

HHS COVID-19 Update – May 26, 2020

Testing

General Information on Antibody Tests: CDC updated their information on [Test for Past Infection \(Antibody Test\)](#). Antibody tests check your blood by looking for antibodies, which can show if you had a past infection with the virus that causes COVID-19. Antibodies are proteins that help fight off infections and usually provide protection against getting that disease again (immunity). Antibodies are disease specific.

Guidance on Antibody Testing: CDC released [Interim Guidelines for COVID-19 Antibody Testing](#) in clinical and public health settings. Data that will inform serologic testing guidance is rapidly evolving. Recommendations on the use of serologic tests to determine protective immunity and infectiousness among persons recently infected with SARS-CoV-2 will be updated as new information becomes available.

Information on CDC Serology Testing: CDC has updated their information on [Serology Testing for COVID-19 at CDC](#). CDC has developed a laboratory test to help estimate how many people in the United States have been infected with SARS-CoV-2, the virus that causes COVID-19. Clinicians and researchers refer to this as a serology test, and many commercial laboratories call it an antibody test. CDC is using this serologic (antibody) test to evaluate the performance of commercial antibody tests. We do not know if the antibodies that result from SARS-CoV-2 infection will provide someone with protection (immunity) from getting infected again. If antibodies do provide immunity, we don't know how much antibody is protective or how long protection might last. CDC scientists are currently conducting studies to answer these questions.

Large Scale Geographic Seroprevalence Survey: CDC released information about their [Large Scale Geographic Seroprevalence Survey](#). 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. To help answer those questions and others, CDC is collaborating with public health and private partners on a variety of seroprevalence surveys of different sizes, locations, populations studied, and purposes. CDC is partnering with commercial laboratories to conduct a large-scale geographic seroprevalence survey that will first test clinical blood specimens from Washington State and the New York City metro region for SARS-CoV-2 antibodies. CDC, in partnership with state and local health

departments, plans to expand this seroprevalence survey to an additional eight states, including California, Connecticut, Florida, Louisiana, Minnesota, Missouri, Pennsylvania and Utah.

Information for Laboratories: CDC updated their webpage on [Information for Laboratories about Coronavirus \(COVID-19\)](#). The webpage includes resources, CDC labwork, advisories and alerts and publications.

Updated Information for Testing Clinical Specimens: CDC updated their [Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19](#). The update includes a change in specimen shipping address.

Contact Tracing Resources: CDC updated their information on [Contact Tracing](#). Specifically, new guidance and resources were made available on [Key Information to Collect During a Case Interview](#).

Testing FAQs and Unauthorized COVID-19 Tests: The FDA updated the [FAQs on Testing for SARS-CoV-2](#) to clarify information about at-home self-collection and what tests should no longer be distributed for COVID-19. Test developers can offer their COVID-19 tests for at-home self-collection of a specimen if at-home self-collection of a specimen is specifically authorized under the Emergency Use Authorization (EUA) for the test. In addition, COVID-19 tests for at-home self-collection may be used as part of an Institutional Review Board-approved study. The FDA is supportive of at-home self-collection and has authorized several COVID-19 tests for home collection of specimens to be sent to a laboratory for processing and test reporting. The FDA added a new section to the FAQs to clarify [what tests should no longer be distributed for COVID-19](#). Yesterday, the FDA posted a list of commercial manufacturers' antibody tests that have been removed from the "notification list" of tests being offered under the Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency. Antibody tests on this new removal list include those voluntarily withdrawn from the notification list by the test's commercial manufacturer and those for which there is not a pending EUA request or issued EUA. FDA expects that the tests on the removal list will not be distributed.

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 109 tests under EUAs, which include 96 molecular tests, 12 antibody tests, and 1 antigen test.

Treatment

Transmission of COVID-19: CDC updated their information on [How COVID-19 Spreads](#). COVID-19 is thought to spread mainly through close contact from person-to-person. Some people without symptoms may be able to spread the virus. We are still learning about how the virus spreads and the severity of illness it causes.

Complete List of Approved Medical Devices: FDA released an [updated list of approved Medical Devices](#) to date to treat COVID-19.

Information on MIS-C: CDC updated information on their webpage [For Parents: Multisystem Inflammatory Syndrome in Children \(MIS-C\) associated with COVID-19](#). The webpage includes known information, what to do if you think your child is sick with MIS-C, how doctors will care for your child, what is not known about MIS-C, what CDC is doing to learn more and how to protect your child from COVID-19.

