



CLINICAL LABORATORY IMPROVEMENT AMENDMENTS (CLIA)

CLIA-Certified Labs: New CMS SARS-CoV-2 Testing Resource Available

New CMS Tool Outlines Testing Requirements for SARS-CoV-2

CMS has released a new tool [ADMIN 20-06-CLIA](#) for CLIA-certified laboratories that are testing for SARS-COV-2. The tool provides information on:

- The types of SARS-CoV-2 testing and FDA authorization/notification
- CLIA certifications under which each test can be performed
- An explanation of requirements under each testing scenario
- Information for Medicare beneficiaries on testing services and coverage

A CLIA memo [ADMIN 20-06-CLIA](#) has been released with the tool that provides further guidance about SARS-CoV-2 testing, such as:

- Background on CMS's commitment to respond to SARS-CoV-2
- Requirement for laboratories to have a CLIA certificate to perform SARS-CoV-2 testing
- Different policies for [FDA authorization/notification](#) that laboratories and manufacturers can use for their SARS-CoV-2 assays
- Overview of four different certificate types

The new tool and memo can be found on the CMS CLIA website [ADMIN 20-06-CLIA](#).

For questions or concerns relating the new tool and memo, please contact LabExcellence@cms.hhs.gov

Additional Resources:

- [CLIA Lab Policy Guidance for COVID-19](#)
- [CLIA FAQs for COVID-19](#)
- [FDA Emergency Use Authorization](#)
- [FDA policy guidance for COVID-19 diagnostic tests](#)
- [FDA FAQs on Diagnostic Testing for SARS-CoV-2](#)
- [CDC 2019 Novel Coronavirus Laboratory Biosafety](#)
- [CDC Information for Laboratories: 2019-nCov](#)
- [CDC 2019 Novel Coronavirus](#)
- [CDC Standard Operating Procedure for Labs to Create VTM](#)

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For more information, visit the [CMS CLIA Program website](#)

Centers for Medicare & Medicaid Services