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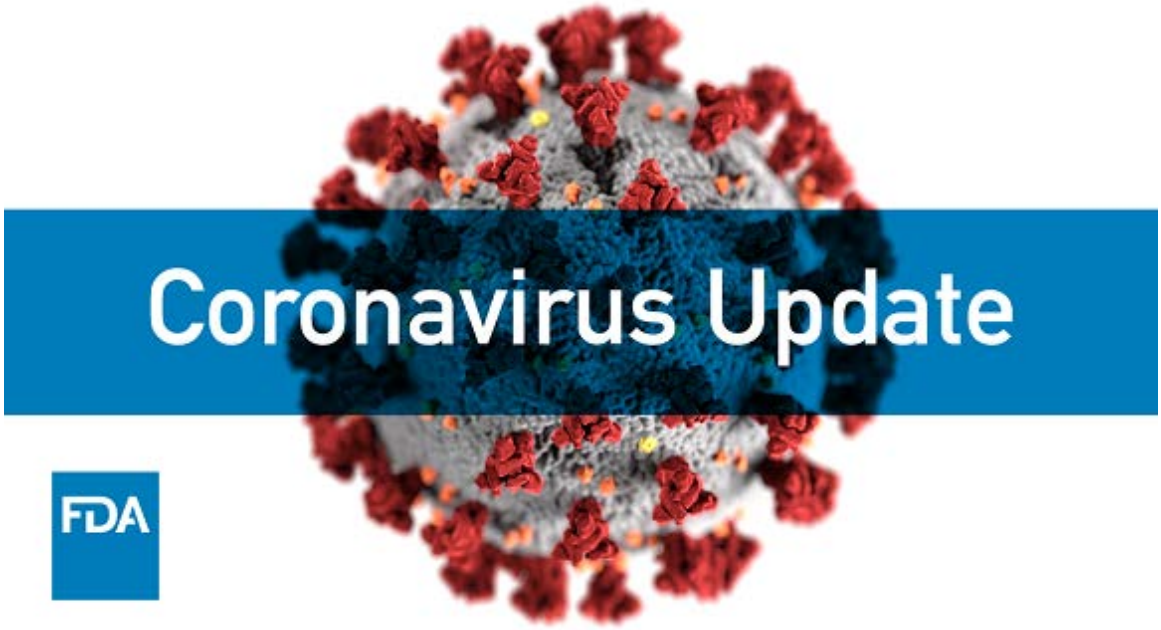
U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

March 18, 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. Here's what's new since our last MCMi email update on March 11, 2020.

FDA Provides More Regulatory Relief During Outbreak, Updates Feb. 29 Policy to Help Expedite Availability of Diagnostics

Statement from FDA Commissioner Stephen M. Hahn M.D.

On March 16, 2020, as part of our ongoing and aggressive commitment to address the coronavirus outbreak, the FDA updated a policy originally issued on Feb. 29 on diagnostic testing for coronavirus (COVID-19) in order to achieve more rapid testing capacity in the U.S. We believe the unprecedented policy set forth in today's updated guidance, which addresses laboratories and commercial manufacturers, will help address these urgent public health concerns by helping to expand the number and variety of diagnostic tests, as well as available testing capabilities in health care settings, and reference and commercial laboratories.

This action demonstrates the FDA's ability to pivot and adapt as the situation warrants in light of a public health emergency. We are taking steps to support diagnostic development considering the urgent need. We urge state authorities and commercial developers to take all necessary steps to ensure the availability of accurate tests. Inaccurate diagnoses during a pandemic can impair prevention efforts and delay appropriate treatment for sick patients.

Read the FDA statement

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. *(March 12, 2020)*

FDA Issues Temporary Policy for FSMA Onsite Audit Requirements

On March 17, 2020, the FDA took steps to help prevent disruptions in the food supply-chain by issuing a temporary policy for FDA Food Safety Modernization Act (FSMA) supplier verification onsite audit requirements during the coronavirus (COVID-19) public health emergency.