Information for Exposed Healthcare Personnel: CDC updated their [Interim U.S. Guidance for Risk Assessment and Work Restrictions for Healthcare Personnel with Potential Exposure to COVID-19](#). The interim guidance was updated to clarify the definition of exposure for HCP not wearing eye protection as well as simplifying exposures warranting work restrictions for healthcare personnel, changing the definition of prolonged exposure to more closely align with the definition used for community exposures and contact tracing (15 minutes or longer), and providing flexibility in approaches for healthcare facilities depending on the degree of community transmission and availability of resources to perform contact tracing.

Additional Information on Remdesivir: FDA released updated [QA](#) and [FAQs](#) on Remdesivir. IHS also released a [fact sheet on Remdesivir](#) that outlines what the drug is, how it is distributed to tribes and how it should be used.

Accelerating Vaccine Development: [BARDA](#) announced that they will [collaborate with Merck and IAVI](#) to accelerate development of an rVSV-SARS-CoV2 (recombinant) COVID-19 vaccine. By leveraging experience from the manufacturing process for the [FDA](#)-licensed Ebola vaccine, ERVEBO®, this partnership allows streamlined development of a COVID-19 vaccine. Based on experience with the rVSV-based Ebola vaccine, a COVID-19 vaccine using the same rVSV platform, has potential to provide a rapid and robust immune response that could provide protection against COVID-19 after a single dose.

Donating Plasma: In a new video, [Donate Blood and Plasma to Make a Difference](#), the FDA explains one way you can make a difference is to donate blood or plasma if you are eligible to donate.

Ensuring Availability of Medical Devices: The FDA issued the guidance “[Supplements for Approved Premarket Approval \(PMA\) or Humanitarian Device Exemption \(HDE\) Submissions During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency](#)” to help foster the continued availability of medical devices during the COVID-19 public health emergency. As described in the guidance, the FDA does not intend to object to limited modifications to the design and manufacturing of devices approved through either a PMA or HDE without prior submission of a PMA or HDE supplement or 30-day notice for the duration of the public health emergency. The policy set forth in the guidance does not apply to design or manufacturing changes made for reasons other than addressing manufacturing limitations or supply chain issues resulting from the COVID-19 public health emergency or to any proposed changes described in a regulatory submission already received by FDA.

Information for Compounding Pharmacies: FDA has updated their policy for [Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Pharmacy Compounders not Registered as Outsourcing Facilities During the COVID-19 Public Health Emergency \(Revised\)](#). FDA has issued a temporary policy regarding the compounding of certain drugs for hospitalized patients by outsourcing facilities during the COVID-19 public health emergency, when, among other things, hospitals are unable to obtain FDA-approved versions of these drugs. As noted in FDA’s guidance announcing this policy, outsourcing facilities are required to register with FDA, are inspected by FDA according to a risk-based schedule, and are subject to current good manufacturing practice (CGMP) requirements, among other conditions and requirements. Similarly, FDA also updated their [Temporary Policy for Compounding of Certain Drugs for Hospitalized Patients by Outsourcing Facilities During the COVID-19 Public Health Emergency \(Revised\)](#).

Approval of New Drug Applications: The FDA approved two abbreviated new drug applications: [Dexmedetomidine hydrochloride](#) in 0.9% sodium chloride injection, is 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. [Succinylcholine chloride injection](#) USP 200 mg/10 mL, is indicated in addition to general anesthesia, to facilitate tracheal intubation and to provide skeletal muscle relaxation during surgery or mechanical ventilation. Side effects of succinylcholine chloride injection include anaphylaxis, hyperkalemia, and malignant hyperthermia.

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.

Warning to Fraudulent Actors: The FDA and the Federal Trade Commission issued a warning letter to two companies for selling fraudulent COVID-19 products, as part of the agency’s effort to protect consumers. 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 warned, [Apollo Holding LLC](#), offers “NoronaPak” products, including cannabidiol (CBD) and other supplement products for sale in the U.S. with claims that misleadingly represent the products as safe and/or effective for the prevention and treatment of COVID-19. The second seller warned, [North Coast Biologics LLC](#), has offered the unapproved “nCoV19 spike protein vaccine” for sale in the U.S. with misleading claims that the product is safe and/or effective for the prevention of COVID-19.

