IDAHO DEPARTMENT OF HEALTH & WELFARE
DIVISION OF PUBLIC HEALTH

Idaho Interim Guidance on Use of Pooled Testing for Detection of SARS-CoV-2

August 31, 2020

Pooling Overview

Pooling or pooled testing is an approach that combines aliquots of specimens from several people into a composite sample that is tested using a very sensitive method like polymerase chain reaction (PCR). If the composite sample tests negative, then all specimens contributing to the composite sample can be presumed to be negative. If the composite sample tests positive, then each specimen must be retested individually to determine the patient's status. Pooling increases test volume and conserves materials when almost all samples in composite sample are negative. Pooling efficiency decreases (*i.e.,* retesting rates increase) when a larger number of specimens is in the composite sample and when the positivity rate in the test population goes up. As the positivity rate increases the composite sample size must decrease to reduce the number of reruns and maintain pooling efficiency. Ultimately, at high positivity rates (10-15% or more), pooling takes more time and materials than individual testing. When the positivity rate is less than 3-5%, pooling allows laboratories to test more people using fewer resources if the laboratory has the infrastructure in place to process and report a higher volume of tests.

Recent Developments

As of August 24, 2020, the Food and Drug Administration (FDA) has issued Emergency Use Authorization (EUA) for pooled testing at Quest Diagnostics (4:1 composite), LabCorp (5:1 composite), and Poplar Healthcare (7:1 composite) utilizing upper respiratory swab specimens in viral transport media. These EUAs are limited to the platforms and laboratories referenced by the FDA and do not pertain to the commonly utilized platforms throughout Idaho including Hologic, BD Max and ThermoFisher, among others. The use of pooled testing in diagnostic settings is currently limited to those utilizing the services of those laboratories with an EUA in place.

Recommendations for Idaho Laboratories

It is the opinion of Idaho's Testing Task Force that pooling should not be used for diagnostic purposes, especially in sick individuals or exposed patients with high clinical suspicion of COVID-19. The Task Force is also not recommending early adoption of pooling through an individual EUA for most laboratories. Early adoption of a pooling strategy will require a CLIA laboratory director to have approved full analytical validation of the method, which will require substantial time and effort, a very large validation panel, regular monitoring of population positivity rates,

and will require review and authorization by the FDA for each site. Use of sample pooling at the individual lab level may also add substantial certification or accreditation compliance risks and liabilities.

The Task Force would prefer to see pooling authorized under the EUA for the commonly used molecular tests before widespread adoption in Idaho, so that it can be run on-label. This will simplify future compliance issues and provide a community of practice that could rapidly identify accuracy issues or non-conforming events. If pooling is not added to current EUAs as an on-label option before Idaho's positivity decreases to below 3-5%, then use of pooled testing through individual EUAs should be revisited.

In the interim, the Task Force does recommend a limited exploration of pooled testing for public health screening or surveillance measures in certain large populations with a very low pre-test probability of being positive. Pursuant to the Centers for Disease Control and Prevention (CDC) guidelines issued on July 23, 2020, and updated August 1, 2020, we adopt the following screening and surveillance definitions:

- **Screening.** As defined by the CDC, screening is "*intended to identify occurrence at the individual level even if there is no reason to suspect infection—e.g., there is no known exposure".* When deployed, pooled testing for screening will identify instances of infection which should be verified through separate diagnostic testing at the individual level.
- **Surveillance.** As defined by the CDC, surveillance is the set of "*ongoing systematic activities, including collection, analysis, and interpretation of health-related data that are essential to planning, implementing, and evaluating public health practice".* Such approaches may be considered throughout Idaho at the local public health district, county and municipal levels of government to measure the progress of public health pandemic response and intervention efforts as a part of a broader public health toolkit. Of note, surveillance samples can only be reported in aggregate – no individual level results are provided.

Proposed Pilots

The Task Force proposes several potential pilots to evaluate the potential use of pooled testing:

1. Facilities should consider partnering with their reference laboratories to implement short-term pilots with Quest, LabCorp, and Poplar Health (or other authorized sites) to test applicability of pooled testing in certain low risk populations like elective medical procedure screening with hospital system and surgery center partners.
2. When the new high-throughput laboratories in Moscow, Pocatello and the Treasure Valley are operational, those facilities should pilot programs focused on screening or surveillance of essential and frontline employees in the absence of any reported outbreaks or exposures and in locations with without community spread.

3. State university systems and the Department of Veterans Affairs should consider pilot projects to test applicability of pooled testing for screening and surveillance in congregate settings, in the absence of any reported outbreaks or exposures and in locations with without community spread.

Additional Information and Limitations

For additional information around the use of pooled testing for diagnostic, surveillance and screening purposes as well as important limitations, visit:
https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html

References:

- Interim Guidance for Use of Pooling Procedures in SARS-CoV-2 Diagnostic, Screening, and Surveillance Testing, CDC https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html
- Letter to LabCorp https://www.fda.gov/media/136148/download
- FDA Press Release https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-first-diagnostic-test-screening-people-without-known-or
- CDC Definition of Surveillance: https://www.cdc.gov/publichealth101/surveillance.html