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?
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 surveillance testing is not considered by CMS to be diagnostic of SARS-CoV-2 infection, and individuals undergoing testing should not rely on information received from this type of testing for decision making purposes.

2. **With some of the other surveillance platforms that use next-generation sequencing, there is no need for a pooling strategy (the samples are all bar-coded) – in that instance, is it acceptable for the university to notify a specific person that he or she should seek testing in a CLIA lab?**
Generally, SARS-CoV-2 surveillance testing can be performed in a facility that is NOT CLIA certified, and may use a test or technique NOT authorized by the FDA, provided that patient-specific results are not reported. If at any time a patient-specific result is reported, the facility is subject to CLIA and required to obtain an appropriate CLIA certificate in accordance with 42 CFR part 493.

However, CMS is temporarily exercising enforcement discretion under CLIA for SARS-CoV-2 surveillance testing where patient-specific results are reported (e.g., SARS-CoV-2 surveillance testing that does not utilize a pooling strategy). Specifically, neither CMS nor the State survey agencies on its behalf will cite non-CLIA certified facilities, such as university laboratories, that are performing such testing, provided that the facility does not report actual test results, but only refers an individual with a presumptive positive or inconclusive test result to a CLIA-certified laboratory for further testing.

3**. If my University lab is not currently CLIA certified, what options are available to become CLIA certified or operate under an existing CLIA certificate?**
As noted on our March 26, 2020 memorandum (https://www.cms.gov/files/document/qso-20-21-clia.pdf-0), CMS is committed to taking critical steps to ensure America's clinical laboratories are prepared to respond to the threat of COVID-19 and to expand laboratory capacity during the public health emergency. University laboratories have several pathways to begin testing during the public health emergency:

- University labs may operate under the existing CLIA certificate of an affiliated University lab, including as a temporary remote location of an existing lab. During this public health emergency, CMS is not enforcing the requirement to have a separate certificate for laboratories that are located at a temporary testing site, provided that the designated primary site has such a certificate and the work being performed in the temporary testing site falls within the parameters of the primary site's certificate.
- University labs may also apply for a CLIA certificate. CMS wants to ensure that laboratories located in the United States wishing to perform COVID-19 testing are able to begin testing as quickly as possible during the public health emergency, and have therefore expedited our review of CLIA certificate applications. Once the lab has identified a qualified lab director and has provided all required information, a CLIA number will be assigned and the lab can begin testing.
    - University labs may utilize the same lab director as an existing University CLIA-certified lab, even if the laboratory director supervises from a different university location.
    - Labs may also contract with a non-university affiliated lab director who meets CLIA requirements to operate the lab and fill the role of laboratory director.