NOVACYT GROUP

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Bioinformatics Surveillance Report

Daily bioinformatic analysis of the Coronavirus SARS-CoV-2 ORF1ab, S gene and M gene assays confirm the assays demonstrate a level of sequence identity which predicts over 99.4% detection of all good quality[1] SARS-CoV-2 sequences published on the GISAID EpiCoV database as of 2nd September 2021. These include variants identified as Variants of Concern (VoC) and Variants under Investigation (VuI) including the Delta variant as well as variants that carry the N501Y, E484K and L452R mutations.

Assay Target	Number of Sequences Analysed	Detection Level
ORF1ab	2,805,569	99.9%[2]
S gene	2,789,621	99.5%[2]
M gene	2,687,709	100%[2]

Our new SNPsig® range of assays have the following level of detection of the Variants of Concern (VoC), Variant under Investigation (VuI) and clinically significant mutations. *

Variants of Concern	Detection Level
SARS-CoV-2 (20I/501Y.V1 / Alpha)[4]	99.6%[3]
SARS-CoV-2 (20H/501Y.V2 / Beta)[5]	98.9%[3]
SARS-CoV-2 (20J/501Y.V3 / Gamma)[6]	98.9%[3]
SARS-CoV-2 (N501Y)[7]	99.8%[3]
SARS-CoV-2 (E484K)[8]	99.4%[3]
SARS-CoV-2 (20B/S.484K / P2 / Zeta)[9]	99.5%[3]
SARS-CoV-2 (L452R)[10]	99.5%[3]

SNPsig® EscapePLEX has the following level of detection.

Assay Target	Number of Sequences Analysed	Detection Level
E484K	159,018	99.6%[11]
K417N	30,513	98.5%[11]
K417T	67,579	99.8%[11]
P681R	838,014	99.4%[11]

Tables above represent coverage of gene targets across our COVID-19 portfolio

[1] Full length sequence i.e. >29,000 nucleotides with fewer than 5% ambiguous nucleotides plus exclusion of sequences with ambiguous nucleotides in the assay target.

[2] On average, 0.7% of sequences contain mismatches. The predicted detection levels are shown in the table.

[3] On average, 1.3% of sequences contain mismatches. The predicted detection levels are shown in the table.

[4] Variant of concern (VoC) originally identified in the UK

[5] Variant of concern (VoC) originally identified in South Africa

[6] Variant of concern (VoC) originally identified in Japan (ex Manaus, Brazil)

[7] Variants of concern (VoC) sharing the N501Y mutation

[8] Variants of concern (VoC) sharing the E484K mutation

[9] Variant under Investigation (VuI) originally identified in Brazil

[10] Variants of concern (VoC) sharing the L452R mutation

[11] On average, 1% of sequences contain mismatches. The predicted detection levels are shown in the table.

*2,648,240 sequences have been analysed (November 2020 - September 2021)

genesig® SARS-CoV-2 Winterplex (CE IVD) Real Time PCR Assay

The genesig® SARS-CoV-2 Winterplex (CE IVD) Real Time PCR Assay (catalogue number D00020) is a multiplexed assay for the simultaneous detection and discrimination of SARS-CoV-2, influenza A, influenza B and RSV (A&B) viruses from a single patient sample.

United States Food and Drug Administration approve Emergency Use Authorization Only (EUA) for Primerdesign Ltd COVID-19 assay:

The United States FDA approve Emergency Use Authorization for Primerdesign COVID-19 assay (Z- COVID-19 (US ONLY)) which can be used by USA laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. § 263a, to perform high complexity tests.

World Health Organisation Emergency Use Listing

The genesig® Real Time PCR Coronavirus COVID-19 CE IVD assay (Catalogue: Z-Path-COVID-19-CE) was listed as eligible for World Health Organisation (WHO) Emergency Use Listing (EUL) procurement on 7th April 2020.

Independent Clinical Performance Evaluations with genesig® Real Time PCR Coronavirus COVID-19 CE IVD assay (Z-Path-COVID-19-CE)

The independent clinical performance evaluation confirms that the Primerdesign COVID-19 assay is highly specific for the detection of SARS-CoV-2 virus and detection of coronavirus COVID-19 disease.

Public Health England Clinical Performance Evaluation

Independent Clinical Performance Evaluation of Primerdesign COVID-19 assay by the National Infection Service, Public Health England, Colindale confirmed the specificity of this assay using upper or lower respiratory clinical samples from patients and known SARS-CoV-2 positive material. PHE confirmed the assay showed >98% specificity to SARS-CoV-2 virus in clinical samples.

NHS Clinical Pathology Laboratory Performance Evaluation

An Independent Clinical Performance Evaluation by an NHS Clinical Pathology Laboratory using patient samples with respiratory symptoms confirmed the assay was 100% specific when tested against known positive and negative SARS-CoV-2 clinical samples.

FIND (WHO Collaborating Centre for Laboratory Strengthening and Diagnostic Technology Evaluation) Performance evaluation and LOD verification

An independent performance evaluation of the COVID-19-CE assay and LOD verification by FIND at the University Hospitals of Geneva confirmed 100% sensitivity and 100% specificity with the limit of detection at 1-10 copies/reaction when tested against 50 positive and 100 negative SARS-CoV-2 clinical samples. Full results can be obtained from:

https://www.finddx.org/covid-19/sarscov2-eval-molecular/molecular-eval-results/

Technologies Validation Group (TVG) Validation

The independent TVG performance evaluation performed at four NHS sites confirmed that the performance of the PROmate® assay aligns with the acceptable performance characteristics for sensitivity and specificity of the testing product. Primerdesign Ltd PROmate® direct qRT-PCR (publishing.service.gov.uk).

NOVACYT
GROUP

Novacyt Group (UK) Unit 1, Watchmoor Point
Watchmoor Road, Camberley, Surrey GU15 3AD, UK

T +44 (0) 1276 600081
F +44 (0) 1276 600151
www.novacyt.com

Registered Office:
Novacyt Group (UK) Unit 1, Watchmoor Point
Watchmoor Road, Camberley
Surrey GU15 3AD, UK
Registered Number: FC033649

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