Related links:

- Coronavirus Disease 2019 (COVID-19) information from FDA
- Coronavirus Disease 2019 (COVID-19) Frequently Asked Questions (www.fda.gov/coronavirusFAQ)
- For more updates from FDA, follow @SteveFDA, @US_FDA, @FDA_Global, and @FDA_MCMi on Twitter
- 2019 Novel Coronavirus (CDC)

Emergency Use Authorization (EUA) Updates

- **March 17, 2020:** FDA issued EUAs to Quidel Corporation for its Lyra SARS-CoV-2 Assay, and to Quest Diagnostics Infectious Disease, Inc. for its Quest SARS-CoV-2 rRT-PCR test.
- **March 16, 2020:** FDA issued EUAs to Hologic for its Panther Fusion SARS-COV-2 Assay, and Laboratory Corporation of America (LabCorp) for its COVID-19 RT-PCR test.
- **March 15, 2020:** FDA reissued an EUA to CDC for the 2019-nCoV RT-PCR Diagnostic Panel, with amendments intended to help expand test and component availability and reduce the time to final results. FDA also issued an amendment to the New York State Dept of Health's Wadsworth Center for their SARS-CoV-2 Real-time Reverse Transcriptase (RT)-PCR Diagnostic Panel. **Both of these actions reduce the need for**

confirmatory tests for these diagnostics, thereby helping to reduce the number of tests that need to be used per patient and helping to reduce the time of final result reporting.

- **March 13, 2020:** FDA issued an EUA to Thermo Fisher for its TaqPath COVID-19 Combo Kit diagnostic test within 24 hours of receiving the request. This is the second commercially distributed test to receive an EUA during the COVID-19 outbreak.
- **March 13, 2020:** FDA issued an EUA to Roche for its cobas SARS-CoV-2 Test. On March 13, FDA also issued enforcement discretion and is not objecting to the New York State Department of Health (NYSDOH) authorizing certain laboratories in New York to begin patient testing after validating their tests and notifying the NYSDOH. Under NYSDOH's approach, laboratories will provide validation data to NYSDOH within 15 days in lieu of pursuing an EUA with FDA.

Related links:

- FAQs on Diagnostic Testing for SARS-CoV-2 (frequently updated)
- Emergency Use Authorizations (Devices)
- Information for Laboratories Implementing IVD Tests Under EUA
- FDA Issues New Policy to Help Expedite Availability of Diagnostics *(February 29, 2020)*

MCMi Annual Report

New Medical Countermeasures Initiative (MCMi) Program Update (FY 2019)

MCMi is an FDA-wide initiative to coordinate medical countermeasure (MCM) development, preparedness and response. This report provides an update on FDA's work to support MCM-related public health preparedness and response efforts each fiscal year.

View the report

Events

- **POSTPONED March 18-19, 2020:** Joint Civil & DoD CBRN Symposium (Alexandria, VA) - Hosted by the Defense Strategies Institute *(fee) - new dates June 10-11, 2020*
- **POSTPONED: March 31 - April 3, 2020:** Preparedness Summit (Dallas, TX) - Hosted by the National Association of County & City Health Officials (NACCHO) *(fee) - new dates August 23-26, 2020*

You can find more information about these and other events on the MCMi News and Events page.

Information for industry

- Updated Information for Blood Establishments Regarding the Novel Coronavirus Outbreak *(March 11, 2020)*
- Due to the Coronavirus Disease 2019 (COVID-19) pandemic, the FDA has received a number of queries concerning compounding of alcohol-based hand sanitizers. The agency issued guidance: Policy for Temporary Compounding of Certain Alcohol-Based Hand Sanitizer Products During the Public Health Emergency *(March 15, 2020)*
- **Personal protective equipment (PPE) update:**
    - FAQs on Shortages of Surgical Masks and Gowns *(March 11, 2020)*
    - Surgical Mask and Gown Conservation Strategies - Letter to Healthcare Providers *(March 11, 2020)*

In case you missed it

- Fraudulent Coronavirus Disease 2019 (COVID-19) Products
- From NIH - NIH Clinical Trial of Investigational Vaccine for COVID-19 Begins *(March 16, 2020)*
- HHS Solicits Proposals for Development of Medical Products for Novel Coronavirus *(March 6, 2020)*

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U.S. Food and Drug Administration

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