

Is this a PCR test?

Yes, the test we are using is a Real Time-PCR Diagnostic Test for the CDC 2019 Novel Coronavirus (2019-nCoV).

What is the analytical sensitivity and specificity of this test?

All of the current COVID-19 molecular tests commercially available in the US have a high analytical sensitivity (defined as 95% positive tests at the lower limit of detection, which is approximately 400-600 total viral copies in the specimen, depending on the assay). At 2-3 times the lower limit of detection, the available assays have virtually 100% analytical sensitivity IF viral RNA is present in the collected specimen. Our current test has an analytic limit of detection of 1-3.3 viral copies/microliter, which is a very low limit of detection.

How sensitive is the test?

None of the currently available COVID-19 molecular tests (including ours) have an established clinical sensitivity and specificity as providers are used to knowing about a test (determined from a known cohort of true positive and true negative patients, with calculation of positive and negative predictive values). This determination was WAIVED as part of the FDA exceptional release for testing. WE DO NOT KNOW the clinical sensitivity of any of the non-FDA approved assays. This will be determined in the future once FDA/CLIA regulations for COVID 19 testing are implemented.

I heard that COVID tests were only 70% sensitive?

The limited Chinese data reported attempted to assess clinical sensitivity and specificity, but their cohort only included sick patients, used a different test than the current US developed tests, and was based on radiologic/clinical diagnosis as their "gold standard" for diagnosis. We do not know the true clinical sensitivity and specificity of any currently available US based tests.

What does a positive test mean?

A positive test is confirmatory of active COVID-19 infection and warrants appropriate action, including quarantine and reporting to the county health department.

What does a negative test mean?

In the setting of high clinical suspicion for disease, a negative test does not mean the patient does not have COVID-19. It only means that viral RNA was not present in the tested specimen. In these cases, repeat testing may prove helpful, but clinical judgment should prevail in determining further treatment and isolation.

What can cause a false negative COVID-19 test?

The likelihood of a false negative COVID molecular test is influenced predominantly by specimen collection (source and technique), patient variability in site of infection (lung/respiratory tree vs nasopharynx), specimen handling/transport between collection and testing, and patient viral load. As we are just beginning to truly understand the pathophysiology of this disease, additional confounding factors to testing may yet be discovered.

What is the turnaround time (TAT) for COVID-19 test results?

Current TAT is 3 days for test results because we are sending the tests overnight out of state. Our sister lab in Denver is currently validating COVID-19 molecular testing and is estimated to have this available on or before April 20. Once in-state testing is available, test results should be available in 24-36 hours if not sooner, as we are driving the specimens to Denver daily for testing.