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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

April 22, 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 15, 2020 include:

Coronavirus (COVID-19) Updates:

- April 21, 2020: Daily Roundup: FDA actions on the first diagnostic test with an at-home sample collection option, food supply and safety information, and more
- 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
- April 21, 2020: FDA Authorizes First Test for Patient At-Home Sample Collection
- April 18, 2020: Serological Test Validation and Education Efforts
- April 17, 2020: Federal judge enters temporary injunction against Genesis II Church of Health and

Healing, preventing sale of Chlorine Dioxide Products Equivalent to Industrial Bleach to Treat COVID-19

- April 17, 2020: NIH to launch public-private partnership to speed COVID-19 vaccine and treatment options
- April 16, 2020: FDA Encourages Recovered Patients to Donate Plasma for Development of Blood-Related Therapies
- April 16, 2020: FDA, Gates Foundation, UnitedHealth Group, Quantigen, and U.S. Cotton Collaborate to Address Testing Supply Needs
- April 16, 2020: FDA Continues User-Fee Related Reviews Through COVID-19
- April 16, 2020: FDA Warns Two Firms Marketing Unapproved Chloroquine Phosphate Animal Drug Products
- *Also see Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

Shopping for food during the COVID-19 pandemic

As grocery shopping remains a necessity during this pandemic, many people have questions about how to shop safely. We want to reassure consumers that there is currently no evidence of human or animal food or food packaging being associated with transmission of the coronavirus that causes COVID-19.

Read more

Related links:

- Printable PDF - tips on shopping for food during COVID-19
- FDA Voices: FDA Provides Flexibility to the Food Industry to Support Food Supply Chain and Meet Consumer Demand During COVID-19 *(April 21, 2020)*
- Compra de comestibles durante la pandemia del COVID-19 - Información para los consumidores (Shopping for food during the COVID-19 pandemic - Information for consumers, in Spanish)

The Path Forward: Coronavirus Treatment Acceleration Program

Given the urgent nature of the pandemic, the FDA launched a new program called the Coronavirus Treatment Acceleration Program (CTAP) to move new treatments to patients as soon as possible, while at the same time finding out whether they are helpful or harmful. So far, 72 clinical trials of potential therapies for COVID-19 are underway with FDA oversight.

Read more

Emergency Use Authorization (EUA) Updates

Updated EUA allows at-home collection
FDA authorized the first diagnostic test with a home sample collection option for COVID-19. Specifically, the FDA re-issued (PDF) the EUA for the Laboratory Corporation of America (LabCorp) COVID-19 RT-PCR Test to permit testing of samples self-collected by patients at home using LabCorp's Pixel by LabCorp COVID-19 Test home collection kit. *(April 20, 2020)*

Diagnostic test EUAs
During the COVID-19 pandemic, FDA has worked with more than 350 test developers who have said they will be submitting EUA requests to FDA for tests that detect the virus.

To date, FDA has issued 43 individual EUAs for test kit manufacturers and laboratories, including 4 serology tests. In addition,17 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 210 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.

Additional device EUA updates

FDA has issued EUAs for 5 systems to decontaminate N95 respirators for re-use, including the Stryker STERIZONE VP4 N95 Respirator Decontamination Cycle authorized (PDF) on April 15 for use in decontaminating compatible N95 and N95-equivalent respirators for single-user reuse by healthcare personnel, and the Sterilucent HC 80TT Hydrogen Peroxide Sterilizer authorized (PDF) on April 20 for use in decontaminating compatible N95 or N95-equivalent respirators for single-user reuse by healthcare providers.

FDA has also issued EUAs for 3 extracorporeal blood purification devices, including the Seraph 100 Microbind Affinity Blood Filter device authorized (PDF) on April 17 to treat patients 18 years of age or older with confirmed COVID-19 admitted to the intensive care unit with confirmed or imminent respiratory failure to reduce pathogens and inflammatory mediators from the bloodstream.

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! April 22, 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 also plans to hold a virtual town hall for clinical laboratories and commercial manufacturers to help answer questions on **April 29.**

Related links:

- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- Emergency Use Authorizations (Devices)
- FDA Combating COVID-19 with Medical Devices (PDF)
- Information for Laboratories Implementing IVD Tests Under EUA
- Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency *(updated March 16, 2020)*

Information for industry

- The FDA is committed to providing timely recommendations, regulatory information, guidance, and technical assistance necessary to support rapid COVID-19 response efforts. FDA guidance updates this week:
    - FDA added content to the question-and-answer appendix in its guidance Conduct of Clinical Trials of Medical Products during COVID-19 Public Health Emergency for industry, investigators, and institutional review boards *(April 17, 2020)*
    - Enforcement Policy for Telethermographic Systems During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency - to help expand the availability of telethermographic systems used for body temperature measurements for triage use *(new April 16, 2020)*
    - FDA Guidance on Conduct of Clinical Trials of Medical Products during COVID-19 Public Health

Emergency *(new April 16, 2020) - Also see: Clinical Trial Conduct During the COVID-19 Pandemic*

- Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency *(new April 16, 2020)*
- FDA updated 3 guidances for industry, for firms that choose to temporarily produce hand sanitizers and the alcohol used in them *(April 15, 2020)*

- Reminder: FDA-ARGOS SARS-CoV-2 reference grade sequence data now available *(April 1, 2020)*

COVID-19-Related Guidance Documents

In case you missed it

- Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions
- FDA COVID-19 Response At-A-Glance Summary PDF *(April 14, 2020)*
- Multilingual COVID-19 Resources - information from FDA available in Español (Spanish), 体中文 (Simplified Chinese), 한국어 (Korean), Tiếng Việt (Vietnamese), and Tagalog
- How you can make a difference during the COVID-19 pandemic
- 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.
- FDA Combating COVID-19 with Therapeutics (PDF) *(April 9, 2020)*
- HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus *(March 6, 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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10903 New Hampshire Avenue, Silver Spring, MD 20993
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