April 20, 2020

GenoSensor GS™ COVID-19 RT-PCR KIT was granted by the FDA Emergency Use Authorization for high throughput COVID-19 RT-PCR Diagnostic on April 16, 2020.

The GS™ COVID-19 RT-PCR KIT

The GS™ COVID-19 RT-PCR KIT provides accurate, reproducible, high-quality results for clinical decision-making for patients with suspected COVID-19 (coronavirus) infection.

The GS™ COVID-19 RT-PCR test is a molecular test specifically detecting the SARS-CoV-2 virus that causes COVID-19. The test is intended for the qualitative detection of nucleic acids from SARS-CoV-2 in nasopharyngeal and oropharyngeal swab samples from patients who meet the CDC SARS-CoV-2 clinical criteria. The test has a full-process positive, negative and internal controls.

The GS™ COVID-19 RT-PCR test is a real-time reverse transcription polymerase chain reaction (RT-PCR) test which detects three genes from the SARS-CoV-2 virus from clinical nasopharyngeal swab specimens. In addition, the GS™ COVID-19 RT-PCR KIT also includes an internal positive control gene (GUSB) that serves as an extraction, reverse transcription, and PCR amplification control for each sample to minimize false negative results.

The GS™ COVID-19 RT-PCR KIT provides:

- Accuracy: Assay 3 target genes unique to SARS-CoV-2 having higher specificity
- Specificity: Targeted specificity to 100% of currently available complete genomes for SARS-CoV-2
- Simplicity: Ready to use all-in-one master mix reagents and controls minimize variability
- Throughput: Two kit package options of viral detection for up to 94 specimens
- High quality, high performance and reliability

The GS™ COVID-19 RT-PCR test runs on the Applied Biosystems™ 7500 Fast Dx Real-Time PCR Instrument. Kits are available for the 96 well plate (22 clinical samples) and 384 well plate (94 clinical samples) and provides test results in less than 90 minutes.

The GS™ COVID-19 RT-PCR KIT is intended for use by trained clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures.

About SARS-CoV-2 (coronavirus) and COVID-19

Coronaviruses (CoV) are a large family of viruses that cause illness ranging from the common cold to more severe diseases such as Middle East Respiratory Syndrome (MERS-CoV), Severe Acute Respiratory Syndrome (SARS-CoV) and COVID-19 (SARS-CoV-2), a new coronavirus strain which has not previously been identified in humans. To learn more about SARS-CoV-2 (coronavirus) and COVID-19 please visit Coronavirus.gov.

About GenoSensor Corporation

GenoSensor Corporation is a genomic technology company, aiming to improve human healthcare by developing and marketing products and services for genomic research, drug discovery, predisposition gene screening, therapeutic assessment and other bioscience applications. GenoSensor's focus is to provide products and services to customers who conduct genomic research and/or are in needs of genomic solutions in all life sciences. The company also develops assays for specific applications.

The GS™ COVID-19 RT-PCR KIT has not been cleared or approved by the FDA. However, it has been authorized by the FDA under an EUA. The test has been authorized only for the detection of RNA from SARS-CoV-2 virus to aid in the diagnosis of SARS-CoV-2 virus infection, not for any other viruses or pathogens. The test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostic tests for detection and/or diagnosis of COVID-19 under Section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.