Respiratory Infections

FTD SARS-CoV-2 Assay

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

FTD SARS-CoV-2 Assay*

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 CE-IVD marked 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 potential for 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 respiratory assays.

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

FTD SARS-CoV-2 assay target regions

**CE-IVD labeled for diagnostic use in the EU. 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.*

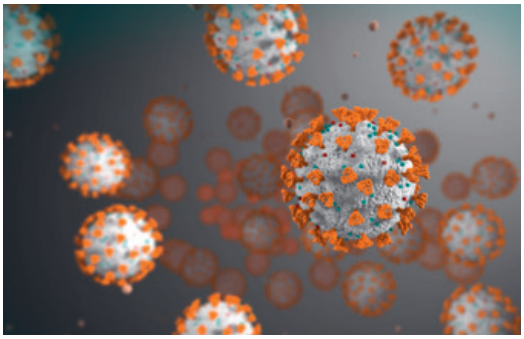
†FTD SARS-CoV-2 Assay (CE-IVD) Instructions for Use 11416283_en Rev. A, 2020-05.
FTD SARS-CoV-2 Assay (EUA) Instructions for Use 11416299_en Rev. A, 2020-05.

SIEMENS Healthineers

Fast Track Diagnostics multiplex real-time PCR assays

Siemens Healthineers offers a comprehensive solution for the simultaneous detection and identification of common, rare, and emerging respiratory pathogens. The FTD syndromic assays can be used to rule out other respiratory pathogens in symptomatic individuals:

- **FTD SARS-CoV-2** for the detection of SARS-CoV-2
- **FTD Respiratory Pathogens 21‡** for the detection of 20 viruses and 1 bacterium
- **FTD FLU/HRSV‡** for the detection of influenza A, influenza B, and human respiratory syncytial viruses A and B



Kit information:

FTD SARS-CoV-2 Assay		
Product numbers	**CE-IVD** FTD-114-96 SMN 11416284	**EUA** FTD-114-96 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 methods	NucliSENS easyMAG (bioMerieux)§ VERSANT® kPCR Molecular System SP (SP Module)§	
Validated thermocyclers	Applied Biosystems 7500 Real-Time PCR System (Thermo Fisher Scientific)§ VERSANT® kPCR Module System AD (AD Module)§[1]	

FTD SARS-CoV-2 Diagnostic Performance

	CE IVD[2]	EUA[3]
Target genes	N gene and ORF1ab region	
Specimen types	Nasopharyngeal and oropharyngeal swabs	Nasal swabs, nasopharyngeal swabs, oropharyngeal swabs, nasopharyngeal wash/ aspirate, nasal aspirate, BAL
Clinical sensitivity	Diagnostic sensitivity of 100% (95% CI = 91.78–100)	Positive percent agreement of 100% (95% CI = 91.97–100)
Clinical specificity	Diagnostic specificity of 100% (95% CI = 93.84–100)	Negative percent agreement of 100% (95% CI = 88.65–100)
Analytical sensitivity	1155 copies/mL (11.5 copies/rxn)	0.0023 $TCID_{50}$/mL

FTD respiratory 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.

‡CE-IVD for diagnostic use in the EU.

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1. The VERSANT® kPCR Molecular System AD is a QuantStudio™ 5 Dx real-time thermocycler (originally supplied by ThermoFisher) modified to run the MiPLX Software Solution (Siemens Healthineers).
2. FTD SARS-CoV-2 Assay (CE-IVD) Instructions for Use 11416283_en Rev. A, 2020-05.
3. FTD SARS-CoV-2 Assay (EUA) Instructions for Use 11416299_en Rev. A, 2020-05.

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

Fast Track DIAGNOSTICS
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