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COVID-19 Testing: Frequently Asked Questions

August 11, 2020

Congressional Research Service
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R46481

CRS REPORT
Prepared for Members and
Committees of Congress

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SUMMARY

R46481

August 11, 2020

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COVID-19 Testing: Frequently Asked Questions

The United States is reporting some of the highest number of cases and deaths from the Coronavirus Disease 2019 (COVID-19) pandemic globally, and the disease is affecting communities nationwide. In response, federal, state, and local governments have undertaken containment and mitigation efforts to "flatten the curve"—that is, to slow widespread transmission that could overwhelm the nation's health care system and to reduce spread of the disease while treatments and vaccines are being developed that will lessen the health impact of the virus.

Diagnostic testing is a critical part of the clinical management of COVID-19, which is caused by the SARS-CoV-2 virus. Both diagnostic (i.e., testing for active infection) and serology testing (i.e., testing for the presence of antibodies, potentially indicating a previous infection) over a wide population may be a key component of efforts to ease mitigation measures and allow people to return safely to work and school. Ongoing testing can be used for public health purposes to identify and isolate positive cases of COVID-19, thereby reducing spread of the disease. However, the use of testing for public health purposes rather than for the clinical diagnosis of individuals poses legal and policy complications, because regulation and payment policies can differ based on how the test is used.

Further, COVID-19 testing in the United States is provided in a number of health care and community-based settings. Insurance coverage and payment for a given COVID-19 test can depend on a number of factors, including the entity administering the test or processing test results, and the reason for which the test is administered. These factors can determine whether a certain payment mechanism may be used to pay for a given test. Congress, through several coronavirus legislative packages, has enacted various insurance coverage requirements along with other funding mechanisms to help pay for testing.

This CRS report provides answers to numerous questions related to COVID-19 testing, including

- types of testing available and their reliability;
- testing capacity and infrastructure;
- delivery of testing, including the settings where testing is available;
- payment for testing, including the provision by federally operated health systems and payment by federal and private payors and payment sources available for people who are uninsured;
- reporting of test results; and
- federal funding for testing infrastructure and for the clinical provision of COVID-19 testing.

This report concludes with several appendices: **Appendix A** identifies acronyms used in this report, **Appendix B** lists CRS experts on the various testing topics discussed, and **Appendix C** provides testing-related resources.

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Introduction

The United States is reporting some of the highest number of cases and deaths from the Coronavirus Disease 2019 (COVID-19) pandemic globally, and the disease is affecting communities nationwide. In response, federal, state, and local governments have undertaken containment and mitigation efforts to "flatten the curve"—that is, to slow widespread transmission that could overwhelm the nation's health care system and to reduce spread of the disease while treatments and vaccines are being developed that will lessen the health impact of the virus.

Diagnostic testing is a critical part of the clinical management of COVID-19, which is caused by the SARS-CoV-2 virus. Both diagnostic (i.e., testing for active infection) and serology testing (i.e., testing for the presence of antibodies, potentially indicating a previous infection) over a wide population may be a key component of efforts to ease mitigation measures and allow people to return safely to work and school. Ongoing testing can be used for public health purposes to identify and isolate positive cases of COVID-19, thereby reducing spread of the disease. However, the use of testing for public health purposes rather than for the clinical diagnosis of individuals poses legal and policy complications, because regulation and payment policies can differ based on how the test is used.

Further, COVID-19 testing in the United States is provided in a number of health care and community-based settings. Insurance coverage and payment for a given COVID-19 test can depend on a number of factors, including the entity administering the test or processing test results, and the reason for which the test is administered. These factors can determine whether a certain funding source or payment mechanism may be used to pay for a given test. Congress, through several coronavirus legislative packages, has enacted various insurance coverage requirements along with other funding mechanisms to help pay for testing.

This report provides answers to numerous questions related to COVID-19 testing. These include, among others, questions about the types of tests and their uses, where individuals can access testing, funding for testing-related efforts, and how different payers will reimburse providers for testing. As testing has become more widely available, questions have arisen about the settings where people can access testing, and how payment for such testing and accompanying services occurs. In addition, in anticipation of serology testing becoming more frequent, questions have arisen about the availability of and payment for those tests. **Appendix C** provides a list of testing-related resources; it will be updated as additional information becomes available or additional issues arise.

This report does not address issues related to the development and regulation of COVID-19 tests. For information about those issues, see

- CRS Report R46261, *Development and Regulation of Domestic Diagnostic Testing for Novel Coronavirus (COVID-19): Frequently Asked Questions*;
- CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*;
- CRS In Focus IF11516, *COVID-19 Testing: Key Issues*; and
- CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

Although this report addresses public and private payment for testing, it does not address payment or other issues related to COVID-19 treatment or vaccination. For information about those issues, see

- CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*
- CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)*
- CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions*
- CRS Report R46340, *Federal Response to COVID-19: Department of Veterans Affairs*
- CRS Insight IN11273, *COVID-19: The Basics of Domestic Defense Response*
- CRS Insight IN11333, *COVID-19 and the Indian Health Service*
- CRS Insight IN11367, *Federal Health Centers and COVID-19*
- CRS Insight IN11438, *The COVID-19 Health Care Provider Relief Fund*

Other CRS products on COVID-19 are available at https://www.crs.gov/resources/coronavirus-disease-2019.

COVID-19 Testing Overview

COVID-19 testing—including its development, regulation, accuracy, supply, capacity, infrastructure, availability, coverage, and payment—has been a central and ongoing issue throughout the COVID-19 public health emergency. Early efforts to develop a national test, led by the Centers for Disease Control and Prevention (CDC), encountered challenges.[1] Actions taken by the Food and Drug Administration (FDA) to increase the flexibility of COVID-19 in vitro diagnostics (IVDs) regulation[2] facilitated access to testing, but also created an environment of uncertainty for commercial manufacturers and clinical laboratories, as well as for health care providers and patients.[3] Issues have arisen around the accuracy of tests, their broad uses, and the settings in which they may be used for clinical purposes, as well as for nondiagnostic purposes such as screening. In addition, considerations regarding these issues may vary based on whether a test is diagnostic or serological.

What Are the Different Types of COVID-19 Tests?

Generally, coronavirus diagnostics (IVDs) may be molecular, serological, or antigen tests.[4] From a technical perspective, tests are characterized by their methods, as well as by the substance they

[1] See *Development and Regulation of Domestic Diagnostic Testing for Novel Coronavirus (COVID-19): Frequently Asked Questions*.

[2] See CRS In Focus IF11516, *COVID-19 Testing: Key Issues*.

[3] Medium, "Regulatory uncertainty made COVID responses difficult," April 6, 2020, https://medium.com/cgo-benchmark/regulatory-uncertainty-made-covid-responses-difficult-c7e6e5e8f7c3.

[4] FDA, "Coronavirus Testing Basics," https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics.

directly identify: antigens,[5] antibodies,[6] or viral nucleic acid. To date, development of COVID-19 tests has largely focused on molecular tests, and specifically tests using a technique called Polymerase Chain Reaction (PCR), as well as on serology tests, those tests that identify the presence of antibodies to the SARS-CoV-2 virus. Only a handful of antigen tests have been authorized by the FDA, although more may be authorized in the future.[7] This type of test directly identifies the presence of a SARS-CoV-2 antigen, or protein, through the use of SARS-CoV-2 antibodies which preferentially bind to the SARS-CoV-2 antigen.

From a clinical perspective, tests may be used to diagnose an active infection (by detecting the virus directly) or a prior infection (by detecting antibodies to the virus). Molecular and antigen tests are used to diagnose current infection, whereas serology tests are used to determine prior infection.[8] **Table 1** provides a summary of the types of tests, their uses, and accuracy.

Molecular Diagnostic Testing

Molecular diagnostic testing for COVID-19 generally relies on nucleic acid amplification techniques (NAATs), such as PCR, to detect viral genetic material. These tests identify viral nucleic acid in samples taken from individuals' noses or throats using swabs and are technically complex but well characterized, generally requiring both specific instruments and highly trained laboratory personnel. PCR-based testing involves sample collection (usually a swab, as noted), viral nucleic acid extraction, and direct testing to identify the presence of the SARS-CoV-2 viral nucleic acid through reverse transcription, amplification, and detection techniques. PCR tests may be high-throughput, whereby many samples may be run simultaneously; in that case, the run time is generally several hours. PCR or other NAAT-based tests may also be point-of-care tests, which are typically faster and simpler to run, but often run only a single or a few samples at one time.

Antigen Testing

An antigen test uses antibodies to a specific antigen (e.g., SARS-CoV-2 virus) to identify the virus in a patient's sample. Unlike a COVID-19 serology test, which can determine prior infection, an antigen test can determine an active infection. This difference is accounted for by the fact that a serology test identifies antibodies, a product of the immune response whose generation lags infection, whereas an antigen test directly identifies the virus. Rapid antigen tests—of which only a handful have been authorized for use in the United States for COVID-19 to date[9]—can detect viral antigens, generally in a throat or nose swab. These tests, used for diagnostic purposes,

[5] An antigen is defined by the National Cancer Institute (NCI) as follows: "Any substance that causes the body to make an immune response against that substance. Antigens include toxins, chemicals, bacteria, viruses, or other substances that come from outside the body," https://www.cancer.gov/publications/dictionaries/cancer-terms/def/antigen.

[6] An antibody is defined by NCI as follows: "A protein made by plasma cells (a type of white blood cell) in response to an antigen (a substance that causes the body to make a specific immune response). Each antibody can bind to only one specific antigen. The purpose of this binding is to help destroy the antigen," https://www.cancer.gov/publications/dictionaries/cancer-terms/def/antibody.

[7] Food and Drug Administration (FDA), "In Vitro Diagnostics EUAs," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas. EUA is an emergency use authorization.

[8] FDA, "FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2.

[9] FDA, "In Vitro Diagnostics EUAs," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

are usually point-of-care, relatively low-cost, and easy to manufacture and use. However, they tend to be less accurate than molecular diagnostic tests.

Serology Testing

A COVID-19 serology test identifies antibodies to the SARS-CoV-2 virus, usually in an individual blood sample. Antibodies are proteins generated by the immune system in response to an antigen, or foreign substance, and their generation lags infection by a week or more. An antigen may be a pathogenic virus or bacteria, for example, or generally any substance recognized by the immune system as both foreign and harmful. Serology tests for SARS-CoV-2 indicate exposure to and recovery from prior infection with the virus. The FDA has stated that such tests are not authorized to be used alone for the diagnosis of COVID-19.[10] However, serology testing may be used to identify individuals who can donate convalescent plasma[11] as a possible therapeutic, to help guide development of a vaccine, and to determine the extent and spread of COVID-19 in the general population, as well as the true infection fatality rate. In addition, as scientists learn more about the extent and duration of immunity that antibodies may confer after natural infection, serology testing could be informative about a given individual's immunity.

For What Purposes Is COVID-19 Testing Used?

Broadly, testing may be used for surveillance, screening, or diagnosis.[12] *Surveillance* may be used to provide information at a population or community level; it does not generally guide decisions at the individual level. Surveillance testing may guide decisions, for example, about public health mitigation or other measures. Such testing may employ serology testing to help determine what proportion of a given population or subpopulation has had and recovered from coronavirus infection, or it may use diagnostic testing to provide early indicators of emerging outbreaks or population-level estimates of the number of individuals with COVID-19 infections.

Screening is typically carried out in individuals who are asymptomatic and who have no reason to believe that they are currently infected (e.g., due to recent exposure or travel history). This type of testing is generally done in groups of individuals, such as students at a school or employees in a workplace, as a way to prevent the spread of disease to others rather than to inform treatment for an individual. Although screening in the case of COVID-19 in a setting such as a workplace or a school can guide decisions about individuals—for example, whether they should stay home or self-isolate for a period of time—it does not necessarily guide clinical decisions about an individual's care. Screening may use molecular- or antigen-based tests, rather than serology tests, to directly detect the presence of the virus, and this type of testing would generally be confirmed with additional testing were an individual to begin to show symptoms.

Finally, *diagnosis* involves a molecular or antigen test to directly test for the presence of the virus, either in the presence of signs or symptoms, or with a reason to suspect that an individual may be actively infected with SARS-CoV-2. Such testing would guide clinical decisions and disease

[10] FDA, "FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2.

[11] *Convalescent plasma* refers to blood plasma that is collected from an individual who has recovered (i.e., "convalesced") from a disease, in this case COVID-19, and then administered to a patient actively sick with COVID-19 for treatment. See CRS Report R46375, *The U.S. Blood Supply and the COVID-19 Response: In Brief*.

[12] For a high-level overview of these three types of testing, see FDA, "FAQs on Testing for SARS-CoV-2," "Q: What is the difference between surveillance, screening, and diagnostic testing for COVID-19 testing?," https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2.

management at the individual level. Serology tests are not currently used for clinical diagnostic purposes or to establish the exclusion of infection, per relevant FDA guidance on diagnostic testing for COVID-19 during the COVID-19 emergency period.[13]

When Is COVID-19 Testing Clinically Useful?

The answer to this question depends on the type of test and the circumstances of the testing. Serology testing at the current time is not generally clinically useful for the treatment or management of COVID-19 at an individual level.[14] Moreover, serology testing does not provide reliable information about an active, current infection, nor does it currently provide information about immunity to reinfection. The mechanism of the immune response to infection with SARS-CoV-2—whether antibodies provide immunity and, if so, for what duration, and what level of antibody might be required for this effect—is largely unknown at this time. In certain fact-specific cases, serology testing results may inform clinical treatment or management, but these cases are not the norm.

Molecular diagnostic or rapid antigen testing is clinically useful *in the presence of signs or symptoms, or in the context of a known or suspected exposure*. This type of testing in the absence of any reason to suspect infection, or in the absence of signs or symptoms of illness, is generally not clinically useful. Individuals who receive a positive result in this case may be either *asymptomatic* (meaning they will not ever exhibit clinical disease) or *presymptomatic* (meaning they are infected but have not yet begun to show clinical signs or symptoms of the disease). In the case of an asymptomatic case, no clinical treatment will be needed, so the test result is not clinically useful. In the case of a presymptomatic case, once the tested individual begins to exhibit symptoms, clinical treatment may become necessary, but testing would likely be repeated at that time to confirm the diagnosis. At this time, there are no therapeutic options for individuals who have been exposed, but are asymptomatic or presymptomatic. In the future, it is possible that screening tests could be used to guide clinical decisions, such as giving an exposed individual treatment to prevent transmission to others and/or severe health outcomes.

How Accurate Are Diagnostic and Serology Tests?

The accuracy of diagnostic testing is primarily determined by assessing two test performance characteristics: (1) the ability of the test to identify true positives (people with disease) and (2) the ability of the test to identify true negatives (people without the disease). These are referred to as *sensitivity*—the ability to detect a true positive—and *specificity*—the ability to detect a true negative.[15] A test with high sensitivity will have a low rate of false negatives, whereas a test with high specificity will have a low rate of false positives. These distinctions have different implications in the context of an infectious disease; specifically, a false negative may result in the unknowing transmission of the disease to others, whereas a false positive may result in incorrect therapeutic treatment decisions or unnecessary use of Personal Protective Equipment (PPE), among other things.

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[13] FDA, "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)," May 11, 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.

[14] See for example, the American Medical Association, "Serological testing for SARS-CoV-2 antibodies," May 14, 2020, https://www.ama-assn.org/delivering-care/public-health/serological-testing-sars-cov-2-antibodies.

[15] Cochrane UK, "Sensitivity and specificity explained: A Cochrane UK Trainees blog," https://uk.cochrane.org/news/sensitivity-and-specificity-explained-cochrane-uk-trainees-blog.

Accuracy concerns have arisen with respect to both diagnostic and serological COVID-19 testing.[16] With respect to molecular diagnostic testing for COVID-19, tests are generally highly specific (i.e., false positives are unlikely) but problems can occur with respect to sensitivity, or false negatives. Recent research indicates that the false negative rate varies based on the timing of the test, with the most accurate testing occurring approximately three days after the onset of symptoms.[17] Although no diagnostic test performs with perfect accuracy, certain issues may result in lower accuracy. PCR-based tests are usually very accurate and will generally reliably identify viral nucleic acid if it is present in amounts above the limit of detection for a given diagnostic. However, problems can occur with sampling technique, storage, and transport of the sample (e.g., over-dilution, temperature maintenance), and the extraction step.[18] In addition, viral load varies during the course of an infection by site (e.g., throat, nose), thereby affecting the amount of virus present in a collected sample, which can in turn affect the test results.

Serology tests authorized by the FDA are now required to meet specified thresholds for sensitivity and specificity, although the tests' accuracy can still vary based on the underlying prevalence of the infection in the tested population.[19] In terms of accuracy, serology tests may have the opposite problem that molecular diagnostics generally have—that is, they tend to have issues with specificity and the return of false positive results. This inaccuracy may occur because cross-reactivity with antibodies from commonly circulating coronaviruses or other viruses can return false positives (the result is not specific enough to SARS-CoV-2). Serology tests were initially allowed to be marketed and used without an Emergency Use Authorization (EUA), which contributed to uncertainty about how well these tests perform initially.[20] An EUA is an authorization granted by the FDA when certain conditions are met (e.g., a public health emergency) that allows an unapproved medical product to be marketed and used clinically.[21] The FDA is currently working with other federal agencies (e.g., the National Institutes of Health (NIH)) to provide independent validation for these tests, and it has modified its guidance to require manufacturers to receive authorization for commercially manufactured and marketed serology tests.[22]

[16] S. Woloshin et.al., "False Negative Tests for SARS-CoV-2 Infection—Challenges and Implications," *New England Journal of Medicine,* 383(6), August 6, 2020, https://www.nejm.org/doi/full/10.1056/NEJMp2015897.

[17] LM Kucirka et al., "Variation in False-Negative Rate of Reverse Transcriptase Polymerase Chain Reaction–Based SARS-CoV-2 Tests by Time Since Exposure," *Annals of Internal Medicine,* May 13, 2020, https://www.acpjournals.org/doi/10.7326/M20-1495.

[18] FDA, "Coronavirus Testing Basics (Molecular Tests)," https://www.fda.gov/consumers/consumer-updates/coronavirus-testing-basics.

[19] FDA, "Medical Countermeasures Initiative Update," May 6, 2020, https://www.fda.gov/media/137706/download; and FDA, "In Vitro Diagnostics EUAs," Serology Template for Commercial Manufacturers, updated June 26, 2020, https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

[20] FDA, "Insight into FDA's Revised Policy on Antibody Tests: Prioritizing Access and Accuracy," May 4, 2020, https://www.fda.gov/news-events/fda-voices/insight-fdas-revised-policy-antibody-tests-prioritizing-access-and-accuracy.

[21] For more information about the EUA mechanism, see CRS In Focus IF10745, *Emergency Use Authorization and FDA's Related Authorities*.

[22] FDA, "Immediately in Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff," May 11, 2020, https://www.fda.gov/media/135659/download.

Table 1. Summary of COVID-19 Testing Types, Uses, and Accuracy

Type of test	What it tests for	Approval status	Appropriate for			Accuracy issues
			Diagnosis	Screening	Surveillance	
Molecular	Detects viral genetic material	More than 100 EUA authorized tests	Yes	Yes (e.g., workplace or school testing)	Yes (for outbreaks)	False negatives may occur where samples have low amounts of virus or due to poor sampling technique
Serological	Detects serum antibodies	More than 40 EUA authorized tests	No	No	Yes (for prevalence estimates)	False positives may occur from cross-reactivity of antibodies from non-SARS-CoV-2 common coronaviruses
Antigen	Detects viral antigen	Fewer than 5 EUA authorized tests	Yes	Yes (e.g., workplace or school testing)	Yes (for outbreaks)	False negatives or false positives may occur

Sources: CRS Analysis of "What Are the Different Types of COVID-19 Tests?," and FDA, "In Vitro Diagnostics EUAs," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

Note: EUA = emergency use authorization.

Testing Capacity and Infrastructure

Testing for COVID-19—including for diagnostic, screening and surveillance purposes—is straining the clinical laboratory infrastructure in the United States and placing stress on the testing supply chain.[23] Clinical diagnostic testing is done by a network of private and public laboratories, as well as at the point of care by health care providers in health care settings. Clinical laboratories include large commercial reference laboratories (e.g., Quest); academic and university laboratories (e.g., University of Washington Medicine Virology Laboratory[24]); and hospital and other clinical laboratories. Testing is also carried out by CDC and other federal laboratories and the U.S. network of state and local public health laboratories, including some Department of Defense (DOD) and international laboratories.[25]

Clinical laboratories report that the supply chain has been stressed at every point, and that access to testing and testing turn-around time continues to vary significantly across the country, with excess capacity in some areas and excess demand in others.[26] In late May, the Department of

[23] American Association for Clinical Chemistry (AACC), "COVID-19 Survey Results," https://www.aacc.org/science-and-practice/aacc-covid-19-testing-survey/full-survey-results.

[24] University of Washington Medicine, "UW Virology COVID-19 Dashboard," http://depts.washington.edu/labmed/covid19/.

[25] See CDC, "Introduction to Public Health Laboratories," https://www.cdc.gov/publichealth101/laboratories.html.

[26] Association of Molecular Pathology, "SARS-CoV-2 Molecular Testing, Summary of Recent SARS-CoV-2

Health and Human Services (HHS) released a strategic plan compiling certain testing-related information pursuant to a requirement in the Paycheck Protection Program and Healthcare Enhancement Act (PPPHCEA, P.L. 116-139).[27] However, a uniform and centralized federal-level testing plan is not currently in place to establish and guide testing nationally.[28] A federal testing plan would likely involve assessing the amounts of each type of test needed and for what purpose; identifying existing and needed nationwide testing capacity; and completing an inventory of existing supplies, and tracking and overseeing their distribution, among other things. The HHS strategic plan defers to states to implement testing.[29] States and jurisdictions have developed strategies to test their populations, specifically with respect to the types and amount of tests needed, as well as their current capacity and plans for overall testing, including for diagnosis, contact tracing, surveillance, testing in congregate or high-risk health care and employment settings, and general workplace and school-based screening.[30]

What Is Point-of-Care vs. Centralized Testing?

Clinical testing may be *centralized*, in which a sample is collected and sent to a central laboratory for testing, or *decentralized*, in which the testing occurs entirely at or near the patient or point of care (POC), commonly referred to as point-of-care testing. The FDA notes that "point of care" includes patient care settings such as "hospitals, physician offices, urgent care, outreach clinics, pharmacies, and temporary patient care settings that have appropriately trained personnel to perform the test and are operating under a CLIA Certificate of Waiver or Certificate of Compliance."[31] In addition, the agency notes that, in general, "point of care" does not apply to at-home testing or at-home sample collection.[32] The FDA has authorized a handful of molecular diagnostic point-of-care tests (e.g., Abbott IDNow) and two antigen point-of-care tests to date, but the majority of EUA-authorized tests are not authorized for use in a point-of-care setting.[33] Sample collection alone may also occur in point-of-care settings (e.g., a drive-through testing site), with the test sample being collected at the site but sent to a central laboratory for processing and return of results.

Molecular Testing Survey," https://www.amp.org/AMP/assets/AMP_SARS-CoV-2_Survey_Report_FINAL.pdf?pass=28.

[27] P.L. 116-139, Division B "Additional Emergency Appropriations for Coronavirus Response," Title I, "Department of Health and Human Services."

