



OKLAHOMA

State Department of Health

CMS Direction on COVID-19 Testing

September 29, 2022

CMS Rescinds Use of SARS-CoV-2 Tests Under Specific Situations

On September 26, 2022, CMS issued [QSO-22-25-CLIA Memo](#) indicating CMS is rescinding the December 7, 2020, Enforcement Discretion for the Use of SARS-CoV-2 Tests on Asymptomatic Individuals Outside of the Test's Instructions for Use.

Overview of revisions effective immediately:

- CMS is rescinding the enforcement discretion that allowed Certificate of Waiver labs to perform SARS-CoV-2 molecular and antigen Point of Care (POC) tests on asymptomatic individuals outside of the test's authorization.
- CMS is also rescinding the enforcement discretion that allowed non-waived labs to perform SARS-CoV-2 molecular and antigen tests on asymptomatic individuals outside of the test's authorization without establishing performance specifications.
- All CLIA certified laboratories are required to follow the manufacturer's instructions for use with regards to the intended use for SARS-CoV-2.
- In order to use any test for SARS-CoV-2 outside of the test's authorization, a laboratory must be a high-complexity laboratory.
- In addition, the laboratory must establish performance specifications as required by the CLIA regulations at 42 CFR 493.1253 before reporting patient test results.

Review [QSO-22-25-CLIA](#) for complete information.

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