Product Highlight

FTD SARS-CoV-2 Assay: Extensive *in silico* study demonstrates excellent inclusivity*

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

Background

- Since SARS-CoV-2 was first identified in China in December 2019, the COVID-19 pandemic has spread across the globe.
- This spread has led to an accumulation of mutations in the viral genome.
- It is very important to ensure that RT-PCR assays are able to detect the circulating variants.

Study design

- *In silico* analysis was performed on 65,243 full-length SARS-CoV-2 sequences downloaded from NCBI and GISAID database. Due to the presence of undetermined bases, 64253 and 65051 sequences were finally tested for the N gene and ORF1ab assays, respectively.
- Primers and probes were mapped to the sequences to check for potential matches producing amplicons.
- A maximum of 4 mismatches between individual primer/probe and the target sequence was allowed.

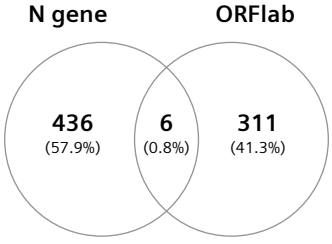
FTD SARS-CoV-2 Assay†

- Targets highly conserved regions within ORF1ab and N gene.
- Robust dual target design for high sensitivity.
- Dual target design reduces potential for inconclusive results and the need for repeat testing.
- The same setup protocol and thermal-cycling profile as other FTD respiratory assays enables batch testing in single run.

Results

- 100% detection rate for SARS-CoV-2 N gene assay: From these 64253 detected sequences, 63811 sequences showed no mismatches, 442 sequences showed 1 mismatch.
- 100% detection rate for SARS-CoV-2 ORF1ab assay: From these 65051 detected sequences, 64734 sequences showed no mismatches, 317 sequences showed 1 mismatch.
- 0.8% (6/753) overlap between the sequences showed mismatches with the N gene and Orf1ab assay.

Assay	Databases	Complete Genomes Tested with Genomes Detected	Detection Rate (%)
N gene	GenBank + GISAID	64253/64253	100
ORF1ab	GenBank + GISAID	65051/65051	100



FTD SARS-CoV-2 assay shows excellent inclusivity in this comprehensive *in silico* study. This test is suitable to detect RNA from circulating SARS-CoV-2 variants globally.

** Analytical and Clinical Performance Characteristics of the FTD SARS-CoV-2 Assay (CE-IVD) (EUA) Poster et al, ECCVID 2020, 11416297_en Rev. A, 2020-04 (CE-IVD), 11416299_en Rev. B, 2020-07 (EUA)*

†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.

SIEMENS Healthineers

At Siemens Healthineers, our purpose is to enable healthcare providers to increase value by empowering them on their journey toward expanding precision medicine, transforming care delivery, and improving patient experience, all made possible by digitalizing healthcare.

An estimated 5 million patients globally benefit every day from our innovative technologies and services in the areas of diagnostic and therapeutic imaging, laboratory diagnostics, and molecular medicine, as well as digital health and enterprise services.

We are a leading medical technology company with over 120 years of experience and 18,000 patents globally. Through the dedication of more than 50,000 colleagues in 75 countries, we will continue to innovate and shape the future of healthcare.

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

Siemens Healthineers Headquarters
Siemens Healthcare GmbH
Henkestr. 127
91052 Erlangen, Germany
Phone: +49 9131 84-0
siemens-healthineers.com

Legal Manufacturer
Fast Track Diagnostics
Luxembourg S.à.r.l.
29, rue Henri Koch
4354 Esch-sur-Alzette
Luxembourg

for the Product
Fast Track Diagnostics Assays

Published by
Siemens Healthcare Diagnostics Inc.
Molecular Diagnostics
725 Potter Street
Berkeley, CA 94710-2722
USA
Phone: +1 510-982-4000

Published by Siemens Healthcare Diagnostics Inc. · Order No. 30-21-DX-532-76 · 01-2021 ·