PPE

Considerations for Using N95s Beyond Their Shelf Life: CDC updated their information on [Considerations for Release of Stockpiled N95s Beyond the Manufacturer-Designated Shelf Life](#). Some U.S. stockpiles include N95 filtering facepiece respirators (N95s) that have exceeded their

manufacturer-designated shelf life. U.S. Government decision makers are considering whether these products should be released for use during the COVID-19 response. Information is provided below that may be used to inform these product release decisions. In times of respiratory protective device shortage, such as during the COVID-19 response, supplies must be managed so that protection against exposure is adequate.

State by State Data on PPE and Resources: FEMA released an updated tally of [resources disbursed to states](#) for COVID-19. The federal government continues to meet demands for personal protective equipment through new acquisition, federal interagency allocation, private industry donations and the Strategic National Stockpile. Resources listed are deliveries made by FEMA Regions, and are separate from all supplies delivered through Project Airbridge distributions.

Considerations for Prioritization of Critical Supplies in the Food Industry: FDA released [Considerations for Prioritization of PPE, Cloth Face Coverings, Disinfectants, and Sanitation Supplies During the COVID-19 Pandemic](#). The purpose of this document is to share recommendations for addressing shortages of personal protective equipment (PPE), cloth face coverings, disinfectants, and sanitation supplies in the food and agriculture industry in order to help maintain employee safety, continuity of the food supply, food safety, and employee/consumer confidence. As PPE, cloth face coverings, disinfectants, and sanitation supplies become available, it is highly encouraged that available supplies be distributed with first priority to the following industries: Hospitals, healthcare, long-term care, retirement homes, hospice, and other healthcare-providing establishments and the emergency responder community. Second priority should go towards the Food and Agriculture Sector (as well as the other [Critical Infrastructure Sectors](#)), including food manufacturers/producers, suppliers of agricultural inputs and facilities that store, process and/or market agricultural products, grocery stores, food retail, food service, and food storage and distribution.

Reopening Information

Repository of Information for Health Departments: In order to get and keep America open states, tribes, localities, and territories must be able to quickly identify new cases, break chains of transmission, and protect first responders and health care workers from infection. The purpose of this [site](#) is to serve as an easily accessible repository of guidelines, tools, and resources from CDC and others for states, tribes, localities, and territories.

Guidance and Resources for Communities of Faith: CDC released a series of guidances and resources for Communities of Faith. CDC has compiled all of the resources on their webpage with information for [Community and Faith-based Organizations](#). In the [Interim Guidance for Faith Communities](#), CDC offers these suggestions for faith communities to consider and accept, reject, or modify, consistent with their own faith traditions, in the course of preparing to reconvene for in-person gatherings while still working to prevent the spread of COVID-19. They also released an [FAQ for faith-based organizations](#).

Guidance for Reopened Facilities: CDC updated their information and resources for [Child Care, Schools, and Youth Programs](#), as well as [Businesses and Workplaces](#) for how to respond to situations If You're Open.

Information on Community Mitigation Measures: FEMA released a [fact sheet and tool](#) in coordination with HHS, CDC and other federal partners to provide the data that state, local, tribal, and territorial (SLTT) government officials need as they continue to adjust community mitigation measures. The goal of this new fact sheet is to make SLTT decision makers aware of a tool that puts all the data they need on cases, symptoms, and healthcare capacity in their community in one place. The tool itself aims to support communities as they continuously adjust their mitigation measures. Note that users need a .gov email address to access the tool.

When to End Home Isolation: CDC updated their information on [When You Can be Around Others After You Had or Likely Had COVID-19](#). They note that when you can be around others (end home isolation) depends on different factors for different situations. Recommendations are based on if you think or know you had COVID-19 and had symptoms, if you tested positive for COVID-19 but didn't have symptoms, if you have a weakened immune system, and if you have been around a person with COVID-19.

Provider Relief Fund Updates

Provider Relief Fund Updates: HHS announced a [45 day deadline extension](#) for providers who are receiving payments from the Provider Relief Fund to accept the Terms and Conditions for Provider Relief Fund payments. This announcement means providers have now been granted 90 days from the date they received a payment to accept HHS Terms and Conditions or return the funds. Late last week, HHS also announced nearly [\\$4.9 billion in additional relief funds to skilled nursing facilities \(SNFs\)](#) to help them combat the devastating effects of this pandemic. This funding, which supplements previously announced provider relief funds, will be used to support nursing homes suffering from significant expenses or lost revenue attributable to COVID-19. HHS will make relief fund distributions to SNFs based on both a fixed basis and variable basis. Each SNF will receive a fixed distribution of \$50,000, plus a distribution of \$2,500 per bed. All certified SNFs with six or more certified beds are eligible for this targeted distribution. HHS also announced [\\$500 million in payments from the Provider Relief Fund to the Indian Health Service \(IHS\) and tribal hospitals](#), clinics, and urban health centers to support the tribal response to COVID-19. IHS and tribal hospitals will receive a \$2.81 million base payment plus three percent of their total operating expenses. IHS and tribal clinics and programs will receive a \$187,000 base payments plus five percent of the estimated service population multiplied by the average cost per user. IHS urban programs will receive a \$181,000 base payment plus six percent of the estimated service population multiplied by the average cost per user.

