Shimadzu SARS-CoV-2 real time RT-PCR Test

Test Description

The Shimadzu 2019 Novel Coronavirus Detection Kit is a molecular in vitro reagent set that aids in rapid detection of SARS-CoV-2 RNA and is based on widely used real time nucleic acid amplification technology with additional reagents that eliminate the need for RNA extraction. The product contains oligonucleotide primers and dual-labeled hydrolysis probes (TaqMan®) and control material used in RT-PCR for the in vitro qualitative detection of SARS-CoV-2 RNA in respiratory specimens.

Intended Use

The Shimadzu 2019 Novel Coronavirus Detection Kit is a rapid sample preparation for Real Time PCR (RT-PCR) testing intended for the qualitative detection of the novel coronavirus SARS-CoV-2 RNA in upper respiratory specimens. Results are for the identification of SARS-CoV-2 RNA. The SARS-CoV-2 RNA is generally detectable in respiratory specimens during the acute phase of infection. While 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. The agent detected may not be the definite cause of disease. Positive results do not rule out bacterial infection or co-infection with other viruses. Laboratories within the United States and its territories are required to report all positive results to the appropriate public health authorities.

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.

Additional testing and confirmation procedures should be performed in consultation with public health and/or other authorities to whom reporting is required. Positive results should also be reported in accordance with local, state, and federal regulations. Performance is unknown in asymptomatic patients.

The Coronavirus (SARS-CoV-2) Real Time RT-PCR Nucleic Acid Detection Kit is based on the PCR method, which uses primers to amplify three specific regions within the novel coronavirus (SARS-CoV-2) nucleocapsid protein N gene, and a fluorescent probe to detect amplification. The kit includes 3 primer-probe sets corresponding to those used in the CDC 2019-Novel Coronavirus (2019-nCoV) Real-Time RT-PCR Diagnostic Panel (cat no. 2019-nCoVEUA-01).

The oligonucleotide primers and probes for detection of SARS-CoV-2 RNA in this kit are designed for a multiplex assay that amplify and detect the N1 and N2 gene regions of the virus specific to SARS-CoV-2 RNA. An additional internal control primer and probe set detects the RNaseP in human nucleic acid to confirm that the amplification process has proceeded correctly.

First, virus from nasopharyngeal or nasal swabs are lysed to release encapsulated viral RNA and human DNA. The RNA from the virus is reverse transcribed to cDNA and subsequently amplified. In the process, the probe anneals to a specific target sequence located between the forward and reverse primers. During the extension phase of the PCR cycle, the 5' exonuclease activity of Taq polymerase degrades the probe, causing the reporter probe to separate from the quencher probe, generating a fluorescent signal. With each cycle, additional reporter probes are cleaved, increasing the fluorescence intensity. Fluorescence intensity is monitored at each PCR cycle.

Targets detected by this assay are listed below. Primer-probe sets N1 and N2 detect SARS-COV-2 specifically, with no expected false-positive detection of other coronaviruses or human microflora. The kit also includes a primer-probe set specific to the human housekeeping gene, ribonuclease P (RNP), to serve as an internal reference to monitor sample collection, lysis, and amplification.