



May 2022

COVID-19

FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed

Why GAO Did This Study

Diagnostic testing for COVID-19 is critical to tracking the virus, informing treatment, and suppressing transmission. However, because COVID-19 is caused by a novel virus, no test existed at the beginning of the pandemic. Typically, medical devices, such as diagnostic tests, must be approved or cleared by FDA before they can be offered. However, FDA's EUA authority requires a lower level of evidence than the effectiveness standard normally required for FDA product approval; therefore, it can help tests become available in a shorter amount of time. Test developers submit EUA requests to FDA that include data on a test's performance, and FDA reviews the data to determine whether to grant an EUA.

GAO was asked to review FDA's oversight of tests for COVID-19. This report examines, among other things, 1) the actions FDA took to help make COVID-19 tests available for use, 2) the number of tests FDA authorized and those for which it exercised enforcement discretion, and 3) FDA's monitoring of these tests after they were available for use. GAO reviewed agency documentation, and interviewed FDA and associations that represent test developers.

What GAO Recommends

GAO recommends that FDA develop a policy for the use of enforcement discretion regarding unauthorized tests in future public health emergencies. This policy should include the conditions under which FDA would begin and end the use of such discretion. The Department of Health and Human Services concurred with our recommendation.

View [GAO-22-104266](#). For more information, contact Mary Denigan-Macauley at (202) 512-7144 or DeniganMacauleyM@gao.gov.

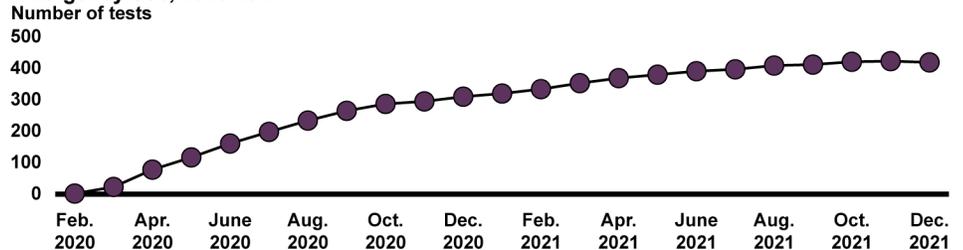
COVID-19

FDA Took Steps to Help Make Tests Available; Policy for Future Public Health Emergencies Needed

What GAO Found

The Food and Drug Administration (FDA) took several actions aimed at increasing the availability of COVID-19 tests in the United States. This included granting emergency use authorizations (EUA) for more than 400 COVID-19 tests and sample collection devices by the end of 2021 (see figure). In a public health emergency, FDA may grant EUAs to temporarily allow the use of unapproved medical products, provided there is evidence that the product may be effective and that the known and potential benefits outweigh known and potential risks. FDA also exercised enforcement discretion for certain COVID-19 tests—that is, it did not object to laboratories' use of these COVID-19 tests before FDA had authorized them; this did not apply to tests that could be used at home. FDA's use of enforcement discretion helped increase test availability early in the pandemic.

Cumulative Number of COVID-19 Tests and Sample Collection Devices Authorized by FDA for Emergency Use, 2020-2021



Source: Food and Drug Administration (FDA). | GAO-22-104266

As of September 30, 2021, FDA had exercised its enforcement discretion for 370 tests. Test developers had submitted EUA requests for these tests, but FDA had not yet reviewed them. FDA officials told GAO they had concerns about the lack of review for these unauthorized tests, and as the number grew, the risks of this policy began to outweigh the benefits. Nevertheless, it was not until November 2021 that FDA updated its COVID-19 test policy with the intention of phasing out the agency's use of enforcement discretion and reducing the number of unauthorized tests. However, FDA has no policy for when it would begin and end exercising enforcement discretion for the use of unauthorized tests in a future public health emergency. Without such a policy, if FDA were to exercise similar enforcement discretion in the future, the agency could face the risk that tests with uncertain accuracy and reliability could be available for use for an extended period of time, even when a sufficient number of authorized tests are available. This could hamper an effective response and recovery during a crisis.

FDA monitors the performance of all COVID-19 tests—whether granted an EUA or not—through reports of performance problems submitted to FDA by test developers, health care providers, and consumers. According to FDA, this includes reports of false positive or false negative test results. By December 31, 2021, FDA had received more than 18,000 such reports for COVID-19 tests and took action to address identified problems. For example, FDA issued 10 letters to clinical laboratory staff and health care providers to inform them of safety concerns about COVID-19 tests.

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Abbreviations

CARES Act	Coronavirus Aid, Relief, and Economic Security Act
CDC	Centers for Disease Control and Prevention
CLIA	Clinical Laboratory Improvement Amendments of 1988
EUA	emergency use authorization
FDA	Food and Drug Administration
HHS	Department of Health and Human Services
LDT	laboratory developed test
RADx	Rapid Acceleration of Diagnostics

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May 12, 2022

Congressional Addressees

The COVID-19 pandemic has had devastating effects on public health and the economy. As of May 4, 2022, more than 81 million cases of COVID-19 have been reported in the U.S. since COVID-19 was first identified in January 2020, and as of the week ending April 30, 2022, over 997,000 deaths associated with COVID-19 have been reported.¹ Testing for COVID-19 is critical to diagnosing cases and tracking the virus, informing treatment, and suppressing transmission. Because COVID-19 was caused by a novel virus, no diagnostic test existed at the beginning of the pandemic. CDC data show that as of May 1, 2022, more than 870 million COVID-19 tests have been performed in the United States.²

The Food and Drug Administration (FDA), within the Department of Health and Human Services (HHS), is responsible for ensuring that medical devices sold in the United States, including diagnostic tests, provide reasonable assurance of safety and effectiveness. As such, one

¹Data on COVID-19 cases in the U.S. are based on aggregate case reporting to CDC and include probable and confirmed cases as reported by states and jurisdictions. CDC COVID-19 counts are subject to change due to delays or updates in reported data from states and jurisdictions. According to CDC, the actual number of COVID-19 cases is unknown for a variety of reasons, including that people who have been infected may have not been tested or may have not sought medical care. See CDC, "COVID Data Tracker: United States COVID-19 Cases, Deaths and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction," accessed May 5, 2022, https://covid.cdc.gov/covid-data-tracker/#cases_totaldeaths.

CDC's National Center for Health Statistics COVID-19 death counts in the U.S. are based on provisional counts from death certificate data, which do not distinguish between laboratory-confirmed and probable COVID-19 deaths. Data are provisional and subject to updates. In more recent weeks, the data are more likely to be incomplete due to an average delay of 2 weeks (a range of 1–8 weeks or longer) for death certificate processing. See CDC, National Center for Health Statistics, "Provisional Death Counts for Coronavirus Disease 2019 (COVID-19)," accessed May 5, 2022, <https://www.cdc.gov/nchs/nvss/vsrr/covid19/index.htm>.

²According to CDC, the testing data represents COVID-19 test results from laboratories in the United States, including commercial and reference laboratories, public health laboratories, hospital laboratories, and other testing locations. The data represent laboratory nucleic acid amplification tests, which include reverse transcriptase-polymerase chain reaction tests and exclude antibody and antigen tests. See, CDC, "COVID Data Tracker: United States COVID-19 Cases, Deaths, and Laboratory Testing (NAATs) by State, Territory, and Jurisdiction," accessed May 5, 2022, https://covid.cdc.gov/covid-data-tracker/#cases_totaltests.

of FDA's roles, according to FDA officials, includes determining whether these tests provide sufficiently accurate and reliable results, and helping to provide timely access to such tests. Typically, before a medical device can be marketed in the U.S., it must be approved or cleared by FDA.³ However, during a public health emergency like the COVID-19 pandemic, the Secretary of HHS may declare that circumstances justify the emergency use of unapproved medical products.⁴ On February 4, 2020, the Secretary of HHS declared that circumstances justified FDA's issuance of emergency use authorizations (EUA) for tests to detect or diagnose SARS-CoV-2, the virus that causes COVID-19, until the public health emergency declaration is terminated.

FDA's EUA authority allows the agency to authorize tests that it reasonably believes may be effective to be made available for use. This authority generally allows for products to be available in a shorter time frame than typically would be necessary for full approval because it requires a lower level of evidence than the "effectiveness" standard that is normally required for FDA product approvals.⁵ Additionally, during the COVID-19 public health emergency, FDA exercised enforcement discretion for certain COVID-19 tests –that is, FDA did not object to laboratories' use of these tests before authorizing them. As part of its mission to ensure that medical devices are safe and effective, FDA monitors COVID-19 tests after they reach the market to detect performance problems or other potential safety issues.

We placed HHS's leadership and coordination of public health emergencies on GAO's High Risk list in January 2022, in part due to concerns related to HHS' handling of COVID-19, including testing. HHS's response to the COVID-19 pandemic has highlighted longstanding concerns we raised about the department's ability to execute its role

³Medical devices must also meet other requirements, such as registration of manufacturing establishment and device listing with FDA. See 21 C.F.R. pt. 807 (2021).

⁴See 21 U.S.C. § 360bbb-3(b).

⁵Medical devices are generally subject to one of two types of FDA premarket review processes. The premarket approval process, the most stringent type of premarket review, requires the sponsor to submit evidence providing reasonable assurance that the new device is safe and effective. The 510(k) process requires the sponsor to demonstrate to FDA that the new device is substantially equivalent to a device already legally on the market.

For example, according to FDA, EUA submissions from a commercial manufacturer are substantially shorter (100 to 200 pages) than what is required when seeking full FDA approval for a test (about 2,000 pages).

leading federal public health and medical preparedness for, and response to, such public health emergencies.

You asked us to review issues related to FDA's oversight of COVID-19 tests. In this report, we examine

1. FDA's actions to help make COVID-19 tests available for use and stakeholders' views on those actions;
2. the number of tests FDA authorized and the number for which it exercised enforcement discretion; and
3. how FDA monitors COVID-19 tests after they are available for use.

In addition, this report is part of our body of COVID-19 work in response to the Coronavirus Aid, Relief, and Economic Security (CARES) Act.⁶ The CARES Act included a provision for us to report on our ongoing monitoring and oversight efforts related to the COVID-19 pandemic.⁷

To address all three objectives, we reviewed relevant agency documentation related to EUAs and COVID-19 tests and interviewed agency officials from FDA's Center for Devices and Radiological Health to understand FDA's policies and processes applicable to COVID-19 tests. For example, we reviewed multiple iterations of FDA's *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency*.⁸

⁶We have regularly issued government-wide reports on the federal response to COVID-19. For the latest report, see GAO, COVID-19: Current and Future Federal Preparedness Requires Fixes to Improve Health Data and Address Improper Payments, GAO-22-105397 (Washington, D.C.: Apr. 27, 2022). All of these reports are available on GAO's website at <https://www.gao.gov/coronavirus>.

⁷Pub. L. No. 116-136, § 19010, 134 Stat. 281, 579-81 (2020).

⁸Department of Health and Human Services, Food and Drug Administration, *Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing Under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency (Immediately In Effect Guidance for Clinical Laboratories and Food and Drug Administration Staff)* (Silver Spring, Md.: Feb. 29, 2020).

Department of Health and Human Services, Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (Immediately In Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff)* (Silver Spring, Md.: Mar. 16, 2020).

Department of Health and Human Services, Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (Immediately In Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff)* (Silver Spring, Md.: May 4, 2020).

We reviewed publicly available information on FDA’s website about COVID-19 tests, such as information about tests FDA has authorized and not authorized and FDA’s responses to frequently asked questions. The scope of our review did not include an examination of the appropriateness of FDA’s EUA decisions for COVID-19 tests. Throughout this report, when we discuss “COVID-19 tests,” we are referring broadly to diagnostic and antibody tests, unless otherwise specified.