OIG CARES Act Audit: The Office of the Inspector General will examine the [effectiveness of HHS controls](#) over the awarding and disbursement of \$50 billion in Provider Relief Fund (PRF) payments to hospitals and other providers. We will obtain data and interview program officials to gain an understanding of how PRF payments were calculated and review PRF payments for

compliance with Coronavirus Aid, Relief, and Economic Security (CARES) Act requirements. Among other things, we will seek to determine whether HHS controls over PRF payments ensured that payments were correctly calculated and disbursed to eligible providers.

Information for Specific Populations

Caring for Someone with COVID-19: CDC updated their webpage on what to do [If You Are Sick or Caring for Someone](#). The webpage includes information on what to do if you are sick, if you are caring for someone at home, when you can be around others, disinfecting your home if someone is sick, and information on quarantine and isolation.

Supporting Loved Ones in Long-Term Care Facilities: CDC released a fact sheet with advice on [Supporting Loved Ones in a Long-Term Care Facility](#) to be shared by facility owners with resident's families. During this challenging time, we are committed to helping residents stay connected with their families and loved ones. We would like to work together with you to make this possible. The fact sheet includes some ideas on how to keep in touch, and ways we are supporting communication between our residents and their families.

Information for Children and COVID-19: CDC updated their [FAQs for Children and COVID-19](#). The updates reflect new information on how to protect children from COVID-19.

Cloth Face Coverings: CDC updated their information on the [Use of Cloth Face Coverings to Help Slow the Spread of COVID-19](#). The webpage includes information about cloth face coverings, how to wear cloth face coverings, how to make cloth face coverings, how to wash cloth face coverings and recommendations.

Guidance for Dental Settings: CDC updated their [Interim Infection Prevention and Control Guidance for Dental Settings During the COVID-19 Response](#). Recommendations are provided for resuming non-emergency dental care during the COVID-19 pandemic. New information is included regarding facility and equipment considerations, sterilization and disinfection, and considerations for the use of test-based strategies to inform patient care. The guidance also includes expanded recommendations for provision of dental care to both patients with COVID-19 and patients without COVID-19.

Food Labeling Flexibility: The FDA issued a guidance document to [provide additional temporary flexibility](#) in food labeling requirements to manufacturers and vending machine operators. The agency is providing flexibility for manufacturers to make minor formulation changes in certain circumstances without making conforming label changes. Also, the FDA is providing temporary flexibility to the vending machine industry and will not object if covered operators do not meet vending machine labeling requirements to provide calorie information for foods sold in the vending machines at this time.

Guidance on Flexibilities Related to Produce: FDA released guidance on [Temporary Policy During the COVID-19 Public Health Emergency Regarding the Qualified Exemption from the](#)

[Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption](#). FDA is issuing this guidance to announce flexibility in the eligibility criteria for the qualified exemption from the Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption (Produce Safety Rule) (21 CFR Part 112) due to disruptions to the supply chain for the duration of the COVID-19 public health emergency.

Flexibility for Farms on Produce Safety Rule: FDA released information for [Farms Regarding Eligibility for the Qualified Exemption Under the Produce Safety Rule](#). Because of COVID-19, state and local governments across the United States have instituted public health orders that have resulted in many restaurants and retail food establishments either closing or significantly limiting their operations, leaving many farmers without their usual buyers. The guidance issued today is intended to allow affected farmers to shift their sales away from qualified end-users while still being considered eligible for the qualified exemption.

Information on Rodent Control: CDC has published [Rodent Control](#) recommendations in response to reports of rodents searching for new sources of food while restaurants are closed due to COVID-19. Residents and business owners should eliminate conditions that may attract and support rodent presence. If a rodent infestation occurs, it is important to follow established guidelines when cleaning up to prevent exposure to rodent-borne diseases. Environmental health programs should continue rodent monitoring and control activities.

