SARS-CoV-2/COVID-19 PCR*

The **SARS-CoV-2** assay is a real-time reverse transcription PCR assay intended for the qualitative detection of nucleic acid from the SARS-CoV-2 virus in nasopharyngeal (NP) swabs from individuals suspected of COVID-19 disease. SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection.

Positive results are indicative of the presence of SARS-CoV-2 RNA; clinical correlation with patient history and other diagnostic information is necessary to determine patient infection status. Positive results do not rule out bacterial infection or co-infection with other viruses. The agent detected may not be the definite cause of disease.

Negative results do not preclude SARS-CoV-2 infection and should not be used as the sole basis for patient management decisions. Negative results must be combined with clinical observations, patient history, and epidemiological information.

Targets	**SARS-CoV-2 RNA***
Accepted Specimens	Nasopharyngeal swab (**NP**), collect using a Dacron-tipped, plastic-shafted swab (Copan Flocked swab, if available) and place in UTM media. Maintain at 4ºC.
Specimens Receipt	Specimens accepted Monday through Friday.
Assay Schedule	**SARS-CoV-2** assay is set up Monday through Friday, with final results usually available by 2:00 pm on the day of receipt.
Normal Range	Not detected
CPT Codes	**SARS-CoV-2:** 87635

**This test was developed, and its performance characteristics determined by the Infectious Diseases Laboratory using Analyte Specific Reagents. It has not been cleared or approved by the FDA. The performance of this test was established based on the evaluation of a limited number of clinical specimens. Clinical performance has not been established with all circulating variants but is anticipated to be reflective of the prevalent variants in circulation at the time and location of the clinical evaluation. Performance at the time of testing may vary depending on the variants circulating, including newly emerging strains of SARS-CoV-2 and their prevalence, which change over time. This test is used for clinical purposes and should not be regarded as investigational or for research. This laboratory is regulated under the CLIA Amendments of 1988, 42 U.S.C. §263a as qualified to perform high-complexity clinical testing of this nature.*