

HHS COVID-19 Update – June 5, 2020

Reopening Information

Opening Up America Again Testing Blueprint: Along with the White House, Ambassador Birx announced an [addendum](#) to the “[Opening Up America Again Testing Blueprint](#)”, which will focus on using tests for diagnosis and proactive surveillance. This document provides additional guidance regarding the optimal deployment and use of testing formats and testing platforms for both the diagnosis of and proactive surveillance for COVID-19. In achieving this optimization, certain testing formats and platforms are better suited for diagnosis, while others are better positioned to enable proactive surveillance (monitoring) within communities or populations known to be at high-risk of contracting the virus. Accordingly, such optimization is critical to maximizing the efficacy of States’ testing programs and determining appropriate payment mechanisms. The considerations for optimizing testing should be reflected in each State’s July through December Jurisdictional Testing Plans. A Federal peer review panel led by the Centers for Disease Control and Prevention (CDC), will assess the quality of States’ plans for using proactive surveillance to complement diagnostic testing in responding to requests for Federal financial support of their testing initiatives. These requests are due by June 15, 2020.

Contact Tracing Communications Toolkit: CDC released a [Contact Tracing Communications Toolkit for Health Departments](#). We all need to work together with health departments to help slow the spread of COVID-19. Contact tracing and self-quarantining of people with COVID-19 and close contacts are critical to help slow transmission of COVID-19 in our communities.

Funding

\$66 Million to Improve Delivery of Mental and Substance Use Disorder Treatment: SAMHSA awarded nearly \$66 million in grants to provide training, education, and resources at no cost to individuals, communities, states, and the healthcare field to [improve the delivery of mental and substance use disorder treatment](#) in America’s communities. These are important grants to support those who need treatment during the COVID-19 pandemic.

Testing

Test Performance Data from Antibody, Serology Test Kits: 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.

Diagnostic Tests vs. Antibody Tests Video: FDA issued a new [video](#) resource 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.

EUA Authorized Serology Test Performance: FDA updated their webpage on [EUA Authorized Serology Test Performance](#). Serology tests detect the presence of antibodies in the blood when the body is responding to a specific infection, like COVID-19. Serology tests could play a role in the fight against COVID-19 by helping healthcare professionals identify individuals who may have developed an immune response to SARS-CoV-2. In addition, these test results can aid in determining who may donate a part of their blood called convalescent plasma, which may serve as a possible treatment for those who are seriously ill from COVID-19.

Biosafety Guidelines for Handling Specimens: CDC updated their [Interim Laboratory Biosafety Guidelines for Handling and Processing Specimens](#) Associated with Coronavirus Disease 2019 (COVID-19). The updates include the addition of anatomic pathology guidance for COVID-19 and updated Point-of-Care testing guidance for COVID-19. Related, the [FAQs on biosafety](#) and COVID-19 were also updated.

Testing Updates: During the COVID-19 pandemic, the FDA has worked with more than 400 test developers who have already submitted, or said they will be submitting, EUA requests to the FDA for tests that detect the virus or antibodies to the virus. To date, the FDA has authorized 124 tests under EUAs, which include 106 molecular tests, 17 antibody tests, and 1 antigen test.

Treatment

Antibiotic to Treat Hospital-Acquired Bacterial Pneumonia and Ventilator-Associated Bacterial Pneumonia: FDA approved the antibiotic [Recarbrio](#) (a combination of imipenem-cilastatin and relebactam) to treat hospital-acquired bacterial pneumonia and ventilator-associated bacterial pneumonia (HABP/VABP) in patients 18 years of age and older. Recarbrio was previously FDA-approved to treat patients with complicated urinary tract infections and complicated intra-abdominal infections who have limited or no alternative treatment options.

New Drug Application Approved for Ventilated Patients: FDA approved an abbreviated new drug application for [dexmedetomidine hydrochloride in 0.9% sodium chloride injection](#) (ANDA 209307), indicated for sedation of initially intubated and mechanically ventilated patients during

treatment in an intensive-care setting and sedation of non-intubated patients prior to and/or during surgical and other procedures. The most common side effects of dexmedetomidine hydrochloride injection are hypotension, bradycardia and dry mouth. This drug is listed in the FDA Drug Shortage Database. The FDA recognizes the increased demand for certain products during the COVID-19 public health emergency, and remains deeply committed to facilitating access to medical products to help address critical needs of the American public.

