If your email program has trouble displaying this email, view it as a web page.

U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

July 1, 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:

- June 30, 2020: Daily Roundup: FDA actions on topics including a vaccine guidance, new FDA Insight podcast, new EUA, and a testing update
- June 30, 2020: Update on Progress Toward Safely Getting Back to Work and Back to School - testimony from FDA Commissioner Stephen M. Hahn, MD and other HHS officials
- June 30, 2020: FDA Takes Action to Help Ensure Facilitate Timely Development of Safe, Effective COVID-19 Vaccines
- June 25, 2020: FDA Voices: Partnering with the European Union and Global Regulators on COVID-19

- June 24, 2020: Joint Statement from USDA and FDA on Food Export Restrictions Pertaining to COVID-19
- June 23, 2020: FDA Holds Meetings with the European Commission (EC) and the European Medicines Agency (EMA) to Strengthen Medical Products Cooperation
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

FDA Takes Action to Help Facilitate Timely Development of Safe, Effective COVID-19 Vaccines

On June 30, 2020, the FDA took important action to help facilitate the timely development of safe and effective vaccines to prevent COVID-19 by providing guidance with recommendations for those developing COVID-19 vaccines for the ultimate purpose of licensure.

The guidance, which reflects advice the FDA has been providing over the past several months to companies, researchers, and others, describes the agency's current recommendations regarding the data needed to facilitate the manufacturing, clinical development, and approval of a COVID-19 vaccine.

Read the news release

Related links:

- Guidance: Development and Licensure of Vaccines to Prevent COVID-19
- Coronavirus (COVID-19) | CBER-Regulated Biologics

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

Emergency Use Authorization (EUA) Updates

Ventilators: Public-private partnership in action
FDA's list of EUAs for Ventilators and Ventilator Accessories has been updated, adding the AustinP51 (resuscitator) to Appendix B of the ventilator EUA. The AustinP51 is a portable emergency-use resuscitator designed to provide either continuous or intermittent ventilatory support for patients requiring mechanical ventilation through volume control. The AustinP51 emergency-use system (EURS) is for use by professionals qualified and trained in the use of general ventilation equipment, or who are specifically trained on the AustinP51 system. This EURS is intended for use in healthcare settings to treat adults during the COVID-19 pandemic. *(June 25, 2020)*

Updated serology test EUA template
FDA updated the templates for laboratories and commercial manufacturers to help facilitate submission of EUA requests for serology tests. The updates clarify FDA's previous recommendations for demonstrating clinical performance and presenting validation data, and provide new recommendations for validation of point-of-care tests. *(June 26, 2020)*

Testing supply substitution strategies - reminder
FDA is offering as a resource, Testing Supply Substitution Strategies (1.5 MB), a 22-slide PowerPoint file containing detailed information to help support labs performing authorized COVID-19 tests. This interactive tool includes validated supply alternatives that labs can use to continue performing testing when there is a supply issue with some components of a test. To navigate through the strategies in the file, download the file, open it, and click Slide Show > From Beginning. *(June 3. 2020)*

Diagnostic test EUAs
To date, FDA has authorized 157 tests under EUAs, which include 132 molecular tests, 24 antibody tests, and 1 antigen test. *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 1, 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 7, 2020:** Save the date for the next event in the webinar series Respirators for Health Care Personnel Use during COVID-19 Pandemic.

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

- Convalescent Plasma Fact Sheets and Toolkit for Health Professionals
- Coronavirus Disease 2019 (COVID-19) Resources for Health Professionals
- COVID-19 Educational Resources
- Multilingual COVID-19 Resources

Did someone forward you this email? ***Subscribe***
(select Emergency Preparedness and Response - FDA Medical Countermeasures Initiative (MCMi) News)

Twitter: @FDA_MCMi
www.fda.gov/medicalcountermeasures

U.S. Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993
1-888-INFO-FDA (1-888-463-6332)