CDC Centers for Disease Control and Prevention

04/09/2020: Lab Update: FDA Clarifies CLIA-waived Status for Point-of-Care SARS-CoV-2 Tests under Emergency Use Authorizations

Audience: Clinical Laboratory Professionals

Level: Laboratory Update

FDA Clarifies CLIA-waived Status for Point-of-Care SARS-CoV-2 Tests under Emergency Use Authorizations

The U.S. Food and Drug Administration (FDA) recently clarified that, when it grants an Emergency Use Authorization (EUA) for a point-of-care test, that test is deemed to be CLIA-waived. For the duration of the national emergency declaration for COVID-19, such tests can be performed in any patient care setting that operates under a CLIA Certificate of Waiver or Certificate of Compliance/Certificate of Accreditation.

In addition, FDA clarified that tests for SARS-CoV-2 that are offered prior to or without an EUA have not been reviewed by FDA, are not FDA authorized, and have not received a CLIA categorization. Thus, those tests are considered high complexity by default until they receive an EUA or other FDA approval that indicates they may be performed as moderate complexity or waived tests.

For more information, visit this FDA Web page, navigate to the section titled "General FAQs," and view the first two questions and their corresponding answers.

Additional Resources:

- Clinical Laboratory Improvement Amendments (CLIA)
- Clinical Laboratory COVID-19 Response Weekly Calls
- CDC COVID-19 Information for Laboratories
- CDC COVID-19 Website
- Register for CDC Health Alert Network (HAN) notifications, including updates about COVID-19. Enter your email address to sign up.

Laboratory Outreach Communication System | Division of Laboratory Systems (DLS)

Center for Surveillance, Epidemiology, and Laboratory Services (CSELS)

Centers for Disease Control and Prevention (CDC)

LOCS@cdc.gov

www.cdc.gov/csels/dls/locs

Page last reviewed: April 10, 2020