To examine FDA’s actions to help make COVID-19 tests available for use, stakeholders’ views on those actions, and the extent to which FDA exercised enforcement discretion for COVID-19 tests, we also reviewed FDA data and interviewed a selection of associations that represent test developers. We reviewed FDA data from February 2020 through December 2021 on the number of EUA requests for tests FDA received, authorized, and revoked, and on FDA’s EUA review times. In some cases, we present data in this report as of September 30, 2021 because it was the end fiscal year 2021 and because it fell in the period prior to FDA’s issuance of revised guidance in November 2021, which sought to reduce the number of unauthorized tests that could be used. We assessed the reliability of these data by asking agency officials about how FDA stores and maintains the information, and any known reliability issues. We determined that these data were sufficiently reliable for our reporting purposes. To examine stakeholders’ views on FDA’s actions, we conducted interviews with or received written responses from a nongeneralizable selection of laboratory and device manufacturer associations.⁹ We selected these associations because their members included COVID-19 test developers. We asked them about their perspectives on FDA’s policies and processes for reviewing and authorizing COVID-19 tests.

Department of Health and Human Services, Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (Immediately In Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff)* (Silver Spring, Md.: May 11, 2020).

Department of Health and Human Services, Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (Guidance for Developers and Food and Drug Administration Staff)* (Silver Spring, Md.: Nov. 15, 2021).

⁹These interviews included the Association of Public Health Laboratories; AdvaMedDx; the Medical Device Manufacturers Association; American Clinical Laboratory Association; the National Independent Laboratory Association; the American Hospital Association; and the Infectious Diseases Society of America.

To keep apprised of FDA’s updates and information FDA shares with test developers, we listened to FDA’s public Town Hall conference calls for COVID-19 test developers between February 2021 and January 2022, which FDA generally held weekly or biweekly. We also reviewed FDA’s standard operating procedure for COVID-19 test authorization and publications authored by FDA officials that described FDA’s challenges in making COVID-19 tests available for use and lessons learned for future public health emergencies.¹⁰ We also collected information in April 2021 using an email-based questionnaire from the eight states and one territory that chose to authorize laboratories within their state or territory to develop COVID-19 tests for emergency use and that perform testing; in addition, we interviewed officials from one of the states to collect more in-depth illustrative information about their test review process and standards.¹¹ We reviewed the websites of a non-generalizable sample of 25 COVID-19 test developers to determine if their tests appeared to be available for purchase before FDA had authorized them. In evaluating FDA’s actions, we considered recommendations in FDA’s 2021 COVID-19 Pandemic Recovery and Preparedness Plan and FDA’s stated mission of ensuring access to safe and effective medical devices.

To examine how FDA monitors COVID-19 tests after they are available for use, we examined FDA documentation and interviewed FDA officials. We summarized FDA’s use of its enforcement tools for post-market monitoring of COVID-19 tests. We gathered data on FDA’s use of enforcement tools from its public website. We interviewed FDA officials about the process of conducting post-market monitoring for COVID-19 tests, FDA’s use of enforcement tools, and any challenges the agency has faced in doing so.

We conducted this performance audit from April 2020 to May 2022 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our

¹⁰Jeffrey Shuren and Timothy Stenzel, “COVID-19 Molecular Diagnostic Testing—Lessons Learned,” *New England Journal of Medicine*, (Sept. 9, 2020), accessed Sept. 14, 2020, <https://www.nejm.org/doi/full/10.1056/NEJMp2023830>

Jeffrey Shuren and Timothy Stenzel, “The FDA’s Experience with Covid-19 Antibody Tests,” *New England Journal of Medicine*, vol. 384, no. 7 (2021): 592-594.

¹¹The U.S. territory of Puerto Rico did not respond to our email questionnaire, and thus its responses are not included.

findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

We previously reported that CDC developed the first COVID-19 diagnostic test in January 2020.¹² However, as we describe in our report, CDC's test was flawed, which contributed to the delayed rollout of testing nationwide. FDA granted an EUA for CDC's test on February 4, 2020, and CDC began distributing it to public health laboratories on February 6; however, many laboratories immediately discovered problems with it.¹³ CDC worked to correct the issues with its test and began distributing new test kits to the laboratories on February 28, 2020. However, no other tests were available for use outside of CDC until February 29, 2020.¹⁴

COVID-19 Test Types

There are three primary types of COVID-19 tests: molecular, antigen, and antibody. Molecular and antigen tests are diagnostic tests used to detect a current COVID-19 infection whereas antibody tests are used to identify if a person had COVID-19 in the past. (See fig. 1.) According to FDA, diagnostic testing can be performed when a person has signs or symptoms of infection, when a person is asymptomatic but had recent exposure, or for screening purposes even if there is no reason to suspect an individual is infected.

¹²GAO, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, [GAO-21-551](#) (Washington, D.C.: July 19, 2021).

¹³CDC's first COVID-19 test was called the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel. CDC also distributed its test to Department of Defense laboratories.

We previously reported that a number of public health laboratories reported to CDC that they could not validate two of the test's three primer-probe sets, short fragments of genetic code that can be used to detect a virus's genetic code.

¹⁴According to FDA, the agency did not receive a clinical validation dataset from any test developer other than CDC until the end of February 2020.

Figure 1: COVID-19 Test Types

TEST TYPE	 MOLECULAR (DIAGNOSTIC)	 ANTIGEN (DIAGNOSTIC)	 ANTIBODY (NOT DIAGNOSTIC)
HOW IT WORKS	Detects the presence of genetic material from SARS-CoV-2, the virus that causes COVID-19. Considered the gold standard for diagnosis; generally highly sensitive and specific.	Detects the presence of a protein that is part of the SARS-CoV-2 virus. More likely to miss an active COVID-19 infection than a molecular test.	Detects antibodies produced in people who have had COVID-19 in the past. Cannot be used to detect an active infection and so is not used for diagnosis.
WHERE IT CAN BE PERFORMED	Can be performed in a laboratory, at the point-of-care (e.g., a clinic), or at home.	Typically performed at the point-of-care or at home.	Can be performed in a laboratory or at the point-of-care.
HOW LONG IT TAKES TO GET RESULTS	Delivers results typically in 1 to 3 days (or more) for laboratory tests; less than an hour for point-of-care or home tests.	Delivers results typically in 30 minutes or less.	Delivers results typically in 1 to 3 days for laboratory tests or on the same day for point-of-care tests.

Source: GAO analysis of Department of Health and Human Services information. | GAO-22-104266

COVID-19 tests may be developed by a laboratory or by a commercial manufacturer.

- **Laboratory developed test (LDT):** a test designed, manufactured, and used within a single laboratory, for example, a hospital laboratory.¹⁵
- **Commercial test:** a test that is developed by a commercial manufacturer and distributed for use in laboratories or other settings, such as a physician’s office or an individual’s home.¹⁶

¹⁵FDA does not consider tests to be LDTs if they are designed or manufactured completely, or partly, outside of the laboratory that offers and uses them.

¹⁶According to FDA officials, tests developed by large multistate laboratory companies are considered commercial tests if they are distributed to multiple labs within their network.

Commercial COVID-19 tests can be performed in multiple settings and may or may not require a prescription or order from a health care provider. Some tests are designed to be performed in a clinical laboratory, while others are designed to be performed at home or at the point-of-care, such as a physician's office, nursing facility, or school, and generally return a result within 30 minutes or less.¹⁷ Tests that are designed to be performed in a laboratory require the sample (nasal or saliva) to be transported from the collection site to the laboratory. Tests that do not require a prescription are available for purchase over-the-counter at places such as pharmacies or online.¹⁸

EUAs for COVID-19 Tests

Medical products are eligible for EUA if they meet the following broad statutory criteria, which are described in FDA guidance.¹⁹

- They may be effective to prevent, diagnose, or treat a serious or life-threatening disease or condition,
- The known and potential benefits of the product outweigh the known and potential risks, and
- No adequate, approved and available alternatives to the product exist.

¹⁷We define a clinical laboratory as a facility that examines samples derived from humans for the purpose of disease diagnosis, prevention, and treatment, or health assessment of individuals. See 42 U.S.C. § 263a(a). Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), clinical labs that perform tests on human specimens to diagnose, prevent, or treat disease must meet certain requirements. See Pub. L. No. 100-578, § 2, 102 Stat. 2903 (codified as amended at 42 U.S.C. § 263a). The Centers for Medicare & Medicaid Services has issued regulations to implement CLIA and is responsible for overseeing and certifying compliance with these regulations.

Point-of-care testing is testing that is performed at a patient care setting, such as a doctor's office or school, and must be performed in a facility operating under a CLIA Certificate of Waiver, Certificate of Compliance, or Certificate of Accreditation.

¹⁸FDA distinguishes between direct-to-consumer tests, which are non-prescription tests where the sample collection device is purchased over the counter and the sample is mailed to a laboratory to perform the test, and over-the-counter tests, which are performed entirely at home.

¹⁹Department of Health and Human Services, Food and Drug Administration, *Emergency Use Authorization of Medical Products and Related Authorities (Guidance for Industry and Stakeholders)* (Silver Spring, Md.: Jan. 2017).

The criteria for an EUA listed in these bullets are only a partial list of the criteria and requirements for authorization under section 564 of the Food, Drug, and Cosmetic Act (see 21 USC 360bbb-3(c)).

An EUA continues in effect unless and until it is revoked or the declaration allowing FDA to issue EUAs terminates.

Under FDA's process, a test developer submits an EUA request to FDA that includes data on the test's accuracy and reliability. FDA reviews the EUA request and evaluates, among other things, whether the developer has provided sufficient data to demonstrate that the test meets the agency's expectations for reliability and accuracy and whether the scientific evidence provided supports the test's intended use. According to FDA officials, the agency quickly became inundated with EUA requests from COVID-19 test developers, receiving over 100 requests by the end of March 2020 and more than 3,000 by the end of fiscal year 2021.

FDA recommends that EUA requests for COVID-19 tests include information about the test, its intended use and testing capacity and data showing the results of studies developers conducted to validate the test's performance characteristics.²⁰ FDA may work with the test developer to correct any problems identified during the review of the request. FDA may grant, deny, or decline the EUA request.²¹ If FDA grants the EUA request, the test is then authorized and may be used or distributed, as set forth in the terms of the EUA. If FDA denies or declines the EUA request, then it may not be used or distributed.

Receipt of an EUA carries certain benefits for COVID-19 test developers. For example, medical products, including tests, with an EUA are qualified for coverage under the Public Readiness and Emergency Preparedness Act, which may provide certain liability protection to individuals and entities, such as test manufacturers, against claims of loss caused by or

²⁰Validation studies are designed to assess a test's sensitivity and specificity, among other things. Sensitivity is the measure of how often the test correctly returns a positive result for someone who has a SARS-CoV-2 infection, and specificity is the measure of how often the test correctly returns a negative result for someone who does not have a SARS-CoV-2 infection. For example, FDA recommended a minimum sensitivity of 95 percent and specificity of 98 percent for laboratory based molecular diagnostic tests.

²¹According to FDA officials, the agency may decline to issue the EUA if the request does not include all the necessary data and information for a substantive review. FDA may deny the request if the totality of evidence in the request does not meet statutory criteria. FDA officials told us they give test developers 48 hours to address any deficiencies FDA finds in the EUA submission before declining to issue the EUA. FDA may also decline to review the request if the test is not a priority that will address the public health needs at the current stage of the public health emergency.

relating to their manufacture, distribution, administration, or use.²² In addition, section 6001 of the Families First Coronavirus Response Act, as amended by section 3201 of the CARES Act, requires most private health insurance plans to cover the cost of COVID-19 testing, administration of the test, and related items and services, as defined by the acts.²³ This includes insurance coverage for COVID-19 tests that have been approved, cleared, or authorized by FDA, or where the developer has requested or intends to request an EUA, unless and until that EUA has been denied or the developer does not submit a request within a reasonable time frame.

