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TO: Clinical Laboratories
FROM: Wadsworth Center New York State Department of Health

Health Advisory: SARS-CoV-2 Surveillance (non-diagnostic) Testing on Pooled Samples

Background

Accommodating large testing workloads has presented a major challenge to laboratory facilities during the COVID-19 pandemic. Sample pooling has been suggested as an additional strategy to address this issue. Information and guidance on SARS-CoV-2 testing on pooled specimens has been provided by the U.S. Food and Drug Administration (FDA) and the Center for Medicare and Medicaid Services (CMS). This advisory is being issued to:

- describe how CMS' ruling impacts laboratories performing SARS-CoV-2 surveillance (non-diagnostic) testing on pooled specimens originating from New York State (NYS).
- provide guidance on approaches for performing SARS-CoV-2 testing on pooled specimens.

Oversight of SARS-CoV-2 Surveillance (non-diagnostic) Testing on Pooled Samples

- CMS issued a Frequently Asked Questions (FAQs) document describing requirements for laboratories performing SARS-CoV-2 surveillance and diagnostic testing on pooled specimens. The FAQs can be found at: https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf.
- CMS determined that 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.
- Based on CMS' determination, a laboratory performing SARS-CoV-2 surveillance (non-diagnostic) testing on pooled specimens originating from NYS will not be required to hold a New York State clinical laboratory permit or have temporary approval to perform SARS-CoV-2 testing.
- If patient specific results will be reported by a laboratory, this is considered to be diagnostic testing and the laboratory will need to have the appropriate approvals from the New York State Department of Health (the Department) prior to performing testing. Additional information on requirements for performing SARS-CoV-2 diagnostic testing using pooled sampling can be found in the Advisory on Diagnostic Testing on Pooled Samples.

Considerations when performing SARS-CoV-2 Surveillance (non-diagnostic) Testing on Pooled Samples

- There are multiple ways to pool specimens for testing. For example:
  - Multiple swabs are placed into a single tube of transport medium at the time of collection and an aliquot of transport media from the pooled specimens is tested. This requires performing a repeat specimen collection on each patient, to facilitate retesting, should the pool test as positive.
  - Individual swabs are placed into individual tubes of transport media, an aliquot of transport media is taken from each individual sample, pooled into another tube and then an aliquot of the pooled specimen is added into the first stage of the sample processing tube (lysis buffer). The individual residual specimens remain separate and available for retesting if needed.
  - Individual swabs are placed into individual tubes of transport media and an aliquot of transport media is taken from each individual sample and added into the first stage of the sample processing tube (lysis buffer). The individual residual specimens remain separate and available for retesting if needed.
- It is recommended that the published literature on this topic be reviewed before making a final decision on which sample pooling method to use.
- The pooling strategy is only useful when disease prevalence is low, otherwise pools are too frequently positive and too frequently have to be deconvoluted for retesting of individual specimens.
- Some methods have an inherent risk of reduced sensitivity and pooling large numbers of specimens will always reduce the detection sensitivity.
- Even when there is no calculated theoretical loss of sensitivity, it is imperative that laboratories perform empirical testing to determine the impact on the limit of detection and ensure that it has not been significantly adversely impacted by the process.
- The impact on the entire laboratory process needs to be carefully assessed prior to implementing a pooling strategy. Other aspects of the testing process should be considered, such as specimen accessioning, the protocols that need to be established to identify patient specimens that need retesting if a pooled specimen is positive, and reporting of results, which are not streamlined and may be complicated by pooling procedures.
- For additional guidance on strategies that can be used to validate methods used for testing pooled samples, see the Department's Health Advisory on Diagnostic Testing on Pooled Samples and the FDA's Molecular Diagnostic Template for Laboratories that is found in the General FAQs section in the question about sample pooling (see https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-testing-sars-cov-2).
- SARS-CoV-2 surveillance testing on pooled specimens should be used in conjunction with other approaches for surveillance such as performing temperature screening of individuals and checking for symptoms of possible infection.