SARS-CoV-2 (COVID-19) Molecular (NAAT) Testing
Using Patient Specimen Pooling

Intended use

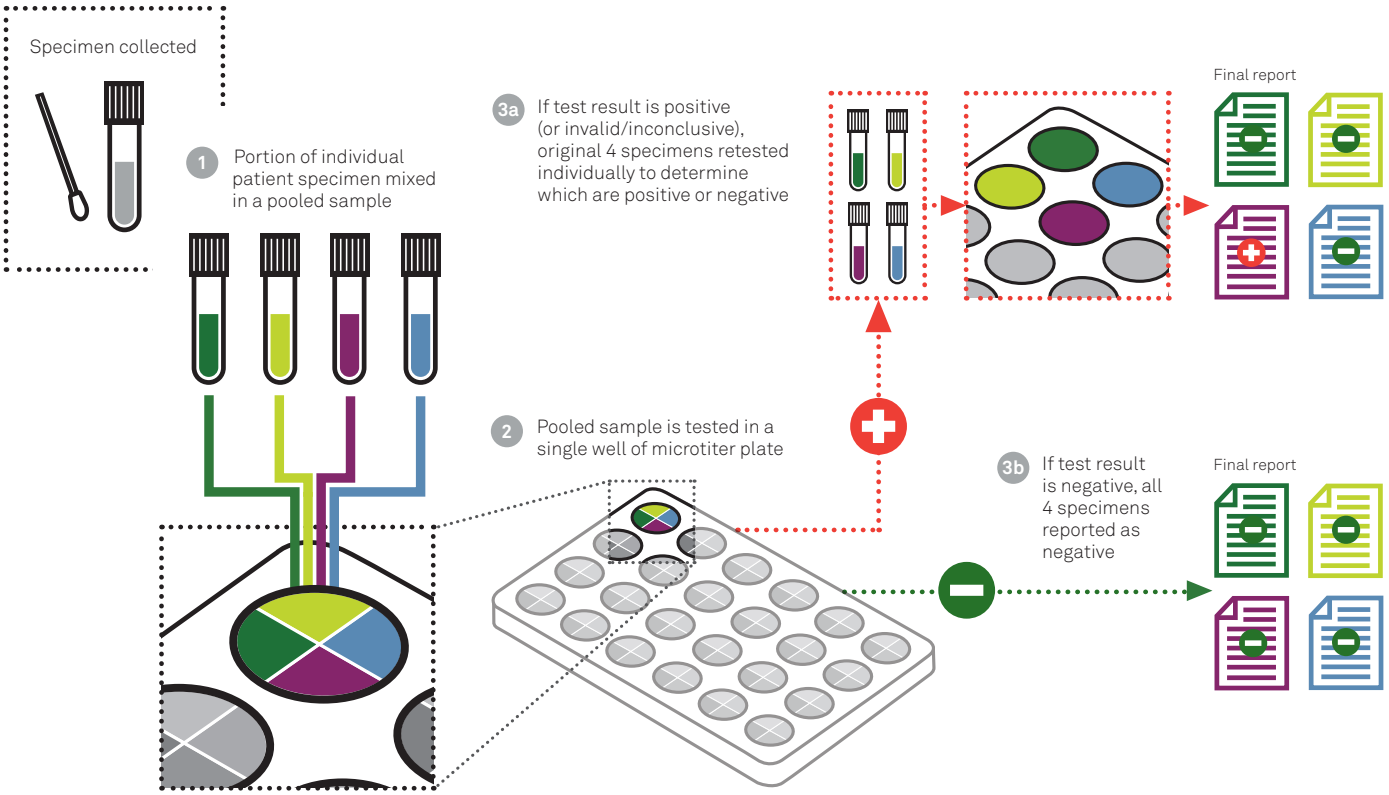
- On July 18, 2020, the pooling technique was granted an EUA from the US Food and Drug Administration (FDA) for use with the Quest Diagnostics SARS-CoV-2 RNA ("Quest SARS-CoV-2 rRT-PCR") with upper respiratory specimens (nasopharyngeal, mid-turbinate, anterior nares or oropharyngeal swabs) collected from patients suspected of COVID-19 by their healthcare provider. Specimens must still be collected into individual vials, and then pooled by the laboratory. Self-collected specimens that were not observed by a healthcare professional are not eligible for pooling[1]

