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

As of September 30, 2021, FDA had exercised its enforcement discretion for 370 tests. Test developers had submitted EUA requests to FDA that include data on a test’s performance, and FDA reviews the data to determine whether to grant an EUA. 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.