CMS Updates

Medicare Plans Announce Lower Insulin Costs for Medicare Beneficiaries: CMS [announced that over 1,750 standalone Medicare Part D prescription drug plans and Medicare Advantage plans](#) with prescription drug coverage have applied to offer lower insulin costs through the Part D Senior Savings Model for the 2021 plan year. Across the nation, participating enhanced Part D prescription drug plans will provide Medicare beneficiaries access to a broad set of insulins at a maximum \$35 copay for a month's supply, from the beginning of the year through the Part D coverage gap.

Changes to Medicare Advantage and Part D: CMS [finalized requirements](#) that will increase access to telehealth for seniors in Medicare Advantage (MA) plans, expand the types of supplemental benefits available for beneficiaries with an MA plan who have chronic diseases, provide support for more MA options for beneficiaries in rural communities, and expand access to MA for patients with End Stage Renal Disease (ESRD). Together, the changes advance President Trump's Executive Orders on Protecting and Improving Medicare for Our Nation's Seniors and Advancing American Kidney Health as well as several of the CMS strategic initiatives.

Research and Tools

Remdesivir Study Results: NIH released information on [Peer-Reviewed Data Shows Remdesivir for COVID-19 Improves Time to Recovery](#). The investigational antiviral remdesivir is superior to the standard of care for the treatment of COVID-19, according to a report

published today in *The New England Journal of Medicine*. The preliminary analysis is based on data from the [Adaptive COVID-19 Treatment Trial \(ACTT\)](#), sponsored by the [National Institute of Allergy and Infectious Diseases \(NIAID\)](#), part of the National Institutes of Health. The randomized, controlled trial enrolled hospitalized adults with COVID-19 with evidence of lower respiratory tract involvement (generally moderate to severe disease). Investigators found that Remdesivir was most beneficial for hospitalized patients with severe disease who required supplemental oxygen. Findings about benefits in other patient subgroups were less conclusive in this preliminary analysis.

Importance of Testing at Skilled Nursing Facilities: CDC released an MMWR report on [Universal and Serial Laboratory Testing for SARS-CoV-2 at a Long-Term Care Skilled Nursing Facility for Veterans — Los Angeles, California, 2020](#). In the study, after identification of two cases of COVID-19 in an SNF in Los Angeles, universal, serial reverse transcription–polymerase chain reaction (RT-PCR) testing of residents and staff members aided in rapid identification of additional cases and isolation and cohorting of these residents and interruption of transmission in the facility. The findings suggest that universal and serial RT-PCR testing in SNFs can identify cases during an outbreak, and rapid isolation and cohorting can help interrupt transmission.

Updated COVIDView Data: CDC released their weekly [COVIDView findings](#). For the week ending May 16, they found that nationally, levels of influenza-like illness (ILI) and COVID-19-like illness (CLI) continue to decline, as do the percentage of specimens testing positive for the virus that causes COVID-19. Visits to outpatient providers and emergency departments for illnesses with symptoms consistent with COVID-19 continued to decline. The decrease in the percentage of people presenting for care with ILI and CLI may be due to a decline in COVID-19 illness, which could be in part a result of widespread adoption of social distancing in addition to changes in healthcare seeking behavior. Mortality attributed to COVID-19 also decreased compared to the previous week but remains elevated above baseline.

COVID19 Surge: CDC updated their [COVID-19 Surge](#) tool for hospital administrators. COVID-19Surge is a spreadsheet-based tool that hospital administrators and public health officials can use to estimate the surge in demand for hospital-based services during the COVID-19 pandemic. A user of COVID-19Surge can produce estimates of the number of COVID-19 patients that need to be hospitalized, the number requiring ICU care, and the number requiring ventilator support. The user can then compare those estimates with hospital capacity, using either existing capacity or estimates of expanded capacity.

Impacts on Healthcare Delivery System: ASPR released a quick sheet on [COVID-19 Healthcare Delivery Impacts](#). This tip sheet can help healthcare system planners prepare to mitigate these potential healthcare delivery impacts. For a more in-depth review of considerations and potential mitigation strategies, access the ASPR TRACIE COVID-19 [Healthcare Delivery Impacts tip sheet](#).

COVID-19 Clinical Experiences from the Field: ASPR updated a document on [Clinical Experiences from the Field](#). The report is a compilation of early reports and findings from

published articles and clinical rounds presentations, webinars, and news articles through May 18, 2020.