Non-Invasive Monitoring Devices: Effective immediately, new [guidance](#) issued by the FDA expands the availability and capability of non-invasive monitoring devices. These remote devices facilitate patient monitoring while reducing patient and healthcare provider contact and exposure to COVID-19 for the duration of the COVID-19 public health emergency. This guidance replaces the March 20, 2020, guidance, titled “Enforcement Policy for Non-Invasive Remote Monitoring Devices Used to Support Patient Monitoring During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency.” The new guidance expands the scope to include additional device types (product codes) and provides additional references and standards for consideration.

Unapproved and Misbranded COVID-19 Products: As part of FDA’s effort to protect consumers, the agency issued warning letters to operators of four websites (www.roidsmall.net, www.emedkit.com, www.4nrx.md and www.chloroquineonline.com) that market unapproved and misbranded COVID-19 products. There are currently no FDA-approved drugs to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider. Consumers can visit [BeSafeRx](#) to learn about how to safely buy medicine online.

Biosafety FAQ’s and Specimen Handling: CDC updated [biosafety FAQs](#) on specimen handling, specimen packing and shipping, and anatomic pathology in the midst of COVID-19.

Moderna to Expand Domestic Manufacturing of Vaccine: BARDA is expanding an existing partnership with MODERNATX, Inc to [increase the domestic manufacturing capacity of Moderna’s mRNA-1273 vaccine](#) being developed for the prevention of COVID-19. Expansion activities are expected to begin mid-year to deliver material and could be available as soon as the end of 2020. Moderna has previously announced its new collaboration with Lonza in the United States and this funding supports that manufacturing capacity expansion.

EUA for Roche Diagnostics with Elecsys IL-6: [FDA issued an EUA to Roche Diagnostics for Elecsys IL-6](#). Elecsys IL-6 immunoassay is an in vitro diagnostic test for the quantitative measurement of IL-6 (interleukin 6) in human serum and plasma. This assay is used to assist in identifying severe inflammatory response in patients with confirmed COVID-19 illness to aid in determining the risk of intubation with mechanical ventilation, in conjunction with clinical findings and the results of other laboratory testing. Emergency use of this test is limited to authorized laboratories.

FDA Response to COVID-19: The FDA issued an updated [FDA COVID-19 Response At-A-Glance Summary](#) that provides a quick look at facts, figures and highlights of the agency's response efforts.

PPE

Respirators for Health Care Personnel Use: FDA announced that on Tuesday, June 9, 12:00 pm – 1:00 pm ET, the FDA will launch 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 emergency use authorizations (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. Hear from speakers, including Stephen M. Hahn, MD, Commissioner of Food and Drugs at the FDA; Jeffrey E. Shuren, MD, JD, Director of the Center for Devices and Radiological Health (CDRH) at the FDA; William H. Maisel, MD, MPH, Director, Office of Product Evaluation and Quality (OPEQ) at CDRH; and Suzanne Schwartz, MD, MBA, Director, Office of Strategic Partnerships and Technology Innovation (OST) at CDRH. Registration is not necessary.

Information for Specific Populations

Community Related Exposure: CDC updated public health recommendations for people in U.S. [communities exposed to a person with known or suspected COVID-19](#), other than health workers or other critical infrastructure workers. There is growing evidence of transmission risk from infected people without symptoms (asymptomatic) or before the onset of recognized symptoms (presymptomatic) and an increased community transmission in many parts of the country. Continued focus on reducing transmission through social distancing and other [personal prevention strategies](#). Updates include the addition of exposure to people with confirmed COVID-19 who have not had any symptoms to this Guidance.

Guidance for Handlers of Service and Therapy Animals: CDC released additional guidance for animals focused on [handlers of service and therapy animals](#). Facilities that normally use therapy animals may not allow them at this time because people in many of these settings are at higher risk for serious illness with COVID-19. If you have a service or therapy animal, follow your local guidance for acceptable business and social practices. Consider local levels of COVID-19 transmission when evaluating the risk to yourself, your animal, and the people you might come into contact with.