[28] See, for example, Politico, "A dangerous new chapter of the outbreak: Every state for itself," July 14, 2020, https://www.politico.com/news/2020/07/14/states-look-to-trump-for-a-national-plan-to-fight-coronavirus-361906.

[29] Department of Health and Human Services (HHS), "COVID Strategic Testing Plan," May 24, 2020, "The role of the Federal government is to enable innovation, help scale supplies, and provide strategic guidance. States, territories, and tribes are responsible for formulating and implementing testing plans; and the private sector will continue to develop and produce technologies, supplies, and services to meet the needs of the States," pp. 7, https://delauro.house.gov/sites/delauro.house.gov/files/HHS_COVID_Testing_Report.pdf.

[30] HHS, "Coronavirus (COVID-19) Testing Plans by State and Jurisdiction," https://www.hhs.gov/coronavirus/testing-plans/index.html.

[31] CLIA refers to the Clinical Laboratory Improvement Amendments of 1988 (P.L. 100-578), a law that regulates all clinical laboratories in the United States. For more information, see https://www.cms.gov/Regulations-and-Guidance/Legislation/CLIA.

[32] FDA, "FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2.

[33] FDA, "In Vitro Diagnostics EUAs," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas.

POC tests are particularly important in cases where an individual is seriously ill and a test result is needed quickly to care for the individual and conserve PPE, as well as in places that are far away from centralized laboratories—particularly rural and remote areas. POC tests are generally noted for being faster, less expensive, less technically complex to run, and simpler to manufacture.[34] However, these tests are also often less accurate and, in particular, may be less sensitive, meaning they return more false negatives than a comparable non-POC molecular diagnostic would.[35] There have been accuracy issues with at least one of the FDA-authorized POC molecular diagnostics, which led the FDA to require confirmation of negative results with an authorized high-sensitivity molecular diagnostic.[36] Consequently, the speed and cost-effectiveness associated with POC tests may potentially be offset if additional steps are needed to mitigate accuracy issues. However, POC diagnostics' sensitivity can be weighed against their turnaround time and frequency, particularly in the context of screening and surveillance. Specifically, research suggests that frequent testing with a faster turnaround time is more important than test sensitivity to effective control of virus spread. A recent article notes that "[t]esting frequency was found to be the primary driver of population-level epidemic control, with only a small margin of improvement provided by using a more sensitive test."[37]

Is There a Federal COVID-19 Testing Plan or Program?

There has been substantial discussion about how to coordinate and organize COVID-19 testing efforts in the United States. Numerous experts in public health and medicine have weighed in on this issue, with many preparing model testing strategies and recommending various approaches to a coordinated national plan.[38] Many experts have called for a national strategy coordinated and led by the federal government;[39] however, to date, the states have been generally tasked with carrying out their own testing programs and strategies, with strategic guidance from the federal government. Recently, HHS announced the launch of the National COVID-19 Testing Implementation Forum, described as "a new program to capture feedback between federal officials and the private sector."[40] Information about the initiative is limited, but stated goals

[34] National Academy of Sciences, "Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic (April 8, 2020)," https://www.nap.edu/catalog/25775/rapid-expert-consultation-on-sars-cov-2-laboratory-testing-for-the-covid-19-pandemic-april-8-2020.

[35] See for example Office of the Assistant Secretary for Health, "Guidance – Proposed Use of Point-of-Care (POC) Testing Platforms for SARS-CoV-2 (COVID-19)," https://www.cdc.gov/coronavirus/2019-ncov/downloads/OASH-COVID-19-guidance-testing-platforms.pdf.

[36] FDA notes that "negative results should be treated as presumptive and, if inconsistent with clinical signs and symptoms or necessary for patient management, should be tested with different authorized or cleared molecular tests." See Abbott IDNow Letter of Authorization, updated June 1, 2020, https://www.fda.gov/media/136522/download.

[37] Daniel B. Larremore et. al., "Test sensitivity is secondary to frequency and turnaround time for COVID-19 surveillance," medRxiv, June 27, 2020, https://www.medrxiv.org/content/10.1101/2020.06.22.20136309v2.full.pdf.

[38] See for example: (1) Rockefeller Foundation, "National Covid-19 Testing & Tracing Action Plan," July 2020, https://www.rockefellerfoundation.org/national-covid-19-testing-and-tracing-action-plan/; (2) Harvard Center for Ethics, "ROADMAP TO PANDEMIC RESILIENCE: Massive Scale Testing, Tracing, and Supported Isolation (TTSI) as the Path to Pandemic Resilience for a Free Society," April 20, 2020, https://ethics.harvard.edu/files/center-for-ethics/files/roadmaptopandemicresilience_updated_4.20.20.pdf; and (3) American Enterprise Institute, "National coronavirus response: A road map to reopening," March 29, 2020, https://www.aei.org/research-products/report/national-coronavirus-response-a-road-map-to-reopening/.

[39] See, for example, LabPulse.com, "The case for a national COVID-19 testing strategy: A Q&A with Dr. Gary Procop," June 26, 2020, https://www.labpulse.com/index.aspx?sec=sup&sub=pth&pag=dis&ItemID=801411.

[40] HHS, "HHS Announces National COVID-19 Testing Implementation Forum," July 21 2020, https://www.hhs.gov/about/news/2020/07/21/hhs-announces-national-covid-19-testing-implementation-forum.html.

include gathering private sector input on end-to-end supply chain issues and implementation of a national surveillance strategy. In addition, seven states—Louisiana, Maryland, Massachusetts, Michigan, Ohio, North Carolina and Virginia—recently announced the formation of a bipartisan purchasing compact to procure large volumes of rapid antigen tests directly from the tests' manufacturers, bypassing the federal government and using their combined leverage in an effort to secure needed tests and ensure manufacturers of demand for their product.[41]

PPPHCEA required HHS to develop and submit to Congress a COVID-19 strategic testing plan.[42] The plan was required to help states understand the types of testing available for COVID-19, provide guidelines for testing and estimates of testing production, and outline how the HHS Secretary will increase testing capacity and testing supplies. This testing plan was submitted in report form to statutorily designated congressional committees on May 24, 2020, and was not required to be released publicly. The report provides detailed background on the types of COVID-19 tests, as well as an overview of the types of laboratories carrying out testing (the testing "ecosystem"), among other things, but it did not provide an overarching federal level strategy. Instead, the report notes that the responsibility for implementing testing rests with the states.[43]

The PPPHCEA also required states and other jurisdictions receiving funding pursuant to the act to submit testing plans that include the following information: the number of tests needed; estimates of laboratory and testing capacity, including related to workforce, equipment and supplies, and available tests; and a description of how the state, locality, territory, tribe, or tribal organization will use its resources for testing, including how such use relates to easing any COVID-19 community mitigation policies.[44] According to the national report submitted by HHS to Congress, "States are requested to detail how a minimum of two percent of the State's population will be tested each month beginning immediately; as well as plans to increase that number by the fall of 2020."[45] The state plans were initially required to be submitted to HHS 30 days post-enactment, but states were given an extension to May 30 for plans covering May and June, and until June 15 for plans covering the remainder of 2020. Although these state plans were not required to be released publicly, HHS made them publicly available on July 10, 2020.[46] In late June, Representative Frank Pallone sent a letter to HHS requesting the public release of the state testing plans.[47]

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[41] Washington Post, "There's no national testing strategy for coronavirus. These states banded together to make one.," August 4, 2020, https://www.washingtonpost.com/coronavirus/coronavirus-state-testing-compact/2020/08/04/8b73bed8-d66f-11ea-9c3b-dfc394c03988_story.html.

[42] P.L. 116-139, Division B, "Additional Emergency Appropriations for Coronavirus Response," Title I, Department of Health and Human Services.

[43] HHS, "Report to Congress: COVID Strategic Testing Plan," May 24, 2020, "The role of the Federal government is to enable innovation, help scale supplies, and provide strategic guidance. States, territories, and tribes are responsible for formulating and implementing testing plans; and the private sector will continue to develop and produce technologies, supplies, and services to meet the needs of the States," pp. 7, https://delauro.house.gov/sites/delauro.house.gov/files/HHS_COVID_Testing_Report.pdf.

[44] P.L. 116-139, Division B, "Additional Emergency Appropriations for Coronavirus Response," Title I, Department of Health and Human Services.

[45] HHS, "Report to Congress: COVID-19 Strategic Testing Plan," May 24, 2020, pp. 71-81, https://delauro.house.gov/sites/delauro.house.gov/files/HHS_COVID_Testing_Report.pdf (hereinafter, HHS, "COVID-19 Strategic Testing Plan").

[46] HHS, "Coronavirus (COVID-19) Testing Plans by State and Jurisdiction," July 10, 2020, https://www.hhs.gov/coronavirus/testing-plans/index.html.

[47] 360dx.com, "US Congressman Requests State COVID-19 Testing Plans From HHS," June 26, 2020, https://www.360dx.com/infectious-disease/us-congressman-requests-state-covid-19-testing-plans-hhs#.XxY7EJ5Kg4k.

What Supply Chain-Related Issues Are Affecting COVID-19 Testing?

It has been widely reported that supply chain issues related to COVID-19 diagnostic testing have affected access to testing nationally.[48] The supply chain for molecular diagnostics—the type of testing most in demand and, as a result, the one putting the most stress on its supply chain—is not streamlined and has not been developed to support the high-volume capacity, rapid sample-to-answer testing required during the pandemic. The testing industry has been described as "bespoke,"[49] meaning it has generally focused on developing tailor- or custom-made products, rather than mass production of a uniform product. It is not centrally coordinated, is composed of multiple providers, facilities, and laboratories, and relies on a wide variety of platforms and instruments that are not interoperable. As a result, most laboratories' supply chains rely on a unique combination of inputs from various manufacturers, which can be difficult to characterize and optimize.

As the FDA has granted EUAs for more laboratory-developed tests (LDTs) and test kits—including POC tests—and testing volume has increased, laboratories across the country have reported shortages of virtually all necessary supplies for testing.[50] PCR-based molecular diagnostic testing involves sample collection, nucleic acid extraction, and testing to identify the presence of the SARS-CoV-2 virus. Since testing began, there have been shortages of the supplies needed for each of these steps: swabs needed for sample collection; viral transport media needed to stabilize and store the samples after collection and during transport; ribonucleic acid (RNA)[51] extraction kits and reagents needed to extract viral RNA from the samples prior to testing; test kits and testing reagents needed to amplify and detect viral nucleic acid; and instruments needed to run tests. PPE needed during sample collection has similarly been in short supply, as has laboratory space and trained personnel needed to physically run the tests, as well as common laboratory consumables (e.g., pipette tips).

[48] See for example McKinsey & Company, "COVID-19: Overcoming supply shortages for diagnostic testing," July 15, 2020, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/covid-19-overcoming-supply-shortages-for-diagnostic-testing#.

[49] Andrew Slavitt, "Here's How The US Can Start Testing More People for Covid-19," May 5, 2020. https://coronavirus.medium.com/heres-how-the-us-can-start-testing-more-people-for-covid-19-ed3f10bb9952.

[50] Association of Molecular Pathology, "SARS-CoV-2 Molecular Testing, Summary of Recent SARS-CoV-2 Molecular Testing Survey," survey conducted from late April to early May, 20202, https://www.amp.org/AMP/assets/AMP_SARS-CoV-2_Survey_Report_FINAL.pdf?pass=28.

[51] RNA (ribonucleic acid) is defined as a "complex compound of high molecular weight that functions in cellular protein synthesis and replaces DNA (deoxyribonucleic acid) as a carrier of genetic codes in some viruses." https://www.britannica.com/science/RNA.

Selected Approaches to Increasing Testing Capacity: Sample Pooling and Point-of-Care (POC) and At-Home Tests

As the country faces increasing demand for all types of COVID-19 testing—especially as cases increased in the Sun Belt states and consideration is being given to reopening schools and nonessential workplaces—several approaches have been touted as possible partial solutions to easing testing capacity and supply chain concerns. One of these is using sample pooling to screen asymptomatic individuals in low-prevalence areas. Sample pooling combines multiple individual samples (the number varies depending on disease prevalence and test sensitivity) to create a single sample to be tested, using only a single test for the pooled sample. If this returns a positive result, then the individual samples are each tested. In this way, test reagents and other supplies may be conserved. The FDA has provided guidance to test manufacturers and laboratories that would like to use sample pooling in their test EUA to help manage concerns about decreased sensitivity due to sample dilution resulting from combining multiple samples, and the agency has authorized Quest to use pooled sampling with its COVID-19 PCR diagnostic test.

In addition, POC tests, and specifically antigen tests, have been identified as key to a rapid and cost-effective scale-up of testing. The FDA has approved two rapid antigen tests, and millions are expected to be made available over the coming months. However, as currently authorized, these tests must be carried out under the auspices of CLIA and require a physician or other health care professional to order them. As a result, their use in decentralized non-health care or community settings is limited. An at-home test that does not require a physician order—similar to a home pregnancy test—would improve access, capacity, and turnaround time, and would facilitate testing in any setting at any frequency (e.g., homes, workplaces, schools). These types of tests are currently under development by several researchers using a paper-based and CRISPR-based (gene editing) method.

Sources: (1) FDA, "Molecular Diagnostic Template for Commercial Manufacturers," https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas; (2) FDA, "Coronavirus (COVID-19) Update: FDA Issues First Emergency Authorization for Sample Pooling in Diagnostic Testing," July 18, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-issues-first-emergency-authorization-sample-pooling-diagnostic; (3) 360dx.com, "HHS to Purchase BD Rapid Antigen Tests, Instruments for Coronavirus Detection," July 15, 2020, https://www.360dx.com/immunoassays/hhs-purchase-bd-rapid-antigen-tests-instruments-coronavirus-detection#.Xw-MAShKg4k; and (4) 360dx.com, "SARS-CoV-2 Pandemic May Promote Progress in Paper MDx," July 10, 2020, https://www.360dx.com/molecular-diagnostics/sars-cov-2-pandemic-may-promote-progress-paper-mdx#.Xw-MSihKg4k.

These testing shortages have been anecdotally reported by laboratories and were documented in an April 3 report by the HHS Office of the Inspector General (OIG) addressing hospitals experience responding to COVID-19. The report notes that "severe shortages of testing supplies and extended waits for test results limited hospitals' ability to monitor the health of patients and staff."[52] In an April-May survey of clinical laboratories on a number of issues relevant to that community, the Association for Molecular Pathology (AMP) found that 85% of clinical laboratories reported that supply interruptions have delayed testing or decreased their testing capacity, and that "the types of supply chain interruptions that laboratories experienced were vast and include testing platforms, testing kits, reagents, swabs, viral transport media (VTM), laboratory consumables, and PPE."[53] Overall, AMP received 118 completed responses from U.S.-based labs, including community hospital or health system laboratories, academic medical centers, and commercial reference laboratories. In addition, states have reported significant and

[52] HHS Office of Inspector General (OIG), "Hospital Experiences Responding to the COVID-19 Pandemic: Results of a National Pulse Survey March 23–27, 2020," April 2020, OEI-06-20-00300, https://www.oig.hhs.gov/oei/reports/oei-06-20-00300.pdf.

[53] Association of Molecular Pathology, "SARS-CoV-2 Molecular Testing, Summary of Recent SARS-CoV-2 Molecular Testing Survey," https://www.amp.org/AMP/assets/AMP_SARS-CoV-2_Survey_Report_FINAL.pdf?pass=28.

ongoing difficulty in obtaining needed supplies and, in some cases, have noted that competition for limited supplies has been intense.[54]

Which Federal Agencies are Involved in the Testing Supply Chain?

The FDA has worked with industry to identify and mitigate shortages by modifying test EUAs to allow for the use of alternate supplies when carrying out a test and by providing information for manufacturers and laboratories relating to testing supply substitution strategies.[55] However, as noted above, shortages reportedly persist due to global demand and the unprecedented level of testing, as well as a lack of coordinated ascertainment, production, and allocation of supplies. The FDA does not have the authority to allocate or distribute supplies.

By virtue of the national emergency, Federal Emergency Management Agency (FEMA) has played a key federal role in procuring and distributing testing supplies (see the "What Is FEMA's Role in Distributing Testing Materials to Providers?" section of this report), and the Defense Production Act (DPA) is an available mechanism for compelling production of testing supplies.[56] For example, the President invoked the DPA for the production of nasal swabs, and the Department of Defense announced $75 million in DPA investments to increase nasal swab production.[57] The Assistant Secretary of Preparedness and Response (ASPR) at HHS also has a significant role in supply chain issues for medical countermeasures in public health emergencies, including, for example, through the management of the Strategic National Stockpile.[58]

What Is FEMA's Role in Distributing Testing Materials to Providers?

FEMA procures and distributes testing materials directly to states, tribes, territories, local governments, and nonprofit medical facilities to expand testing capacity.[59] In addition, FEMA and HHS lead the Laboratory Diagnostics Task Force, which supports testing efforts undertaken by state and local governments, health care providers, and public health labs.[60]

FEMA and the White House have advised that the COVID-19 response, like other emergency and disaster response, is locally executed, state-managed, and federally supported.[61] However, FEMA

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[54] See, for example, Forbes, "States Are Being Forced Into Bidding Wars To Get Medical Equipment To Combat Coronavirus," March 28, 2020, https://www.forbes.com/sites/claryestes/2020/03/28/states-have-are-being-forced-into-bidding-wars-to-get-medical-equipment-to-combat-coronavirus/#6f27fb571cde.

[55] FDA, "FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2.

[56] For more information about the Defense Production Act, see CRS Insight IN11387, *COVID-19: Defense Production Act (DPA) Developments and Issues for Congress*.

[57] Department of Defense (DOD), "DOD Details $75 Million Defense Production Act Title 3 Puritan Contract," April 29, 2020, https://www.defense.gov/Newsroom/Releases/Release/Article/2170355/dod-details-75-million-defense-production-act-title-3-puritan-contract/.

[58] See "HHS Office of the Assistant Secretary for Preparedness and Response," https://www.phe.gov/about/aspr/Pages/default.aspx.

[59] Federal Emergency Management Agency (FEMA), "FEMA, "Federal Support to Expand National Testing Capabilities," May 5, 2020, https://www.fema.gov/fact-sheet/federal-support-expand-national-testing-capabilities.

[60] Ibid.

[61] The White House, *Testing Blueprint*, April 5, 2020, p. 2, https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Blueprint.pdf; submitted testimony of FEMA Administrator Peter Gaynor and DOD representative John Polowczyk, in U.S. Congress, Senate Homeland Security and Governmental Affairs Committee (HSGAC), *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic*, hearings, 116th Cong., 2nd sess., June 6, 2020, p. 7, https://www.hsgac.senate.gov/imo/media/doc/Testimony-Gaynor%20&

may provide assistance directly when states, tribes, territories, local governments, and eligible private nonprofit organizations (public assistance applicants) are overwhelmed; this is referred to as direct federal assistance.[62] In these cases, FEMA tasks its own personnel or other federal agencies, such as HHS and CDC, to perform work eligible for public assistance on behalf of the requesting applicants. According to FEMA, the agency exercised this authority to procure and distribute testing supplies and services directly to states, tribes, territories, local governments, and eligible nonprofits.[63]

FEMA entered into a memorandum of understanding (MOU) with ASPR of HHS in April 2020 that enabled FEMA to acquire and distribute critical medical supplies through the Strategic National Stockpile.[64] The MOU specifically included "testing supplies." The MOU called for ASPR to reimburse FEMA for the cost of acquired materials, as specified in subsequent interagency agreements.[65] According to FEMA, this MOU and subsequent interagency agreements enabled FEMA to procure and distribute testing supplies directly to states, tribes, territories, local governments, and nonprofits free of charge.[66]

Beginning in early May 2020, FEMA announced that the agency would begin delivering a limited amount of testing materials to states, tribes, and territories to support each government's own testing plan, in accordance with the Administration's *Testing Blueprint*.[67] FEMA Administrator Peter Gaynor explained that each government would begin receiving testing swabs and transport media from FEMA on May 15, 2020, and would continue to receive weekly distributions through the end of June 2020.[68] States, tribes, and territories are responsible for determining a distribution strategy to meet the needs of their own populations.[69]

Delivery of Testing for COVID-19

This set of questions addresses issues related to individuals accessing testing, including (1) who can receive testing, (2) the settings where testing is available, and (3) the settings where testing is available for individuals who are unable to pay for the full costs of testing.

%20Polowczyk-2020-06-09.pdf (hereinafter, Gaynor and Polowsczyk, HSGAC hearing).

[62] Authorized in Stafford Act Sections 402, 403, 418, 419, and 502; 42 U.S.C. §§5170a-b, 5185, 5186, and 5192. See also 44 C.F.R. §206.208.

[63] Email from FEMA Office of Congressional and Legislative Affairs to CRS, June 19, 2020.

[64] FEMA and HHS, "Memorandum of Understanding Between the Federal Emergency Management Agency and the Department of Health and Human Services, Office of Assistance Secretary of Preparedness Response," executed April 5, 2020, provided to CRS by FEMA Office of Congressional and Legislative Affairs.

[65] Ibid.

[66] Ibid and email from FEMA Office of Congressional and Legislative Affairs to CRS, June 19, 2020.

[67] FEMA, "Federal Support to Expand National Testing Capabilities;"; HHS, "Report to Congress: COVID-19 Strategic Testing Plan," May 24, 2020, pp. 20-21, https://www.democrats.senate.gov/imo/media/doc/COVID%20National%20Diagnostics%20Strategy%2005%2024%202020%20v%20FINAL.pdf (hereinafter, HHS, "COVID-19 Strategic Testing Plan").

[68] Gaynor and Polowsczyk, HSGAC hearing

[69] FEMA, "Federal Support to Expand National Testing Capabilities," May 5, 2020, https://www.fema.gov/fact-sheet/federal-support-expand-national-testing-capabilities.

How Is Diagnostic Testing Prioritized?

States and other jurisdictions are primarily responsible for setting prioritization criteria for COVID-19 testing. At an individual level, testing recommendations may rely on clinician judgement.[70] State approaches may differ depending on their respective testing capacities and the level of COVID-19 transmission in their communities.[71] The federal government, particularly through CDC, can inform these criteria by issuing guidance. In the early stages of the epidemic, CDC guidance recommended limiting COVID-19 testing mostly to individuals with relevant travel or exposure history.[72] As of July 17, 2020, CDC guidance includes considerations for the uses of diagnostic and serologic testing, and for testing symptomatic and asymptomatic individuals. CDC recommends that diagnostic tests be prioritized for the following five populations:

- individuals with signs or symptoms consistent with COVID-19;
- asymptomatic individuals with recent known or suspected exposure to SARS-CoV-2 to control transmission;
- asymptomatic individuals without known or suspected exposure to SARS-CoV-2 for early identification in special settings (e.g., congregate living settings); and
- individuals being tested for purposes of public health surveillance for SARS-CoV-2.[73]

CDC has also developed more specific guidance related to testing certain populations or testing programs in specific settings.[74]

Targeted screening testing of certain populations may be a key component of broader state or other jurisdictional plans to control the spread and impact of COVID-19. The National Governors Association (NGA) encourages states to consider public health criteria for testing recommendations, including considering prioritizing certain communities of color (such as American Indian/Native American populations) and lower-income populations. According to NGA, "Communities of color and lower-income Americans are more often essential workers, often live and work in densely populated areas, are more likely to have underlying conditions putting them at higher risk, and have chronic access to healthcare challenges."[75]

Where Can Individuals Get a COVID-19 Test?

