

## Is the Cedar Diagnostics COVID-19 test a PCR test?

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

## How sensitive is the test?

None of the currently available COVID-19 molecular tests (including ours) have a determined clinical sensitivity and specificity as providers are used to knowing about a test. 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 down the road 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 COVID-19 PCR test mean?

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

## What does a negative COVID-19 PCR test mean?

In the setting of high clinical suspicion for disease (symptoms of fever, cough, shortness of breath, or contact with someone positive for COVID-19), a negative test does not mean you do not have COVID-19 infection. It only means that viral RNA was not present in the tested specimen. In these cases, repeat testing may prove helpful, but clinical judgment by your provider or the health department should determine further treatment and isolation requirements. If you have a negative test result, you should not assume that you are "safe" to those around you and society in general, particularly if you have symptoms of cough, fever, shortness of breath, or have been exposed to someone who tested positive for COVID-19.

## What can cause a false negative COVID-19 test?

The likelihood of a false negative COVID-19 molecular test is influenced predominantly by specimen collection (source and technique), patient variability in site of infection (lung versus nose and throat), specimen handling/transport between collection and testing, and patient viral load (how infected and contagious you are). As we are just beginning to truly understand the mechanisms of this disease, additional inhibiting factors to testing may yet be discovered that can contribute to a false negative test result.

## 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.