

HHS COVID-19 Update – June 1, 2020

Testing

State Plans on Testing Due Yesterday: As dictated by statute, states must create a plan for making testing accessible, including how they will ensure testing of vulnerable populations like nursing home residents. Next, HHS will review and, where needed, engage in further dialogue with individual states.

Antibody Testing: CDC updated information on [Using Antibody Testing for COVID-19](#). CDC has developed [interim guidance](#) for how healthcare providers, laboratories, and public health staff should use antibody tests. The webpage includes recommendations for professionals and interim guidelines for clinical and public health settings.

Community-level Seroprevalence Surveys: CDC announced a [seroprevalence survey](#) in Atlanta, Georgia. CDC partnered with the Georgia Department of Public Health, Fulton County, and Dekalb County Boards of Health to conduct a community-level seroprevalence survey within these counties. Specific areas within these counties were randomly selected using U.S. Census Bureau census blocks. The survey will help CDC learn more about how COVID-19 might be spreading in other communities with similar populations.

Large-scale Geographic Seroprevalence Survey Samples: CDC also updated their webpage on [large-scale geographic seroprevalence](#) survey samples. CDC wants to learn more about the percentage of people in the United States who have been infected with SARS-CoV-2, the virus that causes COVID-19 and to better understand how the virus is spreading through the U.S. population over time. Because infected people can have mild illness or may not get medical care or testing, CDC also wants to use this information to estimate the number of people who have been previously infected with SARS-CoV-2 and were not included in official case counts.

Community Based Testing Sites: HHS updated their information on [Community Based Testing Sites](#). The site includes information on the public-private partnerships between HHS and pharmacy and retail companies to accelerate testing for more Americans in more communities across the country. The webpage also lists where to find a testing location by company and state.

Contact Tracing: CDC updated their information on [Contact Tracing](#). Revisions were made on May 29, 2020 to [Health Departments: Interim guidance on developing a COVID-19 case investigation & contact tracing plan](#) to reflect the contact elicitation window for asymptomatic cases was changed from 10 days before obtaining the specimen that tested positive for COVID-19 to 2 days to accommodate pragmatic and operational considerations for the implementation of case investigation and contact tracing programs. Additionally, recent data suggests that

asymptomatic persons may have a lower viral burden at diagnosis compared to symptomatic cases. Thus, the longer contact elicitation window (beginning 10 days prior to specimen collection) may have limited impact in identification of new COVID-19 cases. Furthermore, the recommendation for the shorter contact elicitation window (beginning 2 days prior to specimen collection) will help focus case investigation and contact tracing resources towards activities most likely to interrupt ongoing transmission. This time period is also now in alignment with WHO, European CDC, and Public Health Canada.

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 114 tests under EUAs, which include 101 molecular tests, 12 antibody tests, and 1 antigen test.

Treatment

Advancing Manufacturing Abilities: HHS [announced a task order with Emergent BioSolutions](#) to advance manufacturing capabilities and capacity for a potential COVID-19 vaccine as well as therapeutics. The task order is worth approximately \$628 million and falls under an existing contract with BARDA and ASPR. Under the task order, Emergent will commit manufacturing capacity valued at up to \$542.75 million for production of COVID-19 vaccine candidates through 2021, in addition to an investment of approximately \$85.5 million for the rapid expansion of Emergent's vial-filling contract development and manufacturing capacity for vaccines and therapeutics.

Advancing Clinical Trial for Therapeutics: BARDA and Genentech, part of the Roche Group and headquartered in South San Francisco, are [partnering to support the acceleration of a Phase 2 clinical trial](#) to evaluate two novel therapeutics for the potential treatment of hospitalized patients with severe COVID-19 pneumonia. The single, randomized, placebo controlled Phase 2 clinical trial will evaluate the safety and efficacy of the two investigational drugs in approximately 300 patients with severe COVID-19 pneumonia requiring supplemental oxygen.

Responding to Community Transmission of COVID-19 in Outpatient and Ambulatory Care Settings: CDC updated their information for [Outpatient And Ambulatory Care Settings](#). This interim guidance outlines goals and strategies suggested for U.S. ambulatory care settings in response to community spread of COVID-19.

Explaining FDA Terminology and Perspectives on COVID-19: FDA released a new document on [Understanding the Regulatory Terminology of Potential Preventions and Treatments for COVID-19](#), that explains FDA terminology to consumers. FDA Commissioner released a blog highlighting the new resource in his blog post on [Bringing a Cancer Doctor's Perspective to FDA's Response to the COVID-19 Pandemic](#). He notes the FDA role to both help move new medical products to patients as soon as possible, while at the same time determine whether they are effective and if the benefits outweigh the risks.

FAQs for Healthcare Infection and Prevention: CDC updated their [Healthcare Infection Prevention and Control FAQs for COVID-19](#). These FAQs cover a range of topics for clinicians.

Updated Information on MIS-C: CDC updated their webpage on [Multisystem Inflammatory Syndrome in Children \(MIS-C\)](#). Updated include additional handouts and outreach to clinicians for reporting.

