BRIDGE LANE GLOBAL
the new face of healthcare

COVID-19 (SARS-CoV-2 RNA RT-PCR)

Provider:	**Sex:**	**Collected:**
Patient:	**Age:**	**Received:**
Sample Type:	**Accession #:**	**Completed:**

Result: Detected Indication: Critical

What Your Results Mean

A result of "Detected" indicates that SARS-CoV-2-RNA is present and suggests the diagnosis of coronavirus disease 2019 (COVID-19). Test results should always be considered in the context of the patient's clinical history, physical examination, and epidemiologic exposures when making the final diagnosis.

A result on our RT-PCR test is considered critical when positive because this indicates the individual could be infectious. US BioTek Laboratories must notify the individual's doctors immediately as well as the public authority.

The RT-PCR tests for three different pieces of COVID-19 viral RNA. If two thirds of the pieces of viral RNA are identified the test is read as Detected (positive), meaning the virus is present. Quarantine is required if the virus is present; your healthcare provider will tell you how long your quarantine will last. If no viral RNA is found the test is read as Not Detected (negative), indicating there is no virus present. Continue all exposure precautions; a negative test does not guarantee that patient will remain virus-free. Retest if new symptoms develop or if symptoms persist or worsen. If only one piece of viral RNA is found, the test is read as Inconclusive. Consider submitting a fresh sample if the patient is still symptomatic or symptoms worsen, using the CDC-recommended nasopharyngeal swab technique.

The test is specific for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and positive test results do not exclude the possibility of concurrent infection with other respiratory viruses. Negative results do not preclude infection with SARS-CoV-2 and should not be used as the sole basis for decisions on treatment or other patient care management.

For more COVID-19 resources, please visit cdc.gov/coronavirus/2019-ncov/.

About This Test

The United States FDA has provided emergency use authorization (EUA) of this test for testing human upper and lower respiratory 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 performance has been validated by US BioTek Laboratories according to high-complexity testing under Clinical Laboratory Improvement Amendments (CLIA). The sensitivity of the assay is dependent on the quality of the specimen collected for testing.