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
For more information, visit the CMS CLIA Program website.