FDA Took Various Actions to Help Increase the Availability of COVID-19 Tests

FDA took several actions aimed at rapidly increasing the availability of tests in the United States. These actions included granting EUAs for COVID-19 tests; issuing policies that enabled some tests to be used without first obtaining an EUA; and increasing its resources dedicated to COVID-19 tests and prioritizing EUA requests to manage the large number of EUA submissions.

FDA Granted EUAs for COVID-19 Tests

The primary way FDA helped to increase the availability of COVID-19 tests was by authorizing tests for emergency use—that is, granting them EUAs. Following the authorization of CDC’s COVID-19 test on February 4, 2020, FDA granted the second EUA for a COVID-19 test to the New York State Department of Health on February 29, 2020, and had authorized 23 tests by March 31, 2020. By December 31, 2021, FDA had granted EUAs for 420 COVID-19 tests and sample collection devices—290 molecular tests and sample collection devices, 43 antigen tests, and 87 antibody and other immune response tests.²⁴ (See fig. 2.) These included

²²See 42 U.S.C. § 247d-6d. COVID-19 tests that are approved or cleared under FDA’s traditional review process also qualify for coverage under the Public Readiness and Emergency Preparedness Act.

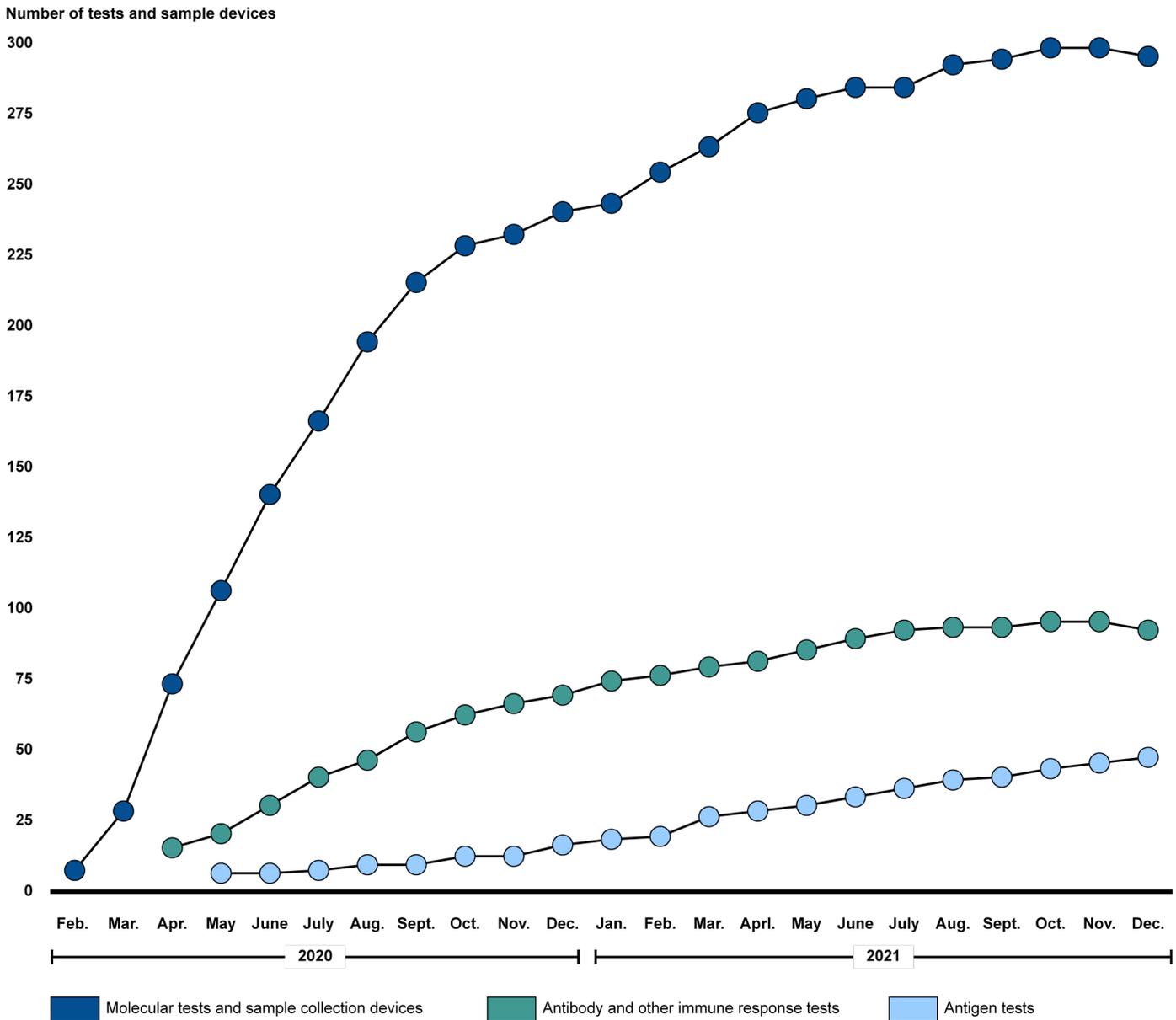
²³Families First Coronavirus Response Act, Pub. L. No. 116-127, § 6001, 134 Stat. 178, 201-02 (2020); CARES Act, Pub. L. No. 116-136, § 3201, 134 Stat. 281, 366-67 (2020).

²⁴A sample collection device can be used for collecting a clinical sample (e.g., nasal or saliva) and sending the sample to a laboratory for testing with a molecular diagnostic test, and, according to FDA officials, may be authorized individually or as part of a home collection kit.

-
- Thirteen over-the-counter antigen tests that could be performed at home and three over-the-counter molecular at-home tests, and
 - 67 molecular tests and one antibody test that could be used with home-collected samples.

With a home collection test, the sample is collected at home but analyzed in a laboratory. With an at-home test, the consumer collects the sample and conducts the test at home.

Figure 2: Rise in the Cumulative Number of COVID-19 Tests and Sample Collection Devices with an EUA by FDA, as of December 2021



Source: Food and Drug Administration (FDA). | GAO-22-104266

Note: According to FDA officials, monthly counts reflect the cumulative total of emergency use authorizations (EUA) granted minus any EUA revocations.

FDA Policy Enabled Some Tests to Be Used Before Authorizing Them for Emergency Use and FDA Took Actions to Support Test Developers

Shortly after the Secretary's February 4, 2020, declaration that circumstances justified FDA's issuance of EUAs for COVID-19 tests, FDA issued four policies, each with the intention of expediting the availability of tests. Specifically, FDA exercised enforcement discretion to not object to the use of certain kinds of COVID-19 before they received an EUA.²⁵ These policies only pertained to tests performed by certain types of laboratories, and did not apply to tests that could be performed at home or on samples collected at home.

- First, on February 29, 2020, FDA issued an enforcement discretion policy that enabled certain types of laboratories to begin using diagnostic tests they developed prior to obtaining an EUA.²⁶ This policy applied only to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) that met the regulatory requirements to perform high complexity testing and that were developing diagnostic tests for use in their own laboratory—LDTs.²⁷ These laboratories could begin using their diagnostic test after they validated them and notified FDA that they intended to begin using their tests while they were preparing or awaiting FDA's review of their EUA requests.²⁸ Under this policy, once a laboratory notified FDA that it had validated its test, it was to submit its EUA request to

²⁵We use the term enforcement discretion to refer to FDA's policy to not object to the use of COVID-19 tests that did not comply with applicable statutory or regulatory requirements, including the requirement to obtain pre-market approval or emergency use authorization prior to use.

²⁶Food and Drug Administration, *Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing Under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency*, Feb. 29, 2020. This document states, "The guidance issued today describes a policy enabling laboratories to immediately use tests they developed and validated in order to achieve more rapid testing capacity in the U.S."

²⁷Laboratories obtain CLIA certificates based on the kinds of diagnostic tests they conduct. FDA assigns the tests to one of three CLIA complexity categories—waived, moderate complexity, or high complexity—that determine which laboratories can use particular tests once they are on the market. Laboratories conducting moderate- to high-complexity tests undergo biennial inspections—also referred to as surveys—that assess laboratory compliance with personnel and testing standards. According to the Centers for Medicare & Medicaid Services, as of August 2021, there were approximately 34,000 CLIA-certified laboratories that may be able to perform high complexity testing if they had appropriately qualified personnel as outlined in the regulations.

²⁸Validation studies are designed to assess a test's performance characteristics.

FDA within 15 business days. Once notified, FDA did not object to the laboratory's use of the test and placed the test on a notification list.²⁹

- Second, on March 16, 2020, FDA announced a similar policy for diagnostic tests developed by commercial manufacturers, in which FDA indicated it would not object to commercial test manufacturers' distribution of the test, provided the manufacturers first validated the tests, notified FDA the tests had been validated, and submitted an EUA request to FDA within 15 business days after validating the test.³⁰ In doing so, FDA cited increasing numbers of COVID-19 cases throughout the country and the urgent need to expand the nation's capacity for COVID-19 testing during the public health emergency. FDA later stated that use of these tests was limited to laboratories certified under CLIA to perform high-complexity testing.³¹ After notification, FDA placed the test on a "notification list."
- Third, on March 16, 2020, FDA announced it did not intend to object to the distribution or use of antibody tests for use by certain laboratories without an EUA if the developer had validated the test and notified FDA.³² Unlike for diagnostic tests falling within the

²⁹FDA maintained four separate notification lists on its website: one for diagnostic tests developed by laboratories, one for antibody tests developed by laboratories, one for diagnostic tests developed by commercial manufacturers, and one for antibody tests developed by commercial manufacturers. Food and Drug Administration, "Notifications and Emergency Use Authorizations: FAQs on Testing for SARS-CoV-2," accessed Oct. 22, 2021, <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/notifications-and-emergency-use-authorizations-faqs-testing-sars-cov-2>.

³⁰Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 Tests During the Public Health Emergency*, Mar. 16, 2020.

³¹Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, May 4, 2020. FDA stated that, unless and until an EUA is issued that authorizes additional testing environments for a specific test, use of that test is limited to laboratories that are certified under CLIA and meet the requirements to perform tests of high-complexity, and at the point-of-care when covered by such a laboratory's CLIA certificate.

³²FDA also recommended developers include certain information in the test result reports, including a statement that the test had not been reviewed by FDA and that results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

FDA later stated in its May 4, 2020, policy that use of antibody tests prior to or without an EUA was limited to laboratories certified under CLIA that met the requirements to perform tests of high-complexity, and at the point-of-care when covered by a laboratory's CLIA certificate. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, May 4, 2020.

enforcement discretion policies, FDA did not at first expect antibody test developers to submit an EUA request to FDA. FDA stated that it issued this policy based, in part, on the fact that antibody tests were not intended to be used for diagnostic purposes and because FDA believed access to antibody tests was important to help the scientific community understand the scope of the COVID-19 outbreak. However, according to FDA officials, many poorly performing or fraudulent antibody tests soon began to flood the market. In response, FDA revised its policy on May 4, 2020, stating that the agency expected commercial manufacturers of antibody tests to request EUAs for these tests.³³ In April 2020, FDA partnered with the National Cancer Institute, the National Institute of Allergy and Infectious Diseases, CDC, and the Biomedical Advanced Research and Development Authority to evaluate the performance of antibody tests to help inform FDA's authorization decisions. Ultimately, FDA removed more than 260 antibody tests developed by commercial manufacturers from FDA's notification list due to significant problems with the test that were not addressed in a timely manner or because the manufacturer did not submit an EUA request within 10 business days, and expected developers to remove them from the market.³⁴ FDA officials stated in a *New England Journal of Medicine* article that the March 16, 2020, antibody test policy was "flawed."³⁵

- Fourth, FDA's policies enabled states and territories to authorize laboratories within their state or territory to develop their own COVID-19 tests and perform testing without an EUA. On March 16, 2020, FDA announced it would not object to the development and use of certain laboratory tests without EUAs where states and territories reviewed and authorized laboratories within their own state or territory

³³Specifically, FDA modified its COVID-19 test guidance to reflect that commercial manufacturers of antibody tests were expected to submit an EUA request to FDA within 10 business days after notifying FDA that the test had been validated or the date of publication of the guidance (May 4, 2020), whichever was later. Laboratories were encouraged, but not required, to submit EUA requests for antibody tests. Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, May 4, 2020.