Testing availability may vary by state and by the type of test sought. Generally, a range of both ambulatory and inpatient *health care settings* and providers (e.g., hospitals, doctors' offices,

[70] Centers for Disease Control and Prevention (CDC), "Testing for COVID-19," last updated June 24, 2020, https://www.cdc.gov/coronavirus/2019-ncov/symptoms-testing/testing.html.

[71] Bill McBride, *Memorandum: Capacity for COVID-19 Testing- Current Status*, National Governors Association, May 14, 2020, https://www.nga.org/wp-content/uploads/2020/04/Testing-Memo-Update-5-13-20.pdf.

[72] CRS Report R46219, *Overview of U.S. Domestic Response to Coronavirus Disease 2019 (COVID-19)*.

[73] CDC, "Coronavirus Disease 2019 (COVID-19): Testing Overview," Updated July 2, 2020, https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fhcp%2Fclinical-criteria.html.

[74] For example, CDC has issued testing guidelines for nursing homes: https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html, and for high-density critical infrastructure workplaces: https://www.cdc.gov/coronavirus/2019-ncov/community/worker-safety-support/hd-testing.html.

[75] Bill McBride, *Memorandum: Capacity for COVID-19 Testing- Current Status*, National Governors Association, May 14, 2020, https://www.nga.org/wp-content/uploads/2020/04/Testing-Memo-Update-5-13-20.pdf.

urgent care centers) provide testing, and some congregate living sites (e.g., nursing homes) may provide testing to their residents. In addition, many jurisdictions have established testing programs in *community-based settings*, such as walk-up or drive-through testing sites, public health departments, and those at retail pharmacies. A number of settings provide free or reduced-cost tests to the general population using another source of payment (see the "Where Are Free or Reduced Cost Tests Available?" section of this report).

Generally, state law governs who may order a test, which in turn may affect the settings where testing is available. For example, not all states permit nurse practitioners to order tests, so in those states a person would need to see a physician to have a test ordered.[76] Two factors inform whether a complete test is available directly from a provider or if a central laboratory must be involved in its processing: (1) the settings that are able to provide tests (e.g., whether testing is available at a pharmacy), which may be affected by both state law and CLIA (Clinical Laboratory Improvement Amendments of 1988) requirements and (2) where a test is FDA-authorized to be provided (e.g., a waived or point-of-care setting). Test availability may also differ based on the locations where a given payor may pay for testing. For example, some payors may require the provider to be recognized as meeting federal (and sometimes state) conditions of participation requirements (e.g., Medicaid participating provider) in order to pay for a test that a program enrollee receives from that provider.

Where Are Free or Reduced Cost Tests Available?

A number of types of health care and other settings may administer COVID-19 tests; however, only a few types of facilities have requirements to provide care to all individuals regardless of their ability to pay. As such, not all testing sites provide free testing nor do all types of facilities test uninsured individuals.

Public Health Department Testing Programs

State, local, territorial, and tribal health departments may operate testing programs, though activities can vary by jurisdiction. For example, some local health departments operate temporary testing sites (e.g., drive-through testing sites), or so-called "mobile strike teams," to provide targeted testing in outbreak areas or for certain populations, such as uninsured or high-risk individuals.[77] Some of the community-based testing sites have been operated jointly by FEMA and/or HHS with health departments, while others have been operated in partnership with health care provider organizations or commercial partners such as retail pharmacies (e.g., CVS).[78] In the early stages of the pandemic, many of the health department testing programs were focused on target populations, such as health care workers and first responders.[79] Some health department

[76] National Alliance of State Pharmacy Associations, "COVID-19 Testing," https://naspa.us/resource/covid-19-testing/. On April 8, 2020, HHS released guidance authorizing pharmacists to order testing and providing immunity to do so. See HHS, "Guidance for Licensed Pharmacists, COVID-19 Testing, and Immunity under the PREP Act," https://www.hhs.gov/sites/default/files/authorizing-licensed-pharmacists-to-order-and-administer-covid-19-tests.pdf.

[77] National Association of City and County Health Officials (NACCHO), *Local Health Departments Standing Strong on the Frontlines of COVID-19 Response*, April 9, 2020, https://www.naccho.org/uploads/downloadable-resources/Press-Release-NPHW-2020-Role-of-LHDs-in-COVID-19-Response_4.9.20.pdf.

[78] Bill McBride, *Memorandum: Capacity for COVID-19 Testing- Current Status*, National Governors Association, May 14, 2020, https://www.nga.org/wp-content/uploads/2020/04/Testing-Memo-Update-5-13-20.pdf.

[79] Association of State and Territorial Health Officials, *16 Key Considerations for Drive-Through or Mobile Testing*, March 19, 2020, https://astho.org/StatePublicHealth/16-Key-Considerations-for-Drive-Through-or-Mobile-Testing/03-19-20/.

testing programs have expanded to become more broadly available in some jurisdictions, though the availability of testing and the populations that can access such testing can vary by jurisdiction.

Testing provided by or in partnership with health departments is often available free of charge to individuals, though testing is often limited to residents of a certain jurisdiction and some programs may seek to bill private health insurance plans or public payors (e.g., Medicaid) for individuals with applicable coverage or to charge certain individuals for testing.[80] CDC grant funding provided through several coronavirus supplemental appropriations measures can support testing programs run by health departments.[81] In particular, the $10.25 billion in funding awards made to states and other jurisdictions pursuant to the PPPHCEA can be used in part to support health department testing programs, especially those aimed at high-risk populations and institutional settings.[82]

Emergency Departments

Hospitals with emergency departments are required to provide an appropriate medical screening examination and stabilization care regardless of a patient's eligibility to participate in Medicare. This obligation is required under the Emergency Medical Treatment and Active Labor Act (EMTALA),[83] and it generally extends to individuals who come to the emergency department and are suspected to have COVID-19.[84] EMTALA does permit hospitals to bill individuals for services provided pursuant to their EMTALA obligation. Although some individuals may pay for these services, hospitals that provide care pursuant to their EMTALA obligation may seek payment from the uninsured testing fund discussed below. As mentioned above, some community-based and facility-specific testing may be available to individuals who do not have a source of payment. In addition, the federal government has created an uninsured fund to reimburse facilities for testing provided to uninsured individuals. Congress has enacted legislation that has expanded Medicaid eligibility under limited circumstances so that Medicaid funds may be available for testing for some individuals who are otherwise ineligible for Medicaid (see the "How Can Facilities That Provide Testing for Uninsured Individuals Be Reimbursed?" section of this report).

Health Centers

Federal health centers (also called federally qualified health centers or FQHCs) are outpatient facilities that receive federal grants to provide primary care and other services. They must be

[80] For example, the District of Columbia (DC) operates free testing sites for D.C. residents experiencing any COVID-19 symptoms or with known exposures and does not bill insurance providers, see https://coronavirus.dc.gov/testing. The Texas Department of State Health Services states "unless otherwise stated, deductible, co-pay, or co-insurance may apply." Public health testing programs vary by local jurisdiction in Texas. See https://dshs.texas.gov/coronavirus/testing.aspx.

[81] For a list of CDC grant amounts to jurisdictions as of June 2, 2020, see "CDC COVID-19 State, Tribal, Local, and Territorial Funding Update," https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/funding-update.pdf.

[82] HHS, "Report to Congress: COVID-19 Strategic Testing Plan," May 24, 2020, pp. 71-81, https://www.democrats.senate.gov/imo/media/doc/COVID%20National%20Diagnostics%20Strategy%2005%2024%202020%20v%20FINAL.pdf (hereinafter, HHS, "COVID-19 Strategic Testing Plan).

[83] 42 U.S.C. §1395dd.

[84] HHS, Center for Medicare and Medicaid Services (CMS), "Emergency Medical Treatment and Labor Act (EMTALA) Requirements and Implications Related to Coronavirus Disease 2019 (COVID-19)," memorandum, March 9, 2020, at https://www.cms.gov/files/document/qso-20-15-emtala-requirements-and-coronavirus-0311-updated-003pdf.pdf-1.

located in medically underserved areas and provide care to all individuals regardless of their ability to pay. They may bill patients with public or private insurance coverage for the services provided, and they are required to use a sliding scale fee schedule for individuals who do not have coverage.[85] Health centers have received more than $2 billion in supplemental funding to provide COVID-19 testing and related care. Of that amount, $600 million was explicitly appropriated for testing; however, all of the funds appropriated to health centers were to prevent, prepare for, and respond to COVID-19, which includes testing.[86] The Health Resources and Services Administration (HRSA), which administers the health center program, surveyed health centers on the impact of COVID-19 on their operations. The survey found that more than 90% of responding health centers were offering testing, with 70% offering drive-up or walk-up testing.[87]

Federally Qualified Health Center Look-Alikes

Federally Qualified Health Center Look-Alikes (called Look-Alikes) are outpatient centers similar to the health centers described above, but Look-Alikes do not receive a health center grant. Like health centers, these entities serve an underserved population, must be located in medically underserved areas, and are required to provide care to all individuals regardless of their ability to pay. As such, Look-Alikes are a setting where uninsured individuals may receive COVID-19 testing. The majority (87.8%) of Look-Alikes reported to HRSA that they have COVID-19 testing capacity, with approximately half providing walk-up or drive-up testing.[88]

Federal Community-Based Testing Sites

FEMA collaborated with HHS to establish community-based testing sites (CBTS) in partnership with state and local governments. Since late March 2020, FEMA and HHS helped establish 41 CBTS throughout the country.[89] Initially, local staff at each site were supplemented by one federal physician and by U.S. Public Health Service personnel. The federal government also provided assistance with contracts, logistics, lab processing, and patient notification.[90] The sites initially focused on testing for health care professionals and first responders, though later they tested a broader population.[91] For example, a number of New Jersey's community-based testing sites offered testing only to symptomatic health care workers, first responders, and law enforcement on

[85] CRS Report R43937, *Federal Health Centers: An Overview*.

[86] CRS Insight IN11367, *Federal Health Centers and COVID-19*.

[87] HHS, Health Resources and Services Administration (HRSA), "Health Center Covid-19 Survey: National Summary Report," https://bphc.hrsa.gov/emergency-response/coronavirus-health-center-data.

[88] HHS, HRSA, "Health Center Program Look-Alike COVID-19 Survey National Summary Report," latest data from June 26, 2020.

[89] FEMA, "Weekly Update: Coronavirus Pandemic Whole-of-America Response," June 18, 2020, p. 2, provided by FEMA Congressional and Legislative Affairs. FEMA, "Coronavirus (COVID-19) Pandemic Whole-of-Government Response," Wednesday, March 25, 2020, p. 3; FEMA, "Option to Transition Federal Community-Based Testing Sites to State Management," April 9, 2020, https://www.fema.gov/news-release/20200726/option-transition-federal-community-based-testing-sites-state-management, hereinafter, FEMA, "Community-Based Testing Sites").

[90] HHS, "Report to Congress: COVID-19 Strategic Testing Plan," May 24, 2020, pp. 24-25, https://www.democrats.senate.gov/imo/media/doc/COVID%20National%20Diagnostics%20Strategy%2005%2024%202020%20v%20FINAL.pdf (hereinafter, HHS, "COVID-19 Strategic Testing Plan").

[91] FEMA, "Community-Based Testing Sites."

Saturdays beginning in early April, but those sites are now open to the public during the rest of the week.[92]

On April 10, 2020, FEMA announced the option for CBTS to transition to full state management, with states assuming responsibilities such as staffing, procurement, and testing.[93] FEMA's guidance explains that states and local governments managing these sites may seek reimbursement for eligible expenses associated with running CBTS (e.g., eligible staff costs, testing supplies) through FEMA's Public Assistance (PA) program, subject to a federal 75% cost share.[94] Alternatively, states, tribes, and territories may request testing supplies for CBTS directly from FEMA for a limited time after transition.[95]

As of June 24, 2020, FEMA reported that 13 sites continued to operate under federal control, 20 have transitioned to state management, and 8 have closed in consultation with states.[96] At that point, FEMA reported that these sites had processed 287,312 samples while under full federal control.[97] HHS reported that CBTS remain operational in Colorado, Illinois, New Jersey, Pennsylvania, and Texas, as of June 9, 2020.[98] According to FEMA, all remaining community-based testing sites were due to close or transition to full state management on June 30, 2020, though the status of federal financial support is unclear.[99] Numerous news outlets reported that federal support for all sites would end on June 30,[100] though FEMA indicated that financial support for state-managed testing sites will continue through the PA program.[101]

In late June, dozens of Members of Congress appealed to FEMA and HHS to extend federal support for sites given record new COVID-19 cases across the country.[102] Several news outlets reported that HHS had extended support for five of seven sites in Texas in response to congressional urging and an appeal by Texas Governor Greg Abbott.[103] Governor Abbott

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[92] New Jersey.gov, "What's the difference between community-based testing, local testing, pharmacy testing sites, and private testing sites?," https://covid19.nj.gov/faqs/nj-information/symptoms-tests-and-treatment/whats-the-difference-between-community-based-testing-local-testing-pharmacy-testing-sites-and-private-testing-sites.

[93] FEMA, "Community-Based Testing Sites," May 24, 2020, https://www.fema.gov/news-release/20200726/option-transition-federal-community-based-testing-sites-state-management.

[94] Ibid.

[95] FEMA, "Community-Based Testing Sites." HHS explains that sites were provided with materials for 7-14 days after the transition to state management (HHS, "COVID-19 Strategic Testing Plan," p. 24).

[96] FEMA, "Weekly Update: Coronavirus Pandemic Whole-of-America Response," June 25, 2020, p. 2, provided by FEMA Office of Congressional and Legislative Affairs.

[97] Ibid.

[98] Submitted testimony of HHS Assistant Secretary for Health Brett Giroir, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic,* hearings, 116th Cong., 2nd sess., June 6, 2020, p. 6.

[99] FEMA Office of Congressional and Legislative Affairs, email to CRS, June 24, 2020, noted that all sites were due to close or transition by June 30, 2020. FEMA guidance indicates community-based testing sites under state management remain eligible for Public Assistance. FEMA, "Community-Based Testing Sites."

[100] See, for example, David Lim, "Trump administration ending support for drive-thru testing sites," *Politico*, June 24, 2020, https://www.politico.com/news/2020/06/24/trump-administration-drive-through-coronavirus-testing-338217.

[101] FEMA, "Community Based Testing Sites"; FEMA, email to CRS, June 26, 2020.

[102] See, for example, Representative James E. Clyburn et. al, Letter to Alex Azar, Secretary, HHS, June 26, 2020, https://coronavirus.house.gov/sites/democrats.coronavirus.house.gov/files/2020-06-25.Clyburn%20Foster%20Kim%20et%20al.%20to%20Azar%20II-HHS%20re%20Federal%20Testing.pdf; Senators John Cornyn and Ted Cruz, Letter to Peter Gaynor, Administrator, FEMA, and Alex Azar, Secretary, HHS, June 25, 2020, https://www.cruz.senate.gov/files/documents/Letters/06.25.20%20-%20Letter%20HHS%20FEMA%20CBTS%20Testing%20Sites%20-%20FV.pdf.

[103] Reese Oxner, "Federal government postpones plans to close five coronavirus testing sites in Texas," *Texas Tribune,*

confirmed the extension, noting, "I thank our federal partners for extending these operations in Texas, and for their flexibility in allocating their resources to the communities of Dallas and Houston that are experiencing a high number of COVID-19 cases right now."[104]

In May, 2020, FEMA announced that the federal government, led by HHS, would build upon the first CBTS model to expand testing nationwide. Under this public-private partnership, the federal government provides a flat fee for each test administered to pharmacy and retail companies to offer testing at hundreds of sites throughout the country.[105] According to HHS, the private sector partners are responsible for coordinating the full testing process, including registration, scheduling, provider order, patient notifications, medical supplies, equipment, and lab testing.[106] FEMA reported that 623 sites established through the public-private partnership were operating in 48 states, Washington, DC, and Puerto Rico, as of June 24, 2020, and had processed 712,849 samples since the program initiation.[107] HHS has asserted that the majority of the sites are located in areas with moderate to high social vulnerability.[108] The HHS-operated Community Based Testing Sites website lists retail partners by state.[109] On June 30, HHS announced that the partnerships will be extended through August 2020.[110] Significant aspects of the community-based sites public-private partnership remain unclear, and official documentation of the effort by FEMA and HHS remains limited. Outstanding questions include, but are not limited to the following:

- What are the terms of the partnership between HHS (or, if applicable, other federal agencies) and private retailers, including questions of eligibility for testing?
- When will the partnership(s) expire?
- What is the source of federal funding supporting payments to private retail partners?
- What is the amount and frequency of bundled federal payments to retailers?
- Do private retailers and pharmacies in the partnership attempt to bill client insurance companies for all or part of the costs associated with testing?

June 26, 2020, https://www.texastribune.org/2020/06/26/texas-federal-coronavirus-testing-sites/; David Lim, "Trump administration restores federal funding for Texas testing sites," *Politico*, June 26, 2020, https://www.politico.com/news/2020/06/26/trump-texas-coronavirus-testing-sites-341795.

[104] Office of the Texas Governor, "Governor Abbott Secures Extension Of Federally-Supported COVID-19 Testing Sites In Texas," June 26, 2020, https://gov.texas.gov/news/post/governor-abbott-secures-extension-of-federally-supported-covid-19-testing-sites-in-texas.

[105] FEMA, "Federal Support to Expand National Testing Capabilities," May 5, 2020, https://www.fema.gov/fact-sheet/federal-support-expand-national-testing-capabilities (hereinafter FEMA, "FEMA, "Federal Support to Expand National Testing Capabilities"). HHS, "COVID-19 Strategic Testing Plan, pp. 24-25; HHS, "HHS Extends COVID-19 Testing Public-Private Partnership," June 30, 2020, https://www.hhs.gov/about/news/2020/06/30/hhs-extends-covid-19-testing-public-private-partnership.html.

[106] HHS, "HHS Extends COVID-19 Testing Public-Private Partnership," June 30, 2020, https://www.hhs.gov/about/news/2020/06/30/hhs-extends-covid-19-testing-public-private-partnership.html.

[107] FEMA, "Weekly Update: Coronavirus Pandemic Whole-of-America Response," June 25, 2020, provided by FEMA Congressional and Legislative Affairs, p. 2.

[108] HHS, "COVID-19 Strategic Testing Plan, p. 25. Submitted testimony of HHS Assistant Secretary for Health Brett Giroir, *Evaluating the Federal Government's Procurement and Distribution Strategies in Response to the COVID-19 Pandemic*, hearings, 116th Cong., 2nd sess., June 6, 2020, p. 7.

[109] HHS, "Community-Based Testing Sites for COVID-19: Public-Private Partnership," https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html.

[110] HHS, "HHS Extends COVID-19 Testing Public-Private Partnership," June 30, 2020, https://www.hhs.gov/about/news/2020/06/30/hhs-extends-covid-19-testing-public-private-partnership.html.

Can COVID-19 Testing Be Done at Home?

There has been significant interest in, and some confusion around, at-home testing for coronavirus. Although testing at home would have benefits—including increased access to testing, decreased use of PPE, decreased risk of illness transmission—this type of testing requires more rigorous FDA oversight to ensure that the lay user conducting the test can do so safely and with accurate results. Although this type of testing has traditionally been termed "at-home" by the FDA, this type of test may actually be carried out in any non-laboratory setting, including and especially relevant for COVID-19, schools, daycares, workplaces, or high-risk settings. The "at-home" designation means that the test may be conducted outside of a CLIA-regulated environment.

Testing for COVID-19 in a home environment can involve either: (1) a sample being self-collected at home using a kit and sent to a central laboratory for processing, or (2) a complete test, including sampling, testing, and interpretation, being conducted in the home. Complete home testing may involve telehealth visits with a health care provider to supervise the sample collection and help interpret the test result and develop a treatment plan, if indicated. Complete at-home testing generally requires a prescription or order from a health care provider, although the FDA does allow certain at-home tests to be offered over-the-counter (OTC), or without a prescription. Although test developers may pursue this option, it requires additional data and studies to determine that its use would be simple and safe, and would not result in harm to the lay user.[111] Advantages to OTC at-home tests would be increased access and the ability to access a test and results entirely outside of the health care setting (with no prescription or interaction with a health care provider necessary).

The FDA must approve or authorize for marketing all at-home COVID-19 tests, at-home sample self-collection kits, or modifications to existing EUAs for tests to specifically allow for at-home sample collection methods. To date, no complete at-home test has been approved or authorized for marketing by the agency, so none of these tests are currently available. However, at-home sample collection kits have been approved and EUAs have been modified to allow for use of at-home sample collection.[112] The agency has noted that it is open to this type of testing and encourages submission of EUAs, as long as the submission contains accompanying data "demonstrating the ability of a lay user to collect their specimen, run the test, and interpret their results accurately."[113] Flexibilities in the EUA process granted for many commercial and laboratory-developed COVID-19 tests do not apply to at-home testing or sample collection, and an EUA is required prior to clinical use or commercial distribution of these tests in any case.[114]

[111] See for example, FDA, "Over-the-Counter Diagnostic Tests for the Detection of Pathogens Causing Infectious Diseases," August 2016, https://www.fda.gov/media/99903/download.

[112] See for example, FDA, "Coronavirus (COVID-19) Update: FDA Authorizes First Test for Patient At-Home Sample Collection," April 21, 2020, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-test-patient-home-sample-collection.

[113] FDA, "FAQs on Testing for SARS-CoV-2," https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2.

[114] FDA, "Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)," May 11, 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised.

Private Health Insurance Coverage of Testing

Private health insurance is the predominant source of health insurance coverage in the United States. Private health insurance includes both the group market (largely made up of employer-sponsored insurance) and the nongroup market (commonly referred to as the individual market, which includes plans directly purchased from an insurer both on and off health insurance exchanges).[115] The federal government may regulate private health insurance plans, including by requiring plans to cover certain benefits. The questions below address federal requirements related to private health insurance coverage of COVID-19 testing, including types of tests that must be covered, coverage of related items and services, coverage of testing for public health surveillance and employment purposes, and coverage of testing conducted by out-of-network providers. The questions address the types of plans subject to federal COVID-19 testing coverage requirements, and whether states may impose their own coverage requirements.

Are Private Health Insurance Plans Required to Cover Testing, and Does That Differ by Type of Test?

Prior to the enactment of the Families First Coronavirus Response Act (FFCRA, P.L. 116-127), no federal requirements specifically mandated that private health insurance cover items or services related to COVID-19 testing.

Section 6001 of the FFCRA, as amended, requires most private health insurance plans to cover COVID-19 testing, including administration of the test and related items and services, as defined in the act. The coverage must be provided without consumer cost-sharing, including deductibles, copayments, or coinsurance.[116] Prior authorization or other medical management requirements are prohibited. These coverage requirements are discussed in more detail below.

FFCRA Section 6001(a)(1), as amended by the Coronavirus Aid, Relief, and Economic Security act (CARES, P.L. 116-136) Section 3201, describes the types of tests that must be covered, along with the administration of such tests. In addition, the Department of Labor (DOL), HHS, and the Treasury issued FAQ documents on April 11, 2020,[117] and June 23, 2020[118] (hereinafter, "Tri-Agency April 11 FAQ" and "Tri-Agency June 23 FAQ," respectively), on the private health insurance coverage requirements in FFCRA and the CARES Act.[119]

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[115] The CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions* has additional background information on private health insurance and types of plans. Also see "What Types of Plans Are Subject to the FFCRA and CARES Act Requirements?" in this report.

