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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

May 20, 2020

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 May 13, 2020 include:

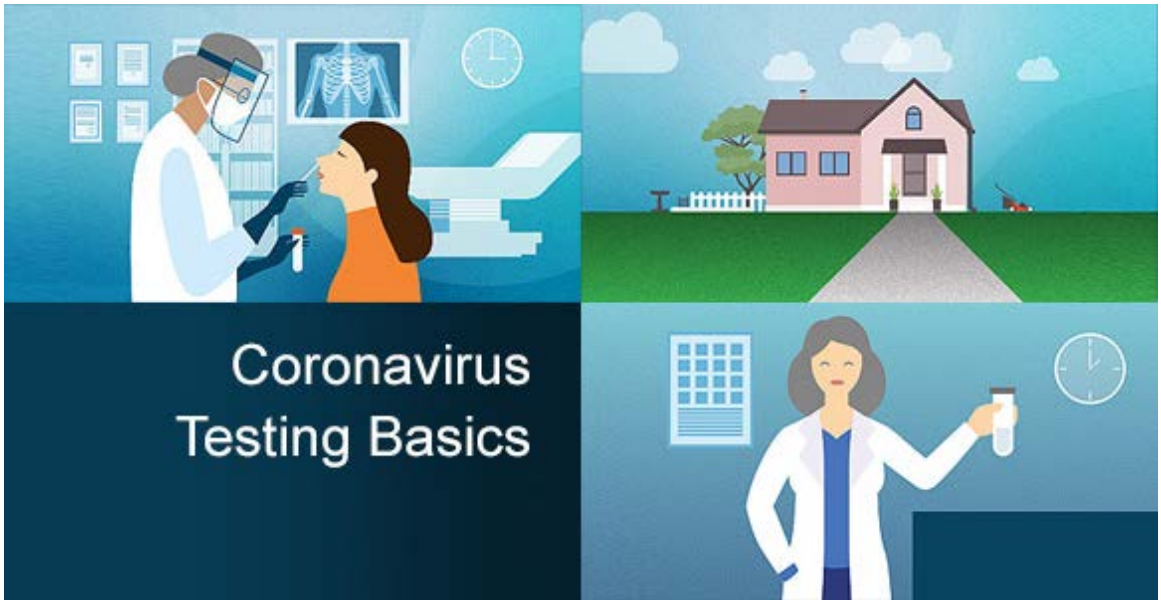
Coronavirus (COVID-19) Updates:

- May 19, 2020: Daily Roundup: FDA actions on diagnostics, succinylcholine chloride injection approval and more
- May 19, 2020: USDA, FDA Strengthen U.S. Food Supply Chain Protections
- May 19, 2020: FDA Collaborations Promote Rigorous Analyses of Real-World Data to Inform Pandemic Response
- May 18, 2020: FDA Voices: COVID-19 Supply Chain Update: Importation of Vital Food and Medical Products
- May 16, 2020: FDA Authorizes First Standalone At-Home Sample Collection Kit That Can Be Used

With Certain Authorized Tests

- May 14, 2020: FDA Informs Public About Possible Accuracy Concerns with Abbott ID NOW Point-of-Care Test
- May 14, 2020: Federal judge enters temporary injunction against Xephyr LLC doing business as N-Ergetics, preventing sale of Colloidal Silver Products for COVID-19
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA



Coronavirus Testing Basics

You've probably heard a lot about coronavirus testing recently. If you think you have coronavirus disease 2019 (COVID-19) and need a test, contact your health care provider immediately. The FDA has been working around the clock to increase the availability of critical medical products, including tests for the coronavirus, to fight the COVID-19 pandemic. Learn more about the different types of tests and the steps involved. *(Also available as a printable PDF)*

Learn more

Emergency Use Authorization (EUA) Updates

Hotline updates and new contact info
The FDA is changing the hours for the COVID-19 Industry Hotline (**1-888-INFO-FDA, press ***). The FDA began this 24/7 Hotline on March

12, 2020 to address the many questions that the agency was receiving on topics such as diagnostic testing and personal protective equipment (PPE). Since that time, we have responded to over 12,000 inquiries.

To best meet current needs, starting on Monday, May 18, 2020, the Hotline will be operating from **8:00 a.m. to midnight Eastern Time Monday-Friday and 8:00 a.m. to 8:00 p.m. Eastern Time on weekends and holidays**. For urgent inquiries, the FDA Emergency Line (1-866-300-4374) remains available after-hours. The FDA has also published and continues to update extensive resources on COVID-19 and medical devices to help answer questions.

Also see: Contacts for Medical Devices During the COVID-19 Pandemic

Infusion pump EUA
In response to concerns relating to insufficient supply and availability of infusion pumps for use by health care providers during the COVID-19 pandemic, FDA issued an EUA (PDF) for infusion pumps and infusion pump accessories, on May 13, 2020.

First stand-alone home sample collection kit EUA
On May 15, 2020, FDA authorized (PDF) an at-home sample collection kit that can then be sent to specified laboratories for COVID-19 diagnostic testing. *Also see the press release*

Diagnostic test EUAs
During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted or said they will be submitting EUA requests to the FDA for tests that detect the virus or antibodies to the virus.

To date, the FDA has authorized 104 tests under EUAs, which include 91 molecular tests, 12 antibody tests, and 1 antigen test.

Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests
Today! **May 20, 2020:** FDA will host a virtual Town Hall for clinical laboratories and commercial manufacturers that are developing or have developed diagnostic tests for SAR-CoV-2, 12:15 p.m. - 1:15 p.m. ET. FDA will host additional town halls in this series on Wednesdays in May.

Related links:

- What is an EUA? (video)
- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- EUA Authorized Serology Test Performance
- FDA Combating COVID-19 with Medical Devices (PDF)

Information for industry

- **Respirators:** Letter to Health Care Providers: Certain Filtering Facepiece Respirators (FFRs) from China May Not Provide Adequate Respiratory Protection - FDA is concerned that certain FFRs from China may not provide consistent and adequate respiratory protection to health care personnel exposed to COVID-19 based on additional filtration performance testing conducted by the National Institute for Occupational Safety and Health (NIOSH) - National Personal Protective Technology Laboratory (NPPTL) of the Centers for Disease Control and Prevention (CDC). As such, FDA has revised and reissued the April 3, 2020 EUA (PDF). *(May 7, 2020)*
- **Thermal imaging systems:** Thermal Imaging Systems (Infrared Thermographic Systems / Thermal Imaging Cameras) *(new web page, May 13, 2020)*
- The FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid COVID-19 response efforts. FDA has issued more than 40 COVID-19-related guidances to date.

COVID-19-Related Guidance Documents

In case you missed it

- FDA At-A-Glance COVID-19 Response Summary (PDF) - a quick look at facts, figures, and highlights of FDA's response efforts *(updated May 15, 2020)*
- Register by **June 5, 2020** for the FDA Training Course: Achieving Data Quality and Integrity in Clinical Trials Involving High-Consequence Pathogens, scheduled for July 27-31, 2020 in Omaha, Nebraska. Professionals who have experience with high-consequence pathogen clinical trials are encouraged to apply to attend.

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