CDC’s Internal Control Weaknesses Led to Its Initial COVID-19 Test Kit Failure, but CDC Ultimately Created a Working Test Kit

What OIG Found
Ultimately, CDC developed a viable COVID-19 test kit within 2 months of China publishing the genome sequence of the novel virus that caused the COVID-19 outbreak. However, some of the initial COVID-19 test kits that CDC developed and distributed to public health laboratories could not be verified by the public health laboratories, and CDC initially identified multiple potential causes of this failure. We identified weaknesses in CDC’s COVID-19 test kit development processes and the agencywide laboratory quality processes that may have contributed to the failure of the initial COVID-19 test kits.

Without effective internal controls, CDC may: (1) experience delays in the development of test kits when responding to future public health emergencies; (2) not identify problems in a timely manner when developing test kits; and (3) risk damaging public trust, which could undermine its ability to accomplish its mission.

What OIG Recommends and CDC Comments
We made several recommendations to CDC, including that CDC: (1) create policies and procedures for developing test kits, (2) ensure that the recently finalized Graduated Response Framework addresses our report findings, (3) develop and implement documented processes to ensure that adequate staffing and laboratory space can be obtained for future responses, (4) re-evaluate the Incident Management System structure at all levels of CDC’s response framework and integrate positions or roles and responsibilities that provide effective oversight of a laboratory-based response effort, (5) implement a CDC-wide laboratory document control system, and (6) ensure that all infectious disease laboratories implement and periodically evaluate a laboratory quality management system.

In response to our draft report, CDC neither concurred nor nonconcurred with our recommendations. Instead, CDC discussed actions it has taken or plans to take to implement our recommendations. CDC stated that it developed a Laboratory Quality Plan to address issues of quality and oversight. CDC also stated that it published documentation outlining laboratory functions during an emergency response, evaluated the operating effectiveness of its internal controls, and elevated oversight of emergency response efforts to ensure accountability. Finally, CDC stated that it is continuing to work on the implementation of the electronic quality management system, which facilitates laboratory quality activities. We commend CDC on the actions it has taken or is taking to address our recommendations.

The full report can be found at https://oig.hhs.gov/oas/reports/region4/42002027.asp.