[116] A *deductible* is the amount an insured consumer pays for covered health care services before coverage begins (with exceptions). *Coinsurance* is the share of costs, figured in percentage form, an insured consumer pays for a covered health service. A *copayment* is the fixed dollar amount an insured consumer pays for a covered health service.

[117] Department of Labor (DOL), HHS, and the Treasury, "FAQS ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 42," April 11, 2020, at https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf. Hereinafter referred to as "Tri-Agency April 11 FAQ."

[118] DOL, HHS, and the Treasury, "FAQS ABOUT FAMILIES FIRST CORONAVIRUS RESPONSE ACT AND CORONAVIRUS AID, RELIEF, AND ECONOMIC SECURITY ACT IMPLEMENTATION PART 43," June 23, 2020, at https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf. Hereinafter referred to as "Tri-Agency June 23 FAQ."

[119] For a discussion of the agencies' implementation authority and the force of law of these documents, see the "Are Plans Required to Cover Testing for Public Health Surveillance or Employment Purposes?" section of this report.

The acts together require coverage of IVDs, as defined in FDA regulation,[120] that detect SARS-CoV-2 or diagnose the virus that causes COVID-19 and that are approved, cleared, or authorized for marketing by the agency or being marketed or clinically used pursuant to an allowed flexibility in FDA guidance. The acts didn't explicitly state whether this included serology testing.[121] The Tri-Agency April 11 FAQ interpreted the coverage requirement as applying to diagnostic (i.e., molecular and antigen) and serological (i.e., antibody) tests.

Together, the acts, as interpreted by the agencies through guidance, also require coverage without cost-sharing of "items and services furnished to an individual during [specified types of visits; discussed below] that result in an order for or administration of [an applicable COVID-19 test; see above], but only to the extent such items and services relate to the furnishing or administration of such product or to the evaluation of such individual for purposes of determining the need of such individual for such product."[122] Per an example provided in guidance, "if the individual's attending provider determines that other tests (e.g., influenza tests, blood tests, etc.) should be performed during a visit…to determine the need of such individual for COVID-19 diagnostic testing, and the visit results in an order for, or administration of, COVID-19 diagnostic testing, the plan or issuer must provide coverage for the related tests under section 6001(a) of the FFCRA."[123] In addition, consumers must not face cost-sharing for "facility fees" or other fees, to the extent they are related to COVID-19 testing or related items and services that are required to be covered under FFCRA Section 6001.[124]

However, the coverage requirements do not encompass treatment for illnesses associated with COVID-19.[125] They also do not apply to any services or items furnished at a testing visit that are not related to COVID-19 (e.g., if someone received testing or treatment for an unrelated condition at the same visit). In addition, the law and guidance do not explicitly address coverage and cost-sharing for the "related" items and services discussed above, if the individual does not ultimately receive the test.[126]

Per FFCRA Section 6001(a)(2), the coverage requirements apply to the specified items and services, discussed above, when furnished at visits including to health care provider offices (including in-person and telehealth visits), urgent care centers, and emergency rooms. Per the Tri-Agency April 11 FAQ, the requirements also apply at "nontraditional" settings, "including drive-through screening and testing sites where licensed healthcare providers are administering

[120] 21 C.F.R. §809.3(a).

[121] Although both serology tests and molecular and antigen diagnostic tests meet the regulatory definition of "in vitro diagnostic," applicability to serology testing was not clear based only on the statutory language, as it refers to detection and identification of the virus. Serology testing does not detect or identify the virus; rather, it detects antibodies. (See the "What Are the Different Types of COVID-19 Tests?" section of this report for more information.)

[122] FFCRA §6001(a)(2). Also see the Tri-Agency April 11 FAQ, including questions five, six, and eight.

[123] Tri-Agency April 11 FAQ, question five.

[124] For more information, see the Tri-Agency June 23 FAQ, question seven, including its footnote 16.

[125] For more information on private health insurance coverage of COVID-19 treatment, see CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions*.

[126] Per the Tri-Agency April 11 FAQ, question five, the coverage of related items and services is required when "the visit results in an order for, or administration of, COVID-19 diagnostic testing." This language also appears in FFCRA Section 6001(a)(2). The statute and guidance do not explicitly address whether the coverage requirements apply if an individual receives the related items and services, even for purposes of determining the need for COVID-19 testing, but does not actually receive a COVID-19 test. Other federal and/or state requirements could be applicable.

COVID-19 diagnostic testing."[127] Also see, in this section, "Are Plans Required to Cover Testing for Public Health Surveillance or Employment Purposes?"

In addition, guidance indicates that the coverage requirements apply to at-home COVID-19 tests, including at-home swab kits that may be sent to a lab for processing, when such tests are "ordered by an attending health care provider who has determined that the test is medically appropriate for the individual," as specified in guidance.[128]

These coverage requirements apply only to the specified items and services furnished during the COVID-19 public health emergency period described in FFCRA, as of the date the FFCRA was enacted (March 18, 2020).[129]

What Types of Plans Are Subject to the FFCRA and CARES Act Requirements?

These requirements apply to individual health insurance coverage and to small- and large-group plans, whether fully insured or self-insured.[130] The individual and small-group markets include plans sold on and off the individual and small-group health insurance exchanges, respectively. This includes grandfathered individual or group plans, which are exempt from certain other federal private health insurance requirements. Per the definition of individual health insurance coverage cited in FFCRA, the coverage requirements do not apply to short-term, limited duration insurance (STLDI). The Tri-Agency April 11 FAQ specifies other types of private health insurance coverage that are, or are not, subject to the COVID-19 testing coverage requirements.

This section of this report focuses mainly on coverage requirements for private sector plans stemming from Section 6001 of the FFCRA and other federal provisions. Section 6006 of the FFCRA separately addresses the Federal Employees Health Benefits Program (FEHB), which provides health insurance to federal employees, retirees, and their dependents. That section requires that no federal civil servants enrolled in a health benefits plan or FEHB enrollees may be required to pay a copayment or other cost-sharing related to COVID-19 testing, administration of the test, or related items and services for visits during the emergency period. For more information, see CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

[127] See Tri-Agency April 11 FAQ, question eight regarding "nontraditional" visits. Also see question 13 for more information about telehealth visits.

[128] Tri-Agency June 23 FAQ, question four. Also see question three regarding "attending providers."

[129] Some coverage requirements in FFCRA and the CARES Act refer to the "emergency period" or similar construction. This emergency period refers to the public health emergency declared with respect to the COVID-19 outbreak by HHS Secretary Alex Azar on January 31, 2020, effective as of January 27, pursuant to Section 319 of the Public Health Service Act (PHSA). Hence, the emergency period began on January 27, 2020, and remains in effect as long as the declaration, or any renewal of it, is in effect. See "Duration of Emergency Period" in CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*, for more information.

[130] The requirements are technically applicable to group health plans and health insurers offering individual and group health insurance coverage. In this section, references to "plans" include applicable plans and insurers. More information on the types of plans discussed in this paragraph, and the applicability of FFCRA and CARES Act requirements to them, is available in CRS Report R46359, *COVID-19 and Private Health Insurance Coverage: Frequently Asked Questions*.

Are Plans Required to Cover Testing for Public Health Surveillance or Employment Purposes?

As discussed above, Section 6001 of the FFCRA, as amended by the CARES Act, generally requires plans to cover specified testing for the detection or diagnosis of COVID-19 and administration of such tests, without cost-sharing, during the COVID-19 emergency period.[131] Following enactment of this provision, questions arose about the parameters of covered testing, including whether plans must pay for testing that is not mainly intended for the clinical or treatment needs of individual patients.[132] These questions centered on whether Section 6001 compels plans to cover testing for other reasons, such as public health surveillance or return-to-work purposes.[133]

Although the statutory language of Section 6001 does not articulate the precise circumstances under which testing must be covered, it generally restricts the ability of plans to limit coverage of COVID-19 testing. More specifically, Section 6001 indicates that plans cannot "impose prior authorization or other medical management requirements" with respect to required COVID-19 testing coverage.[134] Although not defined in the federal statute, medical management requirements commonly refer to standards or processes that plans follow to determine medically appropriate coverage limitations (e.g., limits on the frequency of covered treatments, or the health care setting for a specific item or service).[135] While Section 6001 makes clear that plans cannot use such techniques to restrict coverage of COVID-19 testing, the scope of covered testing, and whether the provision compels plans to cover testing in all instances, have been the subject of debate.[136]

Section 6001 authorizes the Secretaries of HHS, Labor, and the Treasury to implement the provision "through sub-regulatory guidance, program instruction or otherwise."[137] As part of implementation, the agencies issued the aforementioned Tri-Agency April 11 FAQ.[138] According to the agencies, this document constituted a policy statement under the Administrative Procedure Act.[139] Policy statements do not carry the force of law, but they may inform regulated parties

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[131] See Families First Coronavirus Response Act, P.L. 116-127, §6001, 134 Stat. 201 (2020); Coronavirus Aid, Relief, and Economic Security Act, P.L. 116-136, §3201, 134 Stat. 366 (2020) codified at 42 U.S.C. §1320b-5 note. For more information on the definition of "emergency period" see "Duration of Emergency Period" in CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

[132] See, for example, Letter from National Association of Insurance Commissioners and the Center for Insurance Policy and Research, to Alex Azar, Secretary of Health and Human Services, and Seema Verma, Administrator, Centers for Medicare and Medicaid Services, at https://www.naic.org/documents/NAIC_Letter_to_Azar_May_2020.pdf.

[133] See, for example, id.

[134] 42 U.S.C. §1320b-5 note.

[135] See, for example, Amy B. Monahan, T*he Regulatory Failure to Define Essential Health Benefits*, 44 AM. J. L. & MED. 529, 544 (2018).

[136] See, for example, the letter cited in footnote 132. See also generally, Katie Thomas, *Testing Nursing Home Workers Can Help Stop Coronavirus. But Who Should Pay?*, N.Y. TIMES (June 9, 2020), https://www.nytimes.com/2020/06/09/health/testing-coronavirus-nursing-homes-workers.html. Also see Blake Farmer, *Insurers May Only Pay For Coronavirus Tests When They're 'Medically Necessary'*, NATIONAL PUBLIC RADIO (June 19, 2020), https://www.npr.org/sections/health-shots/2020/06/19/880543755/insurers-may-only-pay-for-coronavirus-tests-when-theyre-medically-necessary.

[137] 42 U.S.C. §1320b-5 note.

[138] See Tri-Agency April 11 FAQ.

[139] See Tri-Agency April 11 FAQ at 1.

about the agencies' enforcement priorities.[140] Under the guidance, the agencies interpreted Section 6001 to compel plans to provide testing coverage only "when medically appropriate for the individual, as determined by the individual's attending healthcare provider in accordance with accepted standards of current medical practice." The guidance did not further outline the circumstances in which COVID-19 tests were "medically appropriate"; however, under the agencies' interpretation, the availability of covered testing appeared contingent upon a medical decision by a health care provider responsible for providing care to a specific patient.

In June 2020, the agencies issued a second guidance document, the Tri-Agency June 23 FAQ, that squarely addresses coverage of COVID-19 testing for surveillance or employment purposes.[141] In this guidance, the agencies specified that testing "conducted to screen for general workplace health and safety (such as employee 'return-to-work' programs), for public health surveillance for SARS-CoV-2, or for any other purpose not primarily intended for individualized diagnosis or treatment of COVID-19 or another health condition is beyond the scope of section 6001 of the FFCRA."[142] Some Members of Congress have called on the Trump Administration to reexamine and revise its guidance, as "[t]his interpretation of [FFCRA] is not supported by the statute, which makes clear that health plans are required to cover, without any conditions or limitations, the specified items and services related to diagnostic tests for the detection of COVID-19."[143] As of the date of this report, it appears that the statutory text of Section 6001 has not been examined by a court.

Are Plans Required to Cover Multiple Tests or Tests for Asymptomatic Individuals?

Per the Tri-Agency June 23 FAQ, if individuals receive multiple diagnostic tests for COVID-19, the FFCRA coverage requirements apply each time, "provided that the tests are diagnostic and medically appropriate for the individual, as determined by an attending health care provider in accordance with current accepted standards of medical practice."[144] The guidance suggests that providers "consult guidance issued by the CDC, as well as state, tribal, territorial, and local health departments or professional societies, when determining whether diagnostic testing is appropriate for a particular individual."[145]

That guidance also states that "clinical decisions about testing are made by the individual's attending health care provider and may include testing of individuals with signs or symptoms compatible with COVID-19, as well as asymptomatic individuals with known or suspected recent

[140] For information on agency use and judicial review of general statements of policy, see CRS Report R44468, *General Policy Statements: Legal Overview*.

[141] See Tri-Agency April 11 FAQ.

[142] Id., question five.

[143] Letter from Frank Pallone, Jr., Chairman, Committee on Energy and Commerce, Robert C. "Bobby" Scott, Chairman, Committee on Education and Labor, Richard Neal, Chairman, Committee on Ways and Means, Patty Murray, Ranking Member, Committee on Health, Education, Labor, and Pensions, Ron Wyden, Ranking Member, Committee on Finance, to Alex Azar, Secretary of Health and Human Services, Eugene Scalia, Secretary of Labor, and Steven T. Mnuchin, Secretary of Treasury (July 7, 2020), https://edlabor.house.gov/imo/media/doc/Democratic%20Health%20Leaders%20Demand%20Trump%20Administration%20Immediately%20Revisit%20Guidance%20Limiting%20COVID-19%20Testing%20Coverage.pdf.

[144] Tri-Agency June 23 FAQ, question six. Also see question three regarding "attending providers."

[145] Ibid.

exposure to SARS-CoV-2, that is determined to be medically appropriate by the individual's health care provider, consulting CDC guidelines as appropriate."[146]

What Coverage and Provider Reimbursement Requirements Apply to Out-of-Network Testing?

While Section 6001 of FFCRA establishes requirements for private health insurance plans to cover COVID-19 testing, administration of the test, and related items and services, it does so without regard to whether a provider is in a health plan's network. See the text box below for background on provider networks and private health insurance coverage.

Section 3202 of the CARES Act establishes a methodology for determining insurer payments to in-network and out-of-network providers for COVID-19 testing, and the Tri-Agency April 11 FAQ clarifies that the FFCRA coverage requirements apply both in-network and out-of-network.[147] Per guidance, Section 3202 of the CARES Act does not address the amount that a health plan must reimburse a provider for any other item or service beyond COVID-19 testing.[148]

In-Network and Out-of-Network Coverage in Private Health Insurance

In private health insurance, the amount paid for covered items and services is generally contingent upon whether a consumer's health plan has negotiated with a provider to enter into a contract. The contract between the health plan and the provider generally specifies the total amount that a provider may receive for furnishing particular items or services to that health plan's enrollees. A provider that enters into a contract with a health plan is considered to be part of the health plan's network, otherwise referred to as being *in-network*.

A provider that does not enter into a contract with a health plan is considered *out-of-network*, and as such there is no negotiated rate between the provider and the health plan. In situations involving services provided by an out-of-network provider, the amount that a provider will receive from a health plan depends on whether the health plan covers out-of-network services. In situations where health plans *do not cover* out-of-network services, the health plan will not pay any amount to a provider for services provided to an enrollee of the health plan. In situations where plans *do cover* out-of-network services, as there is no negotiated rate between health plans and out-of-network providers, health plans will use their own methodologies for calculating how much they will pay out-of-network providers for services. If an out-of-network provider's total charge for a service exceeds the amount reimbursed by the health plan, the provider may directly bill (i.e., balance bill) a consumer for the amount of the difference, except when prohibited by applicable state law or other contractual agreements.

For more information, see CRS Report R46116, *Surprise Billing in Private Health Insurance: Overview and Federal Policy Considerations*.

Under the CARES Act, if a health plan had a negotiated rate with a provider of diagnostic testing prior to the declaration of the COVID-19 public health emergency declared under PHSA Section 319, then the health plan must apply that negotiated rate throughout the period of the COVID-19 public health emergency.[149] If a health plan did not have a negotiated rate with a provider of diagnostic testing prior to the emergency declaration, then the health plan must either reimburse

[146] Tri-Agency June 23 FAQ, question five.

[147] Tri-Agency April 11 FAQ, question seven.

[148] Tri-Agency June 23 FAQ, question eight.

[149] Some coverage requirements in FFCRA and the CARES Act refer to the "emergency period" or similar construction. This emergency period refers to the public health emergency declared with respect to the COVID-19 outbreak by HHS Secretary Alex Azar on January 31, 2020, effective as of January 27, pursuant to Section 319 of the Public Health Service Act (PHSA). Hence, the emergency period began on January 27, 2020, and remains in effect as long as the declaration, or any renewal of it, is in effect. See "Duration of Emergency Period" in CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*, for more information.

the provider an amount that equals the cash price for the COVID-19 testing, as listed on the provider's public website, or the health plan and provider may negotiate a rate that is less than the cash price. If there is no cash price listed on the provider's website and the two parties cannot negotiate a rate, then the methodology for determining reimbursement depends on whether there is an applicable state law.[150]

During the period of the COVID-19 public health emergency, providers of COVID-19 diagnostic testing must make public the cash price for the COVID-19 test on the provider's public website. Section 3202 of the CARES Act does not include any further requirements for providers regarding the cash price, including any limitation on the amount that a provider may post as the cash price.

The HHS Secretary may impose a civil monetary penalty on a provider of COVID-19 diagnostic testing that is not in compliance with the above requirement to post the cash price and has not completed a corrective action plan to comply with the requirement. The amount of the civil monetary penalty may not exceed $300 per day that the violation is ongoing.

Are Out-of-Network Providers Allowed to Balance Bill Patients for COVID-19 Testing and Other Related Items and Services?

The Tri-Agency June 23 FAQ clarifies that the combination of the Families First Coronavirus Response Act (FFRCA, P.L. 116-127) requirement to provide coverage for COVID-19 testing without cost-sharing, and the CARES Act methodology for determining reimbursement for COVID-19 testing, means that an out-of-network provider is generally precluded from directly billing a patient for the difference between provider's charge for COVID-19 testing and the amount reimbursed by the health plan (i.e., balance bill).[151] However, a provider is not prevented from balance billing for other items and services unless there is an applicable state law or other prohibition (e.g., pursuant to the terms of the Provider Relief Fund).[152]

May States Require Plans to Cover Additional Types or Purposes of Testing?

States are the primary regulators of private health insurance, and each state may impose coverage requirements on insurers and the plans they sell in that state.

With regard to COVID-19 testing, states may require coverage that exceeds applicable federal requirements, as long as states do not prevent the implementation of any federal requirements.[153] Some states have done so.[154] For example, although the Tri-Agencies have stated that FFCRA

[150] Tri-Agency June 23 FAQ, question 11.

[151] Question nine in the Tri-Agency June 23 FAQ points out that out-of-network providers who accept funds from the Provider Relief Fund may not seek to collect from patients out-of-pocket expenses that would be "greater than what the patient would have otherwise been required to pay if the care had been provided by an in network provider." For background on this funding, see CRS Insight IN11438, *The COVID-19 Health Care Provider Relief Fund*.

[152] Ibid.

[153] See, for example, the introduction of the Tri-Agency April 11 FAQ.

[154] The National Association of Insurance Commissioners (NAIC) is tracking certain state actions related to insurance and COVID-19 at https://content.naic.org/naic_coronavirus_info.htm. To confirm whether a given state has enacted any requirements related to coverage of COVID-19 testing (or related to other topics) that may not be reflected in that tracking document, check with that state's department of insurance: https://content.naic.org/state_web_map.htm.

Section 6001 does not require insurance coverage of COVID-19 testing for public health purposes (see above), New York requires insurers to cover testing for individuals who meet one or more criteria listed in the state's guidance, including "an individual is employed as a health care worker, first responder, or other essential worker who directly interacts with the public while working."[155]

State requirements may apply to individual health insurance coverage, fully insured group coverage, or both, but states cannot regulate self-insured group plans.[156] States may impose requirements on STLDI. (See "What Types of Plans Are Subject to the FFCRA and CARES Act Requirements?" for information on plan types.)

Note that a state or local department of health or other administrative agency may announce requirements or guidelines regarding testing certain populations or testing for certain public health purposes. However, this does not necessarily mean that insurers in that state are required to cover such testing, although that would be the case if the state department of insurance or other relevant agency also requires such coverage, or if federal requirements are applicable.

Payment for Testing by Federal Programs: Medicare, Medicaid, and CHIP

The Social Security Act (SSA) defines a federal health care program as any plan or program that provides health benefits—whether directly, through insurance, or otherwise—and that is funded directly, in whole, or in part by the U.S. government or a state health care program (with the exception of the Federal Employees Health Benefits Program).[157] Key federal health programs include (1) Medicare, the national health insurance program that pays for covered services furnished to beneficiaries (generally the elderly and disabled); (2) Medicaid, the federal-state program for certain low-income individuals; and (3) the State Children's Health Insurance program (CHIP), which provides coverage for low-income, uninsured children. The questions below discuss how these federal health care programs provide, establish coverage, or pay for testing for their beneficiaries. FFRCA required each of these programs to cover COVID-19 testing for their enrollees without beneficiary cost-sharing, under certain circumstances. The specific testing-related requirements associated with each program are discussed below. In general, these federal health care programs provide coverage for testing of beneficiaries when ordered by an enrollee's physician or practitioner.[158]

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[155] New York State Department of Financial Services, "Insurance Circular Letter No. 11 (2020)," May 19, 2020, at https://www.dfs.ny.gov/industry_guidance/circular_letters/cl2020_11.

[156] Some coverage requirements in FFCRA and the CARES Act refer to the "emergency period" or similar construction. This emergency period refers to the public health emergency declared with respect to the COVID-19 outbreak by HHS Secretary Alex Azar on January 31, 2020, effective as of January 27, pursuant to Section 319 of the Public Health Service Act (PHSA). Hence, the emergency period began on January 27, 2020, and remains in effect as long as the declaration, or any renewal of it, is in effect. See "Duration of Emergency Period" in CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*, for more information.

[157] Section 1128B(f) of the Social Security Act (SSA).

[158] For adults under the Medicaid program, states are permitted to limit the extent to which a covered benefit is available under the state plan by defining medical necessity criteria, and the amount, duration, and scope of covered services (see SSA Section(s) 1901; 1902(a)(30)(A); and 1903(m)(2)(A)(vii)). For children under Medicaid and CHIP Medicaid expansion programs, medical necessity requirements are established under Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) (see SSA Section 1905(r)(5)). For separate CHIP programs, medical necessity requirements are established under SSA Section 2110(a)(24).

How Does Medicare Pay for Testing, and Does That Differ by Type or Use of Test?

In general, Medicare covers health care services furnished to diagnose or rule out a possible illness or condition.[159] Medicare pays for clinical laboratory tests that are medically necessary and ordered by a beneficiary's physician or practitioner for such purposes.[160] There is no cost-sharing required under Part B, nor for beneficiaries enrolled in Medicare Advantage (MA) plans, as MA plans must cover all benefits under Medicare Parts A and B.[161] Clinical tests to diagnose or aid in the diagnosis of the coronavirus disease, as well as some tests for related respiratory conditions given with the COVID-19 test, are covered under Medicare Part B.[162] FDA-authorized antibody (serology) tests for those beneficiaries diagnosed with a known current or prior COVID-19 infection or suspected current or past COVID-19 infection are also covered with no cost-sharing.[163] There is no limit on the number of tests, so long as each test satisfies the coverage requirement.