Overview

- Quest is the first lab provider to receive FDA EUA for the pooling technique for COVID-19 molecular diagnostic testing and is deploying this method of testing at the Quest laboratories in Chantilly, VA; Marlborough, MA; Valencia and San Jaun Capistrano, CA; and Lewisville, TX
- Specimen pooling is a proven laboratory technique that can expand COVID-19 molecular diagnostic testing capacity, which is critical to our COVID-19 public health response in the United States. Pooled testing has long been used by the American Red Cross to test donated blood for hepatitis B and C, Zika virus, and HIV
- Specimen pooling will be used as part of the processing of specimens under the existing test code 39448. Pooling is an efficient way to evaluate patients in regions or populations with low prevalence of disease (less than 10% positivity). Priority specimens will not be pooled
- Quest has performed extensive validation testing and identified up to 4 patient specimens as the optimal number of samples to be combined in a single pooled test.[1] This aligns with the FDA guidance that pooling should be limited to 4-5 specimens for a single test
- Specimen pooling has demonstrated minimal effect on the accuracy of COVID-19 PCR diagnostic tests. To minimize the risk of false-negative results, Quest has performed rigorous validation of our specimen pooling lab process and chosen assays with high specificity, high sensitivity, and a low limit of detection[1]
- Negative results from testing should not be treated as definitive. If the patient's clinical signs and symptoms are inconsistent with a negative result or results are necessary for patient management, then the patient should be considered for individual testing. In very rare cases (estimated at about 1 in 1,000 or less frequent), specimens with low viral loads may not be detected in sample pools due to the decreased sensitivity of pooled testing. Please note that based on the FDA reviewed studies, the chance that an infected person is missed because the specimen was pooled is very rare. In one study involving over 3,000 SARS positive patients, none of the over 3,000 positive patients would have been missed as a result of specimen pooling
- If the pooled sample is negative, it can be deduced that all patient specimens are negative. If the pooled sample is positive (or invalid/inconclusive), then each specimen is retested individually to identify which patient is positive. The patient does not need to return for additional specimen collection[1]

How specimen pooling works[1]

- As an example, let's consider how 4 patient specimens are tested together by making a pooled sample. One diagnostic test will be run on the pooled sample, instead of 4 diagnostic tests on 4 specimens
  1. A small portion of each patient specimen is collected and mixed in a pooled sample. The remainder of the patient specimens are safely stored and protected in case they need to be tested individually.
  2. Pooled sample is tested once as a batch.
  3a. **If the test result is positive (or invalid/inconclusive)**, the original 4 specimens in the pooled sample must be tested individually to determine which of the specimens are positive and which are negative. The patient does not need to return for additional specimen collection.
  3b. **If the test result is negative**, all 4 specimens in the pooled sample are deduced as negative and all individual specimens are reported as negative.



Benefits of specimen pooling

- Because specimens are pooled together, ultimately fewer tests are run and more specimens are processed, resulting in potentially higher throughput, increased capacity, and over time potentially reduced turnaround time
- Specimen pooling could also enable frequent surveillance of asymptomatic people to help contain the spread of COVID-19
- Specimen pooling and other lab innovations have increased our capacity across the country to meet the surge in demand for COVID-19 testing

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FAQ

Q. If a test pool is positive, does that mean every patient in the pool has an infection?

A. Not necessarily. If a pool is positive, each original patient specimen in the pool is then tested individually to determine which are positive and which are negative.[1]

Q. Does pooling affect the amount of specimen required for collection?

A. There is no change to the specimen volume requirements for the purposes of pooling.[1]

Q. Will the test report tell me/my client/the patient if a pooling process was used?

A. Yes, this will be notated on the test report.

Q. Is pooling only being used to perform molecular tests, or are antibody test specimens also being pooled?

A. Only molecular samples from the Quest Diagnostics Rt-PCR test are being pooled at this time.

The FDA provides guidance that supports the use of specimen pooling for COVID-19. For further information, access the FDA site: https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-facilitating-diagnostic-test-availability-asymptomatic-testing-and

1. SARS-CoV-2 RNA, Qualitative Real-Time RT-PCR (Test Code 39433) [package insert]. Quest Diagnostics; 2020. Accessed July 21, 2020. https://www.fda.gov/media/136231/download

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