issued to date to diagnose, treat or prevent the spread of COVID-19.

Contents

- [Blood Purification Devices EUAs](#)
- [Continuous Renal Replacement Therapy and Hemodialysis Devices EUAs](#)
- [Decontamination Systems for Personal Protective Equipment EUAs](#)
- [In Vitro Diagnostics EUAs](#)
 - [Individual EUAs for Molecular Diagnostic Tests for SARS-CoV-2](#)
 - [Umbrella EUA for Molecular Diagnostic Tests for SARS-CoV-2 Developed and Performed by Laboratories Certified Under CLIA To Perform High Complexity Tests](#)
 - [Individual EUAs for Antigen Diagnostic Tests for SARS-CoV-2](#)

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- [Individual EUAs for Serology Tests for SARS-CoV-2](#)
- [Individual EUAs for IVDs for Management of COVID-19 Patients](#)
- [Infusion Pump EUAs](#)
- [Personal Protective Equipment EUAs](#)
 - [Umbrella EUA for Surgical Masks](#)
 - [N95 and Other Respirators EUAs \(including EUAs for NIOSH-approved N95s and imported respirators\)](#)
 - [Umbrella EUA for Non-NIOSH-Approved Disposable Filtering Facepiece Respirators \(FFRs\) Manufactured in China](#)
 - [Umbrella EUA for Imported, Non-NIOSH-Approved Disposable Filtering Facepiece Respirators \(FFRs\)](#)
 - [Face Shields and Other Barrier EUAs](#)
- [Remote or Wearable Patient Monitoring Devices EUAs](#)
- [Respiratory Assist Devices EUAs](#)
- [Ventilators and Ventilator Accessories EUAs](#)
- [Other Medical Device EUAs](#)

Additional Resources

- [Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency \(Revised\) Immediately in Effect](#)
- [Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff](#)
- [Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy](#)
- [FDA's Ongoing Work to Support and Advance COVID-19 Diagnostic Test Accuracy and Availability](#)
- [Coronavirus Disease 2019 Testing Basics](#)
- [FAQs on Testing for SARS-CoV-2](#)
- [EUA Authorized Serology Test Performance](#)
- [Hospital Beds, Stretchers, and Mattresses During the COVID-19 Pandemic](#)
- [Emergency Use Authorization— Archived Information](#)