

Sentebiolab Senteligo SARS-CoV-2 (COVID – 19) qPCR Detection Kit



Features and Advantages

- ✓ Fast results, high accuracy, high specificity and sensitivity
- ✓ Optimized primer/probe sequences to minimize false-positives
- ✓ Internal Control to check for patient sample quality to minimize false-negatives and to verify the enzyme and other reagents
- ✓ 100 % inclusivity of published SARS-CoV-2 sequences in unmutated targeted regions

- Senteligo SARS-CoV-2 (COVID-19) tests for the presence and absence of ribonucleic acid (RNA) of strain SARS-CoV-2 coronavirus. Test includes a Primer/Probe set that contains primers and probes for viral N1 and N2 regions. The primers and probes for viral N1 and N2 regions specifically identify two distinct regions on the nucleocapsid (N) gene of the SARS-CoV-2 virus. These primers and probes do not recognize the SARS-CoV virus, whose genetic structure is highly similar to SARS-CoV-2.
- The internal control (primer/probe set for human RNaseP gene) is used to identify possible qPCR inhibition, confirm the integrity of the reagents, and verify the quality of nucleic acid extraction from patient material. RNaseP primers and probes included in the kit recognize the human RNaseP gene.
- Test includes a positive control, which is labelled as “Positive Control”. The Positive Control is a synthetic DNA which contains the target regions of the N1, N2 and RNaseP genes that are amplified with the primer-probe sets included in the test kit.
- The test has been developed to be used as a single one-step reverse transcription qPCR test for each patient sample, utilizing PCR amplification of the targets (N1, N2 and RNaseP) by FAM, HEX and Cy5 labelled probes. The reaction time is approximately 1 hour. The test contains internal controls that monitor the performance of the test.

SUPERIORITY OVER THE COMPETITOR TESTS

Many other tests;

- ❖ Require longer cycles with qPCR which not only elongates the reaction time but also increases the number of false positives.
- ❖ Lack internal control for checking the nucleic acid presence in the human samples after transport which increases the risk of false negatives.
- ❖ Amplify regions which are not specific for SARS-CoV-2, but are used to screen for a family of coronaviruses.

Senteligo SARS-CoV-2 (COVID-19) qPCR Detection Kit performance parameters¹

Test	Virus	Company	Source	Target	Type	Assay Time (h)	Process Type	Manufacturer Data					Trial Data				Use	Clearance
								Sens	Spec	PPV 5%	NPV 5%	LOD	Sens	Spec	PPV	NPV		
Senteligo SARS-CoV-2 (COVID-19) qPCR Detection Kit	SARS-CoV-2	Eryigit Sentebiolab	RNA	Nucleocapsid (N) gene N1, N2 regions & RNaseP	qRT-PCR	< 2 hours	Plate	%100	%100			50 cp/mL	%100	100%			CLIA certified laboratories	FDA Pre P EUA200413

*Assay time between 60-90 minutes depending on the thermocycler used.

** Sensitivity data is based upon 77 measurements on clinical samples.

*** Thermocycler compatibility: Compatible with devices having detection channels for FAM, HEX and CY5.

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¹ Reference for comparison parameters:

<https://stm.sciencemag.org/content/12/546/eabc1931>

<https://csb.mgh.harvard.edu/covid>