

SARS-CoV-2 Point of Care Testing and CLIA Certificate of Waiver Applications

Question: My facility has submitted a CMS-116 application for a Clinical Laboratory Improvement Amendments (CLIA) Certificate of Waiver (CoW) to perform Point of Care (POC) SARS-CoV-2 testing authorized by the Food and Drug Administration (FDA) to be performed in a waived setting. When am I able to begin testing?

Answer: In order to perform SARS-CoV-2 POC testing and report patient-specific results, a facility must be a CLIA-certified laboratory or testing site that meets applicable regulatory requirements.

CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 POC testing when a facility has submitted a CMS-116 application for a CLIA CoW, but has not yet been assigned a CLIA number. Specifically, facilities that have applied for a CLIA CoW to perform SARS-CoV-2 POC testing (as indicated on section VI of the submitted CMS-116) can begin SARS-CoV-2 POC testing and reporting patient-specific results as soon as they have submitted their application to their State Agency (SA). A non-certified facility will be treated as operating under CoW while their application is being processed.

Facilities that have submitted a CMS-116 application for a CLIA CoW should check with their SA before they begin testing as states may have additional licensure requirements that must be met before testing can begin.