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U.S. FOOD & DRUG ADMINISTRATION

Medical Countermeasures Initiative Update

June 10, 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 3, 2020 include:

Coronavirus (COVID-19) Updates:

- June 9, 2020: Daily Roundup: FDA actions on warning letters regarding fraudulent products, approval of an abbreviated new drug application for a drug to facilitate tracheal intubation, and more
- June 8, 2020: Innovation to Respond to COVID-19 - Includes links to and descriptions of the new partnerships FDA is leading or participating in to respond to COVID-19
- June 8, 2020: COVID-19 Educational Resources - Includes links to all the videos, fact sheets and social media toolkits that FDA has created on COVID-19
- June 7, 2020: FDA Reissues Emergency Use Authorizations Revising Which Types of Respirators Can Be Decontaminated for Reuse

- June 4, 2020: FDA Publicly Shares Antibody Test Performance Data From Kits as Part of Validation Study
- *Also see the features and Emergency Use Authorization Updates below*

COVID-19 Updates from FDA

An introduction to COVID-19 tests

FDA issued a **new video** (2:47) explaining the different categories of tests in the fight against COVID-19: diagnostic tests and antibody tests. As the video explains, diagnostic tests can tell if the tested person currently is infected. Antibody or serology tests detect if the person's blood contains antibodies to coronavirus.

The body produces antibodies when one becomes infected by the virus, and they help the immune system fight off the infection. If an antibody test finds antibodies in the blood, it likely means the person has been previously infected with the virus. Antibody tests do not detect whether a person is currently infected and should not be used to diagnose a current COVID-19 infection. The results from antibody tests can help us better understand questions about exposure to COVID-19. *(June 4, 2020)*

Read the Consumer Update: Coronavirus Testing Basics

Emergency Use Authorization (EUA) Updates

Testing Supply Substitution Strategies

On June 3, 2020, the FDA announced a new resource, titled **Testing Supply Substitution Strategies** (1.5 MB). This 22-slide PowerPoint file contains 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.

The information in this resource is not intended to alter any already issued EUA for a COVID-19 diagnostic test nor is it intended to speak to any specific FDA regulatory requirement. Rather, the information is being provided to help address availability concerns regarding certain critical components of COVID-19 diagnostic tests during this pandemic.

To navigate through the strategies in the file, download the file, open it, and click Slide Show > From Beginning.

New NASA-developed ventilator available under EUA

FDA added a second ventilator developed by NASA to the list of authorized ventilators, ventilator tubing connectors and ventilator accessories (PDF) under the ventilator EUA (PDF) that was issued in response to concerns relating to insufficient supply and availability of FDA-cleared ventilators for use in health care settings to treat patients during the COVID-19 pandemic. Learn more in the June 2, 2020 Daily Roundup.

More antibody test performance data now available

On June 4, 2020, FDA publicly posted test performance data from four more antibody, or serology, test kits on open.fda.gov from its independent performance validation study effort with the National Institutes of Health's (NIH) National Cancer Institute (NCI). These results are among the first to come from a collaborative effort by the FDA, NIH, Centers for Disease Control and Prevention (CDC) and Biomedical Advanced Research and Development Authority (BARDA). Additional performance data will be made available as the FDA reviews and determines if any further actions are appropriate for those test kits prior to publication.

Update on which types of respirators can be decontaminated for reuse

In response to public health and safety concerns about the appropriateness of decontaminating certain respirators, on June 6, 2020, FDA reissued certain EUAs to specify which respirators are appropriate for decontamination. Based on the FDA's increased understanding of the performance and design of these respirators, the FDA has decided that certain respirators should not be decontaminated for reuse by health care personnel.

For example, the FDA has learned from the Centers for Disease Control and Prevention's (CDC) National Institute for Occupational Safety and Health (NIOSH) testing that authorized respirators manufactured in China may vary in their design and performance. As such, the FDA has determined that the available information does not support the decontamination of these respirators and has accordingly revised the relevant EUAs. In addition, the FDA is also revising relevant EUAs to no longer authorize decontamination or reuse of respirators that have exhalation valves.

Diagnostic test EUAs

To date, the FDA has authorized 128 tests under EUAs, which include 108 molecular tests, 19 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
- FDA Combating COVID-19 with Medical Devices (PDF)
- Contacts for Medical Devices During the COVID-19 Pandemic

Events

- **Today! June 10, 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 June. *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. ET*
- **June 11, 2020 FDA Grand Rounds webcast:** A Pandemic and a Call to Action for One Health: The FDA One Health Initiative - 12:00 - 1:00 p.m., ET, CE credit available. Register in advance.
- **June 23, 2020:** Save the date for the next event in the webinar series Respirators for Health Care Personnel Use during COVID-19 Pandemic

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Information for industry

- **Devices:**
  - On June 9, 2020, FDA launched a webinar series on the topic of Respirators for Health Care Personnel Use during COVID-19 Pandemic. The webinar will provide FDA information and answer questions about EUAs for respirators, importing respirators, and overall FDA actions to help ensure that health care personnel on the front lines have the necessary supplies of respirators to meet the demand. If you missed the first one, a transcript, recording, and slides will be posted.
  - Certain Filtering Facepiece Respirators from China May Not Provide Adequate Respiratory Protection - Letter to Health Care Providers *(updated June 7, 2020)*
- **Drugs and biologics:**
  - FDA, in collaboration with the European Medicines Agency (EMA), provided procedural assistance to sponsors and applicants who anticipate submission of pediatric product development plans for the treatment and prevention of COVID-19. In issuing this Common Commentary (PDF), the FDA and EMA aspire to streamline administrative processes and facilitate efficient submission of an initial Pediatric Study Plan (iPSP) and Paediatric Investigation Plan (PIP). *(June 2, 2020)*
  - CDER's Work to Protect Public Health During the COVID-19 Public Health Emergency *(new web*

page, June 3, 2020)

- **Food:**
  - As many states move to reopen businesses affected during COVID-19, FDA prepared an infographic and checklist to help those who prepare food to serve or sell to the public directly – restaurants, bakeries, bars – protect employee and public health. *(June 1, 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
- Check out FDA's COVID-19 YouTube playlist for short videos for consumers on coronavirus topics.
- COVID-19 and Beyond: Oversight of the FDA's Foreign Drug Manufacturing Inspection Process - Congressional testimony *(June 2, 2020)*

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