³⁴As of July 30, 2021, FDA had removed 268 commercially developed antibody tests from its notification list.

³⁵Shuren and Stenzel, "The FDA's Experience with Covid-19 Antibody Tests."

to perform COVID-19 testing.³⁶ As stated in FDA's policy, the agency intended this policy to expedite COVID-19 testing. Eight states and one U.S. territory subsequently notified FDA of their intention to do this.³⁷ We contacted these states and the U.S. territory and found that six states had authorized laboratories in their state to develop their own COVID-19 tests, and all six states used FDA's guidance when developing their review processes.³⁸

See appendix I for information about actions FDA took to help increase the availability of tests. See appendix II for a summary of key FDA and HHS policies for the regulation of COVID-19 tests.

Representatives from associations we interviewed whose members include COVID-19 test developers provided various views on FDA's actions and policies to help increase the availability of tests throughout the pandemic. Specifically, these stakeholders told us that FDA's use of enforcement discretion for COVID-19 tests was instrumental in rapidly increasing testing capacity at the beginning of the pandemic, but also expressed some concerns with FDA's policies. For example, representatives from two associations told us they believed FDA's use of enforcement discretion for certain tests without an EUA was helpful because they allowed tests to become available quickly when the demand for tests was great. However, two stakeholders noted that FDA's EUA process at the beginning of the pandemic may have stymied the nation's testing response when the U.S. had limited testing capacity and when testing was crucial to stemming the spread of the virus. A representative from one of these associations noted that they would have liked FDA to not object to the use of LDTs without an EUA earlier in the pandemic. (For more information about the EUA requirements for COVID-19 LDTs, see text box.)

³⁶Food and Drug Administration, *Policy for Diagnostic Tests for Coronavirus Disease-2019 Tests During the Public Health Emergency*, March 16, 2020. Under this policy, the laboratories would not submit an EUA request to FDA for their tests.

³⁷Those states and U.S. territory were Colorado, Connecticut, Maryland, Mississippi, Nevada, New Jersey, New York, Washington, and Puerto Rico. Puerto Rico did not respond to our request for additional information.

³⁸As of April 2021, these six states authorized 91 laboratories that developed 121 molecular tests, and 19 laboratories that developed 23 antibody tests.

Changes to the Emergency Use Authorization Policies for COVID-19 Laboratory Developed Tests

The Food and Drug Administration's (FDA) policies regarding the regulation of laboratory developed tests (LDT), including COVID-19 LDTs, changed over the course of the pandemic. While FDA considers LDTs to be a type of diagnostic device, the agency has generally exercised enforcement discretion for most LDTs and has not asserted its jurisdiction to regulate them because they traditionally were relatively simple tests available on a limited basis. FDA has reconsidered this policy, as some LDTs have become more complex and available nationwide. For example, at the beginning of the COVID-19 pandemic, rather than exercise enforcement discretion for COVID-19 LDTs, FDA required these tests to obtain FDA authorization. FDA officials told us that FDA expected laboratories developing COVID-19 LDTs to comply with the emergency use authorization (EUA) requirements because of FDA's concern that poorly performing tests can undermine the nation's response to a public health emergency. Officials also told us that FDA expected LDTs used in six previous public health emergencies, including the H1N1 and Zika emergencies, to have EUAs.

On August 19, 2020, however, the Department of Health and Human Services (HHS) announced that FDA would no longer require premarket EUA reviews for LDTs unless FDA went through the notice and comment rulemaking process, although laboratories could continue to submit EUA requests for LDTs voluntarily. FDA subsequently announced its intention to decline to review EUA requests for COVID-19 LDTs in October 2020. Two laboratory associations we spoke with had unfavorable views of FDA's decision to decline to review LDTs, noting that it created uncertainty and confusion among laboratories, particularly around insurance coverage and liability protection under the Public Readiness and Emergency Preparedness Act for LDTs without an EUA.

On November 15, 2021, HHS announced that it was withdrawing its LDT policy, thereby reinstating FDA's approach to regulating LDTs. On the same day, FDA issued a policy under which it expected COVID-19 tests, including LDTs, to have an EUA prior to use.

Source: GAO summary of FDA and HHS information and interviews with laboratory associations | GAO-22-104266

Representatives from three associations told us that many laboratories found it difficult to apply for an EUA for their tests because they were unfamiliar with FDA's EUA requirements and did not have the resources or internal expertise needed to navigate FDA's EUA process. FDA acknowledged that some laboratories were unfamiliar with the EUA process, and that this created misunderstandings and confusion. Representatives from two associations noted that the EUA requirements were not very transparent early in the pandemic and one noted they would have liked to see more early education from FDA on the EUA process for laboratories. Representatives from another association told us they often felt there was a disconnect when FDA talked to laboratory test developers because FDA was most accustomed to working with other types of manufacturers. They said it would have been useful to have direct engagement by FDA with clinical laboratories and for FDA to have dedicated staff to work with the clinical laboratory sector. FDA officials told us that communication with laboratories is "ripe for improvement" and the agency intends to develop a plan to improve communication with laboratories to better prepare for a future public health emergency. We recommended in July 2021 that CDC work with appropriate stakeholders

to develop a plan to enhance surge capacity for laboratory testing.³⁹ CDC agreed with our recommendation and noted in its response that FDA also plays a critical role in increasing surge capacity by authorizing tests for emergency use. In May 2022, CDC developed a laboratory testing surge capacity plan in consultation with external partners and FDA joined a memorandum of understanding with CDC and multiple laboratory associations. We are reviewing the plan to determine if it meets our recommendation. These are positive first steps and we will continue to monitor CDC's progress on this effort.

Our review of agency documentation shows that FDA took several actions to improve communication with test developers and support them during the test development and EUA process. For example, FDA developed EUA templates to help guide test developers as they prepared their EUA requests, engaged with test developers through the pre-EUA process, held regular public conference calls, and supplied panels of viral material to test developers. FDA stated that the agency had interacted with over 1,000 COVID-19 test developers. According to the associations we spoke with, test developers generally found these actions to be helpful. See appendix III for additional information and stakeholders' views about FDA's actions to support COVID-19 test developers.

To Manage the Large Number of EUA Requests, FDA Increased Resources and Prioritized Among Requests

FDA took various actions to address the large volume of EUA requests the agency received for COVID-19 tests. According to FDA officials, the agency received a very high number of EUA requests for tests—nearly 3,400—from February 2020 through December 2021, which represents an average of about 150 per month. During this time, FDA data show that the agency's average time to review EUA requests and make authorization decisions increased from 3 days, in March 2020, to 65 days as of December 2021, for all types of tests.⁴⁰ FDA officials told us that as the volume of EUA requests increased, so did FDA's average review times. Representatives from four associations we talked to also told us that FDA's time to review EUA requests increased significantly over time, which, according to one association, caused frustration among some members.

³⁹GAO, *COVID-19: Continued Attention Needed to Enhance Federal Preparedness, Response, Service Delivery, and Program Integrity*, [GAO-21-551](#) (Washington, D.C.: July 19, 2021).

⁴⁰According to data that we received from FDA, average review times varied by test type—about 56 days for antigen tests and about 101 days for antibody tests as of December 2021.

FDA's efforts to address the large number of EUA requests for tests included increasing the number of EUA reviewers and prioritizing which tests to review. FDA officials told us that, as of October 2021, the agency was making an average of 23 EUA decisions for COVID-19 tests per week.

FDA temporarily increased the number of EUA reviewers. According to FDA officials, the agency increased the number of staff working on EUAs for COVID-19 tests from 60 in March 2020 to 180 by March 2021 to handle the high volume of submissions. Officials told us the agency assigned nearly all staff from the Division of Microbiology Devices to respond to COVID-19 in March 2020, leaving only two staff from that division to work on non-COVID devices at that time. FDA also assigned staff from other divisions to work on the COVID testing response. As a result of these staff reassignments, according to FDA officials, non-COVID diagnostic devices experienced longer-than-usual review times and delays in initiating reviews. FDA officials explained that the agency began shifting staff back to non-COVID work in May 2021.

FDA also hired new reviewers and leveraged contractors to support the increased workload due to COVID-19 EUA requests. According to FDA officials, the Division of Microbiology Devices increased in size by 28 reviewers from the beginning of 2020 to November, 2021. FDA also hired term and temporary staff, including contractors, to provide technical expertise to support the review of EUA requests with funds provided under the American Rescue Plan Act of 2021 and the Paycheck Protection Program and Health Care Enhancement Act, according to FDA officials. FDA officials told us the agency intended to hire additional review staff and leverage contractor support where appropriate. FDA noted in a January 2021 report that some of the potential options to improve the agency's pandemic preparedness could require additional staff capacity or funding.⁴¹

FDA prioritized EUA requests for certain tests and declined to review requests for nonpriority tests. FDA shifted its priorities to meet the changing circumstances of the public health emergency. In October 2020, FDA announced on its website and in virtual Town Hall meetings that it would begin prioritizing its review of EUA requests for certain types

⁴¹Food and Drug Administration, *FDA COVID-19 Pandemic Recovery and Preparedness Plan (PREPP) Initiative: Summary Report* (Silver Spring, Md.: Jan. 13, 2021).

of COVID-19 tests and declining to review EUA requests for LDTs.⁴² Specifically, FDA stated it would prioritize its review of EUA requests for tests where authorization would increase testing accessibility (e.g., point of care tests, home collection, or at-home tests) or would significantly increase testing capacity, such as tests that reduced reliance on supplies or high-throughput tests. FDA stated on its website that, in light of the August 2020 HHS announcement that FDA will not require premarket review of LDTs, and to make “best use of [their] resources for the greatest public health benefit,” FDA began declining to review EUA requests for LDTs. FDA officials told us that as of September 30, 2021, they had declined to review 558 EUA requests for COVID-19 tests, including 230 LDTs. In its revised guidance, issued on November 15, 2021, FDA described in detail how it would determine a test’s potential to significantly increase testing capacity and accessibility.⁴³

FDA Authorized 412 Tests and Exercised Enforcement Discretion for 370 Unauthorized Tests

⁴²Food and Drug Administration, “COVID-19 Test Development and Review: FAQs for Testing on SARS-CoV-2,” accessed Jan. 15, 2021, <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/covid-19>. FDA also discussed its priorities for reviewing EUA requests at the public Town Hall conference calls for COVID-19 test developers.

⁴³Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, Nov. 15, 2021. For example, the guidance stated that, for laboratory-based molecular diagnostic tests, FDA intended to focus on tests that were highly sensitive; high volume; intended for pooled testing, home sample collection, or had the ability to detect multiple viruses at once; and that were developed by experienced developers with the ability to scale up manufacturing capacity shortly after authorizations. The guidance stated the FDA’s view that authorization of tests with manufacturing capacities lower than 500,000 tests per week would not sufficiently scale U.S. testing capacity.

