eurofins | Viracor BioPharma Services

COVID-19 Testing for Clinical Trials

As experts in infectious disease assays, Eurofins Viracor 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 Viracor's 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 Omniene), NP swab, serum/plasma	Quantitative to determine viral load
Antibody Testing for Coronavirus (COVID-19) SARS-CoV-2 (IgG only)	Automated ELISA	serum/plasma	Qualitative to determine exposure
SARS-CoV-2 (COVID-19) quantitative IgG	ELISA	serum/plasma	Quantitative to detect exposure, vaccine protection
SARS-CoV-2 Sequencing Assay-Spike Gene	NGS	NP swab in saline matrix, add'l sample types TBD	Confirmation of viral infection; S-gene antigen sub-typing; variant detection
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

*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):

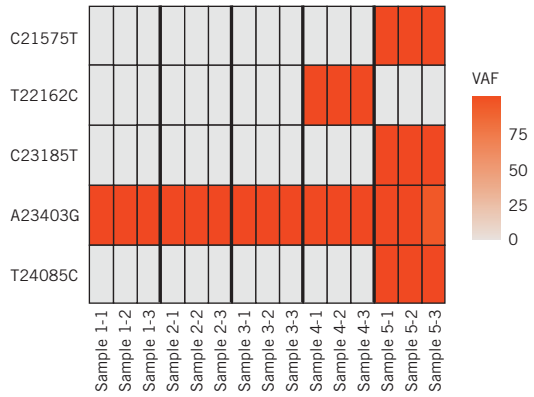
Accuracy & Precision:

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

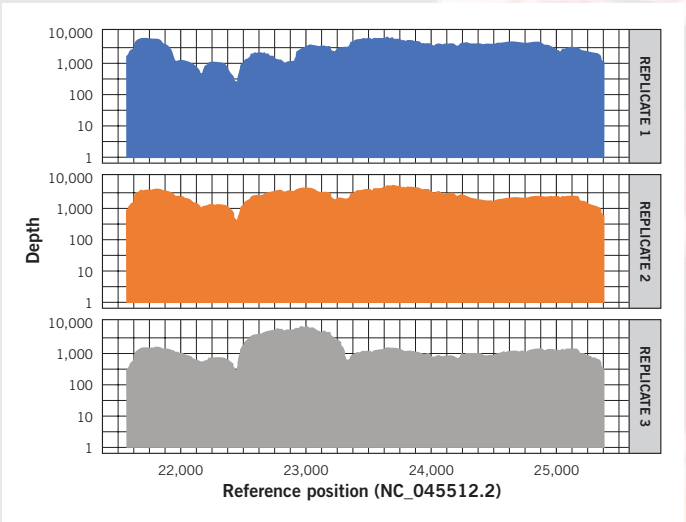
(Variant allele frequency is uniform across all calls)*



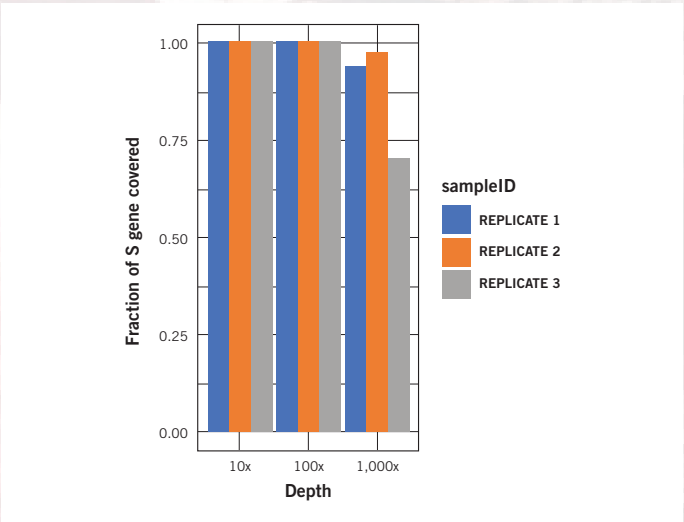
Variants were detected in 2.85 x 10^6 copies/mL samples using the Whole Genome Sequencing assay in a Germany lab (Eurofins Genomic Lab)

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 VIRACOR

- 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 Viracor specializes in custom development, validation and optimization of qPCR and genotyping assays for pathogens.

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

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