

Updated CLIA SARS-CoV-2 Molecular and Antigen Point of Care Test Enforcement Discretion

What is CMS's policy regarding laboratories performing SARS-CoV-2 molecular and antigen tests authorized by the Food and Drug Administration (FDA) under an Emergency Use Authorization (EUA) for use at the point of care (POC) or in patient care settings operating under a Clinical Laboratory Improvement Amendments of 1988 (CLIA) certificate on asymptomatic individuals?

CMS requires facilities with a CLIA Certificate of Waiver to follow the manufacturer's instructions (Instructions for Use) when performing laboratory testing. In addition, CMS requires facilities that perform non-waived testing ("non-waived facilities") that modify an FDA-authorized, cleared or approved test system to establish performance specifications before reporting patient test results. The FDA has granted EUAs to certain molecular and antigen POC tests for particular indications, including antigen tests that are intended to test specimens from individuals who are suspected of COVID-19 by their healthcare provider within a certain number of days after the onset of symptoms, as specified in each test's EUA and Instructions for Use. The FDA has provided recommendations and information for health care providers who are ordering authorized tests outside the test's authorization (e.g., antigen tests for asymptomatic individuals) – see [FDA's FAQ on Testing for SARS-CoV-2](#) ("Q: Does the FDA have recommendations for health care providers using SARS-CoV-2 diagnostic tests for screening asymptomatic individuals for COVID-19?") for further information.

CMS will temporarily exercise enforcement discretion under CLIA for the duration of the COVID-19 public health emergency for the use of authorized SARS-CoV-2 molecular and antigen POC tests on asymptomatic individuals outside of the test's authorization. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when authorized SARS-CoV-2 molecular or antigen POC tests are performed on asymptomatic individuals outside of the test's authorization, when done so considering the information in [FDA's FAQ](#). In addition, CMS will not cite nonwaived facilities when modified authorized, cleared or approved SARS-CoV-2 molecular or antigen POC tests are performed in such manner without establishing performance specifications.

Updated 12/07/2020