TEST INFORMATION

Bio-Speedy® Direct RT-qPCR SARS-CoV-2 Detection kit is a molecular in vitro reagent kit that aids in rapid detection of SARS-CoV-2 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 and control material used in RT-PCR for the in vitro qualitative detection of SARS-CoV-2 RNA in respiratory specimens.

INTENDED USE

Bio-Speedy® Direct RT-qPCR SARS-CoV-2 nucleic acid detection kit is a one-step reverse transcription and real-time RT-PCR test intended for the qualitative detection of nucleic acid from SARS-CoV-2 in nasopharyngeal swabs, oropharyngeal (throat) swabs, combined nasopharyngeal/oropharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal or nasopharyngeal aspirates, nasal washes and bronchoalveolar lavage samples from individuals suspected of COVID-19 by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, that meet requirements to perform high complexity tests.
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. 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. Laboratories within the United States and its territories are required to report all 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.
The Bio-Speedy® Direct RT-qPCR SARS-CoV-2 is intended for use by qualified clinical laboratory personnel specifically instructed and trained in the techniques of real-time PCR and in vitro diagnostic procedures. The Bio-Speedy® Direct RT-qPCR SARS-CoV-2 is only for use under the Food and Drug Administration's Emergency Use Authorization.

TEST PRINCIPLE

The Bio-Speedy® Direct RT-qPCR SARS-CoV-2 nucleic acid detection kit is a real-time reverse transcription polymerase chain reaction (rRT -PCR) test. The SARS-CoV-2 primer and probe set(s) is designed to detect nucleic acid from the SARS-CoV-2 in nasal swabs, nasopharyngeal swabs,
oropharyngeal (throat) swabs, combined nasopharyngeal/oropharyngeal swabs, anterior nasal swabs, mid-turbinate nasal swabs, nasal or nasopharyngeal aspirates, nasal washes and bronchoalveolar lavage samples from patients suspected of COVID-19 by their healthcare

provider.
Detection with the kit is achieved via rapid nucleic acid extraction from respiratory tract samples followed by multiplex real-time RT-PCR targeting the SARS-CoV-2 specific ORF1ab gene and human RNase P gene and mRNA in real-time PCR instruments that are equipped with FAM and HEX detection channels.

The oligonucleotide set targeting human RNase P gene and mRNA functions as a control of the sampling, nucleic acid extraction and inhibition. The kit also contains negative and positive control templates.

The kit contains vNAT® buffer that extracts and preserves viral nucleic acids in respiratory tract samples. The vNAT® component enables the initiation of the real-time RT-PCR within 5 minutes of introduction of the sample. Polyethyleneimine coated tetradecyl dimethyl benzyl ammonium chloride-based nanoparticles (NP) and tween-20 in vNAT® lyse envelope and nucleocapsid of SARS-CoV-2 and release the genome. NP, guanidinium thiocyanate and NaN3 in vNAT® preserve the integrity of the released genomes. BSA in vNAT® is used as a PCR facilitator to compensate negative effects of PCR inhibitors.

Targets detected by this assay are listed below. Primer-probe set ORF1ab detects 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 RNaseP gene to serve as an internal reference to monitor sample collection, lysis, and amplification.

Target Name	**Target Description**
ORF1ab	SARS-CoV-2 specific
RNase P	Human Internal Control