MAYNARDNEXSEN

A Glimpse at Recent State and Federal COVID-19 Testing Developments

Related Professionals

Matthew B. Roberts
803.253.8286
mroberts@maynardnexsen.com

05.12.2020

At both the state and federal level, COVID-19 testing is the focus of regulatory activity. On May 6, 2020, the South Carolina Department of Health and Environmental Control announced that it will conduct statewide COVID-19 testing of nursing home residents and staff, beginning May 11, 2020.

The FDA continues to expand its emergency use authorization (EUA) approvals. On May 7, 2020, the agency authorized the first diagnostic test with the option of using home-collected saliva samples for COVID-19 testing. Specifically, the FDA issued an EUA to Rutgers Clinical Genomics Laboratory for their COVID-19 laboratory developed test (LDT), which had been previously authorized under the high complexity molecular-based LDT "umbrella" EUA, to permit testing of samples self-collected by patients at home using the Spectrum Solutions LLC SDNA-1000 Saliva Collection Device.

On May 9, 2020, the FDA authorized the first antigen rapid detection test. These diagnostic tests quickly detect fragments of proteins found on or within the virus by testing samples collected from the nasal cavity using swabs. The EUA was issued late Friday to Quidel Corporation for the Sofia 2 SARS Antigen FIA. This test is authorized for use in high and moderate complexity laboratories certified by Clinical Laboratory Improvement Amendments (CLIA), as well as for point-of-care testing by facilities operating under a CLIA Certificate of Waiver.

On May 8, 2020, the FDA issued a Daily Roundup summarizing its recent test development activities.

- During the COVID-19 pandemic, the FDA has worked with more than 385 test developers who have said they will be submitting EUA requests to the FDA for tests that detect the virus.
- To date, the FDA has issued 65 individual EUAs for test kit manufacturers and laboratories. In addition, 25 authorized tests have been added to the EUA letter of authorization for high

complexity molecular-based laboratory developed tests (LDTs).

- → The FDA has been notified that more than 245 laboratories have begun testing under the policies set forth in our COVID-19 Policy for Diagnostic Tests for Coronavirus Disease-2019 during the Public Health Emergency Guidance.
- → The FDA also continues to keep its COVID-19 Diagnostics FAQ up to date.

If you have any questions regarding these recent developments, please reach out to Darra James Coleman or Matthew Roberts.

Our insights are published as a service to clients and friends. They are intended to be informational and do not constitute legal advice regarding any specific situation.