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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

July 29, 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 July 22, 2020 include:

Coronavirus (COVID-19) Updates:

- July 28, 2020: Daily Roundup: FDA actions on vaccines, molecular-based diagnostic tests and more
- July 27, 2020: FDA Reiterates Warning About Dangerous Alcohol-Based Hand Sanitizers Containing Methanol, Takes Additional Action to Address Concerning Products
- July 24, 2020: FDA Authorizes First Diagnostic Test for Screening of People Without Known or Suspected COVID-19 Infection - Authorization is also second to allow testing of pooled samples
- July 22, 2020: FDA In Brief: Findings from Real-World Data Study Reveal Higher Risk of Hospitalization and Death Among Cancer Patients with COVID-19, Underscore Health Disparities
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

FDA reiterates warning about dangerous alcohol-based hand sanitizers containing methanol

Agency urges consumers, health care professionals not to use certain products, citing serious adverse events and death

The FDA continues to warn consumers and health care professionals not to use certain alcohol-based hand sanitizers due to the dangerous presence of methanol, or wood alcohol – a substance often used to create fuel and antifreeze that can be toxic when absorbed through the skin as well as life-threatening when ingested.

The agency has also taken additional action to help prevent certain hand sanitizers from entering the United States by placing them on an import alert. The FDA is proactively working with manufacturers to recall products and is encouraging retailers to remove products from store shelves and online marketplaces.

As part of these actions, a warning letter has been issued to Eskbiochem S.A. de C.V. regarding the distribution of products labeled as manufactured at its facilities with undeclared methanol, misleading claims –including incorrectly stating that FDA approved these products—and improper manufacturing practices. *(July 27, 2020)*

Read more: News release

Related links:

- FDA Updates on Hand Sanitizers with Methanol
- Hand Sanitizers | COVID-19

- Safely Using Hand Sanitizer

FDA Insight Podcast

Join Dr. Anand Shah, FDA's Deputy Commissioner for Medical and Scientific Affairs, and other FDA leaders as they provide their **insight** into issues facing the agency – including the COVID-19 pandemic and other emerging topics. New episodes on Tuesdays!

- Ep. 4: Clinical Trials and Treatments for COVID-19
- Ep. 5: Vaccines for COVID-19, Part 1
- Ep. 6: **New!** Vaccines for COVID-19, Part 2

Emergency Use Authorization (EUA) Updates

FDA Authorizes First Diagnostic Test for Screening of People Without Known or Suspected COVID-19 Infection
Authorization is also second to allow testing of pooled samples
On July 24, 2020, FDA reissued (PDF) the LabCorp COVID-19 RT-PCR Test EUA to include two new indications for use: testing for people who do not have COVID-19 symptoms or who have no reason to suspect COVID-19 infection, and to allow pooled sample testing. The FDA reissued the LabCorp COVID-19 RT-PCR Test EUA to expand use of the test to anyone, after the company provided scientific data showing the test's ability to detect SARS-CoV-2 in a general, asymptomatic population.

Additionally, the reissuance includes authorization for LabCorp to test pooled samples containing up to five individual swab specimens collected under observation. Sample pooling allows for fewer tests to be run overall, conserving resources and potentially allowing more samples to be evaluated quicker.

Testing supply substitution strategies
FDA updated the Testing Supply Substitution Strategies slide show. This presentation includes validated supply alternatives that labs can use to continue performing testing when there is a supply issue with some components of a molecular test. Download the 1.5MB PowerPoint slide show file and click Slide Show > From Beginning. *(July 23, 2020)*

Diagnostic test EUAs
To date, FDA has currently authorized 193 tests under EUAs, which include 158 molecular tests, 33 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!** **July 29, 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 July. *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 4, 2020:** Save the date for the next event in the webinar series Respirators for Health Care Personnel Use during COVID-19 Pandemic. Printable slides and transcripts from previous events in this series are available, including sessions on importing respirators for health care personnel use, and decontaminating respirators for health care personnel use.
- **August 4, 2020:** Development Considerations of Antifungal Drugs to Address Unmet Medical Need (virtual workshop). To attend, register by **5:00 p.m. ET August 2, 2020**.
- **August 5, 2020**: Developing Antifungal Drugs for the Treatment of Coccidioidomycosis (Valley Fever) Infection (virtual workshop). To attend, register by **5:00 p.m. ET August 3, 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 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
- COVID-19 Educational Resources
- FDA COVID-19 Response At-A-Glance Summary *(PDF, updated July 23, 2020)*

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