The FFCRA eliminated the Medicare Part B beneficiary cost-sharing for provider visits during which a coronavirus diagnostic test is administered or ordered during the emergency period. Beneficiaries are not responsible for any coinsurance payments or deductibles for any specified COVID-19 testing-related service, defined as a medical visit that falls within the evaluation and management service codes for the following categories: office and other outpatient services; hospital observation services; emergency department services; nursing facility services; domiciliary, rest home, or custodial care services; home services; or online digital evaluation and management services.

Surveillance testing, whether it be for the novel coronavirus or other purposes, does not meet the Medicare coverage criteria that the care be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." Similarly, COVID-19 testing for "return-to-work" would not be covered under Medicare.

[159] SSA Section 1862(a)(1)(A) specifies that Medicare covered health care services must be "reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."

[160] Some preventive or screening tests may also be covered, but these are explicitly addressed in SSA Section 1862(a)(1)(B)-(P) (e.g., screening tests for mammography, prostate cancer, and colorectal cancer).

[161] See CRS Report R40425, *Medicare Primer* for information about Medicare.

[162] CMS, "Coronavirus disease 2019 (COVID-19) tests" at https://www.medicare.gov/coverage/coronavirus-disease-2019-covid-19-tests.

[163] CMS "Coronavirus disease 2019 (COVID-19) antibody test" at https://www.medicare.gov/coverage/coronavirus-disease-2019-covid-19-antibody-test. For information about molecular pathogen tests versus screening antibody serology tests, see CRS In Focus IF11516, *COVID-19 Testing: Key Issues*.

Medicare Coverage of Nursing Home Testing

As of July 2020, under Original Medicare and Medicare Advantage, Medicare covers COVID-19 diagnostic testing of Medicare beneficiaries who are residents of nursing homes. Diagnostic testing includes

- testing residents with signs or symptoms of COVID-19;
- testing asymptomatic residents with known or suspected exposure to an individual infected with SARS-CoV-2, including close and expanded contacts (e.g., if there is an outbreak in the facility);
- initial (baseline) testing of asymptomatic residents without known or suspected exposure to an individual infected with SARS-CoV-2 as part of the recommended reopening process; and
- testing to determine resolution of infection.

Sources: CMS, "Medicare Coverage of COVID-19 Testing for Nursing Home Residents and Patients," June 19, 2020, available at https://www.cms.gov/newsroom/press-releases/cms-news-alert-june-19-2020, and CMS, "Medicare Fee-For-Service (FFS) Response to the Public Health Emergency on the Coronavirus (COVID-19." Medicare Learning Network Matters Document SE20011, July 17, 2020, at https://www.cms.gov/files/document/se20011.pdf.

How Does Medicaid Pay for Testing, and Does That Differ by Type or Use of Test?

Medicaid is a joint federal-state program that finances the delivery of primary and acute medical services, as well as long-term services and supports (LTSS), to a diverse low-income population, including eligible children, pregnant women, adults, individuals with disabilities, and people aged 65 and older. States have flexibility to design their own versions of Medicaid within the federal statute's basic framework. This flexibility results in variability across state Medicaid programs regarding factors such as eligibility and covered benefits.

Section 6004 of the FFCRA, as amended by Section 3717 of the CARES Act, requires state Medicaid programs to cover testing and testing-related services[164] without beneficiary cost-sharing, beginning on or after March 18, 2020, through the public health emergency period, as defined.[165] Testing services are defined as in vitro diagnostic products as defined in FDA regulation[166] including the administration of such products, for the detection of SARS-CoV-2 or the diagnosis of COVID-19. According to guidance from the Centers for Medicare and & Medicaid Services (CMS), the FDA has advised that serological tests for COVID-19 meet the

[164] CMS interpreted COVID-19 testing-related services to include items and services for which payment is available under the Medicaid state plan that are directly related to the administration of COVID-19 testing, or for the evaluation of an individual to determine the need for COVID-19 testing (e.g., an X-ray). For more information, see Centers for Medicare and Medicaid Services (CMS), *Families First Coronavirus Response Act (FFCRA)*, P.L. 116-127*; Coronavirus Aid, Relief, and Economic Security (CARES) Act*, P.L. 116-136*; Frequently Asked Questions (FAQ)*, April 13, 2020.

[165] FFCRA, as amended by the CARES Act, also added a new optional Medicaid "COVID-19 testing" eligibility group to provide testing and diagnosis of COVID-19 for certain specified uninsured individuals during the COVID-19 public health emergency. For more information on this optional eligibility group and the limited benefit coverage enrollees in this group are entitled to, see the "Under What Circumstances Will Medicaid Pay for Uninsured Testing?" section of this report.

[166] 21 C.F.R. 809.3(a) defines in vitro diagnostic products as "reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body." To date, FDA has authorized one emergency use authorization for a serological test that is intended for use by clinical laboratories. See U.S. Food and Drug Administration, Letter to Cellex Inc. Regarding qSARS-CoV-2 IgG/IgM Rapid Test (April 1, 2020), available at https://www.fda.gov/media/136622/download.

FDA definition of an in vitro diagnostic product for the detection of SARS-CoV-2 or the diagnosis of COVID-19, and thus must be covered under Medicaid.[167] To date, the Medicaid specific CMS guidance has not explicitly addressed the question of whether states can use Medicaid as a payer of public health surveillance testing for SARS-CoV-2 (to screen for general workplace health and safety, as in the case of employee "return to work" programs).

How Does CHIP Pay for Testing, and Does That Differ by Type or Use of Test?

CHIP provides health insurance coverage to low-income, uninsured children in families with incomes above applicable Medicaid income standards, and to certain pregnant women. States have the flexibility to design their own versions of CHIP within the federal statute's basic framework. This flexibility results in variability across state CHIP programs regarding factors such as eligibility and covered benefits.

FFCRA, as amended by the CARES Act, also requires CHIP programs to cover COVID-19 testing and testing-related services[168] for CHIP enrollees for the period beginning March 18, 2020, through the duration of the public health emergency period, as specified. States are prohibited from charging beneficiary cost-sharing for such testing, or for testing-related visits furnished to CHIP enrollees during this period. CMS guidance clarifies that, as under Medicaid, such testing must include diagnostic and serological tests for symptomatic and asymptomatic CHIP program enrollees when testing is driven by medical necessity.[169] To date, the CHIP specific CMS guidance has not explicitly addressed the question of whether states can use Medicaid as a payer of public health surveillance testing for SARS-CoV-2 (to screen for general workplace health and safety, as in the case of "return to school" programs).

Provision of and Payment for COVID-19 Testing by Federal Systems: IHS, VA, DOD, and FEMA

In general, the federal government pays for care provided by nonfederal providers. In the cases of the Indian Health Service, the Veterans Health Administration (VHA), and the DOD through the Defense Health System, the federal government may provide care directly to a limited set of beneficiaries enrolled in these programs. Other federal programs, that that do not have as their primary purpose the delivery of health care, may also, in some cases, directly provide services to individuals who reside in their facilities (for example, the Bureau of Prisons may provide care to federal inmates). The questions below focus on federal health systems that have as their main purpose the provision of health care, and how these systems provide and pay for testing for their beneficiaries. FFRCA requires each of these agencies to cover testing for their beneficiaries; the

[167] CMS, "Families First Coronavirus Response Act (FFCRA), P.L. 116-127; Coronavirus Aid, Relief, and Economic Security (CARES) Act, P.L. 116-136; Frequently Asked Questions (FAQs)," April 13, 2020, https://www.medicaid.gov/state-resource-center/downloads/covid-19-section-6008-CARES-faqs.pdf (hereinafter, *CMS Medicaid FAQs*).

[168] CMS interpreted COVID-19 testing-related services to include items and services for which payment is available under the Medicaid state plan that are directly related to the administration of COVID-19 testing, or for the evaluation of an individual to determine the need for COVID-19 testing (e.g., an X-ray). When defining testing-related services available under CHIP, the CMS guidance points to Medicaid specific responses in the Q&A. For more information, see CMS Medicaid FAQs.

[169] CMS Medicaid FAQs.

specific requirements for each agency are discussed in the questions below. In addition, federally operated health systems generally do not provide care to non-beneficiaries except under limited circumstances, some of which have arisen as part of the COVID-19 pandemic. The provision of testing services to non-beneficiaries is also discussed in the questions below.

How Does the Indian Health Service Provide or Pay for Testing?

The Indian Health Service (IHS) within HHS is the lead federal agency charged with improving the health of American Indians and Alaska Natives. In FY2019, IHS provided health care to approximately 2.6 million eligible American Indians/Alaska Natives.[170] IHS has 12 areas, and the Navajo area represents one of the highest COVID-19 death rates nationally.[171] IHS provides care free of charge to its beneficiaries, who are generally members of federally recognized tribes.[172] These services include COVID-19 testing. IHS reports that most of its facilities have testing capacity, and it has been making data on testing at the area level available on its website.[173] To expand testing, IHS received and provided 250 rapid test analyzers to facilities in its system, prioritizing sites near hot spots and those that were not near centralized lab capacity.[174]

IHS has received approximately $1.850 billion in supplemental funding for COVID-19-related testing and care.[175] FFRCA provided an additional $64 million, to remain available until September 30, 2022 (i.e., through FY2021), for specified COVID-19 testing and related health services and administration.[176] The act also requires IHS to pay the cost of providing any COVID-19-related items and services without imposing any cost-sharing requirements for the period of the COVID-19 emergency. This requirement applies to any American Indian[177] receiving services through the IHS,[178] including through Urban Indian Organizations. Generally, IHS facilities operated by the Indian Health Service do not charge cost-sharing; however, facilities that are operated by Indian tribes or by Urban Indian Organizations may do so. The CARES Act provided an additional $1.032 billion to IHS to prevent, prepare for, and respond to the coronavirus. This funding was not explicitly for testing, but it may be used for testing. PPPHCEA also appropriated $750 million the Public Health and Social Services Emergency Fund (PHSSEF) to be allocated

[170] HHS, Indian Health Service (IHS), FY2021, "Justification of Estimates for Appropriations Committees," https://www.ihs.gov/sites/budgetformulation/themes/responsive2017/display_objects/documents/FY_2021_Final_CJ-IHS.pdf. IHS provides health care directly through facilities it operates, or through facilities that are operated by Indian Tribes/Tribal Organizations or Urban Indian organizations.

[171] Kenzi Abou-Sabe, Cynthia McFadden and Didi Martinez, "'Hit us at our core': Vulnerable Navajo Nation fears a second COVID-19 wave," August 3, 2020, https://www.nbcnews.com/specials/navajo-nation-fears-second-covid-19-wave/index.html.

[172] For definition of Indian Tribe see Section 4 of the Indian Health Care Improvement Act (25 U.S.C. §1603(14)).

[173] See HHS, IHS, "Coronavirus (COVID-19)," https://www.ihs.gov/coronavirus/.

[174] HHS, IHS "Coronavirus (COVID-19), FAQs—Federal Response in Indian Country," https://www.ihs.gov/coronavirus/faqs-federal-response-in-indian-country/.

[175] For a discussion of funding provided to the Indian Health Service and Indian Tribes to prepare for and respond to the coronavirus, see CRS Insight IN11333, *COVID-19 and the Indian Health Service*.

[176] CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

[177] FFRCA defines *Indian* with a reference to Section 4 of the Indian Health Care Improvement Act (25 U.S.C. §1603(13)).

[178] The phrase "receiving services through the IHS" is not defined, but it has been used in prior federal guidance to refer to non-IHS facilities that have care coordination agreements with IHS facilities to treat American Indians and Alaska Natives. See Letter to State Health Official: Re: Federal Funding for Services "Received Through" an IHS/Tribal Facility and Furnished to Medicaid-Eligible American Indians and Alaska Natives (SHO #16-002), February 26, 2016, https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/Downloads/sho022616.pdf.

by IHS for testing capacity (see the "What Funds Have Been Appropriated for Testing Capacity and Infrastructure?" section of this report).

Does the Department of Veteran Affairs Offer or Pay for Testing?

The Veterans Health Administration (VHA) of the Department of Veterans Affairs (VA) operates one of the nation's largest integrated direct health care delivery systems.[179] The VHA estimates that in FY2020 it will provide care to about 6.33 million unique veteran patients.[180] In the same year, the VHA estimates that it will employ a staff of about 347,000 full-time equivalent employees[181] at approximately 1,456 VA sites of care,[182] with an appropriation of approximately $80.6 billion.[183] The VHA provides a standard medical benefits package to enrolled veterans for services both related to and unrelated to their military service.[184] These services include COVID-19 testing. The VA reports that it is capable of administering approximately 60,000 tests per week, with the ability to test asymptomatic individuals who request a test.[185] The VA has been making some data regarding testing publicly available on its website.[186]

Diagnostic testing is generally a covered service under the standard medical benefits package.[187] Some veterans are required to pay copayments for care that is not related to a service-connected disability. However, routine lab tests are exempt from copayment requirements.[188] Furthermore, the FFCRA prohibited the VA from charging any copayment or other cost-sharing payments for COVID-19 testing or medical visits during any period of this public health emergency.[189]

The VA has received supplemental funding for COVID-19-related testing and care.[190] The FFRCA provided an additional $30 million to the VHA medical services account, to remain available until September 30, 2022 (i.e., through FY2021) to fund health services and related

[179] The Veterans Health Administration (VHA) operates under a different model from the predominant health care financing and delivery model in the United States, in which there is a payer for health care services (e.g., Medicare or private health insurance plan), a provider (e.g., hospital, physician), and a recipient of care (the patient). The VHA is not a health insurance financing program that provides reimbursement to providers for all or a portion of a patient's health care costs. The VHA is primarily a direct provider of care; it owns the hospitals and employs the clinicians.

[180] Department of Veterans Affairs (VA), *FY2021 Congressional Submission, Medical Programs and Information Technology Programs*, vol. 2 of 4, February 2020, p. VHA-19.

[181] VA, *FY2021 Congressional Submission, Budget in Brief*, February 2020, p. BiB-4.

[182] Ibid., p. BiB-11. (Sites of care used in this calculation are VA hospitals, community living centers, health care centers, community-based outpatient clinics [CBOCs], other outpatient service sites, and dialysis centers.)

[183] VA, *FY2021 Congressional Submission, Supplemental Information &Appendices*, vol. 1 of 4, February 2020, p. Supplemental Information-1.

[184] For more information on the VHA health system in general, including who can enroll and the services that provided, see CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*.

[185] VHA Daily COVID-19 Update, June 18, 2020. Testing capacity is accurate as of June 18, 2020. VA indicates that it is continuing to increase testing capacity.

[186] See VHA, VA, "Novel Coronavirus Disease (COVID-19)," https://www.publichealth.va.gov/n-coronavirus/.

[187] 38 C.F.R. §17.38.

[188] 38 C.F.R. §17.108(e)(14).

[189] Generally, diagnostic testing is a covered service under VA's standard medical benefits package, which is available to all veterans enrolled in the VA health care system (38 C.F.R. §17.38). Some veterans are required to pay copayments for care that is not related to a service-connected disability. However, routine lab tests are exempt from copayments. (38 C.F.R. §17.108(e)(14)). Prior to enactment of FFRCA, it was unclear whether VA was including COVID-19 testing under this exemption.

[190] For a discussion of funding provided to VA to prepare for and respond to the public health emergency, see CRS Report R46340, *Federal Response to COVID-19: Department of Veterans Affairs*.

items pertaining to COVID-19.[191] The CARES Act provides supplemental appropriations for FY2020 for certain VA accounts totaling $19.6 billion, designated as emergency spending. The VHA medical services account received $14.4 billion of that total, which is partially intended for testing.[192]

Can the IHS and the VA Provide Testing for Individuals Who Are Not Otherwise Eligible for Services?

Generally, health services at facilities operated by the IHS are limited to IHS beneficiaries who are generally members of Indian tribes. Facilities operated by Indian tribes, tribal organizations, or Urban Indian Organizations may serve non-IHS beneficiaries, but they may not use IHS funds to do so. The Indian Health Care Improvement Act (IHCIA, P.L. 94-437), which provides general authority for much of IHS's activities, permits IHS facilities to serve non-beneficiaries under limited circumstances, as specified in Section 813 (25 U.S.C. §1680). These circumstances include preventing the spread of a communicable disease or to address a health hazard. IHS provided guidance to tribal facilities stating that tribes may choose to provide care to non-beneficiaries to reduce COVID-19 spread, including, but not limited to, members of Indian households who are not otherwise eligible for IHS services. In this guidance, IHS noted that the decision to provide services to non-beneficiaries would be made at the local level.[193] IHCIA generally requires that services provided to non-beneficiaries be reimbursed. As such, individuals who have another source of coverage would be tested at an IHS-facility billed to the relevant payer. HRSA has stated in its Frequently Asked Questions about the uninsured fund that COVID-19 testing that IHS facilities provide to non-IHS beneficiaries may be reimbursed by the uninsured fund if the individual tested does not have another source of payment.[194]

Similarly, VA health services provided through the VHA are generally limited to veteran enrollees who are subject to specified eligibility and enrollment criteria.[195] The VHA's primary function is to "provide a complete medical and hospital service for the medical care and treatment of veterans" (38 U.S.C. §7301). However, the VA may provide hospital care and medical services through a number of legal authorities to other individuals during periods of war, national disasters, emergencies, or humanitarian crisis.

The Veterans Administration and Department of Defense Health Resources Sharing and Emergency Operations Act (P.L. 97-174) was enacted to serve as the primary health care backup to the military health care system during and immediately following an outbreak of war or a national emergency.[196] Since then, Congress has provided additional authorities to the VA to "use

[191] VHA's annual appropriations consist of five accounts: medical services, medical community care, medical support and compliance, medical facilities, and medical and prosthetic research accounts. The first four accounts cover the provision of health care and related services.

[192] Based on Senate Appropriations Committee, Coronavirus Supplemental Appropriations Summary, available at https://www.appropriations.senate.gov/download/coronavirus-emergency-supplemental-appropriations-summary.

[193] HHS, IHS, "IHS COVID-19 Interim Guidance for Care Services to Non-Beneficiaries," March 20, 2020, https://www.ihs.gov/sites/coronavirus/themes/responsive2017/display_objects/documents/IHS_COVID-19_InterimGuidanceCareServices_Non-Beneficiaries.pdf.

[194] HHS, HRSA, "Frequently Asked Questions," https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions?field_faq_category_tid=All&combine=indian.

[195] For a detailed discussion of eligibility for VA health care and qualification for enrollment, see CRS Report R42747, *Health Care for Veterans: Answers to Frequently Asked Questions*.

[196] 38 U.S.C. §811A.

its vast infrastructure and resources, geographic reach, deployable assets, and health care expertise, to make significant contributions to the Federal emergency response effort in times of emergencies and disasters."[197]

The VHA may care for nonveterans and veterans not enrolled in the VA health care system.[198] The VA also has authority to provide certain health services such as medical counter measures[199] to VA employees.[200] The authority to care for nonveterans applies in situations where the President has declared a major disaster or emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), or where the HHS Secretary has declared a disaster or emergency activating the National Disaster Medical System established pursuant to Section 2811(b) of the Public Health Service Act (42 U.S.C. §300hh-11(b)). The President's March 13, 2020, declaration of a national emergency under Section 501(b) of the Stafford Act allows the VA to use this authority.

Does the Department of Defense Offer or Pay for Testing?

Under Chapter 55 of Title 10, *U.S. Code*, the DOD administers statutory health entitlements to approximately 9.5 million beneficiaries (i.e., servicemembers, military retirees, and family members).[201] Collectively, these entitlements are organized under a program called TRICARE that is administered by the Military Health System (MHS). The MHS offers health care services in military hospitals and clinics—known as military treatment facilities (MTFs)—and through civilian health care providers participating in TRICARE.[202] With the exception of active duty servicemembers, MHS beneficiaries may have a choice of TRICARE plan options depending on their status and geographic location. Each plan option has different beneficiary cost-sharing features, including annual enrollment fees, deductibles, copayments, and an annual catastrophic cap.[203]

COVID-19 diagnostic and serologic testing is a TRICARE-covered benefit when deemed medically necessary by a health care provider.[204] Beneficiaries may receive COVID-19 testing at

[197] VA, *Department of Veterans Affairs FY 2018—2024 Strategic Plan*, Refreshed May 31, 2019, May 31, 2019, p. 35.

[198] 38 U.S.C. §1785 and 38 C.F.R. §17.86 establish VA authority to provide hospital care and medical services to nonveterans responding to, involved in, or otherwise affected by a disaster or emergency. These individuals may include active duty servicemembers, as well as National Guard and Reserve component members activated by state or federal authority. This authority also allows the VA to treat veterans not enrolled in the VA health care system. Unless another federal agency reimburses the VA, individuals could be charged for this care. "[I]ndividuals who receive hospital care or medical services under this section [38 C.F.R. §17.86] are responsible for the cost of the hospital care or medical services when charges are mandated by Federal law (including applicable appropriation acts) or when the cost of care or services is not reimbursed by other-than-VA Federal departments or agencies." 38 C.F.R. §17.86.

[199] Medical counter measures are "are life-saving medicines and medical supplies regulated by the U.S. Food and Drug Administration (FDA) that can be used to diagnose, prevent, protect from, or treat conditions associated with chemical, biological, radiological, or nuclear (CBRN) threats, emerging infectious diseases, or a natural disaster" (https://www.cdc.gov/cpr/readiness/mcm.html); see CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

[200] 5 U.S.C. §7901; also see Appendix A of Department of Veterans Affairs, Veterans Health Administration, *All-Hazards Emergency Cache Program*, VHA Directive 1047, Washington, DC, April 21, 2020, pp. A-1-A-2.

[201] Defense Health Agency, "Patients by Beneficiary Category," accessed June 10, 2020, https://www.health.mil/I-Am-A/Media/Media-Center/Patient-Population-Statistics/Patients-by-Beneficiary-Category.

[202] For more on the Military Health System, see CRS In Focus IF10530, *Defense Primer: Military Health System*.

[203] For more on TRICARE cost-sharing features, see Defense Health Agency, TRICARE Fact Sheet, *TRICARE Costs and Fees 2020*, May 2020, https://tricare.mil/-/media/Files/TRICARE/Publications/Misc/Costs_Sheet_2020.pdf.

[204] DOD generally follows CDC guidance on COVID-19 screening, testing, diagnosis, and treatment. For more on DOD-specific clinical guidance, see DOD, "DoD COVID-19 Practice Management Guide," May 14, 2020,

certain MTFs or through TRICARE-authorized civilian heath care providers or laboratories. DOD has approximately 100 clinical laboratories (stand-alone or embedded at MTFs) worldwide with COVID-19 diagnostic capabilities and can support up to 16,000 tests per day.[205]

There are no out-of-pocket costs for MHS beneficiaries obtaining medically necessary COVID-19 tests. Pursuant to FFRCA Section 6006(a), DOD is required to waive all TRICARE cost-sharing requirements related to COVID-19 testing, administration of the test, and related items and services provided during an associated health care office, urgent care, or emergency department visit for the duration of the declared public health emergency.[206]

In addition to COVID-19 diagnostic and serologic testing, DOD conducts asymptomatic screening and ongoing surveillance testing of certain active duty servicemembers to mitigate potential impacts to national security or ongoing military operations. Servicemembers subjected to mandatory surveillance testing include those assigned to strategic and nuclear deterrence positions, initial recruitment or accession training, and forward-deployed forces.[207]

Does FEMA Pay for COVID-19 Testing?

