

## **IDSA guidance document: COVID-19 sample pooling**

*Last updated August 5, 2020*

Pooled testing is the process of testing specimens in a “pool” (or group) rather than individually. This process is used in a wide variety of applications and is an indispensable tool for laboratories when testing high volumes of clinical specimens for infectious diseases in low or very low prevalence populations. Multiple factors must be considered prior to any implementation of pooled testing.

On June 16, FDA issued an Emergency Use Authorization update<sup>1</sup> regarding the validation of molecular diagnostic tests for assays to be used for pooling COVID-19 patient samples or for screening asymptomatic individuals not suspected of having the disease. The Centers for Disease Control and Prevention (CDC) also issued interim guidance for use of pooling procedures in SARS-CoV-2 diagnostic, screening, and surveillance testing<sup>2</sup>.

This document is intended to help educate policymakers, clinical laboratory stakeholders, and the public about sample pooling for COVID-19; its advantages; limitations; and applications in different settings.

### **Key Considerations for COVID-19 Sample Pooling**

- Pooling tests results in some level of decreased sensitivity. This may impact results in asymptomatic or pre-symptomatic individuals, which could lead to false negative results. Pooling should only be done on samples from asymptomatic persons who are not suspected to have COVID-19 (e.g., workplace/school screening). Pooling samples from symptomatic persons or those who are suspected of being infected risks missing cases with low viral loads and increases turnaround time.
- The appropriate setting for sample pooling depends on several factors:
  - Prevalence should be very low, as positive results require pool splitting/re-testing. Pooling to test in low-prevalence areas can be cost-effective.
  - Given the reduced sensitivity of this method, sample pooling is most often utilized for screening outside of the hospital and for pre-procedure and admissions screens, which have an approximate  $\leq 1\%$  population positivity rate.
  - The labor involved in setting up and managing testing pools favors the work of high-volume testing settings to screen larger populations (e.g., public health settings, school reopening efforts) more so than for laboratories doing lower-volume testing. The logistical and administrative challenges associated with pooling make it impractical for most clinical laboratories.
  - Pooling will delay reporting of positive results due to the additional time required to test the individual samples from a positive pool.
- CDC and FDA recommend pooling no more than 3-5 samples to retain appropriate sensitivity.
- The percent positivity threshold to trigger the shift back from pooled to individual testing depends on the reason for testing and the number of samples per pool.
- Calculating optimal conditions for pooling requires consideration of disease prevalence, size of pools, turnaround time, and the analytic sensitivity (i.e., limit of detection) of the molecular test being used.

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<sup>1</sup> <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-facilitating-diagnostic-test-availability-asymptomatic-testing-and>

<sup>2</sup> <https://www.cdc.gov/coronavirus/2019-ncov/lab/pooling-procedures.html>

Diagnostic test kits and supplies remain critically diminished; while pooling can alleviate some burden in the circumstances described above, it will not sufficiently resolve ongoing testing supply issues across the country.