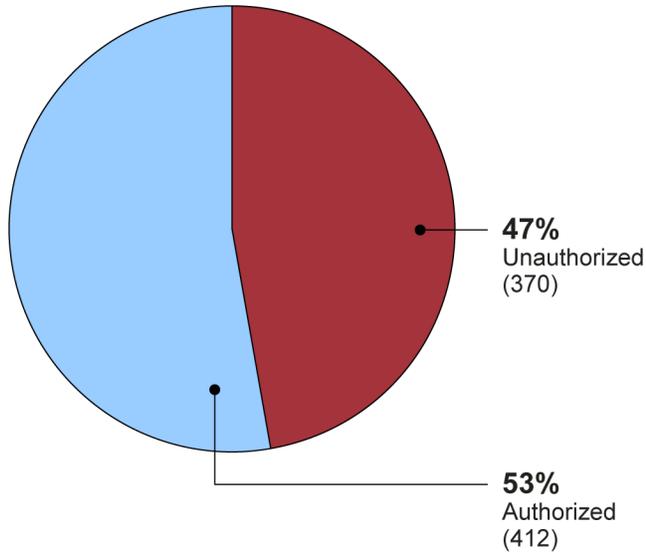
FDA Granted EUAs for 412 Tests and Did Not Object to the Use of 370 Tests It Had Not Authorized, as of the End of September 2021

Our analysis of FDA data shows that as of September 30, 2021, FDA had granted EUAs for 412 COVID-19 tests. In addition, there were 370 tests—285 LDTs and 85 tests developed by commercial manufacturers—for which FDA had received EUA requests but had not yet reviewed to make an EUA determination as of September 30, 2021. FDA exercised its enforcement discretion to not object to the tests' use by certain types of laboratories, or their distribution by test developers. FDA placed these unauthorized tests on notification lists and stated on its website that tests on a notification list that are offered prior to or without an EUA have not been reviewed or authorized by FDA.⁴⁴ FDA did not know whether these tests were actually manufactured, distributed, or used, because according to FDA officials, the agency does not track the number of distributed COVID-19 tests or the number in use. However, we found through a review of a non-generalizable sample of 25 tests on the notification lists that some of the tests on the notification lists appeared to be available for purchase by laboratories.⁴⁵ See Figure 3 for the number of COVID-19 tests that FDA authorized and the number for which it exercised enforcement discretion as of September 30, 2021.

⁴⁴Food and Drug Administration, "FAQs on Testing for SARS-CoV-2," accessed February 14, 2022, <https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/faqs-testing-sars-cov-2>.

⁴⁵We reviewed the websites of a non-generalizable sample of 25 of the 47 commercial diagnostic tests on a notification list, as of October 21, 2021. While it was not always clear from the websites whether the tests were available for purchase, our review found that at least 5 appeared to be available for purchase. For example, one website we considered to be unclear stated that test's availability would be updated once FDA authorized it, but also provided ordering information.

Figure 3: Number of COVID-19 Tests FDA Authorized and the Number for Which It Exercised Enforcement Discretion as of the End of September 2021



Source: Food and Drug Administration (FDA). | GAO-22-104266

Note: COVID-19 tests that were unauthorized as of September 30, 2021, were those for which FDA exercised enforcement discretion—that is, FDA did not object to their use, offering, or distribution, but had not yet authorized for emergency use. Of the 370 unauthorized tests, 285 were developed by laboratories and 85 were developed by commercial manufacturers. FDA officials did not know whether these tests were manufactured, used, or distributed. FDA’s policy limited use of these tests to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 that met the requirements to perform tests of high complexity.

FDA officials told us that by the spring of 2020, they began having concerns about the potential risks these unauthorized tests presented. While FDA checks for obvious problems with the data included in EUA requests, officials said this cursory check did not provide assurance that these tests were sufficiently accurate and reliable. According to FDA officials, it was not until FDA reviewed an EUA request that certain issues that could signal a problem with a test could be found. For example, FDA ultimately denied the EUA requests for several LDTs that had previously been available for use due to performance problems or poor validation.⁴⁶

⁴⁶In 2020, FDA conducted an analysis of the first 125 EUA requests that it received from laboratories. Of these 125 requests the agency identified 82 EUA requests with design and validation problems. FDA worked with the laboratories to correct the issues but the agency ultimately denied authorization to several of these EUA requests.

This concern is understandable given that many tests on the notification lists remained available for use for many months before FDA conducted its review of the EUA requests. For example, in June 2021, FDA officials told us the longest a commercial antibody test was on a notification list was 359 days before the agency declined to authorize it. We also found that 65 percent of the commercial diagnostic tests that were on a notification list in November 2021 had been on the list for at least a year.

On November 15, 2021, FDA issued a revised COVID-19 test policy intended to address the potential risk of the large number of unauthorized tests on the notification lists. The policy sought to phase out the agency's use of enforcement discretion for tests and reduce the number of tests on the notification lists.⁴⁷ FDA stated that the agency no longer intended to add tests to the notification lists and that test developers who had submitted their EUA request prior to February 1, 2021, should inform FDA within 45 calendar days from the issuance date of the policy if they still wanted FDA to review their EUA request. According to the policy, FDA intended to decline to review any tests for which the agency did not receive confirmation from the developer, and expected the developer to cease making their test available for use. FDA officials told us that the agency's goal was to reduce the number of tests remaining on the notification lists and eventually phase out the lists altogether. FDA officials told us that they generally intended to review the remaining tests on the notification lists as time and resources allowed, and as of April 11, 2022, 68 tests remained on the notification lists.⁴⁸

According to FDA officials, an example of an issue that may not be found until FDA did a full review of an EUA request for COVID-19 tests included test developers using contrived samples instead of live viral samples to validate their test.

⁴⁷Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, Nov. 15, 2021.

⁴⁸As of April 8, 2022, 12 diagnostic tests and five antibody tests developed by commercial manufacturers remained on the notification list, as well as 26 laboratory developed diagnostic tests and 25 laboratory developed antibody tests.

FDA Does Not Have a Policy for the Use of Enforcement Discretion Regarding Unauthorized Tests In Future Public Health Emergencies

When FDA exercised enforcement discretion for tests it had not authorized for emergency use, the agency did not indicate when and under what conditions it would end the use of enforcement discretion and begin objecting to the use of unauthorized tests. FDA stated in its policy that its intention for exercising enforcement discretion early in the pandemic was to rapidly increase test availability due to urgent public health concerns at that time.⁴⁹ However, agency officials also told us that by the fall of 2020, when nearly 300 tests had been granted EUAs, they believed the risks of having unauthorized tests available for use began to outweigh the benefits.

FDA officials told us that they have made numerous efforts to prepare for the next pandemic and that they hoped the agency would never again be in a position where it would need to consider the use of unauthorized tests in response to a public health emergency.⁵⁰ However, the COVID-19 pandemic demonstrated that an emerging infectious disease can exceed the nation's existing testing capacity and it is possible that FDA could once again find itself in a position where it would consider it necessary to permit the use of unauthorized tests to rapidly expand testing capacity. If FDA were to again exercise such discretion without a policy for when it would end the discretion, hundreds of unauthorized tests—whose accuracy and reliability would be uncertain—could once again be available for use for an extended period of time.

⁴⁹Food and Drug Administration, *Policy for Diagnostics Testing in Laboratories Certified to Perform High Complexity Testing Under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency (Immediately In Effect Guidance for Clinical Laboratories and Food and Drug Administration Staff)*, Feb. 29, 2020.

⁵⁰FDA officials identified lessons learned from the COVID-19 emergency they said should inform the U.S. government's response to future outbreaks, such as authorizing a small number of well-developed and validated tests and using contract manufacturers at the outset to greatly increase test availability. See Shuren and Stenzel, "COVID-19 Molecular Diagnostic Testing—Lessons Learned."

FDA officials told us they agreed with a recommendation from an independent study to develop a framework for how to conduct validation of diagnostic tests for emerging pathogens in the setting of a public health emergency to speed the availability of future diagnostic devices. See Booz Allen Hamilton, *Deliverable 15: Emergency Use Authorization Assessment – Final Report*, (McLean, Va.: 2021).

FDA officials told us they had not developed a policy or criteria for the use of enforcement discretion regarding unauthorized tests in future public health emergencies. Developing such a policy could potentially minimize the length of time that unauthorized tests would be available for use and would be consistent with FDA's 2021 COVID Pandemic Recovery and Preparedness Plan Initiative Report, which recommends that the agency expand its scenario planning to inform strategic decisions and actions for the agency's ongoing response to COVID-19 and for future emergencies.⁵¹ Additionally, having a policy that outlines the circumstances under which FDA would and would not object to the use of unauthorized tests would be consistent with FDA's mission to protect the public health by ensuring that medical devices are safe and effective, which involves determining if tests are sufficiently accurate and reliable. Unless FDA develops a policy for the use of enforcement discretion in future public health emergencies—including the conditions under which FDA would begin and end such discretion—FDA could face the risk that unauthorized tests with uncertain accuracy and reliability could be used for an extended period of time, even when a sufficient number of tests are available. This could hamper an effective response and recovery during a crisis.

FDA Monitors Reports of Performance Problems with COVID-19 Tests and Takes Action to Address Them

FDA relies on mandatory and voluntary reporting by test developers and others to conduct post-market monitoring of COVID-19 tests. FDA has taken a variety of actions throughout the public health emergency to address problems found through this monitoring process, including test developers' violations of the Food, Drug, and Cosmetic Act. According to FDA officials, FDA shifted its resources to address the resource challenges it faced in conducting post-market monitoring for COVID-19 tests.

⁵¹Food and Drug Administration, *FDA COVID-19 Pandemic Recovery and Preparedness Plan (PREPP) Initiative: Summary Report*, Jan. 13, 2021.

FDA Relies on Test Developers, Health Care Providers, and Consumers to Report COVID-19 Test Performance Problems

Device manufacturers and user facilities, such as nursing homes and hospitals, that use COVID-19 tests are required to report certain types of reportable events to FDA. Reportable events include death and serious injury events that a device has caused or may have contributed to, as well as a device malfunction that would be likely to cause or contribute to a death or serious injury if it were to recur.⁵² According to FDA, in the case of COVID-19 tests, reportable events include instances of false positive or false negative test results. FDA has publicly stated that false test results can contribute to the spread of COVID-19, and that, in a public health emergency, getting an accurate test result is important not only for the individual patient, but for the public at large.

To conduct post-market monitoring of COVID-19 tests, FDA relies on mandatory self-reporting by test developers and user facilities, and voluntary reporting by health care providers and consumers. FDA has two primary systems for receiving adverse event reports, the Electronic Medical Device Reporting system and MedWatch. Device manufacturers are required to submit reports electronically via the Electronic Medical Device Reporting system, and patients and health care providers can submit complaints about COVID-19 tests online via MedWatch. FDA officials told us the agency may also receive emails about false positive or false negative test results or other performance concerns from laboratories and others using diagnostic COVID-19 tests. FDA officials told us the agency internally tracks adverse event reports the same way for each of the three reporting routes.

FDA officials told us that the volume of adverse event reports has been high for COVID-19 tests and that the agency does not investigate every individual report it receives. Specifically, the agency received 18,432 adverse event reports for COVID-19 tests as of December 31, 2021. According to FDA officials, rather than investigate every adverse event report, the agency monitors adverse event reports it receives for signals, such as a high volume of reports on the same test, potential severity of adverse events, or a trend that may indicate a performance problem with a test. FDA officials told us FDA's post-market monitoring team also coordinates with FDA's pre-market review team, which would have initially reviewed the EUA request for a given test to determine whether a

⁵²See 21 C.F.R. Pt. 803 (2021), Medical Device Reporting; 21 C.F.R. § 803.3 (2021) (definition of reportable event).

signal is particularly concerning, and when and if further investigation may be needed.

