

Frequently Asked Questions: SARS-CoV-2 Surveillance Testing

Revised 10/21/21

1. Does my facility need a CLIA certificate if we are performing SARS-CoV-2 surveillance testing using a pooled sampling procedure with non patient-specific reporting?

A. During this COVID-19 Public Health Emergency, facilities performing SARS-CoV-2 surveillance testing using a pooled sampling procedure to report non patient-specific SARS-CoV-2 cohort results will not require CLIA certification. This testing is not considered by CMS to be diagnostic of SARS-CoV-2 infection, and participants should not rely on information received from this type of testing for decision making purposes.

If at any time a patient specific result is to be reported by your facility, you must first obtain a CLIA certificate and meet all requirements to perform testing.

2. What are the potential risks of using a surveillance pooled sampling procedure?

A. ~~Currently, there are no tests authorized by FDA for use on pooled specimens. In addition,~~ There may be a risk of obtaining false negative or false positive results when utilizing a pooled sampling testing model. According to the FDA website, “Surveillance with pooled or batched testing should be validated on a test platform and test of high sensitivity and positive tests should have a confirmatory test. Because samples are diluted, which could result in less viral genetic material available to detect, there is a greater likelihood of false negative results, particularly if not properly validated.” To possibly mitigate this risk, all positive and inconclusive SARS-CoV-2 results from pooled sampling must be confirmed by having each participant whose sample was contained within the cohort to be tested by a CLIA-certified facility.

3. Will CMS have oversight of testing facilities that perform pooled surveillance SARS-CoV-2 testing?

A. As these facilities are not CLIA certified, CMS will have no oversight authority to ensure quality and safety of result reporting.