

Product Description

The ViroKey™ SARS-CoV-2 RT-PCR Test is a real-time RT-PCR in-vitro diagnostic test intended for the qualitative detection of nucleic acids from the SARS-CoV-2 in nasopharyngeal and oropharyngeal swabs from individuals suspected of COVID-19 by their healthcare provider.

The ViroKey™ SARS-CoV-2 RT-PCR Test (CE-IVD) comprises of a ready-to-use system for the detection of SARS-CoV-2 RNA by Reverse Transcription PCR (RT-PCR) on the Applied Biosystems® 7500 Fast Dx Real-Time PCR System or the Sentosa® SA201 Real-Time PCR Instrument, with manual nucleic acid extraction and Reverse Transcription PCR assay set-up.

The ViroKey™ SARS-CoV-2 RT-PCR Test (RUO) can be run on either the manual or automated workflow with Sentosa® SX101 instrument. Positive results are indicative of active infection. 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.

CE-IVD: For in-vitro diagnostic use. Not for distribution in U.S.

Product Specifications

Specifications	Values
Sample Types	Nasopharyngeal and Oropharyngeal swabs
Gene Targets	ORF1a and RdRp
Limit of Detection	50 copies/reaction
Analytical Reactivity	100% match to 105 sequences in NCBI SARS-CoV-2 database
Analytical Specificity	No cross-reactivity with 18 pathogen species
Clinical Sensitivity	100% (88.6 - 100%)
Clinical Specificity	100% (88.6 - 100%)

Features and Benefits



Supporting Research:

- Sensitive and Robust
- Specific to SARS-CoV-2 RNA with no cross-reactivity



Providing Laboratory Efficiency:

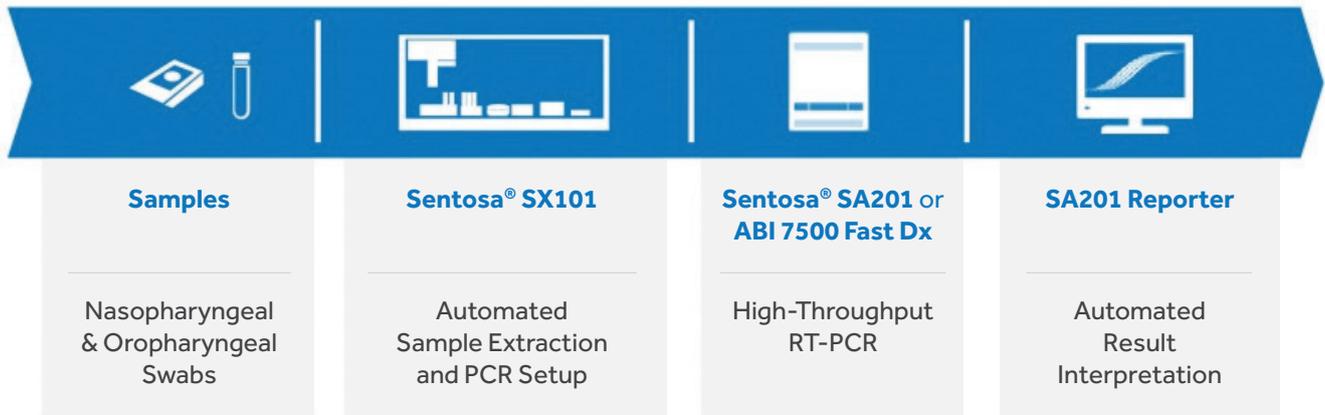
- Samples to results in 3.5 hours
- Only 30 minutes of hands-on time for automated workflow
- Test up to 46 samples per automated run



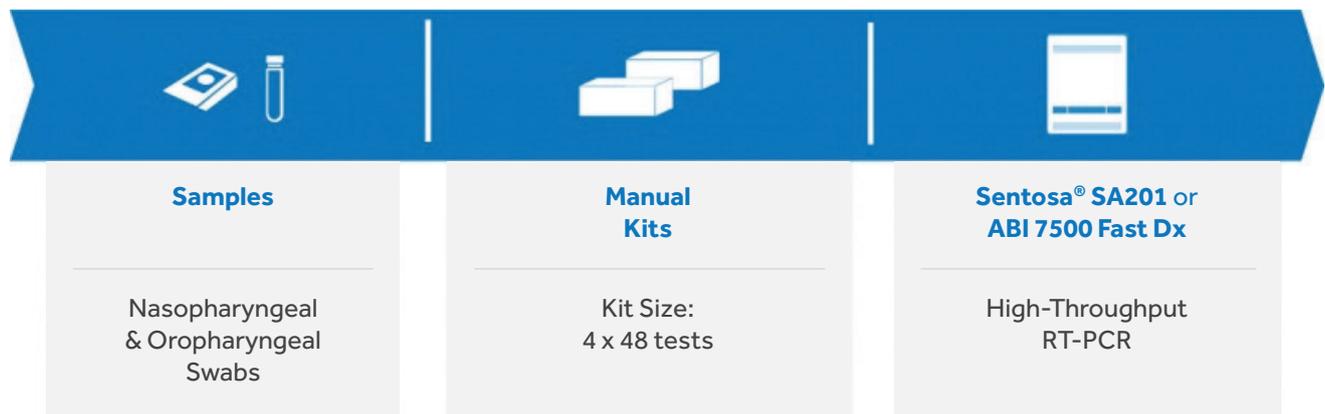
Flexible Workflow:

- Automated workflow available for extraction and PCR set-up (RUO only)
- Manual set-up and extraction protocols available (CE-IVD)

Automated Workflow (For RUO only)



Manual Workflow



Ordering Information

Product	Pack Size	Item Number
Sentosa SX Virus Total Nucleic Acid Kit v2.0 (CE-IVD)	4x24	300042
Sentosa SX Virus Total Nucleic Acid Kit v2.0 (RUO)	4x24	300044
ViroKey SARS-CoV-2 RT-PCR Test (CE-IVD)	4x48	300680
ViroKey SARS-CoV-2 RT-PCR Test (RUO)	4x48	300682
ViroKey SX Virus Total Nucleic Acid Kit (CE-IVD)	4x48	300678
ViroKey SX Virus Total Nucleic Acid Kit (RUO)	4x48	300679