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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

August 5, 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 29, 2020 include:

Coronavirus (COVID-19) Updates:

- August 4, 2020: Daily Roundup: FDA actions on warning letters, Emergency Use Authorizations, and more
- July 31, 2020: FDA Authorizes First Tests that Estimate a Patient's Antibodies from Past SARS-CoV-2 Infection
- July 29, 2020: FDA Posts New Template for At-Home and Over-the-Counter Diagnostic Tests for Use in Non-Lab Settings, Such as Homes, Offices or Schools
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

Investing in Advanced Manufacturing to Support Public Health Preparedness

Americans may be surprised to learn that many 21st century medical products are still being manufactured using technologies commonly employed since the middle of the last century. These manufacturing platforms are not dynamic and can increase the risk of shortages, limit flexibility during an emergency, and contribute to the high cost of medical products. For the past several years, FDA has sought to encourage and facilitate the adoption of “advanced manufacturing,” which refers to new and emerging approaches for the production of medical technologies.

Advanced manufacturing approaches are applicable to different medical product areas. For example, process intensification methods, such as continuous manufacturing, can simplify and centralize the production of many essential medicines. Likewise, techniques such as 3D printing can help produce patient-specific medical devices. Furthermore, digital and smart design and manufacturing processes also promise to increase efficiency and reduce uncertainty.

The potential public health value of advanced manufacturing is even greater in the context of the ongoing COVID-19 pandemic, which has highlighted the strain on supply chains and the need for adaptive manufacturing systems to accelerate the production of medical countermeasures. The FDA has established a strong regulatory foundation to support the uptake of advanced manufacturing, and COVID-19 provides the unique impetus to spur further advancement of medical manufacturing. *(August 3, 2020)*

Read more: FDA Voices

Related links:

- 3D Printing in FDA’s Rapid Response to COVID-19 *(updated August 3, 2020)*

- Advanced Manufacturing at FDA
- What are medical countermeasures?

Donate COVID-19 Plasma

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.

Emergency Use Authorization (EUA) Updates

FDA posts new template for at-home and over-the-counter diagnostic tests for use in non-lab settings
FDA posted a new template (Word doc) for commercial developers to help them develop and submit EUA requests for COVID-19 diagnostic tests that can be performed entirely at home or in other settings besides a lab, such as offices or schools, and that could be available without a prescription. *(July 29, 2020)*

Remdesivir EUA fact sheet, FAQ updates
FDA updated its frequently asked questions on the Emergency Use Authorization for Remdesivir for Certain Hospitalized COVID-19 Patients (PDF). The update includes a question regarding changes to Gilead's PDF Fact Sheets for Health Care Providers and Patients and Parent/Caregivers. Gilead updated the fact sheets to incorporate the sponsor's use of the proprietary name Veklury. *(July 30, 2020)*

New FAQ on antibody testing
FDA posted frequently asked questions for patients and consumers about antibody (serology) testing during the COVID-19 public health emergency. A COVID-19 antibody test, also known as a serology test, is a blood test that can detect if a person has antibodies to SARS-CoV-2, the virus that causes COVID-19. COVID-19 antibody tests can help identify people who may have been infected with the SARS-CoV-2 virus or have recovered from the COVID-19 infection. *(July 30, 2020)*

FDA authorizes first tests that estimate a patient's antibodies from past SARS-CoV-2 infection
FDA issued EUAs to Siemens for its ADVIA Centaur SARS-CoV-2 IgG (COV2G) (PDF) and Atellica IM SARS-CoV-2 IgG (COV2G) (PDF) tests, which are the first COVID-19 serology tests that display an estimated quantity of antibodies present in the tested individual's blood. These tests are known as "semi-quantitative" because they do not display a precise measure, but rather, they provide an estimate of the quantity of a patient's antibodies produced against infection with the virus that causes COVID-19.

Diagnostic test EUAs
To date, FDA has currently authorized 203 tests under EUAs, which include 166 molecular tests, 35 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 5, 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 13, 2020:** FDA Grand Rounds webcast - Nanotechnology: Over a Decade of Progress and Innovation at FDA, 12:00 - 1:00 p.m. ET - *Also see the related report (PDF), issued July 2020*
- **August 18, 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.

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
- Questions about methanol contamination in hand sanitizer? Visit FDA's **searchable list** to help you identify hand sanitizers that should not be used. In addition, FDA continues to find issues with certain hand sanitizer products. Test results show certain products have concerningly low levels of the active ingredient ethyl alcohol or isopropyl alcohol. Do not use these subpotent products, also on the searchable list.
- Take our hand sanitizer quiz to test your knowledge!

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