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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

May 6, 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 April 29, 2020 include:

Coronavirus (COVID-19) Updates:

- May 5, 2020: Daily Roundup: FDA actions on warning letters, generic drug approvals, and more
- May 4, 2020: FDA Voices: Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy
- April 30, 2020: FDA Includes Ventilator Developed by NASA in Ventilator Emergency Use Authorization
- April 29, 2020: Consumer Update: Tips on Good Nutrition and Using the Updated Nutrition Facts Label During the Coronavirus Pandemic
- April 29, 2020: From the Department of Justice, with FDA: Court Orders Halt to Sale of Silver Product

fraudulently Touted as COVID-19 Cure

- More Daily Roundups (Monday - Friday) - Go to www.fda.gov/coronavirus, and select Daily Roundup (Type of Information) under Latest COVID-19 Information From the FDA
- *Also see Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

FDA issues EUA for potential COVID-19 treatment

On May 1, 2020, FDA issued (PDF) an Emergency Use Authorization (EUA) for the investigational antiviral drug remdesivir for the treatment of suspected or laboratory-confirmed COVID-19 in adults and children hospitalized with severe disease. While there is limited information known about the safety and effectiveness of using remdesivir to treat people in the hospital with COVID-19, the investigational drug was shown in a clinical trial to shorten the time to recovery in some patients.

Read the news release

Related information:

- Frequently Asked Questions on the Emergency Use Authorization for Remdesivir for Certain Hospitalized COVID 19 Patients (PDF)
- Emergency Use Authorization - COVID-19 Therapeutics
- FDA Combating COVID-19 with Therapeutics (PDF, updated May 4, 2020)

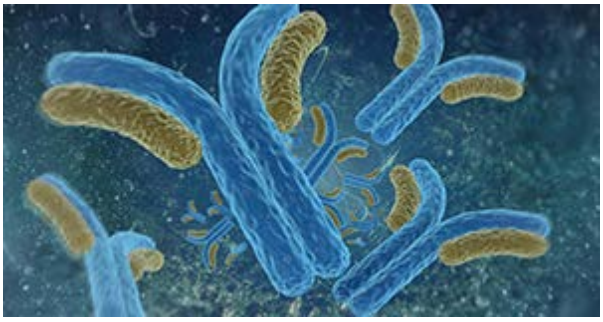
Helpful Questions and Answers about Coronavirus (COVID-19) and Your Pets

FDA offers some questions and answers to help keep you, your family, and your pets safe during the pandemic.

Read more

Serology (antibody) test updates

Policy for Coronavirus Disease-2019 Tests



During the Public Health Emergency (Revised)
On May 4, 2020, FDA announced important updates to our March 16, 2020 policy on commercial manufacturers' serology—or antibody—tests for COVID-19. Under the revised policy, FDA expects commercial manufacturers to submit EUA requests, including their validation data, within 10 days of the updated policy publication date, or the date they notify FDA of their test validation, whichever is later. FDA has also provided specific performance threshold recommendations for specificity and sensitivity for all serology test developers. Two new serology EUA templates are available as Appendix A (for test kit manufacturers) and Appendix B (for laboratories) of the revised policy PDF.

New serology test "umbrella" EUA
On April 28, 2020, FDA issued an EUA (PDF) for SARS-CoV-2 Antibody Tests that have been evaluated in an independent validation study performed at the National Institutes of Health's (NIH) National Cancer Institute (NCI), or by another government agency designated by FDA, and are confirmed by FDA to meet the criteria set forth in the Scope of Authorization.

Under this serology "umbrella" EUA, authorized devices are intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection, by detecting antibodies (IgG, or IgG and IgM, or total), as specified in each authorized device's instructions for use, to SARS-CoV-2 in human plasma and/or serum. Emergency use of the authorized devices is limited to authorized laboratories. Authorized devices will be added to Appendix A and will be posted on the FDA's website.

Emergency Use Authorization (EUA) Updates

Diagnostic test EUAs
During the COVID-19 pandemic, FDA has worked with more than 385 test developers who have said they will be submitting EUA requests to FDA for tests that detect the virus.

To date, FDA has issued 60 individual EUAs for test kit manufacturers and laboratories, including 12 serology tests. In addition, 25 authorized tests have been added to the EUA letter of authorization (PDF) for high complexity molecular-based LDTs.

FDA has been notified that more than 240 laboratories have begun testing under the policies set forth in our Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.

Reminder: FDA Sets up 24/7 Hotline to Help Labs with Diagnostic Test Issues
FDA's 24/7 hotline (1-888-INFO-FDA, choose option *) is available for labs to call regarding difficulties obtaining supplies for collecting patient samples for COVID-19 testing, including swabs and media needed for transport and conservation of the samples.

Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests
Today! **May 6, 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 are EUAs? (video)
- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- EUA Authorized Serology Test Performance
- Emergency Use Authorizations (Devices)
- FDA Combating COVID-19 with Medical Devices (PDF)

Information for industry

- The recording and slides (PDF) from FDA's April 30 webinar, Conducting Clinical Trials During the COVID-19 Public Health Emergency, are now available.
- Medical Gloves for COVID-19: Manufacturing, Purchasing, Importing and Donating Gloves During the Public Health Emergency *(May 1, 2020)*
- Reminder: FDA-ARGOS SARS-CoV-2 reference grade sequence data now available *(April 1, 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

- Given the many questions people have about grocery shopping safety, FDA has posted a video, 12 Tips for Grocery Shopping During the Pandemic, to advise consumers.

- Donate COVID-19 Plasma - If you have fully recovered from COVID-19, you may be able to help patients currently fighting the infection by donating your plasma.
- 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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