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

Health Advisory: Guidance on SARS-CoV-2 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 diagnostic testing on pooled specimens originating from New York State (NYS).
- provide information on requirements that need to be met by clinical laboratories performing SARS-CoV-2 diagnostic testing on pooled specimens.

Oversight of SARS-CoV-2 Diagnostic Testing on Pooled Samples

- CMS issued a Frequently Asked Questions (FAQs) document describing requirements for laboratories performing SARS-CoV-2 surveillance (non-diagnostic) 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.
- 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. Additional information on requirements for performing SARS-CoV-2 surveillance (non-diagnostic) testing on pooled Samples can be found in the [Advisory on SARS-CoV-2 Surveillance \(non-diagnostic\) Testing on Pooled Samples](#).
- If patient specific results will be reported by a laboratory, this is considered to be diagnostic testing and the laboratory will need to meet the requirements described below.

Requirements for SARS-CoV-2 Diagnostic Testing on Pooled Samples

Permit Requirements

- If a laboratory is performing SARS-CoV-2 testing on pooled samples that originate from New York State (NYS) and patient specific results will be reported by the laboratory, the NYS Department of Health (the Department) has determined that the laboratory must hold a clinical laboratory permit that includes the category of virology or have obtained temporary approval in accordance with Executive Order 202.10.
- Executive Order 202.10 allows laboratories holding a Clinical Laboratory Improvement Acts (CLIA) certificate and meeting the CLIA quality standards described in 42 CFR Subparts H, J, K and M, to perform testing for the detection of SARS-CoV-2 in specimens collected from individuals suspected of suffering from a COVID-19 infection.
- For additional information on permit requirements or obtaining temporary approval, please contact the Clinical Laboratory Evaluation Program (CLEP) at clep@health.ny.gov.

Requirements for Test Approval

- The FDA has given the Department's Wadsworth Center the authority to approve molecular-based COVID-19 laboratory developed tests (LDTs) used to detect SARS-CoV-2 for qualified laboratories during this public health emergency.
- Laboratories using SARS-CoV-2 diagnostic tests on pooled samples will be required to validate the LDT. The validation procedures used will depend on whether the test being used has been previously approved by the FDA or NYS or if it is a new test not yet authorized by NYS or the FDA.
- Testing can begin once the appropriate Certificate of Qualification holder/Laboratory Director has signed off on the assay as it will be run in the lab. Send an email to clepval@health.ny.gov stating that you have validated a molecular test for COVID-19, together with a brief description of the method. Please put "COVID-19 molecular LDT approval request" and your PFI number and/or CLIA number in the subject line.
- Within 15 days of your email notification, you will be required to submit your validation studies for review. Information can be submitted to clepval@health.ny.gov. Please put "COVID-19 molecular LDT submission" and your PFI number and/or CLIA number in the subject line.
- If our review identifies any concerns, we will require your laboratory to stop testing until the concerns are addressed.

Pooling Strategy Considerations

- 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.
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- 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 procedures 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.
- Establish the number of samples to be combined in each pool for testing. This should be established for each specimen type that will be pooled (note; pools must consist of the same specimen type).

Validation Requirements

Additional information on the validation studies that need to be performed can be found in the [Wadsworth Center Validation Procedure for SARS-CoV-2 LDTs](#).