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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

July 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 July 15, 2020 include:

Coronavirus (COVID-19) Updates:

- July 21, 2020: Daily Roundup: FDA actions on health fraud, Emergency Use Authorizations (EUAs) for test development, and more
- July 21, 2020: FDA's Ongoing Work to Support and Advance COVID-19 Diagnostic Test Accuracy and Availability
- July 20, 2020: FDA's Continued Commitment to the Safety and Security of Our Laboratories
- July 20, 2020: FDA Extends Enforcement Discretion Policy for Certain Regenerative Medicine Products
- July 18, 2020: FDA Issues First Emergency Authorization for Sample Pooling in Diagnostic Testing

- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

FDA Protects Patients and Consumers from Fraud During COVID-19

Throughout the pandemic, the FDA has found many nefarious actors seeking to exploit consumers during the pandemic by selling unproven medical products often with fraudulent claims. The emergence of fraudulent medical products is a common phenomenon during crisis situations. For example, in 2013, the FDA issued 10 warning letters to firms selling unproven medical products with false or misleading claims to protect against influenza. In 2014, 7 warning letters were issued for unproven and fraudulent Ebola products.

The FDA is well-equipped to rapidly identify and thwart medical product scams to protect consumers. As of June 2020, the FDA has identified more than 700 fraudulent and unproven medical products related to COVID-19. *(July 20, 2020)*

Read more: FDA Voices

Related links:

- Fraudulent Coronavirus Disease 2019 (COVID-19) Products
- Reporting Unlawful Sales of Medical Products on the Internet (in Spanish: Reporte de ventas ilegales de productos medicos a traves del internet)
- Protecting Americans from COVID-19 Scams *(July 21, 2020 testimony)*

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

Emergency Use Authorization (EUA) Updates

Update to tests that should no longer be used and/or distributed for COVID-19
FDA updated its Frequently Asked Questions on Testing for SARS-CoV-2. The revised FAQs now include a list of laboratories that have been removed from the list of laboratories that had notified FDA that they had developed and validated diagnostic tests as set forth in Section IV.A of the *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)* — titled "Laboratories Certified under CLIA that Meet the CLIA Regulatory Requirements to Perform High Complexity Testing Using Their Validated Diagnostic Tests Prior to EUA Submission." Any laboratory on this list has been removed from the notification list because FDA has determined that there are significant problems with its test that cannot be, or have not been, addressed in a timely manner and should no longer be used. *(July 15, 2020)*

FDA Issues First Emergency Authorization for Sample Pooling in Diagnostic Testing
FDA reissued an EUA (PDF) to Quest Diagnostics to authorize its Quest SARS-CoV-2 rRT-PCR test for use with pooled samples containing up to four individual upper respiratory swab specimens collected under observation. The Quest test is the first COVID-19 diagnostic test to be authorized for use with pooled samples.

Sample pooling allows a lab to combine and test samples in a "batch." Ultimately, pooling is expected to require fewer tests, meaning fewer testing supplies are used and more tests can be run at the same time allowing patients to receive their results more quickly in most cases. *(July 18, 2020)*

Diagnostic test EUAs
To date, FDA has currently authorized 186 tests under EUAs, which include 153 molecular tests, 31 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 22, 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.
- **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.

Information for industry

Diagnostic testing

- FDA immediately implemented and issued a guidance to help expand the availability of transport media used to transport certain clinical specimens for testing during the COVID-19 public health emergency. FDA also posted answers to frequently asked questions relating to the development and use of transport media during the COVID-19 public health emergency. *(July 20, 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
- COVID-19 Educational Resources
- Questions about methanol contamination in hand sanitizer? Visit FDAs searchable list to help you identify whether a firms' hand sanitizer product is being recalled or has potential or confirmed methanol contamination. Take our hand sanitizer quiz to test your knowledge!

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