Respiratory Infections

FTD SARS-CoV-2 Assay

↗ **siemens-healthineers.com/ftd-sars-cov-2-assay**

FTD SARS-CoV-2 Assay[1]

The FTD SARS-CoV-2 Assay is a real-time PCR test used to detect the new coronavirus SARS-CoV-2 causing COVID-19. The FTD SARS-CoV-2 Assay uses the same protocol, including PCR cycling profile, as other FTD respiratory assays.

Kit description:

- Single-well, dual target assay covering highly conserved regions within ORF1ab and N gene
- Validated specimen types include nasopharyngeal and oropharyngeal swabs
- Robust dual target design for high sensitivity and specificity
- Dual target design reduces inconclusive results and the need for repeat testing
- *in silico* analysis using more than 900 sequences shows 100% detection rate†
- Uses the same setup protocol and thermal-cycling profile as other FTD assays[2]

Assay	Target Region	Detection Channel
SARS-CoV-2	N	FAM
	ORF1ab	FAM
	IC	Cy5

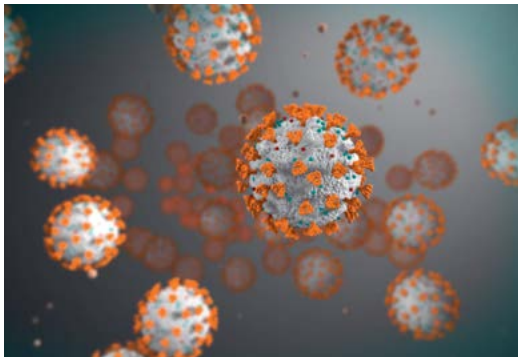
FTD SARS-CoV-2 assay target regions

SIEMENS Healthineers

Fast Track Diagnostics SARS-CoV-2 Assay

Kit information:

FTD SARS-CoV-2 Assay	
Product numbers	SMN 11416302
Kit size	96 tests/kit
Number of primer/probe mix	1 for detection of SARS-CoV-2 and Internal control
Kit components	Primer/probe mix Enzyme and buffer Internal control (Equine arteritis virus) Positive and negative controls
Validated Extraction method	NucliSENS easyMAG (bioMerieux)
Validated Thermocycler	Applied Biosystems 7500 Real-Time PCR System (Thermo Fisher Scientific)



FTD SARS-CoV-2 Diagnostic Performance	
Positive Percent Agreement	100% (91.8-100, 95% CI)
Negative Percent Agreement	100% (88.7-100, 95% CI)

Internal data on file.

FTD assays use the same setup protocol and thermal-cycling profile, enabling consolidation of respiratory testing into batch runs.

This is especially important during outbreaks, when testing for specific respiratory pathogens can be implemented without any disruption to other routine laboratory testing.

[1]CE-IVD labelled for diagnostic use in the EU. Pursuing WHO emergency use listing (EUL). This test has not been FDA cleared or approved. This test has been authorized by FDA under an EUA for use by authorized laboratories. This test has been authorized only for the detection of nucleic acid from SARS-CoV-2, not for any other viruses or pathogens. This test is only authorized for the duration of the declaration that circumstances exist justifying the authorization of emergency use of in vitro diagnostics 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.

[2]CE-IVD labelled for diagnostic use in the EU. For research use only (RUO) in the U.S.

[†]FTD SARS-CoV-2 Instructions for Use.

Product availability may vary from country to country and is subject to varying regulatory requirements. Please contact your local representative for availability.

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for the Product
Fast Track Diagnostics Assays

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