Remdesivir Information: FDA updated their [FAQs on Remdesivir](#). The updated information reflects changes in distribution by Gilead.

App for Informed Consent: FDA is making its previously developed FDA [MyStudies app](#) available to investigators as a free platform to securely obtain patients' informed consent for eligible clinical trials when face-to-face contact is not possible or practical due to COVID-19 control measures. FDA MyStudies is now referred to as [COVID MyStudies](#) in the Apple App store and in the Google Play store.

Warning to Fraudulent Actors: As part of the FDA's efforts to protect consumers, the agency issued warning letters to two companies for selling fraudulent COVID-19 products. There are currently no FDA-approved products to prevent or treat COVID-19. Consumers concerned about COVID-19 should consult with their health care provider. The first seller to whom FDA sent a warning letter was [Quadrant Sales & Marketing, Inc.](#), which offers non-alcohol-based hand sanitizer products for sale in the United States with false or misleading claims including that the products maintain their effectiveness for up to 24 hours. The second seller to whom FDA sent a warning letter was [StayWell Copper Products](#), which offers copper "Germ Stopper" products for sale in the United States with misleading claims that the products are safe and/or effective for the prevention of COVID-19.

Reopening Information

Considerations for Reopening Assisted Living Facilities: CDC updated their [Considerations When Preparing for COVID-19 in Assisted Living Facilities \(ALFs\) Rollout Plan](#). The changes include updated recommendations about visitor restrictions and group activities to assist facilities if, based on guidance from their state and local officials, they begin to relax restrictions and well as added information about the [National Healthcare Safety Network \(NHSN\) Long-term Care Facility \(LTCF\) COVID-19 module](#), which can assist with tracking infections and prevention process measures in a systematic way.

Resuming Business Toolkit: CDC released a [Resuming Business Toolkit](#). The Resuming Business Toolkit is designed to assist employers in slowing the spread of COVID-19 and lowering the impact in their workplace when reintegrating employees into non-healthcare business settings. The toolkit includes an employer sheet, restart readiness checklist, worker protection tool, returning to work infographic, and additional resources.

Employers with Workers at High Risk: CDC released information on [Employers with Workers at High Risk](#). As workplaces consider a gradual scale up of activities towards pre-COVID-19 operating practices, it is particularly important to keep in mind that some workers are at [higher risk for severe illness](#) from COVID-19. The webpage includes information on scaling up operations, safety action, monitoring and preparing and closing.

Resuming Schools and Camps: CDC updated their information for [schools and camps](#). As communities consider a gradual scale up of activities towards pre-COVID-19 operating practices in centers for learning, such as K-12 schools and summer day camps, CDC offers recommendations to keep communities safe while resuming peer-to-peer learning and providing crucial support for parents and guardians returning to work. These recommendations depend on community monitoring to prevent COVID-19 from spreading.

Resuming Childcare Programs: CDC updated information on [Childcare Programs](#). The gradual scale up of activities towards pre-COVID-19 operating practices at childcare programs is crucial to helping parents and guardians return to work. Many states have closed schools for the academic year and, with summer quickly approaching, an increasing number of working parents may need to rely on these programs. CDC's [Interim Guidance for Administrators of US K-12 Schools and Childcare Programs and supplemental Guidance for Childcare Programs that Remain Open](#) provide recommendations for operating childcare programs in low, moderate, and significant mitigation communities.

Youth Sports: CDC updated information on [Considerations for Youth Sports](#). As some communities in the United States begin to start youth sports activities again, the Centers for Disease Control and Prevention (CDC) offers the following considerations for ways in which youth sports organizations can protect players, families, and communities and slow the spread of the Coronavirus Disease 2019 (COVID-19). The webpage includes guiding principles, assessing risk, reducing spread, healthy environments, healthy operations, when someone gets sick, communication and other resources.

Institutes of Higher Education: CDC updated their information for [Institutes of Higher Education](#). As some institutes of higher education (IHE) open in the United States, the Centers for Disease Control and Prevention (CDC) offers the following considerations for ways in which IHEs can help protect students and employees (e.g., faculty, staff, and administrators) and slow the spread of the Coronavirus Disease 2019 (COVID-19). IHEs vary considerably in geographic location, size, and structure. As such, IHE officials can determine, in collaboration with [state and local health officials](#), whether and how to implement these considerations while adjusting to meet the unique needs and circumstances of the IHE and local community.

Information for Specific Populations

Toolkit for Meat and Poultry Processing Facilities: CDC released additional information for a [Meat and Poultry Processing Facility Assessment Toolkit](#). The toolkit includes tools and resources for occupational safety and health professionals and state and local public health officials assessing meat and poultry processing facilities.

Preparedness in a Pandemic Toolkit: FEMA released [Coronavirus Pandemic Response: Preparedness in a Pandemic Exercise Starter Kit](#)_FEMA developed an Exercise Starter Kit with sample documents an organization can use to conduct their own planning workshop on preparedness in a pandemic.