FEMA may provide direct and financial assistance for certain costs incurred for COVID-19 testing. The presidential declarations of emergency and major disaster for COVID-19[208] under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (hereinafter the Stafford Act) specifically authorized Public Assistance (PA) Category B: Emergency Protective Measures, defined as work undertaken to save lives and protect property or public health and safety, or to avert the threat of a catastrophe.[209] This work includes the provision of specific medical care costs

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https://www.health.mil/Reference-Center/Technical-Documents/2020/05/14/DoD-COVID-19-Practice-Management-Guide-Version-2.

[205] Email from the Defense Health Agency (DHA), Armed Forces Health Surveillance Branch, Integrated Biosurveillance Section, June 4, 2020; and CRS discussion with other DHA officials, June 10, 2020.

[206] For more on DOD-specific requirements and appropriations included in the FFCRA, see CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*; and Defense Health Agency, *Decision Memorandum on TRICARE Implementation of the "Families First Coronavirus Response Act*, April 7, 2020, https://www.health.mil/Reference-Center/Publications/2020/04/07/TRICARE-Implementation-of-the-Families-First-Coronavirus-Response-Act.

[207] See Jim Garamone, "DOD Starts Tiered COVID-19 Testing Process to Ensure Safety," *DOD News*, April 22, 2020, https://www.defense.gov/Explore/News/Article/Article/2160008/dod-starts-tiered-covid-19-testing-process-to-ensure-safety/; and DOD, "Force Health Protection Guidance (Supplement 9) – Department of Defense Guidance for Deployment and Redeployment of Individuals and Units during the Novel Coronavirus Disease 2019 Pandemic," May 26, 2020, https://media.defense.gov/2020/May/26/2002305748/-1/-1/1/FORCE-HEALTH-PROTECTION-GUIDANCE-SUPPLEMENT-9.PDF.

[208] The President issued an emergency declaration, and subsequently issued major disaster declarations for all 50 states, five territories, the District of Columbia, and one tribe, authorizing Public Assistance (PA) for COVID-19 response efforts (Federal Emergency Management Agency (FEMA), "COVID-19 Disaster Declarations," https://www.fema.gov/coronavirus/disaster-declarations (Stafford Act Declarations as of June 16, 2020).

[209] Public Assistance (PA) provides grant assistance to state, tribal, territorial, and local governments, as well as eligible private nonprofit organizations, for the costs of urgent response and long-term recovery work following an emergency or major disaster declared under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act; P.L. 93-288, as amended; 42 U.S.C. §§5121 et seq.). Assistance for emergency protective measures is authorized under Stafford Act Sections 402, 403, 407, 418, and 419 for major disasters, and Section 502 for emergencies; 42 U.S.C. §§5170a, 5170b, 5173, 5185, 5186, and 5192. See 44 C.F.R. §206.220 for general eligibility for public assistance. FEMA released guidance specific to COVID-19, including a nonexclusive list of emergency protective measures. FEMA, "Coronavirus (COVID-19) Pandemic: Eligible Emergency Protective Measures," fact sheet, March 19, 2020, https://www.fema.gov/fact-sheet/eligible-emergency-protective-measures.

directly related to the COVID-19 pandemic, including "triage and medically necessary tests and diagnosis related to COVID-19 patients."[210] Related eligible costs include, but are not limited to

- the costs of consumable and durable medical supplies;
- the costs of temporary and expanded medical facilities;
- overtime for budgeted medical staff treating COVID-19 patients;
- regular time and overtime for temporary and contracted medical staff treating COVID-19 patients; and
- the purchase and delivery of specialized medical equipment, PPE, and durable and consumable medical supplies.[211]

For COVID-19, FEMA will reimburse PA Applicants, which can include state, tribal, territorial, and local governments, as well as eligible private nonprofit organizations[212] (including nonprofit medical facilities), for 75% of eligible costs incurred while performing eligible work, including medically necessary tests.[213] For example, news sources have reported that FEMA reimbursed the State of Iowa for contract testing services provided by TestIowa, a public-private partnership to provide COVID-19 testing.[214]

There is no predetermined limit on the amount of funding available through the PA program.[215] However, FEMA will not reimburse costs covered by another source, which may include private or publicly funded insurance, funding provided through the CARES Act (P.L. 116-136), the COVID-19 Uninsured Program for uninsured patients, or programs overseen by HHS, among others.[216] In addition, to be eligible for reimbursement, FEMA must confirm that costs are reasonable.[217] FEMA has advised it will use Medicare rates as the basis to determine cost reasonability for eligible medical care.[218]

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[210] FEMA, "Coronavirus (COVID-19) Pandemic: Medical Care Costs Eligible for Public Assistance," FP 104-010-04, May 9, 2020, p. 3, https://www.fema.gov/media-library-data/1589208038530-19c77b9558076c303b4ebec5f0631697/PA_Medical_Care_Policy_for_COVID-19_508.pdf (hereinafter, FEMA, "COVID-19: Eligible Medicare Care Costs").

[211] Eligibility for the costs of PPE and medical supplies are subject to disposition requirements. For a nonexclusive list of eligible medical care costs and requirements, see FEMA, "COVID-19: Eligible Medicare Care Costs."

[212] FEMA describes eligible private nonprofit organizations in FEMA, *Public Assistance Program and Policy Guide (PAPPG)*, FP 104-009-2, effective June 1, 2020, pp. 43-48, https://www.fema.gov/media-library-data/1594239534694-ea876c73c2135c4273e4914586e7879f/PAPPG_V4_Final_6-1-2020_508.pdf.

[213] FEMA, "COVID-19 Emergency Protective Measures." For information on eligibility of PA applicants, work, and costs, see 44 C.F.R. §206.220 and FEMA, *PAPPG*, pp. 42-47, 51-59, 65-96. To receive reimbursement, work must be the legal responsibility of the applicant (44 C.F.R. §206.223(a)(3)). Emergency protective measures are "generally" the responsibility of state, local, tribal, and territorial governments, but may be the responsibility of certain private nonprofit organizations including medical care providers (FEMA, Coronavirus [COVID-19] Pandemic: Private Nonprofit Organizations," April 2, 2020, https://www.fema.gov/fact-sheet/coronavirus-covid-19-pandemic-private-nonprofit-organizations).

[214] News 7 KWWL.com, "FEMA Awards Iowa with $78 million for COVID-19 Response," May 7, 2020, https://kwwl.com/2020/05/07/fema-awards-iowa-with-78-million-for-covid-19-response/. The TestIowa website is available at https://www.testiowa.com/en.

[215] Stafford Act assistance is subject to the availability of funds in the Disaster Relief Fund, as discussed below.

[216] FEMA, "COVID-19: Eligible Medicare Care Costs," p. 7-8; Stafford Act Section 312 (42 U.S.C. §5155). The HHS Uninsured Program fund is discussed in the "How Can Facilities That Provide Testing for Uninsured Individuals Be Reimbursed?" section of this report.

[217] 2 C.F.R. §200.404; FEMA, *PAPPG*, 65-96; and FEMA, "Public Assistance: Reasonable Cost Evaluation," Job Aid, https://www.fema.gov/media-library-data/1539879525279-d00ae1c43f9765c5a4b415e1a31202c5/PA_Reasonable_Cost_Evaluation_Job_Aid_508_FINAL_10-16-2018.pdf.

[218] FEMA will use standard Medicare rates that do not include the 20% increase in COVID-19 Medicare DRG rates

PA is funded through the Disaster Relief Fund (DRF), the primary source of funding for the federal government's domestic general disaster relief programs. DRF appropriations are not allocated for specific emergencies, disasters, or forms of assistance, including PA. Division B of the CARES Act (P.L. 116-136) included $45 billion for the DRF in March 2020, bringing its available balance for the costs of major disasters to more than $87 billion at the end of that month.[219] This is the first time FEMA has exercised Stafford Act authorities as a primary response to a pandemic, so FEMA has not provided projections for future spending from the DRF—including PA—on the COVID-19 response.[220]

Payment for Testing for Individuals with No Source of Coverage

As mentioned above, some community-based testing and testing at some types of facilities may be available to individuals who do not have a source of payment. The federal government has created an uninsured fund that may reimburse facilities for testing provided to uninsured individuals. In addition, Congress has enacted legislation that has expanded Medicaid eligibility under limited circumstances so that Medicaid funds may be available for testing for some uninsured individuals who are otherwise ineligible for Medicaid.

How Can Facilities That Provide Testing for Uninsured Individuals Be Reimbursed?

Various laws enacted in response to the COVID-19 pandemic may provide reimbursement to providers who offer testing to uninsured individuals. FFRCA provides $1 billion for testing of individuals who are uninsured as defined in FFRCA.[221] The CARES Act appropriated $100 billion for provider relief, termed the Provider Relief Fund (PRF), which was established "to reimburse, through grants or other mechanisms, eligible health care providers for health care related expenses or lost revenues that are attributable to coronavirus."[222] An unspecified portion of this fund will be used to treat the uninsured.[223] PPPHCEA provided an additional $75 billion for the PRF, as well as an additional $1 billion for testing for the uninsured.[224]

These funding streams are being administered by HRSA. Entities that seek reimbursement for testing and related services under the FFRCA/PPPHCEA allocation must comply with certain terms and conditions.[225] For example, entities must register with the fund, provide required

implemented by the CARES Act. FEMA, "COVID-19: Eligible Medicare Care Costs," p. 5.

[219] FEMA, "Disaster Relief Fund: Monthly Report, as of March 31, 2020," April 8, 2020, p. 7, https://www.fema.gov/media-library-data/1586553202915-6ad14cfec022590b2485cba9039190b0/Apr2020DisasterReliefFundReport.pdf.

[220] For more information, see CRS Report R45484, *The Disaster Relief Fund: Overview and Issues*; and CRS Report R46326, *Stafford Act Declarations for COVID-19 FAQ*.

[221] For more information, see CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*, and HHS, HRSA, "COVID-19 Claims Reimbursements to Health Care Providers and Facilities for the Testing and Treatment of the Uninsured," https://coviduninsuredclaim.linkhealth.com/.

[222] P.L. 116-136.

[223] CRS Report R46353, *COVID-19: Overview of FY2020 LHHS Supplemental Appropriations*.

[224] For information on the HHS Provider Relief Fund, see CRS Insight IN11438, *The COVID-19 Health Care Provider Relief Fund*.

[225] HHS, HRSA, "FFCRA Relief Fund Payment Terms and Conditions," https://www.hhs.gov/sites/default/files/terms-

information about the services provided and the patient the services were provided to, agree to accept the Medicare rate as full payment, and may not seek cost-sharing from individuals. For patients who were tested prior to the funds' establishment, and for whom a facility may have already sought reimbursement, the facility must agree to return the already collected cost-sharing to individuals.[226] Facilities are not required to seek reimbursement from this fund, and they may provide care to individuals who are uninsured and seek payment from the patient who received testing or treatment directly.

Under What Circumstances Will Medicaid Pay for Uninsured Testing?

Section 6004 of the FFCRA, as amended by the CARES Act, added, at state option, a new Medicaid eligibility group to provide testing and diagnosis of COVID-19, including testing-related services (as specified under that law's new Medicaid mandatory service category), testing-related visit and the administration of the testing, without beneficiary cost-sharing for certain specified uninsured individuals during the public health emergency period. FFCRA provides a 100% federal medical assistance percentage (FMAP or federal matching rate) for medical assistance and administrative costs associated with Medicaid enrollees under this group.

Medicaid coverage under what is being referred to as the "COVID-19 testing" eligibility group is limited to in vitro diagnostic products for the detection of SARS-CoV-2 or the diagnosis of COVID-19.[227] Coverage under this optional eligibility group is tied to the COVID-19 public health emergency, beginning no earlier than March 18, 2020, through the end of the COVID-19 public health emergency period, as specified. The law defines "uninsured individuals" as

- individuals who are not enrolled in another health care program funded by the federal government, including CHIP, Basic Health Program (BHP), Medicare, TRICARE and the VA, and federal employee health plans;
- individuals who are not enrolled in a group health plan or health insurance coverage offered by a health insurance issuer (as defined in PHSA Section 2791), including a qualified health plan through an exchange, employer-sponsored health insurance, retiree health plans and Consolidated Omnibus Budget Reconciliation Act (COBRA) continuation coverage;[228]
- individuals who are not eligible to receive coverage under one of Medicaid's existing mandatory eligibility groups (e.g., poverty-related children);
- individuals who would be eligible for Medicaid via the Affordable Care Act (ACA, P.L. 111-148) Medicaid expansion pathway in states that have not adopted this eligibility pathway (i.e., non-ACA Medicaid expansion states); and

and-conditions-ffcra-relief-fund.pdf.

[226] HHS, HRSA, "COVID-19 Claims Reimbursements to Health Care Providers and Facilities for the Testing and Treatment of the Uninsured," https://coviduninsuredclaim.linkhealth.com/.

[227] As with the new Medicaid mandatory coverage of in vitro diagnostic testing added under FFCRA, as amended by the CARES Act, diagnostic and serological testing may be covered for symptomatic and asymptomatic Medicaid enrollees determined eligible via the "COVID-19 testing" pathway, as long as such tests are driven by medical necessity. To date, the Medicaid specific CMS guidance has not explicitly addressed the question of whether states can use Medicaid as a payer of public health surveillance testing for SARS-CoV-2 (to screen for general health and safety).

[228] CMS Medicaid FAQs. For questions about these types of private health insurance plans, congressional clients may contact Vanessa Forsberg.

- certain specified Medicaid enrollees who, by virtue of their Medicaid eligibility pathway, are entitled to limited Medicaid benefits, including
  - low-income tuberculosis-infected individuals who are entitled to services related to the tuberculosis infection,
  - individuals eligible only for family planning services and supplies,
  - individuals eligible through the Medically Needy pathway[229] whose coverage does not meet minimum essential health coverage,[230] and
  - certain low-income pregnant woman who are entitled to limited pregnancy-related services.

While there is no income or resource test associated with the "COVID-19 testing" eligibility pathway, applicants must be otherwise eligible for Medicaid (e.g., they must meet federal and state requirements regarding residency, immigration status, and documentation of U.S. citizenship). Like all other Medicaid eligibility pathways, applicants for the optional "COVID-19 testing" pathway are required to provide a Social Security number.[231]

Can the Uninsured Fund Reimburse Testing Provided to the Optional Medicaid COVID-19 Testing Group?

Medicaid enrollees eligible through the optional "COVID-19 testing" group are not eligible for coverage of COVID-19 testing and testing-related services through the HRSA-administered COVID-19 Claims Reimbursement Program. In instances where an HRSA-administered COVID-19 Claims Reimbursement Program pays a claim for COVID-19 testing or testing-related services to a provider, but later determines that such services were delivered to a Medicaid enrollee (regardless of that person's Medicaid eligibility pathway), HRSA is required to recover payment(s) made to the provider and to advise the provider to bill Medicaid as the primary payer.[232]

How Can Individuals Who Are Unauthorized Immigrants Obtain Testing?

Unauthorized (sometimes referred to as *undocumented*) immigrants are eligible to obtain testing anywhere that COVID-19 testing is offered; for example, doctors' offices, public health sites, hospitals' emergency departments, and community health centers.

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[229] Medically needy individuals (e.g., children, pregnant women, aged, blind, or disabled) are those who are otherwise eligible for Medicaid but who have incomes too high to qualify and spend down their income on medical care. For this medically needy subgroup, states may offer a more restrictive benefit package than is available to other enrollees.

[230] For more information on the CMS criteria used to evaluate whether a given state's medically needy coverage meets the minimum essential health coverage standard, see CMS, Dear State Health Official, Dear State Medicaid Director, SHO# 14-002, Re: Minimum Essential Coverage, November 7, 2014, https://www.medicaid.gov/sites/default/files/Federal-Policy-Guidance/downloads/SHO-14-002.pdf. For more general information on minimum essential coverage under Medicaid, see https://www.medicaid.gov/medicaid/eligibility/minimum-essential-coverage/index.html.

[231] 42 C.F.R. §435.910.

[232] Centers for Medicare & Medicaid Services, *NEW FAQs- Released June 30, 2020*, COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies, June 30, 2020, https://www.medicaid.gov/state-resource-center/downloads/covid-19-new-faqs.pdf.

Over half (55%) of the nonelderly[233] unauthorized population in the United States has health insurance.[234] Nonelderly unauthorized immigrants who are uninsured can receive free or reduced-cost testing at some of the aforementioned locations. Health care providers can seek reimbursement through the HRSA-administered COVID-19 Claims Reimbursement Program. HRSA has stated that "health care providers are not required to confirm immigration status prior to submitting claims for reimbursement."[235]

Under What Circumstances Will Medicaid Pay for Testing for Unauthorized Immigrants?

With a few exceptions,[236] state Medicaid programs are prohibited from covering unauthorized immigrants.[237] Under one such exception, emergency Medicaid, unauthorized immigrants who are otherwise eligible for Medicaid except for their immigration status may receive "medical assistance under Title XIX of the Social Security Act … for care and emergency services that are necessary for the treatment of an emergency medical condition (as defined in Section 1903(v)(3) of such Act) of the alien involved and are not related to an organ transplant procedure."[238]

In response to the COVID-19 public health emergency, some states have extended coverage for certain specified COVID-19-related health care expenses (e.g., testing) to otherwise eligible unauthorized immigrants under emergency Medicaid.[239] The duration and scope of COVID-19-related emergency Medicaid coverage vary depending on the state.[240]

Also, on May 20, 2020, CMS approved a temporary Emergency Medicaid State Plan Amendment (SPA) that permits the Commonwealth of Northern Mariana Islands (CNMI) to adopt the FFCRA "COVID-19 testing" eligibility pathway to extend COVID-19 testing without cost-sharing to uninsured individuals (as defined in FFCRA and as amended by CARES).[241] Through this temporary emergency SPA, CMNI is extending the COVID testing for uninsured pathway to individuals regardless of their immigration status. This is done by using the presumptive eligibility Medicaid enrollment facility tool to relax requirements regarding citizenship

[233] Individuals under the age of 65.

[234] Samantha Artiga and Maria Diaz, "Healthcare Coverage and Care of Undocumented Immigrants," Kaiser Family Foundation, July 15, 2019, at https://www.kff.org/disparities-policy/issue-brief/health-coverage-and-care-of-undocumented-immigrants/.

[235] HRSA, "Frequently Asked Questions for the COVID-19 Claims Reimbursement to Health Care Providers and Facilities for Testing and Treatment of the Uninsured Program," at https://www.hrsa.gov/coviduninsuredclaim/frequently-asked-questions.

[236] These exceptions are (1) emergency Medicaid; (2) State Children's Health Insurance Coverage (CHIP) coverage for fetuses as permitted through federal regulation (often referred to as the CHIP unborn child pathway); and (3) the CHIPRA option that allows states to provide Medicaid coverage to certain lawfully residing children and/or pregnant women within the five-year waiting period when certain conditions are met.

[237] For more information, see CRS Report RL33809, *Noncitizen Eligibility for Federal Public Assistance: Policy Overview*.

[238] See Personal Responsibility and Work Opportunity Reconciliation Act of 1996 (PRWORA; P.L. 104-193), §401(a)(1)(A).

[239] For more information about states that are covering COVID-19 testing and treatment under emergency Medicaid, see Jane Shubel, *States are Leveraging Medicaid to Respond to COVID-19*, Center on Budget and Policy Priorities, June 18, 2020, https://www.cbpp.org/sites/default/files/atoms/files/5-7-20health.pdf#page=7.

[240] For more information, see CRS Report R46339, *Unauthorized Immigrants' Eligibility for COVID-19 Relief Benefits: In Brief*.

[241] The Commonwealth of the Northern Mariana Islands (CNMI) emergency Medicaid state plan amendment is available at https://www.medicaid.gov/sites/default/files/State-resource-center/Medicaid-State-Plan-Amendments/Downloads/CNMI/MP-20-0001.pdf.

documentation. This SPA temporarily extends Medicaid to unauthorized immigrants outside of emergency Medicaid and is in place from April 1, 2020, through the end of the public health emergency period, including any extensions.

Emergency Supplemental Funding for Testing

Testing includes the direct provision of diagnostic tests in traditional health care settings, the provision of testing in community-based and other less traditional settings, and the provision of public health testing outside of the clinical context. As described above, the testing supply chain has been under stress, as has the capacity of clinical laboratories to carry out necessary testing. To help address these issues, Congress and the President have appropriated emergency supplemental FY2020 funding to be used for the clinical provision of tests, as well as for support of developing testing infrastructure and capacity.

What Funds Have Been Appropriated for Testing Capacity and Infrastructure?

Recently enacted supplemental appropriations have included funding for several accounts that can be used to support COVID-19 testing capacity and infrastructure. Testing capacity and infrastructure are defined here as activities and functions intended to help provide COVID-19 testing at scale to help control the spread of the virus. Such activities and functions can include increasing laboratory capacity (facilities, equipment, and workforce); procuring testing supplies and improving supply chains; establishing and supporting community-based testing sites; and supporting public health testing programs.

Many of the accounts in the table include funding that can be used for many purposes—testing infrastructure and capacity related activities are among the *possible* uses of the funds. Although this table is inclusive of all budgetary resources in relevant accounts that, among their purposes, could support testing, the dollar amounts in the table should not be interpreted as representing the amount of funding that will eventually go to support testing. It is expected that these funds will also go toward supporting a variety of non-testing-related purposes.

Though funding testing capacity and infrastructure differ from funding for testing individuals (covered in the next question), this distinction is not always clear cut. For example, CDC and FEMA funds can be used for testing capacity and infrastructure, as well as to pay for testing of individuals. In **Table 2**, CDC and FEMA amounts are included because the accounts support testing capacity and infrastructure activities. In addition, CDC- and FEMA-supported testing programs are aimed at providing testing to individuals as a part of multifaceted disease control and emergency response effort rather than to specifically fund COVID-19 testing in health care settings for clinical purposes.

Table 2 shows accounts from which funding can be used in part for testing and infrastructure activities as provided in the following coronavirus-related supplemental appropriations acts:[242]

- Division A, Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123), enacted on March 6, 2020.
- Division B, Coronavirus Aid, Relief, and Economic Security Act (P.L. 116-136), enacted on March 27, 2020.

[242] The second supplemental appropriations measure, the Families First Coronavirus Response Act (P.L. 116-127) did not include available funding for MCM research and development.

- Division B, Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139), enacted on April 24, 2020.

In some cases, funds are appropriated to relevant accounts; in others, transfers or set-asides to relevant agencies or accounts are either directed or allowed. (This transfer authority in several instances is either "not more than" or "not less than" a specified amount.) Funds to be transferred are shown in the account to which they were appropriated, not in the account to which they may be transferred.

The purpose of the funds indicates their allowed uses as specified in the respective appropriations acts. Additional contextual information is included where appropriate. The period of availability is either the date after which funds are no longer available for obligation or "until expended." To identify accounts in this table, CRS exercised professional judgement based on knowledge of agency activities. The goal was to be comprehensive; however, CRS cannot ensure that the below table is comprehensive of all accounts that can be used for testing capacity and infrastructure.

The table does not include funding for research and development for, or FDA approval of, new COVID-19 tests. For an overview of funding for those purposes, see the table in CRS Report R46427, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions*.

Table 2. Funding Available for Testing Infrastructure and Capacity in Coronavirus Supplemental Appropriations

Accounts with funding available for testing capacity and infrastructure. Budget authority in millions or billions of dollars as specified.