Animals and COVID-19: FDA also [updated a FAQ](#) on what animal species can become infected by COVID-19.

Resources for Limited-English-Proficient Populations: CDC created a [communication toolkit](#) to help public health professionals, health departments, community organizations, and healthcare systems and providers reach populations who may need COVID-19 prevention messaging in their native languages. The toolkit provides print resources in multiple languages and audiovisual resources.

People Who Need Extra Precautions: CDC updated [guidance for people at higher risk for severe illness](#) with COVID-19, including those who are immunocompromised and older adults.

Historic Preservation Compliance: FEMA released a [fact sheet](#) in accordance with 36 CFR § 800.12(a) of the Section 106 regulations and in consultation with the Advisory Council on Historic Preservation, State Historic Preservation Officers, and Tribal Historic Preservation Officers, Indian Tribes and Native Hawaiian organizations (consulting parties), developed emergency procedures to govern its Section 106 responsibilities for approval of direct Federal assistance and funding of emergency protective measures to save lives and to protect improved property and public health and safety in response to COVID-19 pandemic (COVID-19 emergency undertakings).

Information on Trafficking Persons and COVID-19 Response: The Office of Trafficking in Person (OTIP) Director, Katherine Chon has penned a [letter](#) to anti-trafficking grantees which highlights flexibilities afforded to funding recipients, as well as efforts OTIP has taken to respond to the COVID-19 pandemic. The two additional documents contain Qs and As regarding [grant administration](#) and provides technical assistance to grantees with [implementing their grant programs](#).

Research Updates

Weekly COVIDView Report: CDC released their weekly [COVIDView](#) report. Nationally, levels of influenza-like illness (ILI) and COVID-19-like illness (CLI) and the percentage of specimens testing positive for SARS-CoV-2, the virus that causes COVID-19, continue to decline or remain stable at low levels. Mortality attributed to COVID-19 also decreased compared to last week but remains elevated above baseline and may increase as additional death certificates are processed.

Clinical Laboratory Staff and Health Care Providers Using Transport Media: FDA issued a [letter](#) to clinical laboratory staff and health care providers about a safety risk with using transport media and SARS-CoV-2 testing platforms that are not compatible. There is a risk of exposure to harmful cyanide gas when certain transport media are used with an incompatible testing platform or laboratory process that uses bleach.

Postmortem Guidance: CDC updated guidance for the [collection and submission of postmortem specimens](#) from deceased persons under investigation (PUI) for COVID-19, plus recommendations for biosafety and infection control practices during specimen collection and handling, including during autopsy procedures.

Study Identifies Potential Approach to Treat Severe Respiratory Distress in Patients with COVID-19: NIH released [early data from a clinical study](#) suggesting that blocking the Bruton tyrosine kinase (BTK) protein provided clinical benefit to a small group of patients with severe COVID-19. Researchers observed that the off-label use of the cancer drug acalabrutinib, a BTK inhibitor that is approved to treat several blood cancers, was associated with reduced respiratory distress and a reduction in the overactive immune response in most of the treated patients. The findings were published June 5, 2020, in *Science Immunology*. The study was led by researchers in the Center for Cancer Research at the NCI, in collaboration with researchers from the NIAID,

as well as the DoD's Walter Reed National Military Medical Center, and four other hospitals nationally.

Household Cleaning and Disinfection for COVID-19 Prevention MMWR: CDC released a MMWR on knowledge and practices [regarding safe household cleaning and disinfection for COVID-19](#) prevention. Since the onset of the COVID-19 pandemic, calls to poison centers regarding exposures to cleaners and disinfectants have increased. This report discusses how an Internet panel survey identified gaps in knowledge about safe preparation, use, and storage of cleaners and disinfectants. Approximately one third of survey respondents engaged in nonrecommended high-risk practices with the intent of preventing SARS-CoV-2 transmission, including using bleach on food products, applying household cleaning and disinfectant products to skin, and inhaling or ingesting cleaners and disinfectants.