According to FDA officials, if FDA identifies a signal from reports of adverse events, FDA will initiate an investigation by reaching out to the test developer to inquire about its awareness of the potential issue. FDA may also request additional information or data from a test developer when it believes that the emergence of a COVID-19 viral variant may affect a test's performance (see text box, below).

Monitoring Test Performance with Emerging COVID-19 Viral Variants

Mutations in the genetic makeup of the SARS-CoV-2 virus—the virus that causes COVID-19—can lead to viral variants that have altered characteristics. For example, the Delta variant demonstrated increased transmissibility and virulence, while the Omicron variant demonstrated increased transmissibility. These genetic mutations can potentially change the performance of a test if the mutation alters the part of the virus that the test is targeting. Mutations can affect all COVID-19 test types and could result in false results.

According to Food and Drug Administration (FDA) officials, to identify the potential impact of viral mutations on test performance, FDA began conducting its own analysis of the genetic sequences used by authorized COVID-19 tests in March 2020 using an extensive public genetics database that contains variant sequences from around the world. FDA officials told us the agency began communicating with the public in January 2021, when FDA issued a safety alert about the potential impact of viral mutations.

On February 22, 2021, FDA issued guidance to provide test developers with information on evaluating the potential impact of emerging and future viral genetic mutations on COVID-19 tests. On September 23, 2021, FDA revised the emergency use authorizations (EUA) of certain authorized molecular, antigen, and serological tests to establish additional conditions of authorization in response to the continued emergence of new variants of SARS-CoV-2. These additional conditions required test developers to update their authorized labeling and evaluate the impact of SARS-CoV-2 viral mutations on their test's performance. On October 6, 2021, FDA updated its diagnostic EUA templates, which described the information and data FDA recommended developers include in their EUA request. These new templates specified that test developers should monitor new and emerging viral mutations and variants that could impact test performance on an ongoing basis. As of December 31, 2021, FDA told us it had sent 164 letters to test developers containing specific recommendations for test developers to investigate test performance with regards to specific variants.

Sources: GAO summary of FDA documentation and FDA interviews | GAO-22-104266.

FDA officials told us adverse event reporting requirements apply to both developers of authorized tests and developers of unauthorized tests that fell under FDA's enforcement discretion. Although the adverse event reporting requirements are the same, FDA's communication of these requirements to test developers differs, depending on whether the test is authorized or unauthorized. Specifically, FDA includes the adverse event reporting requirements as a condition of authorization in the EUA letter FDA sends to developers of authorized tests. However, prior to November 15, 2021, FDA did not explicitly communicate these requirements to developers of unauthorized tests on a notification list either through policy documents or email contact with test developers. As a result, FDA did not have assurance that developers of unauthorized

tests on the notification lists were aware of the need to report adverse events.

We asked FDA officials about the extent to which they had received adverse event reports for unauthorized tests. Officials told us that they had identified five adverse event reports associated with these tests as of September 30, 2021, and attributed this low number to a possible low overall usage of these tests. It is also possible the low number of adverse event reports for these unauthorized tests was due to FDA's unclear communication about adverse event reporting requirements for tests on a notification list. FDA officials told us that as a result of conversations between FDA and GAO during the course of this audit, the agency revised its COVID-19 test guidance on November 15, 2021 to clearly communicate adverse event reporting requirements for developers of tests on notification lists.⁵³

FDA Has Taken Action to Address Test Performance Problems and Violations

FDA has employed a variety of post-market actions to address identified performance problems with a COVID-19 test or violations of the Food, Drug, and Cosmetic Act by test developers. These actions include the following: safety communications, letters to clinical laboratory staff and health care providers, warning letters, recalls, EUA revocations, and import alerts. FDA officials told us that if a potential concern with a COVID-19 test is found, FDA evaluates the risk to patients and the public posed by a test's issues to determine an appropriate action. According to FDA officials, the agency will first attempt to resolve concerns with a test developer to address its concerns in a timely manner prior to taking other action, which could include communicating with the public about safety or performance issues. If the test developer cannot address FDA's concerns in a timely manner, then FDA may choose to use one of the options noted above. According to FDA's website and FDA officials, the agency took the following actions as of December 31, 2021. (See table.)

⁵³Food and Drug Administration, *Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised)*, Nov. 15, 2021. In this guidance, FDA stated that test developers with an unauthorized test on a notification list are expected to comply with medical device reporting requirements.

Table 1: FDA’s Reported Actions to Monitor COVID-19 Tests as of December 31, 2021

Type of FDA Action	Number of Actions
Safety Communication	5
Letter to Clinical Laboratory Staff and Health Care Providers	10
Warning Letter	33
Recall	42
Emergency Use Authorization Revocation	16
Import Alert	348

Source: GAO analysis of Food and Drug Administration Information. | GAO-22-104266

- **Safety communications.** FDA issued five safety communications for COVID-19 tests. In a safety communication, FDA describes appropriate actions that patients, consumers, and health care providers should take to reduce risk. According to FDA officials, a safety communication’s audience is intended to be a lay user when there is an important message for the public. For example, FDA issued a safety communication in May 2021 to advise the public and health care providers to avoid the use of antibody tests to evaluate a person’s level of immunity from COVID-19. FDA may also issue a safety communication when a test has an increased risk of false results.
- **Letters to clinical laboratory staff and health care providers.** FDA issued ten letters to clinical laboratory staff and health care providers related to COVID-19 tests. FDA posts these letters on its website to inform clinical laboratory staff and health care providers about safety concerns with these tests. In these letters, FDA makes recommendations about the appropriate use of COVID-19 tests and alerts clinical laboratory staff and health care providers about potential safety issues with COVID-19 tests that require awareness when performing the test.

According to FDA officials, the audience of these letters is intended to be a technical audience; therefore, such a letter is used when the message is more appropriate for laboratory staff, such as when it is related to the steps used to perform a test in a laboratory. For example, in November 2020, FDA issued a letter recommending that clinical laboratory staff and health care providers only use antigen tests with symptomatic individuals because of the potential for false positive results when antigen tests were used with asymptomatic individuals. In another letter from April 2020, FDA advised health care

providers to avoid using the results of antibody tests as the sole basis to diagnose COVID-19, as this information only indicates whether a person may have been exposed to SARS-CoV-2. In addition, FDA issued another letter in October 2021 regarding the potential for false positive results with two COVID-19 tests unless software was updated.⁵⁴

- **Warning letters.** FDA issued 33 warning letters to manufacturers or distributors of products intended to diagnose or identify antibodies for COVID-19, and ten warning letters for products claiming to diagnose COVID-19 through body temperature. According to FDA officials, if FDA finds that a test developer has violated the Federal Food, Drug, and Cosmetic Act or FDA regulations, FDA may initiate an investigation. FDA officials told us that FDA's post-market monitoring team may work with FDA's fraud team and FDA's pre-market review team during this investigation. After an investigation, FDA may notify the manufacturer of any statutory violations it found with a warning letter. A warning letter identifies the violation, such as COVID-19 tests offered for sale without marketing approval, clearance, or authorization from FDA. A warning letter also makes clear that the company should correct the problem and provides directions and a time frame for the company to inform FDA of its plans for correction. FDA then monitors to ensure that the company's corrections are adequate. If the company fails to address the violation, FDA may take enforcement action.

According to FDA officials, the agency may also communicate with test developers who are in violation of the Federal Food, Drug, and Cosmetic Act or FDA regulations without formally issuing a warning letter. According to FDA officials, as of September 30, 2021, FDA's interactions with test developers resulted in 202 instances in which test developers removed language that falsely indicated a test was FDA approved or withdrew their tests from the market without additional FDA action, such as issuing a warning letter or revoking an EUA.

- **Recalls.** Test developers issued 42 recalls for COVID-19 tests. FDA uses the term recall when a test developer makes a correction to or

⁵⁴Food and Drug Administration, *Potential for False Positive Results with Abbott Molecular Inc. Alinity m SARS-CoV-2 AMP and Alinity m Resp-4-Plex AMP Kits - Letter to Clinical Laboratory Staff and Health Care Providers*, accessed Feb. 2, 2022, <https://www.fda.gov/medical-devices/letters-health-care-providers/potential-false-positive-results-abbott-molecular-inc-alinity-m-sars-cov-2-amp-and-alinity-m-resp-4>.

removes a product from the market that is in violation of the Federal Food, Drug, and Cosmetic Act. Recalls occur when necessary to protect the public health, such as when a product presents a risk of injury or is defective. For example, one test developer recalled its antibody and antigen tests in April 2021 due to the likely risk of false results, and because neither test was authorized by FDA for distribution. Four out of the 42 recalls were Class I, which is the most serious type of recall because there is a reasonable probability that the use of a product will cause serious adverse health consequences or death.

When a test developer learns that its product violates the law, it is expected to do two things: (1) initiate a recall, and (2) notify the FDA. To initiate a voluntary recall, a test developer provides FDA with key information, such as the reason for the recall and contact information for its customers and users who purchased the device. The test developer may be asked to provide FDA with information, such as the reason for the correction or removal of the device, an assessment of the health hazard associated with the device, and the volume of product in distribution and proposed strategy for conducting the recall.

If a company fails to recall a medical device, such as a COVID-19 test, that is associated with significant health problems or death, FDA can require a company to recall the device. However, in practice, the FDA has rarely needed to require a medical device recall. Nearly all medical device recalls are voluntarily initiated by a device manufacturer. FDA's role is generally to oversee a firm's management of a recall.

- **Import alerts.** FDA officials told us FDA had placed 348 tests from 248 firms on Import Alert. According to FDA, the agency may detain at the border and refuse to allow the import of tests that appear to violate the Federal Food, Drug, and Cosmetic Act, including foreign tests that do not have appropriate labeling, are unauthorized at-home tests, or are fraudulent.⁵⁵ FDA officials told us the agency also places tests on Import Alert when FDA has denied or declined to issue an EUA request or when the developer has withdrawn their EUA request.
- **EUA revocations.** FDA revoked 16 EUAs for COVID-19 tests as of December 31, 2021. FDA may revoke an EUA if the declaration of emergency under the Federal Food, Drug, and Cosmetic Act or threat

⁵⁵According to FDA officials, import alerts notify FDA staff and the public that FDA has sufficient information to detain certain products without physical examination because they appear to be in violation of the FD&C Act (actual violation need not be established).

justifying emergency use authorization no longer exists, when the agency concludes that the statutory criteria for issuance of an EUA are no longer met, or when other circumstances make revocation of an EUA appropriate to protect public health or safety. For example, FDA may revoke an EUA based on performance concerns about a test, or, according to FDA officials, when a developer requests the EUA for their test be revoked.

Of the 16 EUAs FDA has revoked, two were revoked for poor antibody test performance. For example, according to FDA officials, FDA revoked the EUA for an antibody test in the summer of 2020, after FDA analyzed new data and determined it was no longer reasonable to believe that the test may be effective in detecting antibodies against SARS-CoV-2 or that the known and potential benefits of the test outweighed the known and potential risks.

FDA revoked the remaining 14 EUAs either because a test was converted to full FDA marketing authorization (1 test), or the test developer requested that FDA revoke the EUA (13 tests). Some of these test developers requested that FDA revoke an EUA because a certain COVID-19 test was no longer in use. (See text box, below, for additional information about FDA authorization of COVID-19 tests for use after the public health emergency ends.)

Authorization of COVID-19 Tests for Use after the Public Health Emergency Ends

As of December 31, 2021, the Food and Drug Administration (FDA) had granted full marketing authorization to two COVID-19 tests that enabled them to be marketed beyond the emergency declaration. In order to grant full marketing authorization for this test, FDA reviewed additional validation data beyond what was needed for an EUA.