Account	Amount	Purpose	Availability
Coronavirus Preparedness and Response Supplemental Appropriations Act, 2020 (P.L. 116-123)[a]			
Department of Health and Human Services (HHS)—Centers for Disease Control and Prevention (CDC)—CDC-Wide Activities and Program Support	$2.2 billion including relevant set-asides or transfers below (less specified set-aside of not less than $300 million)[b]	"to prevent, prepare for, and respond to coronavirus, domestically or internationally." CDC may direct this funding for testing-related activities, such as for public health laboratories and testing programs.	September 30, 2022
Grants/cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes (non-add)	*Not less than $950 million, including $40 million allocated to tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes*	*As above "including to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities."*	*As above*
Transfer to the Infectious Disease Rapid Response Reserve Fund (IDRRRF; non-add)	*$300 million*	*As specified by 42 U.S.C. §247d-4a IDRRRF funds may be used "for carrying out titles II, III, and XVII of the Public Health Service Act to prevent, prepare for, or respond to an infectious disease emergency"* *CDC may direct this funding for testing-related activities, such as for public health laboratories and testing programs.*	*As above*

Account	Amount	Purpose	Availability
HHS Office of the Secretary (OS)—Public Health and Social Services Emergency Fund (PHSSEF)	$3.1 billion and $300 million in contingent appropriations (less specified transfers of not more than $102 million)[c]	"to prevent, prepare for, and respond to coronavirus, domestically or internationally, including the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, and the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, medical surge capacity, and related administrative activities." The HHS Secretary may use funding in this account to pay for procurement of tests or testing-related equipment and supplies.	September 30, 2024
Coronavirus Aid, Relief, and Economic Security Act (CARES Act; P.L. 116-136)[d]			
Department of Defense (DOD)—National Guard Personnel, Army[e]	$746.6 million	"to prevent, prepare for, and respond to coronavirus, domestically or internationally." In some states, National Guard personnel aid in testing programs. DOD personnel accounts fund basic and specialty pays and certain fringe benefits	September 30, 2020
DOD—National Guard Personnel, Air Force	$482.1 million	As above	September 30, 2020
DOD—Operation and Maintenance, Army	$160.3 million	"to prevent, prepare for, and respond to coronavirus, domestically or internationally." DOD Operation and Maintenance accounts fund general mission-related operations, including supporting testing infrastructure and programs.	September 30, 2020
DOD—Operation and Maintenance, Navy	$360.3 million	As above	September 30, 2020
DOD—Operation and Maintenance, Marine Corps	$90.0 million	As above	September 30, 2020
DOD—Operation and Maintenance, Air Force	$155.0 million	As above	September 30, 2020
DOD—Operation and Maintenance, Army Reserve	$48.0 million	As above	September 30, 2020
DOD—Operation and Maintenance. Army National Guard	$186.7 million	As above	September 30, 2020
DOD—Operation and Maintenance, Air National Guard	$75.8 million	As above	September 30, 2020
DOD—Operation and Maintenance, Defense-Wide	$827.8 million	As above	September 30, 2020
DOD—Defense Production Act Purchases	$1 billion	"to prevent, prepare for, and respond to coronavirus, domestically or internationally."[f]	Until expended[g]

Account	Amount	Purpose	Availability
Department of Veterans Affairs (VA)—Veterans Health Administration (VHA)—Medical Services	$14.4 billion	"to prevent, prepare for, and respond to coronavirus, domestically or internationally, including related impacts on health care delivery ... " Per the Senate Appropriations Committee summary, funding can be used for purchase of testing kits and related supplies for the VHA system.[h]	September 30, 2022
Department of Homeland Security—Federal Emergency Management Agency (FEMA)- Disaster Relief Fund[i]	$45 billion	The Disaster Relief Fund (DRF) is the primary source of funding for the federal government's domestic general disaster relief programs. While diagnostic testing and testing sites may get funded from the DRF through the FEMA Public Assistance Program, only a portion of DRF resources will go to COVID-19-related activities.	Until expended
HHS—CDC—CDC-Wide Activities and Program Support	$4.3 billion (less specified set-asides of not less than $1 billion)[j]	"to prevent, prepare for, and respond to coronavirus, domestically or internationally." CDC may direct this funding for testing-related activities, such as for public health laboratories and testing programs.	September 30, 2024
Grants/cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes (non-add)	*$1.5 billion, including $125 million to tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes*	*As above including "to carry out surveillance, epidemiology, laboratory capacity, infection control, mitigation, communications, and other preparedness and response activities."*	*As above*
Transfer to the IDRRRF (non-add)	*$300 million*	*As specified by 42 U.S.C. §247d-4a IDRRRF funds may be used "for carrying out titles II, III, and XVII of the Public Health Service Act to prevent, prepare for, or respond to an infectious disease emergency", CDC may direct this funding for testing-related activities, such as for public health laboratories and testing programs.*	*As above*
HHS—OS—PHSSEF[k]	$27 billion including the set-asides below of not more than $16 billion (less other specified set-asides and transfers of roughly $4 billion)[l]	"to prevent, prepare for, and respond to coronavirus, domestically or internationally, including the development of necessary countermeasures and vaccines, prioritizing platform-based technologies with U.S.-based manufacturing capabilities, the purchase of vaccines, therapeutics, diagnostics, necessary medical supplies, as well as medical surge capacity, addressing blood supply chain, workforce modernization, telehealth access and infrastructure, initial advanced manufacturing, novel dispensing, enhancements to the U.S. Commissioned Corps, and other preparedness and response activities."	September 30, 2024

Account	Amount	Purpose	Availability
		The HHS Secretary may use funding in this account to pay for procurement of tests or testing-related equipment and supplies.	
Strategic National Stockpile (SNS)	*Not more than $16 billion*	*As above. The HHS Secretary may procure testing-related supplies for SNS and use it as a distribution mechanism.*	*As above*
Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139)[m]			
HHS—OS—PHSSEF[n]	$25 billion including set-asides and transfers below (less other specified set-asides or transfers of roughly $4.4 billion)[o]	"to prevent, prepare for, and respond to coronavirus, domestically or internationally, for necessary expenses to research, develop, validate, manufacture, purchase, administer, and expand capacity for COVID–19 tests to effectively monitor and suppress COVID–19, including tests for both active infection and prior exposure, including molecular, antigen, and serological tests, the manufacturing, procurement and distribution of tests, testing equipment and testing supplies, including personal protective equipment needed for administering tests, the development and validation of rapid, molecular point-of-care tests, and other tests, support for workforce, epidemiology, to scale up academic, commercial, public health, and hospital laboratories, to conduct surveillance and contact tracing, support development of COVID–19 testing plans, and other related activities related to COVID–19 testing."	Until expended
Grants/cooperative agreements with states, localities, territories, tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes (non-add).	*Not less than $11 billion, of that amount, not less than $750,000,000 shall be allocated in coordination with the Director of the Indian Health Service, to tribes, tribal organizations, urban Indian health organizations, or health service providers to tribes.*	*"to develop, purchase, administer, process, and analyze COVID–19 tests, including support for workforce, epidemiology, use by employers or in other settings, scale up of testing by public health, academic, commercial, and hospital laboratories, and community-based testing sites, health care facilities, and other entities engaged in COVID–19 testing, conduct surveillance, trace contacts, and other related activities related to COVID–19 testing."*	*As above*
CDC-Wide Activities and Program Support	*Not less than $1 billion*	*"for surveillance, epidemiology, laboratory capacity expansion, contact tracing, public health data surveillance and analytics infrastructure modernization, disseminating information about testing, and workforce support necessary to expand and improve COVID–19 testing."*	*As above*
Rural health clinics	*$225 million*	*"additional funding for COVID–19 testing and related expenses, through grants or other mechanisms, to rural health clinics as defined in section 1861(aa)(2) of the Social Security Act, with such funds also available to such entities for building or construction of temporary structures, leasing of properties, and retrofitting facilities as necessary to support COVID–19 testing."*	*As above*

Source: CRS analysis of COVID-19 response legislation.

a. HHS may transfer nearly all the funds appropriated to it in Title III, Division A, of P.L. 116-123, among accounts at CDC, NIH, or PHSSEF, provided the transfers are made to prevent, prepare for, and respond to the COVID-19 pandemic, domestically or internationally (see §304). HHS is to notify the House and the Senate appropriations committees 10 days in advance of such a transfer.

b. Not less than $300 million of the total $2.2 billion for CDC is for global disease detection and emergency response.

c. Transfers specified are $100 million to the Health Resources and Services Administration (HRSA) for grants for health centers and up to $2 million to the HHS Office of Inspector General (OIG).

d. HHS may transfer nearly all the funds appropriated to it in Title VIII, Division B, of P.L. 116-136 among accounts at CDC, PHSSEF, NIH, Administration for Children and Families, and the Administration for Community Living , provided the transfers are made to prevent, prepare for, and respond to the COVID-19 pandemic, domestically or internationally (see §18111). HHS is to notify the House and the Senate appropriations committees 10 days in advance of such a transfer.

e. Funds in DOD accounts: "Funds appropriated by this title may be transferred to, and merged with, other applicable appropriations of the Department of Defense, except for 'Drug Interdiction and Counter-Drug Activities, Defense,' for expenses incurred in preventing, preparing for, or responding to coronavirus, including expenses of the Department of Defense incurred in support of other Federal Departments and agencies, and State, local, and Indian tribal governments, to be merged with and to be available for the same purposes, and for the same time period, as the appropriation or fund to which transferred."

f. Thus far, the only public announcement of a testing-related allocation of the DPA funding was on April 29 with $75 million for nasal swab production. See CRS Insight IN11387, *COVID-19: Defense Production Act (DPA) Developments and Issues for Congress*.

g. The CARES Act suspended the year-to-year funding cap of $750 million for DPA for two years.

h. Based on Senate Appropriations Committee, Coronavirus Supplemental Appropriations Summary, available at https://www.appropriations.senate.gov/download/coronavirus-emergency-supplemental-appropriations-summary.

i. Public Assistance is funded through the Disaster Relief Fund (DRF), the primary source of funding for the federal government's domestic general disaster relief programs. DRF appropriations are not allocated to specific emergencies, disasters, or specific forms of assistance, including food assistance. Division B of the CARES Act (P.L. 116-136) included $45 billion for the DRF in March 2020, bringing its available balance for the costs of major disasters to more than $87 billion. As of June 30, 2020, almost $7.3 billion had been obligated for COVID-19 costs—and the unobligated balance of the fund was approximately $76 billion.

j. Specified set-asides for purposes that are not primarily related to domestic testing include not less than $500 billion for global disease detection and emergency response and not less than $500 million for "public health data surveillance and analytics modernization." The public health data funds are not included in the table as they are primarily for "modernization" of data systems (including testing-related data among others) rather than to support testing-related data collection specifically.

k. Not more than $4 million per Title VIII, Division B, Section 8113, is to be transferred to the HHS OIG from the $127.29 billion total appropriated to PHSSEF for oversight of all activities supported with funds appropriated to HHS to prevent, prepare for, and respond to the COVID-19 pandemic.

l. Other specified set-asides for purposes that are not primarily related to domestic testing include not less than $250 million for Hospital Preparedness Program grantees or subgrantees; not less than $3.5 billion for the Biomedical Advanced Research and Development Authority; not more than $289 million for other federal agencies for the care of persons under federal quarantine; and $1.5 million for a National Academies of Science, Medicine, and Engineering study on the medical supply chain.

m. HHS may transfer certain funds appropriated to it in Title I, Division B, of P.L. 116-139 among accounts at CDC, NIH, PHSSEF, and FDA, provided the transfers are made to prevent, prepare for, and respond to the COVID-19 pandemic (see §102). HHS is to notify the House and the Senate appropriations committees 10 days in advance of such a transfer.

n. Not more than $6 million per Title I, Division B, Section 103, of P.L. 116-139, is to be transferred to the HHS OIG from the $100 billion total appropriated to PHSSEF for oversight of all activities supported with funds appropriated to HHS to prevent, prepare for, and respond to the COVID-19 pandemic.

o. Other specified set-asides or transfers include not less than $306 million transfer for the National Cancer Institute, not less than $500 million transfer for the National Institute of Biomedical Imaging and Bioengineering, not less than $1 billion transfer for the NIH Office of Director, not less than $1 billion for

BARDA, $22 million transfer to the FDA, $600 million transfer to the HRSA, Community Health Centers program, not more than $1 billion for testing for the uninsured.

Paycheck Protection Program and Health Care Enhancement Act Testing Funding

As noted in **Table 2**, the PPPHCEA appropriated funds specifically to increase testing capacity. Specifically, PPPHCEA appropriated $25 billion to the PHSSEF—an account that may be used in appropriations acts to provide the HHS Secretary with one-time or emergency funding—to support the expansion of testing infrastructure and capacity broadly. These funds were in some cases transferred to specific agencies (e.g., HRSA, CDC) for certain purposes. For example, NIH received $1.5 billion for research and development of rapid point-of-care and other diagnostics, and FDA received a $22 million transfer to support in vitro diagnostic review activities at the agency. In addition, the act appropriated $11 billion to the states, localities, territories, and tribes to support broad public health activities related primarily to testing and contact tracing. The remaining funds were authorized to be used for notably broad activities to boost testing infrastructure, production, capacity, and administration, including for the purchase of testing supplies; for "construction, alteration, renovation, or equipping of non-federally owned facilities for the production of diagnostic, serologic, or other COVID–19 tests"; and "for grants for the rent, lease, purchase, acquisition, construction, alteration, renovation, or equipping of non-federally owned facilities to improve preparedness and response capability at the State and local level for diagnostic, serologic, or other COVID–19 tests."[243] The law also included a number of reporting and other requirements, including the development of a national testing strategy; that each state develop and submit to HHS its own state testing plan; and several on identifying racial and ethnic disparities related to COVID-19 testing, hospitalizations, and outcomes, including mortality.

PPPHCEA appropriated $225 million for testing at rural health clinics (RHCs), outpatient facilities located in rural areas. Each facility received approximately $50,000 for testing infrastructure, including expenses related to implementing a testing program, procuring supplies, and training providers and staff on issues related to testing. HRSA awarded these funds and awarded $500,000 of the amount appropriated for technical assistance to support RHCs in implementing testing programs.[244] IHS also received $750 million in PPHCEA for testing capacity. IHS announced its plan to allocate these funds in a letter to tribal leaders on May 21. The letter stated that the funds may be used to

> analyze COVID-19 tests, including support for workforce, epidemiology, and use by employers or in other settings. In addition, these funds can be used to scale up testing by public health, academic, commercial, and hospital laboratories, and community-based testing sites, health care facilities, and other entities engaged in COVID-19 testing. Funds may also be used to conduct surveillance, trace contacts, and perform other related activities related to COVID-19 testing.[245]

[243] PPPHCEA (P.L. 116-139), Division B—Additional Emergency Appropriations for Coronavirus Response, Title I—Department of Health and Human Services.

[244] HHS, HRSA, "HHS Providers $225 Million for COVID-19 Testing in Rural Communities," https://www.hhs.gov/about/news/2020/05/20/hhs-provides-225-million-for-covid19-testing-in-rural-communities.html.

[245] Letter from Michael D. Weahkee, Director Indian Health Service, to Dear Tribal Leader and Urban Indian Organization Leader, May 20, 2020, https://www.ihs.gov/sites/newsroom/themes/responsive2017/display_objects/documents/2020_Letters/DTLL_DUIOLL_05192020.pdf, p. 1.

In terms of amounts, IHS announced that it will provide $50 million to urban Indian organizations for testing and $550 million for programs operated by the Indian Health Service or by tribes. IHS retains $150 million for nationwide coordination, epidemiological research, and surveillance.[246] Tribes that received funding were, like states, required to submit a testing plan to HHS that includes testing goals for the remainder of 2020. The plan was required to include the number of tests monthly by type; monthly estimates of laboratory and testing capacity, including the workforce needed to process tests and the relevant supplies; and a description of how funds will be used for testing and to meet the goals laid out in the testing plan.[247]

What Funds Have Been Appropriated for the Clinical Provision of Tests?

Congress and the President have also provided supplemental funding in several accounts to help pay for COVID-19 testing for individuals for clinical purposes. **Table 3** shows FY2020 supplemental *discretionary appropriations* for accounts that can primarily be used to pay for testing of individuals for primarily *clinical purposes*.[248] Relevant funding has been included in two coronavirus-related supplemental appropriations measures:

- Division A, Families First Coronavirus Response Act (P.L. 116-127), enacted on March 18, 2020.[249]
- Division B, Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139), enacted on April 24, 2020.

The below table does not include the mandatory spending budgetary effects of clinical testing-related provisions carried in COVID-19 response legislation. For example, FFCRA and the CARES Act included several provisions to expand coverage of testing paid by federal health programs, such as Medicare and Medicaid, as well as private insurance. (Note that these are covered earlier in this report and in other CRS reports.)[250] In addition, discretionary accounts that can be used for a broad set of health care purposes (including testing among others), such as the Provider Relief Fund and funding for the Health Centers program are not included in the below table, as these funds have not been provided specifically for testing.

With regard to the discretionary funding in the below table, in some cases, funds are appropriated to relevant accounts; in others, transfers or set-asides to relevant agencies or accounts are either directed or allowed. (This transfer authority in several instances is either “not more than” or “not less than” a specified amount.) Funds to be transferred are shown in the account to which they were appropriated, not in the account to which may be transferred.

The purpose of the funds summarizes their allowed uses as specified in the respective appropriations acts. Unlike for the previous table, exact bill text is not cited for several accounts because of references to other provisions in the respective bills. For example, several of the provisions in the FFRCA use the construction, “for health services consisting of SARS–CoV–2 or

[246] Ibid., p. 2.

[247] HHS, “HHS Delivers Funding to Expand Testing Capacity for States, Territories, Tribes,” press release, May 18, 2020, https://www.hhs.gov/about/news/2020/05/18/hhs-delivers-funding-to-expand-testing-capacity-for-states-territories-tribes.html.

[248] For more information on clinical testing, see “For What Purposes Is COVID-19 Testing Used?”

[249] Division G of the Families First Coronavirus Response act included requirements about the use of testing funds. See CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

[250] See also CRS Report R46334, *Selected Health Provisions in Title III of the CARES Act (P.L. 116-136)* and CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

COVID–19 related items and services as described in section 6006(b) of division F of the Families First Coronavirus Response Act (or the administration of such products)." Additional contextual information is included where appropriate. The period of availability is either the date after which funds are no longer available for obligation, or "until expended."

As noted previously, CRS exercised professional judgement to distinguish accounts that pay for testing infrastructure and capacity from those that pay for testing of individuals, however this distinction is not always clear cut. Several of the accounts covered in the previous question can also be used to pay for testing of individuals and are not repeated in the below table, as the clinical provision of tests is not the primary purpose of those accounts. In addition, a number of the accounts discussed below received additional appropriations in the CARES Act that was not specific to testing, as such, these funds are not included in the table below. More information about overall supplemental funding for HHS programs can be found in CRS Report R46353, *COVID-19: Overview of FY2020 LHHS Supplemental Appropriations*. The below table shows accounts that primarily fund testing of individuals for clinical (rather than public health or emergency response) purposes.

Table 3. Discretionary Funding for Clinical Provision of Tests in Coronavirus Supplemental Appropriations

Accounts with specific funding available for testing of individuals for clinical purposes ; Budget authority in millions or billions of dollars, as specified

Account	Amount	Purpose	Availability
Families First Coronavirus Response Act (P.L. 116-127)[a]			
Department of Defense (DOD)—Defense Health Programs	$82 million	COVID-19 testing, administration of the test, and related items and services for Defense Health Program beneficiaries.	September 30, 2022
Department of Health and Human Services (HHS)—Indian Health Service	$64 million	COVID-19 testing, administration of the test, and related items and services for Indian Health Service Beneficiaries.	September 30, 2022
Department of Veterans Affairs(VA)—Veterans Health Administration (VHA)—Medical Services	$30 million	COVID-19 testing, administration of the test, and related items and services for covered veterans at Veterans Health Administration facilities.	September 30, 2022
Veterans Health Administration (Medical Community Care)	$30 million	COVID-19 testing, administration of the test, and related items and services through the Veterans Health Administration Community Care program.	September 30, 2022

Account	Amount	Purpose	Availability
HHS—Office of the Secretary (OS)—Public Health and Social Services Emergency Fund (PHSSEF)—Testing for the Uninsured	$1 billion	COVID-19 testing, administration of the test, and related items and services for uninsured individuals as defined.	Until expended
Paycheck Protection Program and Health Care Enhancement Act (P.L. 116-139)[b]			
HHS—OS—PHSSEF-Testing for the Uninsured	Not more than transfer of $1 Billion	COVID-19 testing, administration of the test, and related items and services for uninsured individuals as defined.	Until expended
HHS—OS—PHSSEF—Health Resources and Services Administration Transfer	$600 million	Transferred to the Health Resources and Services Administration for Health Center Grants[c]	Until expended

Source: CRS analysis of legislation.

Notes: Comprehensive information about HHS transfer authorities and relevant transfers to the HHS Office of the Inspector General for the respective appropriations acts is included in **Table 2**.

a. Division A appropriated testing funds, while Division G specified how these funds would be used. See CRS Report R46316, *Health Care Provisions in the Families First Coronavirus Response Act, P.L. 116-127*.

b. CRS Report R46325, *Fourth COVID-19 Relief Package (P.L. 116-139): In Brief*.

c. Health center funds were to supplement grants and were awarded specifically to expand testing capacity. See HHS, HRSA, "HHS Awards More than Half Billion Dollars Across the Nation to Expand COVID-19 Testing," https://www.hhs.gov/about/news/2020/05/07/hhs-awards-more-than-half-billion-across-the-nation-to-expand-covid19-testing.html.

Public Health Reporting of COVID-19 Test Data

What Types of Testing Data Are Collected?

CDC collects many types of data related to testing, some provided by states or other jurisdictions and some provided directly by laboratories to CDC.[251] These data are used to monitor public health trends, understand the virus, and better understand disease trends and affected populations. Some testing data are being collected directly by HHS from hospital-based academic and clinical laboratories.[252] Existing testing-related surveillance (i.e., data collection) systems include the following:

- **Case-based surveillance.** Positive COVID-19 test results are reported by laboratories to jurisdictions that then link and collect detailed information on each case, including demographic and health information. Jurisdictions use a case reporting system to report to CDC.[253] Case reporting occurs through two CDC

[251] CDC, *CDC Activities and Initiatives Supporting the President's Plan for Opening Up America Again*, May 2020, https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf.

[252] HHS, "COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting" updated July 10, 2020," https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf.

[253] CDC, "Coronavirus Disease 2019: Reporting a Confirmed Case," updated May 5, 2020, https://www.cdc.gov/

data systems: the National Notifiable Diseases Surveillance System (NNDSS) and the Data Collation and Integration for Public Health Event Response (DCIPHER) platform.[254]

- **Virological surveillance.** Overall test positivity rates are captured across all public health laboratories and a subset of clinical and commercial laboratories.[255]
- **Virus characterization.** Viral samples from laboratories are used to monitor genomic changes in virus in CDC's SARS-CoV-2 Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance (SPHERES) consortium.[256]

Traditionally, most public health data reporting requirements have been based in state law. States or other jurisdictions can mandate that laboratories or health care providers report data related to certain diseases to jurisdictions' public health departments. States then voluntarily share de-identified data with CDC as a part of national surveillance.[257] CDC can also form partnerships with specific jurisdictions, other federal agencies, and academic and nonprofit research institutions for public health data, an approach taken with SPHERES.[258]

Where Do COVID-19 Results Get Reported, and What Data Are Collected?

