

What is CMS’s policy regarding laboratories performing 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 of Waiver 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. The FDA has granted Emergency Use Authorizations (EUA) to certain antigen tests for testing specimens from individuals who are suspected of COVID-19 by their healthcare provider within a number of days after the onset of symptoms, specific to each authorized test’s validated performance. The FDA has provided recommendations for health care providers who are ordering authorized tests outside their 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 for the duration of the COVID-19 public health emergency under CLIA for the use of SARS-CoV-2 POC antigen tests on asymptomatic individuals. Specifically, CMS will not cite facilities with a CLIA Certificate of Waiver when SARS-CoV-2 POC antigen tests are performed on asymptomatic individuals, as described in the [FDA FAQ](#).