

CLIA SARS-CoV-2 Variant Testing Frequently Asked Question

Date: 3/19/2021

Does a facility that performs surveillance testing to identify SARS- CoV-2 genetic variants need a CLIA certificate?

CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 genetic variant testing on identified specimens in which patient-specific results are reported to State or local Public Health Departments. As defined by Centers for Disease Control and Prevention (CDC), public health surveillance testing for SARS-CoV-2 is intended to monitor community- or population-level outbreaks of disease, or to characterize the incidence and prevalence of disease. Public health surveillance testing is performed on de-identified specimens, and thus results are not linked to individuals. Public health surveillance testing cannot be used for individual decision-making. See CDC's [Testing Strategies for SARS-CoV-2 \(Frequently Asked Questions about Coronavirus \(COVID-19\) for Laboratories\)](#).

Generally, surveillance testing using sequencing technology to identify SARS-CoV-2 genetic variants can be performed in a facility that is NOT CLIA certified, provided that patient-specific results are not reported to (1) the individual who was tested or (2) their health care provider. If at any time a facility intends to perform testing on identified specimens and report a patient-specific SARS-CoV-2 genetic variant test result to the individual who was tested or to their health care provider, the facility must comply with CLIA and is thereby required to obtain the appropriate CLIA certificate in accordance with 42 CFR Part 493, laboratory requirements.

However, as indicated above, CMS will not take action against non-CLIA certified facilities that perform SARS-CoV-2 genetic variant testing on identified specimens and report patient-specific results to State or local Public Health Departments, provided that the facility only reports patient-specific results to a Public Health Department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment. The Public Health Departments should only use these results for public health purposes, such as contact tracing, outbreak detection, etc. If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA certified laboratory and in compliance with all applicable CLIA regulations (42 CFR part 493).

CLIA-certified laboratories continue to be permitted to report patient-specific results to authorized persons, which may include the individual who was tested, their health care provider, or a Public Health Department¹, as applicable, for SARS-CoV-2 genetic variant testing and other tests. If a CLIA certified laboratory performing SARS-CoV-2 genetic variant testing decides to report patient-specific results to an individual or their healthcare provider, then the laboratory must establish performance specifications for their assay. See 42 CFR §493.1253(b)(2). CLIA regulations are not prescriptive as to the number of samples required to establish performance specifications. When a genetic variant is discovered during a public health emergency, there may be very limited number of samples available for the establishment of performance specifications. This does not necessarily prevent laboratories from utilizing assays testing for the novel variant. When the number of samples that a laboratory would normally run for the establishment of performance specifications are not available, it is the responsibility of the laboratory director (LD) to ensure that procedures used are adequate to establish the accuracy, precision, and other pertinent performance characteristics of the method. While initially there may not be many samples to establish performance specifications, as time goes on, and as more samples become

¹ While most if not all public health departments would likely meet the CLIA definition of an "authorized person", see 42 CFR §493.2 ("Authorized person means an individual authorized under State law to order tests or receive test results, or both."), this would technically be determined on a case-by-case basis.

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available, the LD may choose to enhance their assay to the level of other tests in their laboratory.

However, CMS will not cite CLIA certified laboratories that perform SARS-CoV-2 genetic variant testing on identified specimens and report patient-specific variant results to State or local Public Health Departments without establishing performance specifications as required by §493.1253(b)(2), provided that the laboratory only reports patient-specific results to a Public Health Department and the results are not intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment. If at any time the SARS-CoV-2 genetic variant result is intended to be used for purposes of an individual's diagnosis, prevention, treatment, or health assessment, the test must be performed in a CLIA-certified laboratory and in compliance with all applicable CLIA regulations.