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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

July 8, 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 June 24, 2020 include:

Coronavirus (COVID-19) Updates:

- July 7, 2020: Daily Roundup: FDA actions on warning letters, false positive test results, and more
- July 6, 2020: FDA Issued Emergency Use Authorization for Point of Care Antigen Test
- July 2, 2020: FDA Authorizes Additional COVID-19 Combination Diagnostic Test Ahead of Flu Season
- July 2, 2020: FDA Takes Action to Warn, Protect Consumers from Dangerous Alcohol-Based Hand Sanitizers Containing Methanol
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

FDA Updates on Hand Sanitizers with Methanol

FDA warns consumers of risk of methanol contamination in certain hand sanitizers

FDA is warning consumers and health care providers that the agency has seen a sharp increase in hand sanitizer products that are labeled to contain ethanol (also known as ethyl alcohol) but that have tested positive for methanol contamination. Methanol, or wood alcohol, is a substance that can be toxic when absorbed through the skin or ingested and can be life-threatening when ingested.

The agency is aware of adults and children ingesting hand sanitizer products contaminated with methanol that has led to recent adverse events including blindness, hospitalizations and death.

More information and updates

Related links:

- News release: FDA Takes Action to Warn, Protect Consumers from Dangerous Alcohol-Based Hand Sanitizers Containing Methanol *(July 2, 2020)*
- ITECH 361 Issues Voluntary Nationwide Recall of All Clean Hand Sanitizer and Moisturizer and Disinfectant Due to The Potential Presence of Undeclared Methanol (Wood Alcohol) *(July 6, 2020)*
- Transliquid Technologies LLC Issues Voluntary Recall of Mystic Shield Protection Topical Solution Due to Presence of Undeclared Methanol for the States of California, Louisiana, Massachusetts, and Texas *(July 2, 2020)*
- Hand Sanitizers | COVID-19

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. 1: Fighting COVID-19 at the FDA
- Ep. 2: All About COVID-19 Testing
- Ep. 3: **New!** Food Safety and COVID-19

Emergency Use Authorization (EUA) Updates

New EUA for point of care antigen test

On July 2, 2020, FDA issued an EUA (PDF) for a COVID-19 antigen test. An antigen test is a diagnostic test that quickly detects fragments of proteins found on or within the virus by testing samples collected from the patient's nasal cavity using swabs. The EUA was issued to Becton, Dickinson and Company (BD) for the BD Veritor System For Rapid Detection of SARS-CoV-2. Antigen tests can provide results in minutes, be produced at a lower cost than PCR tests, and potentially scale to test millions of Americans per day once multiple manufacturers enter the market. However, antigen tests may not detect all active infections, as they do not work the same way as a PCR test. The FDA will continue to support the development, review, and monitoring of tests to help ensure accuracy while balancing the urgent need for these critical diagnostics.

FDA authorizes additional COVID-19 combination diagnostic test ahead of flu season, updates EUA templates

On July 2, 2020, FDA further assisted health care providers around the country prepare for the upcoming flu season during the COVID-19 pandemic by issuing an EUA (PDF) for the third diagnostic test for detection and differentiation of the viruses that cause flu and COVID-19 in individuals suspected of COVID-19 by their healthcare provider to the U.S. Centers for Disease Control and Prevention (CDC). The FDA has previously issued EUAs to BioFire Diagnostics LLC and QIAGEN GmbH for their tests, which include other respiratory organisms in addition to the viruses that cause flu and COVID-19.

The FDA has updated the Molecular Diagnostic EUA templates to add information about these types of tests to help facilitate the preparation, submission, and authorization of EUAs of combination tests that address the COVID-19 public health emergency. In particular, the Molecular Diagnostic templates include recommendations for laboratories and commercial manufacturers who may choose to use the templates to help facilitate the preparation and submission of an EUA request for combination tests that may be useful in preserving critical testing resources during the upcoming flu season.

On July 6, 2020, the Molecular Diagnostic EUA templates were updated to provide additional recommendations for validation of sample pooling.

False positive results with BD SARS-CoV-2 reagents for the BD Max System
FDA is alerting clinical laboratory staff and health care providers of an increased risk of a false positive result with BD SARS-CoV-2 Reagents for the BD Max System test. In one study, the manufacturer found approximately 3% of results were false positive results. *(July 6, 2020)*

Diagnostic test EUAs
To date, FDA has currently authorized 166 tests under EUAs, which include 138 molecular tests, 26 antibody tests, and 2 antigen tests. *Also see: Coronavirus Testing Basics*

Related links:

- What is an EUA? (video)
- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- EUA Authorized Serology Test Performance
- Coronavirus Disease 2019 (COVID-19) Emergency Use Authorizations for Medical Devices
- FDA Combating COVID-19 with Medical Devices (PDF)
- Contacts for Medical Devices During the COVID-19 Pandemic

Events

- **Today!** **July 8, 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.
- **July 21, 2020:** Save the date for the next event in the webinar series Respirators for Health Care Personnel Use during COVID-19 Pandemic.
- Register by **August 7, 2020** for the FDA Training Course: Achieving Data Quality and Integrity in Clinical Trials Involving High-Consequence Pathogens, rescheduled for August 31 - September 3, 2020 in Omaha, Nebraska. Professionals who have experience with high-consequence pathogen clinical trials are encouraged to apply to attend.

Information for industry

Biologics

- Updated Information for Human Cell, Tissue, or Cellular or Tissue-based Product (HCT/P) Establishments Regarding the COVID-19 Pandemic *(July 2, 2020)*

Clinical trials

- 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. This guidance is intended for industry, investigators, and institutional review boards. The updated guidance clarifies two previously suggested methods for obtaining informed consent from a hospitalized patient in isolation. In addition, the guidance includes a new question-and-answer regarding how to obtain informed consent from a prospective trial participant in certain circumstances where the enrollment timeframe is limited and the patient can receive a copy of an informed consent document electronically but cannot sign it electronically or print it out for signature. The guidance also clarifies recommendations on documenting details when using video conferencing for trial visits. *(July 6, 2020)*

Importers

- Is your shipment of COVID-19 supplies being held up at a port-of-entry? Get help.

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

- FDA's Center for Drug Evaluation and Research (CDER) Small Business and Industry Assistance (SBIA) is making hundreds of recordings available via a YouTube learning library. Popular presentations include Conducting Clinical Trials During the COVID-19 Public Health Emergency (45 minutes). More 2020 videos
- FDA COVID-19 Response Summary At-A-Glance (PDF - updated July 1, 2020)
- Coronavirus Disease 2019 (COVID-19) Resources for Health Professionals
- COVID-19 Educational Resources

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