## Frequently Asked Questions: SARS-CoV-2 Surveillance Testing

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- 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 <u>non patient-specific</u> 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 <u>patient specific result</u> is to be reported by your facility, you <u>must first</u> 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.