COVID-19 cases are reported to 60 U.S.-affiliated jurisdictions that then report to CDC, including the 50 states; the District of Columbia; New York City, the U.S. territories of American Samoa, Guam, the Commonwealth of the Northern Mariana Islands, Puerto Rico, and the U.S Virgin Islands; and three freely-associated states (Federated States of Micronesia, Republic of the Marshall Islands, and Republic of Palau).[259] Case reporting and other surveillance allow jurisdiction-level public health officials to respond to positive cases, conduct contact tracing, and make decisions about state and local public health policy. The data can also be used by researchers to inform an understanding of the disease and affected populations.[260]

Throughout the COVID-19 pandemic, many jurisdictions have faced issues with incomplete data from laboratories. In many reported cases, testing data reported from laboratories were missing

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coronavirus/2019-ncov/php/reporting-pui.html.

[254] CRS correspondence with CDC, May 6, 2020.

[255] CDC, "COVIDView: A Weekly Surveillance Summary of U.S. COVID-19 Activity: Purpose and Methods," updated July 15, 2020, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/purpose-methods.html#virologic.

[256] CDC, "Coronavirus Disease 2019: SARS-CoV-2 Sequencing (SPHERES)," updated July 7, 2020, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/spheres.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fspheres.html.

[257] Lawrence O. Gostin and Lindsay F. Wiley, "Chapter Nine: Surveillance and Public Health Research: Privacy, Security, and Confidentiality of Personal Health Information," in *Public Health Law: Duty, Power, and Restraint*, 3rd ed. (University of California Press), pp. 303-344.

[258] CDC, "Coronavirus Disease 2019: SARS-CoV-2 Sequencing (SPHERES)," Updated July 7, 2020, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/spheres.html?CDC_AA_refVal=https%3A%2F%2Fwww.cdc.gov%2Fcoronavirus%2F2019-ncov%2Fcases-updates%2Fspheres.html.

[259] CDC, "About CDC Data," last updated July 13, 2020, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/about-us-cases-deaths.html.

[260] CDC, *CDC Activities and Initiatives Supporting the President's Plan for Opening Up America Again*, May 2020, https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf.

key patient information needed to contact the patient and conduct contact tracing. In addition, much of the early COVID-19 data lacked information about patient demographic characteristics, such as on race and ethnicity.[261] After a positive test result, public health departments usually have to follow up with patients and providers to obtain full details about the case—a difficult and time-consuming task, especially when cases rise rapidly. In addition, many public health departments rely on fax or paper records shared by health care providers, which can be error-prone and add to delays.[262] Though the situation has somewhat improved, such missing data issues have hindered the public health response and experts' ability to analyze and understand the situation.

Though CDC implements standardized reporting systems, states and other jurisdictions are usually responsible for deciding what information to collect and share with CDC.[263] In the early stages of the pandemic, many states were not collecting and/or reporting patient demographic information, such as on patients' race and ethnicity.[264] Guidance issued pursuant to a provision in the CARES Act changed federal reporting requirements for jurisdictions (as described below). According to July 22nd data, 47 states report COVID-19 cases by race/ethnicity, 45 states report COVID-19 deaths by race, and 5 states report testing data by race.[265]

The CARES Act added new authorities for the HHS Secretary related to COVID-19 testing data. Specifically, Section 18115 of the CARES Act requires that every laboratory that performs or analyzes a test intended to detect or diagnose a possible case of COVID-19 report the test results to the HHS Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe until the end of the Secretary's Public Health Emergency declaration (PHSA §319) with respect to COVID-19 or any extension of such declaration. The provision allows the Secretary to decide which laboratories must submit reports pursuant to that section and does not require the data be made publicly available.

On June 4, 2020, HHS issued guidance to implement Section 18115 of the CARES Act. As a part of the guidance, the Secretary requires that all laboratories report data with a minimum set of required elements to state or local public health departments using existing reporting channels. The minimum required data elements that must be reported for each test include, among other things, patient age, race, ethnicity, sex, zip code, and county. The guidance also states that state and local public health departments should collect information about a patient's address and phone number, but should not share this information with CDC.[266] The press release accompanying the guidance stated,

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[261] Kelly Servick, ""Huge Hole" in Testing Data Blurs Racial, Ethnic Disparities," *Science*, July 17, 2020, https://science.sciencemag.org/content/369/6501/237.

[262] Darius Tahir, "Virus Hunters Rely on Faxes, Paper Records as More States Reopen," *Politico*, May 10, 2020; and Council of State and Territorial Epidemiologists, *Driving Public Health in the Fast Lane: The Urgent Need for a 21st Century Data Superhighway*, September 2019, https://cdn.ymaws.com/www.cste.org/resource/resmgr/pdfs/pdfs2/Driving_PH_Display.pdf.

[263] Lawrence O. Gostin and Lindsay F. Wiley, "Chapter Nine: Surveillance and Public Health Research: Privacy, Security, and Confidentiality of Personal Health Information," in *Public Health Law: Duty, Power, and Restraint*, 3rd ed. (University of California Press), pp. 303-344.

[264] Kelly Servick, ""Huge Hole" in Testing Data Blurs Racial, Ethnic Disparities," *Science*, July 17, 2020, https://science.sciencemag.org/content/369/6501/237.

[265] Johns Hopkins University (JHU) Coronavirus Resource Center, "Racial Data Transparency: States that have Released COVID-19 Data by Race," last viewed July 22, 2020, https://coronavirus.jhu.edu/data/racial-data-transparency.

[266] HHS, "COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115," June 4, 2020,

> "HHS and the entire Trump Administration are deeply concerned that COVID-19 is having a disproportionate impact on certain demographics, including racial minorities and older Americans," said HHS Secretary Alex Azar. "High quality data is at the core of any effective public health response, and standardized, comprehensive reporting of testing information will give our public health experts better data to guide decisions at all levels throughout the crisis."[267]

The guidance gives laboratories several options for submitting the data. Laboratories may use existing reporting systems, as required by state or local law or policy, or through a state or regional health information exchange systems. State governments then share data with CDC on a daily basis.[268] Laboratories also may submit through an automated platform that shares data automatically with both state and local authorities as well as with CDC—the Association of Public Health Laboratories' (APHL's) Informatics Messaging Services (AIMS) platform.[269] According to CDC, as of July 7, 2020, 57% of jurisdictions were using the AIMS platform, with additional jurisdictions converting their systems.[270] A map with compiled case counts from all three systems is available on CDC's website.[271]

Separately, Vice President Michael R. Pence and HHS have issued testing-related data requests from hospital-based academic and clinical laboratories, several of which requested hospital-based laboratories to submit aggregate testing data directly to HHS on a daily basis.[272] As specified in updated guidance for hospitals on July 29, hospitals that perform "in-house" laboratory testing are to follow the June 4 guidelines pursuant to the CARES Act. For hospitals that are not reporting all data to their state health department or are located in a jurisdiction that has not converted to COVID-19 electronic laboratory reporting to CDC, they are requested to submit aggregate daily data to HHS until they confirm that CDC is receiving their data through the state. Such hospitals can use one of three methods: (1) the HHS Protect data system; (2) their state reporting system, if the state is reporting to the APSR administrator; or (3) their health information technology vendor, as authorized by the hospital to submit daily data to HHS/CDC. Hospitals do not need to report testing results for tests sent to commercial laboratories or to public health laboratories.[273]

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https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf.

[267] HHS, "HHS Announces New Laboratory Data Reporting Guidance for COVID-19 Testing," press release, June 4, 2020, https://www.hhs.gov/about/news/2020/06/04/hhs-announces-new-laboratory-data-reporting-guidance-for-covid-19-testing.html.

[268] Ibid.

[269] Association of Public Health Laboratories (APHL), "APHL AIMS Platform," https://www.aphl.org/programs/informatics/pages/aims_platform.aspx.

[270] Correspondence with CDC, July 7, 2020.

[271] CDC, "Coronavirus Disease 2019: Cases in the United States," https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/cases-in-us.html.

[272] CRS Insight IN11361, *COVID-19: U.S. Public Health Data and Reporting*.

[273] HHS, *COVID-19 Guidance for Hospital Reporting and FAQs for Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting Updated July 29, 2020*, July 29, 2020, https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf%3C.

Appendix A. Acronyms Used in This Report

Acronym	Definition
ACA	Patient Protection and Affordable Care Act
AIMS	APHL Informatics Messaging Services
APHL	Association of Public Health Laboratories
AMP	Association for Molecular Pathology
ASPR	Assistant Secretary of Preparedness Response
BHP	Basic Health Program
CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CBTS	Community-Based Testing Sites
CDC	Centers for Disease Control and Prevention
CFR	Code of Federal Regulations
CHIP	Children's Health Insurance Program
CLIA	Clinical Laboratory Improvement Amendments
CMS	Centers for Medicare & Medicaid Services
CNMI	Commonwealth of Northern Mariana Islands
COBRA	Consolidated Omnibus Budget Reconciliation Act
DCIPHER	Data Collation and Integration for Public Health Event Response
DOD	Department of Defense
DOL	Department of Labor
DPA	Defense Production Act
DRF	Disaster Relief Fund
EMTALA	Emergency Medical Treatment and Active Labor Act
EPSDT	Early and Periodic Screening, Diagnostic, and Treatment
EUA	Emergency Use Authorization
FAQ	Frequently Asked Questions
FDA	Food and Drug Administration
FEHB	Federal Employees Health Benefits Program
FEMA	Federal Emergency Management Agency
FFRCA	Families First Coronavirus Response Act
FMAP	Federal Medical Assistance Percentage
FQHC	Federally Qualified Health Center
HHS	Department of Health and Human Services
HRSA	Health Resources and Services Administration
HSGAC	Homeland Security and Governmental Affairs Committee
IDRRRF	Infectious Disease Rapid Response Reserve Fund
IHCIA	Indian Health Care Improvement Act

Acronym	Definition
IHS	Indian Health Service
IVD	In Vitro Diagnosis
LDT	Laboratory-Developed Test
LTCF	Long-Term Care Facility
LTSS	Long-Term Services and Support
MA	Medicare Advantage
MHS	Military Health Services
MOU	Memorandum of Understanding
MTF	Military Treatment Facility
NAIC	National Association of Insurance Commissioners
NCI	National Cancer Institute (of the National Institutes of Health)
NF	Nursing Facility
NGA	National Governors Association
NIH	National Institutes of Health
NNDS	National Notifiable Diseases Surveillance System
OIG	Office of Inspector General (HHS)
OS	Office of the Secretary (HHS)
OTC	Over-the-Counter
PA	Public Assistance (FEMA)
PAPPG	Public Assistance Program and Policy Guide (FEMA)
PCR	Polymerase Chain Reaction
PHSA	Public Health Service Act
PHSSEF	Public Health and Social Services Emergency Fund
POC	Point-of-Care
PPE	Personal Protection Equipment
PPPHCEA	Paycheck Protection Program and Health Care Enhancement Act
PRF	Provider Relief Fund
PRWORA	Personal Responsibility and Work Opportunity Reconciliation Act of 1996
RHC	Rural Health Clinic
RNA	Ribonucleic acid
SNF	Skilled Nursing Facility
SNS	Strategic National Stockpile
SPA	State Plan Amendment
SPHERES	Sequencing for Public Health Emergency Response, Epidemiology, and Surveillance
SSA	Social Security Act
STLDI	Short-term, limited duration insurance

Acronym	Definition
TTSI	Testing, Tracing, and Supported Isolation
USC	United States Code
VA	Department of Veterans Affairs
VHA	Veterans Health Administration
VTM	Viral Transport Media

Appendix B. Policy Experts Table

Topic	Contact
Types of COVID-19 Testing and Their Uses	Amanda K. Sarata
Test Accuracy	Amanda K. Sarata
Testing Infrastructure, Capacity and Strategies	Amanda K. Sarata
Testing Supply Chain	Amanda K. Sarata Erica A. Lee
Priority for Testing Individuals	Kavya Sekar
Role of Federal Emergency Management Agency in Testing: Infrastructure, Delivery and Payment	Erica A. Lee
Role of Public Health Departments in Testing	Kavya Sekar Sarah Lister
Nursing Home Testing	Phoenix Voorhies
Testing for Uninsured Individuals	Elayne J. Heisler
Defense Health Care	Bryce H. P. Mendez Alan Ott
Veterans Health Care	Sidath Viranga Panangala Jared S. Sussman
Indian Health Service	Elayne J. Heisler
Medicaid and the State Children's Health Insurance Program (CHIP)	Evelyne P. Baumrucker
Medicare	Jim Hahn
Private Health Insurance	Vanessa C. Forsberg
Private Health Insurance (Out of Network)	Noah D. Isserman
Private Health Insurance (Legal Issues)	Jennifer A. Staman
Funding for Testing Infrastructure	Amanda K. Sarata Kavya Sekar
Funding for Testing Individuals	Elayne J. Heisler
Unauthorized Immigrants' Access to Testing	Abigail F. Kolker
Use of Uninsured Fund for Testing	Elayne J. Heisler
Medicaid Funding for Testing Uninsured Individuals	Evelyne P. Baumrucker
Testing Data Reporting	Kavya Sekar Sarah Lister
Resources on Testing	Kate M. Costin

Appendix C. Additional Resources

Below are frequently cited resources related to COVID-19 testing in the United States. This appendix includes selected federal, academic, and stakeholder resources available at the time of this report's publication. Federal agencies continue to update guidance to reflect the current situation. Please note, this is not a comprehensive list of resources.

Data Repositories

Preliminary data reported by U.S. Laboratories including Commercial and Reference, Public Health, and Hospital; totals may include antibody data from some states.

Centers for Disease Control and Prevention (CDC)

- CDC COVID Data Tracker: United States Laboratory Testing, updated regularly, https://www.cdc.gov/covid-data-tracker/#testing
- Previous U.S. Viral Testing Data, May 19, 2020, https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/previous-testing-in-us.html

Coronavirus Resource Center, John Hopkins University & Medicine

For a complete list of data contributors, visit https://github.com/CSSEGISandData/COVID-19/blob/master/README.md

- COVID-19 Dashboard by the Center for Systems Science and Engineering (CSSE) at Johns Hopkins University, updated regularly, https://coronavirus.jhu.edu/map.html
- Johns Hopkins COVID-19 Testing Insights Initiative, updated regularly, https://coronavirus.jhu.edu/testing
- Testing Trends Tool, updated regularly, https://coronavirus.jhu.edu/testing/tracker/overview
- All State Comparison of Testing Efforts, updated regularly, https://coronavirus.jhu.edu/testing/states-comparison
- Daily State-by-State Testing Trends, updated regularly, https://coronavirus.jhu.edu/testing/individual-states
- Testing Trends Tool, updated regularly, https://coronavirus.jhu.edu/testing/tracker/overview
- Which U.S. States Meet WHO Recommended Testing Criteria?, updated regularly, https://coronavirus.jhu.edu/testing/testing-positivity
- International Comparison of Positivity Rates and Tests Per Capita, updated regularly, https://coronavirus.jhu.edu/testing/international-comparison
- Racial Data Transparency: States that have released breakdowns of Covid-19 data by race, updated regularly, https://coronavirus.jhu.edu/data/racial-data-transparency

The COVID Tracking Project by The Atlantic

- Our Data, updated regularly, https://covidtracking.com/data

Department of Health and Human Services (HHS) Guidance

Department of Health and Human Services (HHS)

- COVID-19 Pandemic Response, Laboratory Data Reporting: CARES Act Section 18115, https://www.hhs.gov/sites/default/files/covid-19-laboratory-data-reporting-guidance.pdf
- COVID-19 Guidance for Hospital Reporting and FAQs For Hospitals, Hospital Laboratory, and Acute Care Facility Data Reporting, https://www.hhs.gov/sites/default/files/covid-19-faqs-hospitals-hospital-laboratory-acute-care-facility-data-reporting.pdf%3C

Centers for Disease Control and Prevention (CDC)

- Interim Guidelines for Collecting, Handling, and Testing Clinical Specimens for COVID-19, https://www.cdc.gov/coronavirus/2019-ncov/lab/guidelines-clinical-specimens.html
- Testing Guidelines for Nursing Homes, https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
- Interim Guidance on Testing Healthcare Personnel for SARS-CoV-2, https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-healthcare-personnel.html
- Interim SARS-CoV-2 Testing Guidelines for Nursing Home Residents, https://www.cdc.gov/coronavirus/2019-ncov/hcp/nursing-homes-testing.html
- Interim Considerations for Institutions of Higher Education Administrators for SARS-CoV-2 Testing, https://www.cdc.gov/coronavirus/2019-ncov/community/colleges-universities/ihe-testing.html
- Interim Guidelines for COVID-19 Antibody Testing, https://www.cdc.gov/coronavirus/2019-ncov/lab/resources/antibody-tests-guidelines.html

Centers for Medicare & Medicaid Services (CMS)

- Clinical Laboratory Improvement Amendments (CLIA) Laboratory Guidance During COVID-19 Public Health Emergency, https://www.cms.gov/files/document/qso-20-21-clia.pdf-0
- Frequently Asked Questions: SARS-CoV-2 Surveillance Testing, https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf
- Medicare Administrative Contractor (MAC) COVID-19 Test Pricing, https://www.cms.gov/files/document/mac-covid-19-test-pricing.pdf
- COVID-19 Frequently Asked Questions (FAQs) for State Medicaid and Children's Health Insurance Program (CHIP) Agencies, https://www.medicaid.gov/state-resource-center/downloads/covid-19-faqs.pdf
- Current emergencies, Coronavirus Disease 2019, updated regularly, https://www.cms.gov/About-CMS/Agency-Information/Emergency/EPRO/Current-Emergencies/Current-Emergencies-page
- Coronavirus Disease 2019 (COVID-19) Guidance, Updated as new Center for Consumer Information and Insurance Oversight guidance documents are

published, https://www.cms.gov/CCIIO/Resources/Fact-Sheets-and-FAQs#COVID-19

Food and Drug Administration (FDA)

- Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised), May 2020, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-coronavirus-disease-2019-tests-during-public-health-emergency-revised
- FAQs on Testing for SARS-CoV-2, https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2
- HHS, Department of Labor, and the Treasury
- FAQS about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 42, April 11, 2020, https://www.cms.gov/files/document/FFCRA-Part-42-FAQs.pdf
- FAQS about Families First Coronavirus Response Act and Coronavirus Aid, Relief, and Economic Security Act Implementation Part 43, June 23, 2020, https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf

Federal COVID-19 Guidance (Non-HHS)

U.S. Equal Employment Opportunity Commission (EEOC)

- What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws

White House

- Testing Blueprint: Opening Up America Again, April 2020, https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Blueprint.pdf
- Testing Overview: Opening Up America Again, April 2020, https://www.whitehouse.gov/wp-content/uploads/2020/04/Testing-Overview-Final.pdf
- Guidance on Interpreting COVID-19 Test Results, May 6, 2020, https://www.whitehouse.gov/wp-content/uploads/2020/05/Testing-Guidance.pdf
- Addendum to the Testing Blueprint, June 2020, https://www.whitehouse.gov/wp-content/uploads/2020/06/Addendum-to-the-testing-blueprint-FINAL.pdf

Test Strategies

Centers for Disease Control and Prevention (CDC)

- SARS-CoV-2 Testing Strategy: Considerations for Non-Healthcare Workplaces, https://www.cdc.gov/coronavirus/2019-ncov/community/organizations/testing-non-healthcare-workplaces.html
- Testing Strategy for Coronavirus (COVID-19) in High-Density Critical Infrastructure Workplaces after a COVID-19 Case is Identified,

https://www.cdc.gov/coronavirus/2019-ncov/community/worker-safety-support/hd-testing.html

- COVID-19 Serology Surveillance Strategy, https://www.cdc.gov/coronavirus/2019-ncov/covid-data/serology-surveillance/index.html

Department of Health and Human Services (HHS)

- Report to Congress: COVID-19 Strategic Testing Plan, May 24, 2020, https://www.democrats.senate.gov/imo/media/doc/COVID%20National%20Diagnostics%20Strategy%2005%2024%202020%20v%20FINAL.pdf
- Coronavirus (COVID-19) Testing Plans by State and Jurisdiction, updated regularly, https://www.hhs.gov/coronavirus/testing-plans/index.html

The Johns Hopkins Center for Health Security

- Developing a National Strategy for SARS-CoV-2 Serosurveys in the United States, June 18, 2020, https://www.centerforhealthsecurity.org/our-work/publications/developing-a-national-strategy-for-sars-cov-2-serosurveys-in-the-united-states

The John Hopkins Bloomberg School of Public Health

- A National Plan to Enable Comprehensive COVID-19 Case Finding and Contact Tracing in the US, April 2020, https://www.centerforhealthsecurity.org/our-work/pubs_archive/pubs-pdfs/2020/200410-national-plan-to-contact-tracing.pdf

The Rockefeller Foundation

- National COVID-19 Testing and Tracing Action Plan, https://www.rockefellerfoundation.org/national-covid-19-testing-and-tracing-action-plan/

Relevant Reports and Other Resources

Centers for Disease Control and Prevention (CDC)

- Overview of Testing for SARS-CoV-2, https://www.cdc.gov/coronavirus/2019-ncov/hcp/testing-overview.html
- Report to Congress on Paycheck Protection Program and Health Care Enhancement Act Disaggregated Data on U.S. Coronavirus Disease 2019 (COVID-19) Testing, May 2020, https://www.help.senate.gov/imo/media/doc/FY%202020%20CDC%20RTC%20on%20COVID-19%20Testing%20Data%20-%20CDCfinalclean.pdf
- CDC Activities and Initiatives Supporting the COVID-19 Response and the President's Plan for Opening America Up Again, May 2020, https://www.cdc.gov/coronavirus/2019-ncov/downloads/php/CDC-Activities-Initiatives-for-COVID-19-Response.pdf

Centers for Medicare & Medicaid Services (CMS)

- Frequently Asked Questions: COVID-19 Testing at Skilled Nursing Facilities/ Nursing Homes, August 5, 2020, https://www.cms.gov/files/document/covid-faqs-snf-testing.pdf

Department of Health and Human Services (HHS)

- Community-Based Testing Sites for COVID-19, updated regularly, https://www.hhs.gov/coronavirus/community-based-testing-sites/index.html

Federal Emergency Management Agency (FEMA)

- Federal Support to Expand National Testing Capabilities, May 4, 2020, https://www.fema.gov/fact-sheet/federal-support-expand-national-testing-capabilities

Food and Drug Administration (FDA)

- Independent Evaluations of COVID-19 Serological Tests, updated regularly, https://open.fda.gov/apis/device/covid19serology/

Government Accountability Office (GAO)

- COVID-19: Opportunities to Improve Federal Response and Recovery Efforts, June 25, 2020, https://www.gao.gov/products/GAO-20-625

National Academy of Medicine (NAM)

- Evaluating Data Types: A Guide for Decision Makers using Data to Understand the Extent and Spread of COVID-19, 2020, https://www.nap.edu/catalog/25826/evaluating-data-types-a-guide-for-decision-makers-using-data
- Rapid Expert Consultation on SARS-CoV-2 Laboratory Testing for the COVID-19 Pandemic, April 8, 2020, https://www.nap.edu/catalog/25775/rapid-expert-consultation-on-sars-cov-2-laboratory-testing-for-the-covid-19-pandemic-april-8-2020

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