US BioTek LABORATORIES RAPID COVID-19 (SARS-CoV-2 RNA RT-PCR)

Provider:
Patient:
Sample Type:
Email:

Sex:
Date of Birth:
Accession #:

Collected:
Received:
Completed:
External ID:

Result:

Reference Range: Negative

What Your Results Mean

This Rapid PCR test determines whether or not Nucleocapsid gene proteins found only in coronavirus COVID-19 are present in the sample. Each test cassette has built in positive and negative quality controls for accuracy. Test results must always be interpreted by the health care provider in conjunction with the patient's medical history and clinical presentation. The test is able to detect the Omicron variant and all previous variants of concern. The test is not affected by vaccination status.

"Positive" means that the COVID-19 nucleic acids are present. Quarantine is required if the virus is present; your healthcare provider will tell you how long your quarantine will last.

"Negative" means that there are no COVID-19 nucleic acids detected. If there are symptoms consistent with COVID-19 infection the patient should continue all exposure precautions until it is certain they are virus-free. "Negative" could also mean that it is too early to detect the COVID-19 virus because it can take 3-5 days for the viral load to increase to detection levels. "Negative" could also mean that not enough virus was collected on the sample swab.

If indicated by patient history or clinical presentation, additional testing using the CDC-recommended nasopharyngeal swab may be required. For more COVID-19 resources, please visit cdc.gov/coronavirus/2019-ncov/. The laboratory is forbidden by law to discuss results interpretations with patients. Any questions regarding the interpretation of test results should be discussed with a health care provider.

"Invalid" means that the test has been run twice and the results could not be determined. Retesting with a fresh sample is recommended.

About This Test

This test has been granted an FDA EUA for testing human nasal swab specimens.

This test is not yet approved or cleared by the FDA as IVD (In Vitro Diagnostic Medical Device). When there are no FDA-approved or cleared tests available, and other criteria are met, the FDA can make tests available under an emergency access mechanism called an Emergency Use Authorization (EUA). The EUA for this test is supported by the Secretary of Health and Human Service's declaration that circumstances exist to justify the emergency use of vitro diagnostics for the detection and/or diagnosis of the virus that causes COVID-19. This EUA will remain in effect, meaning this test can be used, for the duration of the COVID-19 declaration justifying emergency use of IVDs, unless it is terminated or revoked by the FDA, after which the test may no longer be used.

The test is authorized for use in US BioTek operating under Clinical Laboratory Improvement Amendments (CLIA) Certificate of Accreditation. The sensitivity of the assay is dependent on the quality of the specimen collected for testing.

US BioTek is required to report SARS-CoV-2 RNA RT-PCR test results to appropriate public health authorities.

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