To help device manufacturers prepare for the eventual termination of the COVID-19 public health emergency, FDA issued draft guidance on December 22, 2021, titled, Transition Plan for Medical Devices Issued Emergency Use Authorizations (EUAs) During the Coronavirus Disease 2019 (COVID-19) Public Health Emergency: Draft Guidance for Industry and Food and Drug Administration Staff. This draft guidance was intended to, among other things, describe FDA's recommendations for medical device manufacturers, including COVID-19 test developers, on how to transition from EUA to full marketing authorization in order to continue distributing their tests after the emergency declaration ends.

Source: GAO summary of FDA information. | GAO-22-104266

FDA Shifted Resources to Conduct Post-Market Monitoring of COVID-19 Tests

FDA officials told us they have been able to adequately conduct post-market monitoring of COVID-19 tests, but, similar to reviewing EUA requests, had to shift resources from other areas in order to do so. Officials told us that FDA had been challenged by the increasing volume of adverse event reports for tests, and by an increase in the number of allegations of fraudulent tests being distributed outside their EUAs. FDA officials told us there was also an increase in reporting of adverse events

to the Electronic Medical Device Reporting system by test developers during this emergency as well.

To address the increase in adverse event reports, FDA officials told us the agency increased the number of staff on the post-market monitoring team for COVID-19 tests. According to FDA officials, this team was composed of eight staff early in the pandemic, as of the second quarter of 2020. To supplement these existing staff, FDA reassigned 12 additional staff in 2020 to assist the existing team. According to FDA officials, these staff reassignments negatively affected FDA's post-market surveillance for other products. According to FDA officials, reassigned staff had to deprioritize their previous workload, which led to shortfalls in non-COVID recall work, among other areas. Officials told us that some of the 12 reassigned staff will become permanent, and others have been gradually reassigned back to their previous FDA divisions.

FDA officials said they also hired four additional staff for the COVID-19 test post-market monitoring team. During the pandemic response, two staff members left this FDA team; thus, the team had a net gain of two full-time equivalent employees aside from the 12 reassigned staff. According to FDA officials, these two additional staff allowed the team to conduct post-market monitoring reviews of COVID tests in more detail. Additionally, to help FDA address the high volume of adverse event reports for tests during the public health emergency, this FDA team automated some of the internal processes to compile adverse event information.

FDA officials told us the agency has submitted a proposal to HHS requesting to hire additional staff to implement an initiative that would, among other goals, help identify COVID-19 test performance problems in real time using real-world data. This initiative is called Semantic Harmonization and Interoperability Enhancement for Laboratory Data.⁵⁶ The purpose of the initiative is to improve the quality, interoperability, portability, and utility of laboratory data and evaluate the real-world performance of SARS-CoV-2 diagnostic and antibody tests. FDA officials told us that FDA is currently able to use laboratory data on COVID-19 tests for surveillance to identify outliers in terms of test performance for

⁵⁶Semantic Harmonization and Interoperability Enhancement for Laboratory Data was established in 2019 and is a multistakeholder collaboration to improve the quality, interoperability and portability of laboratory data within and between institutions so that diagnostic information can be drawn from different sources or shared between institutions.

specific COVID-19 test brands.⁵⁷ FDA officials told us that, with more resources, the initiative could integrate existing laboratory data with patient data from electronic health records to see how test results align with patient diagnoses and outcomes.

Conclusions

Testing is a critical tool in our nation's fight against COVID-19 and FDA took steps to increase the availability of tests early in the pandemic when there was an urgent need for tests. This included issuing policies that enabled certain types of tests to be used prior to FDA review of their accuracy and reliability. However, once hundreds of tests were reviewed and authorized for emergency use, the risks of unauthorized tests being used outweighed the benefits. FDA eventually took action to mitigate this risk in the current pandemic. However, until FDA develops a policy for the use of enforcement discretion regarding unauthorized tests in a future public health emergency—including the conditions under which FDA would begin and end such discretion—the agency could face the risk that unauthorized tests could be used for an extended period of time, even when a sufficient number of authorized tests are available. This could hamper an effective response and recovery during a future crisis.

Recommendation for Executive Action

The Commissioner of FDA should develop a policy for the use of enforcement discretion regarding unauthorized tests in future public health emergencies. This policy should include the conditions under which FDA would begin and end the use of such discretion. (Recommendation 1)

Agency Comments

We provided a draft of this report to HHS for review. In its comments, reproduced in appendix IV, HHS concurred with our recommendation and also stated that FDA did not permit the use of unauthorized tests but instead exercised enforcement discretion to not object to their use. HHS also described some lessons learned from the COVID-19 pandemic that it said could enable faster authorization of tests during a future public health emergency. HHS also provided technical comments, which we incorporated as appropriate.

We are sending copies of this report to the appropriate congressional committees, the Secretary of Health and Human Services and the

⁵⁷The CARES Act included a provision requiring laboratories to submit the result of each COVID-19 test to the Secretary of Health and Human Services in a manner specified by the Secretary. Pub. L. No. 116-136, div. B, § 18115, 134 Stat. 281, 574 (2020).

Commissioner of FDA. In addition, the report is available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff have any questions about this report, please contact Mary Denigan-Macauley at 202-512-7114 or DeniganMacauleyM@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made major contributions to this report are listed in appendix V.



Mary Denigan-Macauley
Director, Health Care

List of Addressees

The Honorable Patrick Leahy
Chairman
The Honorable Richard Shelby
Vice Chairman
Committee on Appropriations
United States Senate

The Honorable Ron Wyden
Chairman
The Honorable Mike Crapo
Ranking Member
Committee on Finance
United States Senate

The Honorable Patty Murray
Chair
The Honorable Richard Burr
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate

The Honorable Gary C. Peters
Chairman
The Honorable Rob Portman
Ranking Member
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Kyrsten Sinema
Chair
The Honorable James Lankford
Ranking Member
Subcommittee on Government Operations and Border Management
Committee on Homeland Security and Governmental Affairs
United States Senate

The Honorable Rosa L. DeLauro
Chair

The Honorable Kay Granger
Ranking Member
Committee on Appropriations
House of Representatives

The Honorable Frank Pallone, Jr.
Chairman
The Honorable Cathy McMorris Rodgers
Republican Leader
Committee on Energy and Commerce
House of Representatives

The Honorable Bennie G. Thompson
Chairman
The Honorable John Katko
Ranking Member
Committee on Homeland Security
House of Representatives

The Honorable Carolyn B. Maloney
Chairwoman
The Honorable James Comer
Ranking Member
Committee on Oversight and Reform
House of Representatives

The Honorable Richard E. Neal
Chairman
The Honorable Kevin Brady
Republican Leader
Committee on Ways and Means
House of Representatives

The Honorable Abigail D. Spanberger
House of Representatives

Appendix I: Additional FDA Actions to Help Increase Access to COVID-19 Tests

In addition to the actions described earlier in this report, the Food and Drug Administration (FDA) took additional actions during the pandemic to help increase access to COVID-19 tests.

FDA Authorization of Tests Based on Data from Contrived Samples

Because of the lack of availability of natural viral material early in the pandemic, FDA authorized tests that used contrived samples—which are made from viral material that may come from a range of sources—to validate test performance from February through mid-May 2020. According to FDA, test developers experienced challenges obtaining the viral material needed for test validation early in the pandemic.¹ Once positive patient samples became more widely available in April and May 2020, FDA began recommending test developers to validate their tests using patient specimens, and required developers of tests that had previously been authorized using contrived material to conduct post-authorization validation studies using patient specimens. According to FDA, the agency authorized 59 COVID-19 tests that had been validated using contrived viral material.

FDA Authorization of Tests Intended for Screening

In June 2020, FDA issued updated emergency use authorization (EUA) templates outlining expectations for the validation of tests for screening asymptomatic individuals. Then, on March 16, 2021, FDA announced it was providing information for test developers about a streamlined path to authorization for tests intended for screening asymptomatic individuals in a serial manner, including tests that could be used at-home and purchased over-the-counter.² According to FDA, serial testing involves testing the same individual multiple times within a few days, and can

¹According to FDA, live virus was listed as available to developers with Biosafety Level-3 capabilities on or about February 6, 2020 from the Biodefense and Emerging Infections Research Resources Repository and on or about February 18, 2020 from the University of Texas Medical Branch. However, most test developers do not have Biosafety Level-3 capabilities. To address the needs of these developers, after conducting testing to ensure that the viral material did not contain any infectious viral particles, these entities produced lots of viral material for developers' use by late February. FDA supported federal government efforts to prioritize the first distribution of viral material to developers working on assays that already had FDA-cleared platforms in U.S. health care centers. FDA also proactively contacted many other developers with whom it had engaged to connect those in need of viral material with the Biodefense and Emerging Infections Research Resources Repository.

²Food and Drug Administration, "FDA Statement: Coronavirus (COVID-19) Update: FDA takes steps to streamline path for COVID-19 screening tools, provides information to help groups establishing testing programs" (March 16, 2021), accessed Mar. 17, 2021, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-steps-streamline-path-covid-19-screening-tools-provides>.

increase chances of detecting asymptomatic infection that might not be identified with a single test. FDA announced that in certain circumstances, a point-of-care or at-home test could be authorized for use without the need for validating its use in asymptomatic individuals prior to authorization.³ FDA stated that it made this change to further expand the availability of tests authorized for screening asymptomatic individuals and increase consumer access to testing.

To increase access to over-the-counter at-home tests, on October 25, 2021, FDA further revised the path to authorization. Specifically, FDA announced that developers of those tests could request authorization to add single-use testing for individuals experiencing COVID-19 symptoms without needing to submit additional data to FDA. According to the Department of Health and Human Services (HHS), this change would allow for manufacturers of these tests to sell the tests singly, rather than in packs of two tests, potentially at a lower price. On the same day, HHS announced the creation of the Independent Test Assessment Program at the National Institutes of Health (NIH). Through this program, experts from NIH, HHS, and the Centers for Disease Control and Prevention (CDC) conducted studies, supported test developers, and provided data for FDA to use when evaluating the tests. HHS stated that the program prioritized new over-the-counter tests with the potential to be manufactured at significant scale. As of April 13, 2022, FDA had authorized five tests that had participated in this program.

³FDA stated in the press announcement the agency's belief that evidence of a test's strong performance in symptomatic patients combined with serial testing can mitigate the risk of false results when testing asymptomatic individuals. Food and Drug Administration, "FDA Statement: Coronavirus (COVID-19) Update: FDA takes steps to streamline path for COVID-19 screening tools, provides information to help groups establishing testing programs" (Mar. 16, 2021).

