eurofins | Clinical Trial Solutions

COVID-19 Testing for Clinical Trials

As experts in infectious disease assays, Eurofins Clinical Trial Solutions offers a broad array of testing solutions for biomarker detection, immunogenicity, and other safety and efficacy assessments to support anti-viral and vaccine candidate clinical programs.

We also offer several validated molecular and serology tests for SARS-CoV-2, including both qualitative and quantitative QPCR assays, as well as an automated ELISA-based antibody test, a SARS CoV-2 next generation sequencing assay for infection confirmation, and a full-length genome sequencing assay for variant detection.

Amongst Eurofins Clinical Trial Solutions' COVID-19/SARS COV-2 testing options, our RT-PCR assay was reported by the US FDA to be the most sensitive assay (180 NDU/mL) of the 117 evaluated.*

COVID-19 TESTING PORTFOLIO

TEST NAME	TECHNOLOGY	SAMPLE	UTILITY
Coronavirus SARS-CoV-2 RT-PCR Test*	PCR (RT-PCR)	Nasopharyngeal swab (NP), nasal wash, BAL	Qualitative to detect active infection
Coronavirus SARS-CoV-2 RT-qPCR Test (quantitative)	PCR (RT-PCR)	Saliva (Isohelix or OMNIgene®), NP swab, serum/plasma	Quantitative to determine viral load
SARS-CoV-2 Full-length Genome Sequencing	Whole Genome Sequencing (WGS)	NP swab in saline, VTM/UTM, add'l sample types TBD	Variant detection under ISO 17025
Coronavirus SARS-CoV-2 Neutralizing Antibody (NAb) Test	ELISA	serum/plasma	Indication of adaptive immunity to SARS-CoV-2

*US FDA SARS-CoV-2 Reference Panel Comparative Data: Sensitivity Mean Estimates of the EUA authorized molecular diagnostic tests using the FDA SARS CoV-2 Reference Panel. https://www.fda.gov/medical-devices/coronavirus-covid-19-and-medical-devices/sars-cov-2-reference-panel-comparative-data

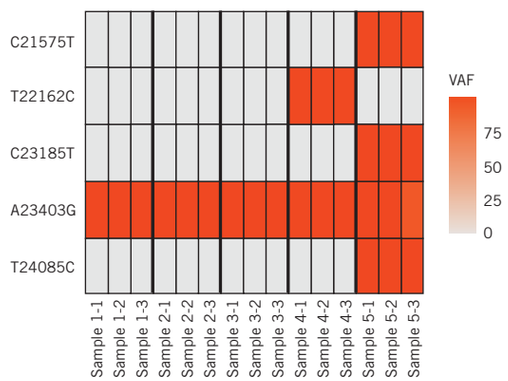
Performance Characteristics or the SARS CoV2 Spike gene sequencing assay (from validation):

Accuracy & Precision:

ID	Expected Variants*	Detected Variants	Concordance
Sample 1	A23403G/D614G	A23403G/D614G	100%
Sample 2	A23403G/D614G	A23403G/D614G	100%
Sample 3	A23403G/D614G	A23403G/D614G	100%
Sample 4	T22162C/Y200Y; A23403G/D614G	T22162C/Y200Y; A23403G/D614G	100%
Sample 5	C21575T/L5F; C23185T/F541F; A23403G/D614G T24085C/L841L	C21575T/L5F; C23185T/F541F; A23403G/D614G T24085C/L841L	100%

*Obtained from 5 different samples with 3 replicates each

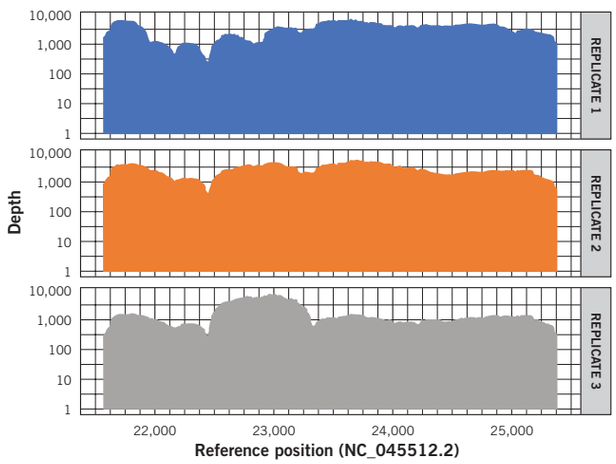
Spike gene variant detection
(Variant allele frequency is uniform across all calls*)



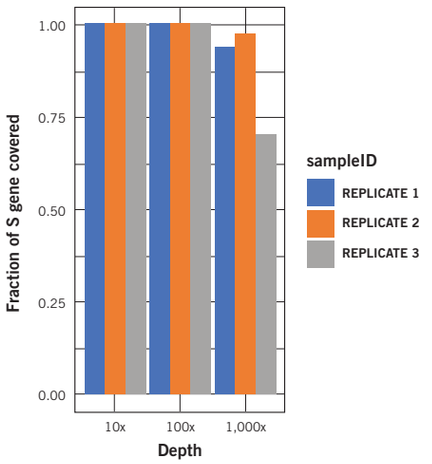
*Variants were detected in 2.85 x 10^9 copies/mL samples using the Whole Genome Sequencing assay in a Germany lab (Eurofins Genomic Lab)

COVID-19 Testing for Clinical Trials

S gene coverage depth



Fraction Covered



Sensitivity (limit of detection/LOD):

Estimated Conc. (copies/mL)	Average Reads	Median Depth of Coverage
15,000	120,703	4,229
10,000	104,897	3,194
6,667	112,825	2,692

Depth of coverage of S gene. (Input: 6,667 copies per mL)
>100x coverage of entire S gene sequence

Summary of Additional Viral Assays

- Immunogenicity (Viral T-Cell Immunity Panel (TCIP))
- Viral Load Monitoring (qPCR- NP swab, eye swab, fecal, tissue, saliva)
- Serology Testing (IgG EIA, IgM EIA, Total Antibody EIA)
- Sequencing & Genotyping (AVR)
- Custom Assay Designs (Client-Specific) – ELISA, PCR, ELISpot
- Vector copy number (PK)
- Viral shedding assays (qPCR)
- TCID50 infectivity (reflex)

WHY USE EUROFINS CLINICAL TRIAL SOLUTIONS

- We offer a comprehensive menu of real-time PCR and sequencing assays for viral and bacterial pathogen detection and monitoring.
- Our R&D team has extensive experience performing pathogen load monitoring, antiviral resistance assessment, sequencing and other pathogen characterization for clinical trials.
- Eurofins Clinical Trial Solutions specializes in custom development, validation and optimization of qPCR and genotyping assays for pathogens.

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Contact us today to discover how the Eurofins Clinical Trial Solutions team can make the difference in your projects.