

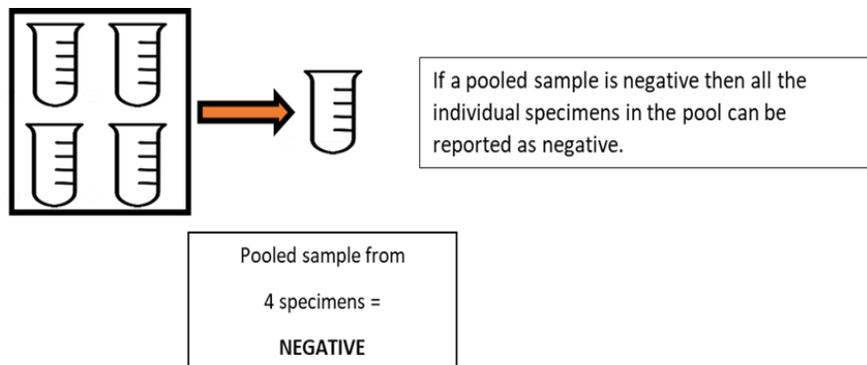
## CALIFORNIA TESTING TASK FORCE GUIDANCE FOR SAMPLE POOLING

The California COVID-19 Testing Task Force (TTF) recommends sample pooling (also referred to as “group testing”) for regions with low prevalence of COVID-19 when test reagents are in low supply. Testing capacity has been hampered by limited supplies of testing reagents. Sample pooling is an approach to maintain testing capacity while simultaneously conserving scarce test reagents and may reduce the cost of testing particularly when used for testing of low prevalence populations. When validated and performed correctly, sample pooling should not compromise the accuracy of test results.

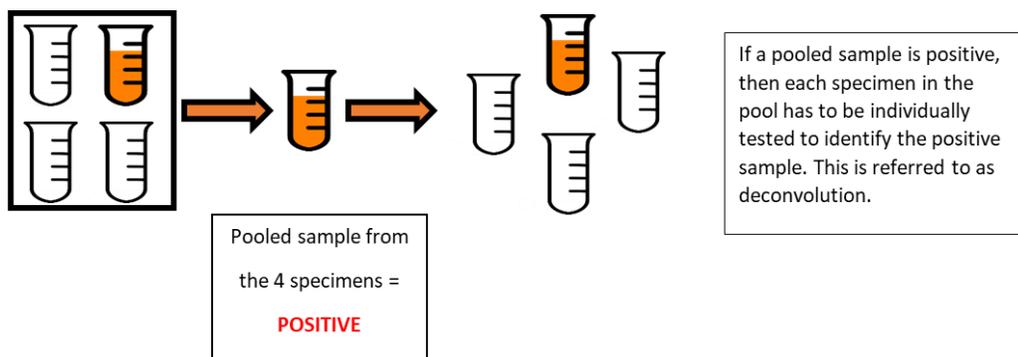
### What is sample pooling?

SARS-CoV-2 nucleic acid amplification testing is the mainstay for identifying individuals who have an active COVID-19 infection. Pooling, or batching, of individual patient samples and testing them together as a single specimen can significantly increase testing capacity (e.g., at least 69% increase when prevalence is  $\leq 10\%$ )(1). It is optimally used in settings where there is a low prevalence of COVID-19 and therefore most individuals tested are expected to be negative (e.g., testing of asymptomatic individuals or surveillance screening). Sample pooling may be useful to facilitate occupational health and resident screening in some workplaces and facilities with healthy, low-risk populations.

#### Example 1. Four negative specimens pooled into one sample that is tested:



#### Example 2. One positive and 3 negative specimens pooled into one sample:



## How can a lab adopt a sample pooling method?

The FDA recently updated the Molecular Diagnostic Templates to include [guidance for validation of SARS-CoV-2 molecular tests for specimen pooling](https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-facilitating-diagnostic-test-availability-asymptomatic-testing-and) (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-facilitating-diagnostic-test-availability-asymptomatic-testing-and). The U.S. Centers for Medicare & Medicaid Services have also released [regulatory guidance pertaining to sample pooling](https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf) (https://www.cms.gov/files/document/06-19-2020-frequently-asked-questions-covid-surveillance-testing.pdf). At this time, there are no FDA EUA SARS-CoV-2 assays approved for pooling, but some manufacturers are in the process of validating pooling methods. Please monitor the [FDA COVID EUA website](https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas) that will post updates to EUA protocols (https://www.fda.gov/medical-devices/coronavirus-disease-2019-covid-19-emergency-use-authorizations-medical-devices/vitro-diagnostics-euas).

## Other considerations

The number of specimens to pool should be carefully considered(1) and should be verified with negative and positive samples of varying molecular cycle threshold (Ct) values to validate the sensitivity of the molecular assay with pooled samples. Ct is defined as the number of cycles required for the fluorescent amplification signal to cross the threshold or background level to indicate a positive result.

Other potential barriers to pooling include logistic issues, such as the time and coordination needed to pool and track the individual samples. Automated liquid handlers and smart interfacing of laboratory instruments with laboratory information management system (LIMS) software can help streamline these processes.

Testing efficiency gained by sample pooling decreases as the prevalence of COVID-19 rises(1).

## References

1. Abdalhamid, B., et al. 2020. Assessment of Specimen Pooling to Conserve SARS CoV-2 Testing Resources. *American Journal of Clinical Pathology*, Volume 153. <https://doi.org/10.1093/ajcp/aaaa064>
2. Ben-Ami, R., et al. 2020. Pooled RNA extraction and PCR assay for efficient SARS-CoV-2 detection. 10.1101/2020.04.17.20069062.
3. Hogan, CA, et al. 2020. Sample Pooling as a Strategy to Detect Community Transmission of SARS-CoV-2. *JAMA*. 2020;323(19):1967-1969. doi:10.1001/jama.2020.5445