Appendix II: Summary of Key FDA and HHS Policies That Guided the Regulation of COVID-19 Tests

Table 2: Key FDA and HHS Policies for the Regulation of COVID-19 Tests

Date	Description of Policy
February 29, 2020	FDA issued a policy stating that FDA did not intend to object to laboratories using their diagnostic laboratory developed tests (LDTs) prior to authorization when the laboratories validated their tests, notified FDA, and submitted an emergency use authorization (EUA) request to FDA within 15 business days after notification. ^a
March 16, 2020	FDA issued a policy stating that FDA did not intend to object to commercial manufacturers developing and distributing their diagnostic tests prior to authorization where the manufacturers validated their tests, notified FDA, and submitted an EUA request to FDA within 15 business days after notification. ^{b,c}
	FDA issued a policy stating that FDA did not expect developers of antibody tests, including commercial manufacturers and laboratories, to seek an EUA for these antibody tests where the developers validated their tests, notified FDA, and included certain information in the test reports. ^{c,d}
	FDA issued a policy stating that FDA did not intend to object to states and territories authorizing laboratories within their state or territory to develop and use their own COVID-19 LDTs. ^c
May 4, 2020	FDA issued a policy modifying its previous policy for antibody tests stating that commercial manufacturers of antibody tests were expected to submit an EUA request to FDA within 10 business days after notification or the date on which the guidance was published. ^e
August 19, 2020	HHS announced a policy under which FDA would no longer require premarket review for LDTs, absent notice and comment rulemaking. ^f
March 16, 2021	FDA announced it had taken steps to help streamline the path to authorization for tests intended for screening asymptomatic individuals in a serial manner, including tests that could be used at-home and purchased over-the-counter. ^g
November 15, 2021	HHS withdrew its August 2020 policy under which FDA would not require premarket review for LDTs, thereby reinstating FDA’s approach to regulating COVID-19 LDTs. ^h
	FDA issued a policy stating that the agency generally expected COVID-19 tests to have been issued an EUA prior to the tests being distributed or offered, that FDA would no longer add commercial or laboratory developed tests to the notification lists, and that FDA no longer intended to apply the March 16, 2020 policy to additional states or territories to authorize laboratories within that state or territory to develop and use their own COVID-19 tests. FDA also expected laboratories offering LDTs without submission of an EUA request to submit an EUA request to FDA within 60 calendar days from the date of issuance of the updated guidance or to cease marketing and offering their LDT. ⁱ

Source: GAO summary of guidance and announcements from the Food and Drug Administration (FDA) and the Department of Health and Human Services (HHS). | GAO-22-104266

^aDepartment of Health and Human Services, Food and Drug Administration, Policy for Diagnostic Testing in Laboratories Certified to Perform High Complexity Testing under CLIA prior to Emergency Use Authorization for Coronavirus Disease-2019 during the Public Health Emergency (Immediately In Effect Guidance for Clinical Laboratories and Food and Drug Administration Staff) (Silver Spring, Md.: Feb. 29, 2020).

^bFDA recommended manufacturers post on their websites the test’s instructions for use and data about test performance characteristics.

^cDepartment of Health and Human Services, Food and Drug Administration, Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency (Immediately In Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff) (Silver Spring, Md.: Mar. 16, 2020).

^dFDA recommended developers of antibody tests include certain information in test reports, such as statements that the test had not been reviewed by FDA and that results from antibody testing should not be used as the sole basis to diagnose or exclude SARS-CoV-2 infection.

Appendix II: Summary of Key FDA and HHS Policies That Guided the Regulation of COVID-19 Tests

^eDepartment of Health and Human Services, Food and Drug Administration, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (Immediately In Effect Guidance for Clinical Laboratories, Commercial Manufacturers, and Food and Drug Administration Staff) (Silver Spring, Md.: May 4, 2020).

^fDepartment of Health and Human Services, “Rescission of Guidances and Other Informal Issuances Concerning Premarket Review of Laboratory Developed Tests,” (Aug. 19, 2020), accessed Aug. 20, 2020, <https://www.hhs.gov/coronavirus/testing/recission-guidances-informal-issuances-premarket-review-lab-tests/index.html>.

^gFood and Drug Administration, “FDA Statement: Coronavirus (COVID-19) Update: FDA takes steps to streamline path for COVID-19 screening tools, provides information to help groups establishing testing programs” (March 16, 2021), accessed Mar. 17, 2021, <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-steps-streamline-path-covid-19-screening-tools-provides>.

^hDepartment of Health and Human Services, “Statement by HHS Secretary Xavier Becerra on Withdrawal of HHS Policy on Laboratory-Developed Tests” (Nov. 15, 2021), accessed Nov. 16, 2021, <https://www.hhs.gov/about/news/2021/11/15/statement-hhs-secretary-xavier-becerra-withdrawal-hhs-policy-laboratory-developed-tests.html>.

ⁱDepartment of Health and Human Services, Food and Drug Administration, Policy for Coronavirus Disease-2019 Tests During the Public Health Emergency (Revised) (Immediately In Effect Guidance for Developers and Food and Drug Administration Staff) (Silver Spring, Md.: Nov. 15, 2021).

Appendix III: Additional FDA Actions to Support COVID-19 Test Developers

The Food and Drug Administration (FDA) took several actions during the pandemic to support COVID-19 test developers and assist them as they developed their tests.

- **FDA developed EUA templates.** FDA developed emergency use authorization (EUA) templates to help guide test developers as they developed their tests and prepared their EUA requests.¹ According to FDA officials, the first EUA template for test developers was available to test developers by request in January 2020, and later posted on FDA's website on February 29, 2020.² According to FDA officials, FDA had shared the template with over 100 laboratory and commercial manufacturer developers by the end of February 2020.

As of November 2021, eight EUA templates were available on FDA's website.³ The templates varied by factors such as the type of test and setting for use of the test; officials told us the agency updated, added, and removed templates as necessary to support developers of COVID-19 tests. These templates described the information and data FDA recommended developers include in their EUA request, the types and sizes of validation studies FDA recommended developers conduct to demonstrate the test's performance, and recommended minimum clinical performance standards.⁴ Representatives from one association we spoke with told us the EUA templates were very useful because they showed what types of data FDA was looking for and helped developers know what they needed to focus on to be successful with their EUA request.

¹Test developers were not required to use the EUA templates. FDA encouraged developers who intended to use alternative approaches to consider seeking FDA's feedback or recommendations to help them through the EUA process.

²FDA officials stated that FDA posted a statement on its website regarding the template's availability on January 27, 2020.

³According to FDA officials, FDA had as many as ten posted templates and continues to update, add, combine, and remove templates as the science evolves and as necessary to support developers of COVID-19 tests.

⁴For example, FDA recommended that certain types of validation studies be conducted for SARS-CoV-2 molecular diagnostic assays, including a limit of detection study and a cross-reactivity study. Limit of detection is the minimum amount of target in a sample that a test can accurately measure. Cross-reactivity studies are performed to demonstrate that the test does not react with other pathogens, disease agents, or flora that are reasonably likely to be encountered in a clinical specimen. FDA also recommended that validation studies include data from at least 30 suspected-positive and 30 negative clinical samples.

- **FDA engaged with test developers through the pre-EUA process.** Test developers could submit a pre-EUA request or communicate with FDA via email prior to submission of an EUA request. The pre-EUA process allowed FDA scientific and technical subject matter experts to help facilitate the submission of a complete EUA request. FDA officials told us pre-EUA submissions could also assist in the development of conditions of authorization, fact sheets, and other documentation that would be needed for an EUA. FDA received 1,275 pre-EUA requests for COVID-19 tests between January 2020 and September 2021, according to FDA officials.⁵ Representatives from two associations we spoke with told us that some members found the pre-EUA process to be useful. However, some test developers from one of these associations felt it added to the length of time to develop an EUA request and some wished the process was more transparent.
- **FDA held regular public conference calls.** Beginning March 25, 2020, FDA held weekly or biweekly public Town Hall teleconference calls with test developers to communicate recent updates and to answer questions about the development and validation of COVID-19 tests. As of September 30, 2021, the FDA had held 70 town halls for COVID-19 test developers.
- **FDA posted frequently asked questions on its website.** FDA updated its website with answers to frequently asked questions that test developers could refer to about the development and performance of COVID-19 tests, uses for different types of tests, settings where they can be used, FDA's priorities for reviewing EUA requests, and review times, among other topics.
- **FDA supplied panels of viral material to test developers.** Beginning in May 2020, FDA supplied a reference panel, which contained strains of inactivated virus, to developers of molecular tests to meet a condition of authorization requiring EUA holders to assess their assay performance with an FDA-recommended reference material. Use of this reference panel allowed FDA to more accurately compare the performance of different molecular tests to each other. Representatives from one association told us that the reference panel was helpful to some developers.
- **Collaborated with the National Institutes of Health (NIH).** FDA officials told us they have worked closely with NIH on the Rapid Acceleration of Diagnostics (RADx) program, which aims to speed the development of innovative COVID-19 tests. According to officials,

⁵According to FDA, a pre-EUA package contained data and information about the safety, quality, and efficacy of the product and its intended use.

Appendix III: Additional FDA Actions to Support COVID-19 Test Developers

FDA meets regularly with RADx participants to answer questions and provide feedback on validation plans. Officials told us that as of February 2022, FDA had authorized over 30 tests that participated in RADx programs. These tests included over-the-counter at-home tests, point-of-care tests, high throughput laboratory-based tests, and tests that detect multiple viruses, many of which include novel technologies.

Appendix IV: Comments from the Department of Health and Human Services



DEPARTMENT OF HEALTH & HUMAN SERVICES

OFFICE OF THE SECRETARY

Assistant Secretary for Legislation
Washington, DC 20201

April 8, 2022

Mary Denigan-Macauley
Director, Health Care
U.S. Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Ms. Denigan-Macauley:

Attached are comments on the U.S. Government Accountability Office's (GAO) report entitled, **"COVID 19: FDA Took Steps to Make Tests Available; Policy for Future Public Health Emergencies Needed"** (Job code 104266/GAO-22-104266).

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Melanie Anne Egorin

Melanie Anne Egorin, PhD
Assistant Secretary for Legislation

Attachment

**Appendix IV: Comments from the Department
of Health and Human Services**

**GENERAL COMMENTS FROM THE DEPARTMENT OF HEALTH & HUMAN
SERVICES ON THE GOVERNMENT ACCOUNTABILITY OFFICE'S DRAFT REPORT
ENTITLED — COVID 19: FDA TOOK STEPS TO HELP MAKE TESTS AVAILABLE;
POLICY FOR FUTURE PUBLIC HEALTH EMERGENCIES NEEDED (GAO-22-104266)**

The U.S. Department of Health & Human Services (HHS) appreciates the opportunity from the Government Accountability Office (GAO) to review and comment on this draft report.

Recommendation 1

The Commissioner of FDA should develop a policy that governs its use of enforcement discretion to permit the use of unauthorized tests in future public health emergencies. This policy should include the conditions under which FDA would begin and end permitting the use of such tests.

HHS Response

HHS *concur*s with GAO's recommendation. However, FDA did not permit the use of these tests. Rather, FDA exercised its enforcement discretion to not object to the use of certain COVID-19 tests even though these tests had not yet obtained pre-market approval or emergency use authorization.

The FDA has publicly discussed some of the lessons learned from the COVID-19 pandemic. These center around it being more effective for public health to authorize a small number of high-capacity tests, rather than diffuse resources for the authorization of many lower capacity tests. This approach would necessarily include government investment and pre-planning to have relationships in place with contract manufacturers, commercial manufacturers, and laboratories, as well as collaborative development of validation protocols for commonly anticipated pathogens and sample types before an outbreak. While this advanced preparation would enable faster authorization of tests to address the public health needs in a potential future public health emergency, there may still be instances where an FDA policy of generally not objecting to the use of certain unauthorized tests would be beneficial to address a specific public health need for a discrete period of time. Development by the FDA of a policy regarding use of enforcement discretion policies in such situations, including factors relating to its start and end, would provide some predictability, a more streamlined process, and transparency regarding what FDA may consider in determining the scope, risk mitigations, and duration of the enforcement discretion policy.

Appendix V: GAO Contact and Staff Acknowledgments

GAO Contact

Mary Denigan-Macauley at (202) 512-7144 or DeniganMacauleyM@gao.gov

Staff Acknowledgments

In addition to the named contact above, Tom Conahan, Assistant Director; Laura Tabellion, Analyst-In-Charge; Margot Bolon; Carolyn Garvey; and Cathy Whitmore made key contributions to this report. Also contributing were George Bogart, Sandra George, Vikki Porter, Jeffrey Tamburello, Janet Wilson, and Chris Zakroff.

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