NOVACYT GROUP

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Bioinformatics Surveillance Report

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Daily bioinformatic analysis of the Coronavirus SARS-CoV-2 ORF1ab and S gene assays confirm the assays demonstrate a level of sequence identity which predicts 99.9% detection of all good quality[1] SARS-CoV-2 sequences published on the GISAID EpiCoV database as of 25th March 2021, which include the variants of concern.

Assay Target	Number of Sequences Analysed	Detection Level
ORF1ab	685,681	99.9%[2]
S gene	685,682	99.8%[2]

Our new SNPsig® range of assays have the following level of detection Variants of Concern (VOC)*.

Variants of Concern	Detection Level
SNPsig® SARS-CoV-2 (20I/501Y.V1)[4]	99.7%[3]
SNPsig® SARS-CoV-2 (20H/501Y.V2)[5]	99.9%[3]
SNPsig® SARS-CoV-2 (20J/501Y.V3)[6]	99.9%[3]
SNPsig® SARS-CoV-2 (N501Y)[7]	99.8%[3]

[1] Full length sequence i.e. >29,0000bp with fewer than 5% ambiguous nucleotides plus exclusion of sequences with ambiguous nucleotides in the assay target.

[2] This includes 0.6% of sequences containing mismatches of which our bioinformatics analysis predicts our assays will still detect.

[3] This includes 0.7% of sequences containing mismatches of which our bioinformatics analysis predicts our assays will still detect

[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 Brazil

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

*562,710 sequences have been analysed (November 2020 - March 2021)

Catalogue numbers-ORF1ab

Z-Path-COVID-19-CE (CE-IVD)
Z-Path-2019-nCoV (RUO)
Z-Path-2019-nCoV-EASY (RUO)
Z-Path-2019-nCoV-std (RUO) Z-COVID-19 (US ONLY)
Z-Path-COVID-19-HT-CE (CE IVD)
Z-exsig™ COVID-19 direct (CE IVD)
D00050 (PROmate™ COVID-19 q16)
D00051 (PROmate™ COVID-19 q32)

Catalogue number-2 gene kit (ORF1ab and S gene)

D00020 (name: genesig® SARS-CoV-2 Winterplex (CE-IVD)

D00011 (name: genesig® COVID-19 2G (CE IVD)

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 performed on Z-Path-COVID-19-CE

The following independent clinical performance evaluation studies confirm 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 PROMateTM assay aligns with the acceptable performance characteristics for sensitivity and specificity of the testing product. Primer Design Ltd PROmate direct qRT-PCR (publishing.service.gov.uk).

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