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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

August 19, 2020

Coronavirus Disease 2019 (COVID-19)

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 August 12, 2020 include:

Coronavirus (COVID-19) updates:

- August 18, 2020: Daily Roundup: FDA provides supporting information on respirators for healthcare providers and manufacturers amid the COVID-19 pandemic
- August 18, 2020: From the Health Affairs Blog, FDA leadership on:
    - The FDA Response To COVID-19 At Six Months: Regulatory Innovation In The Face Of A Pandemic
    - FDA Initiatives To Accelerate The Development Of COVID-19 Therapeutics
    - FDA Support For Expedited Access To COVID-19 Diagnostics

Ensuring The Safety And Effectiveness Of A COVID-19 Vaccine

- August 18, 2020: FDA Insight podcast: Health Fraud and COVID-19 + listen to more episodes
- August 15, 2020: FDA Issues Emergency Use Authorization to Yale University for Saliva Direct, a New Method of Sample Processing
- August 12, 2020: Help Stop the Spread of Coronavirus and Protect Your Family
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

Updates on hand sanitizers consumers should not use

FDA expanded hand sanitizer warnings to include certain products labeled to contain ethanol or isopropyl alcohol but have tested positive for 1-propanol contamination, which can be toxic and life-threatening when ingested.

We've expanded our "do-not-use" list of hand sanitizers to include hand sanitizers that are or may be contaminated with 1-propanol, in addition to hand sanitizers that are or may be contaminated with methanol or are subpotent.

If you have product on the list of hand sanitizer w/ potential methanol or 1-propanol contamination, stop using the product & dispose of it in a hazardous waste container or contact local waste management/recycling center. Do not pour these products down the drain or flush them.

Bookmark this link for future updates: **www.fda.gov/unsafehandsanitizers**

Hand sanitizers consumers should not use

Emergency Use Authorization (EUA) updates

EUA for REGIOCIT replacement solution
FDA issued an EUA (PDF) for the emergency use of Baxter Healthcare Corporation's REGIOCIT for adult patients being treated with continuous renal replacement therapy (CRRT) and for whom regional citrate anticoagulation is appropriate. The use of this product under the EUA is limited to critical care settings. CRRT is a "dialysis" treatment that provides renal support for critically ill patients with acute kidney injury. Baxter Healthcare Corporation's REGIOCIT is available for use only in healthcare facilities that the company has qualified for receiving this product. *(August 14, 2020)*

FDA issues EUA to Yale School of Public Health for SalivaDirect, which uses a new method of saliva sample processing
FDA issued an EUA (PDF) to Yale School of Public Health for its SalivaDirect COVID-19 diagnostic test, which uses a new method of processing saliva samples when testing for COVID-19 infection. SalivaDirect does not require any special type of swab or collection device; a saliva sample can be collected in any sterile container. This test is also unique because it does not require a separate nucleic acid extraction step. This is significant because the extraction kits used for this step in other tests have been prone to shortages in the past. *(August 15, 2020)*

Risk of inaccurate results with Thermo Fisher Scientific TaqPath COVID-19 Combo Kit
FDA is alerting clinical laboratory staff and health care providers of a risk of false results with the Thermo Fisher Scientific TaqPath COVID-19 Combo Kit. This alert addresses two issues:

1. The first is about the instructions for vortexing and centrifugation of RT-PCR reaction plates, which Thermo Fisher Scientific has updated.
2. The second is related to the assay Internal Positive Control (IPC) and requires laboratory staff to upgrade software to resolve the issue. *(August 17, 2020)*

Diagnostic test EUAs
To date, FDA has currently authorized 217 tests under EUAs, which include 176 molecular tests, 39 antibody tests, and 2 antigen tests. *Also see: Coronavirus Testing Basics*

Related links:

- FAQs on Testing for SARS-CoV-2 (frequently updated)
- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices

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Events

- **Today! August 19, 2020:** Virtual Town Hall Series - Immediately in Effect Guidance on Coronavirus (COVID-19) Diagnostic Tests - 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 August. *There is significant interest in this Town Hall. Connecting early is highly recommended. To ensure you are connected, please dial-in at 12:00 p.m.*
- **August 25-27, 2020:** Preparedness Summit (virtual) - FDA's Elizabeth Sadove, JD, will present along with CDC speakers as part of the session "Federal Regulatory Updates on Use of Medical Countermeasures." *(fee)*
- **September 1, 2020:** Save the date for the next event in FDA's webinar series to share information and answer your questions on respirators and other personal protective equipment (PPE). Printable slides and transcripts from previous events in this series are available.
- **September 17-18, 2020:** Considerations for the Use of Real-World Evidence to Assess the Effectiveness of Preventive Vaccines - virtual workshop - agenda (PDF)
- **October 2, 2020:** Vaccines and Related Biological Products Advisory Committee (webcast) - At this meeting the committee will recommend strains for the 2021 Southern Hemisphere influenza vaccines licensed in the U.S., which is part of FDA's year-round efforts to flight flu, along with other public health partners like CDC and NIH.

Information for industry

Medical device shortages during the COVID-19 public health emergency

- FDA is providing a **device shortage list** as part of the implementation of section 506J of the Federal Food, Drug, and Cosmetic Act (FD&C Act). The device shortage list reflects the categories of devices that the FDA has determined to be in shortage at this time, and will be updated as the COVID-19 pandemic evolves. In addition, the FDA is providing a list of medical devices for which manufacturing has been permanently discontinued. Under section 506J, manufacturers of certain devices must notify the FDA of an interruption or permanent discontinuance in manufacturing. The publication of these lists allows for transparency to the public and stakeholders about devices shortages and manufacturing that has been permanently discontinued. *(August 14, 2020)*

FDA is providing two new flowcharts and supporting information on respirators

- For healthcare providers and facilities: Considerations for Selecting Respirators for Your Health Care Facility
- For manufacturers and distributors: Manufacturing and Distributing Respirators for Health Care Use in the United States Under an Existing Emergency Use Authorization (EUA) During the COVID-19 Pandemic *(August 18, 2020)*

FDA posts regulatory science tools to help assess new medical devices

- FDA posted to our website a catalog of regulatory science tools to help assess new medical devices. This catalog collates a variety of regulatory science tools that the FDA's Center for Devices and Radiological Health's (CDRH) Office of Science and Engineering Labs (OSEL) developed and plans to expand as new tools become available. The tools include: laboratory methods, computational

models and simulations, and physical and virtual phantoms. *(August 17, 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 50 COVID-19-related guidances to date.

COVID-19-Related Guidance Documents

In case you missed it

- Coronavirus Disease 2019 (COVID-19) Resources for Health Professionals
- If you have recovered from COVID-19, confirmed by a positive test, you're in a special position to help us fight the virus. Donate plasma now.
- FDA COVID-19 Response: At-A-Glance Summary *(PDF, updated August 14, 2020)*

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