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PRIMER DESIGN

Bioinformatics Surveillance Report

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Bioinformatic analysis of the SARS-CoV-2 ORF1ab, S, M and nsp16 assays, against currently circulating variants and subvariants, confirm the assays demonstrate a level of sequence identity which predicts over 95.2% detection of all good quality[1] SARS-CoV-2 sequences. The sequences analysed were published on the GISAID EpiCoV database and collected between 1st and 31st August 2023. Analysis was conducted on the variants outlined in the UKHSA SARS-CoV-2 genome sequence prevalence and growth rate update dated 30th August 2023: https://www.gov.uk/government/publications/sars-cov-2-genome-sequence-prevalence-and-growth-rate/sars-cov-2-genome-sequence-prevalence-and-growth-rate-update-30-august-2023#variant-prevalence. BA.2.86 has been included in the analysis due to recent media coverage.

Variant	Number of Sequences Analysed (Average)	Overall Detection Level			
		ORF1ab	S	M	nsp16
EG.5.1	318	>99.37	>95.2*	>98.8	>99.4
EG.5.1.1	329				
EG.5.1.3	147				
FL.1.5	106				
GE.1	133				
XBB.1.5	274				
XBB.1.9.2	159				
XBB.1.16	711				
XBB.1.16.1	85				
XBB.1.16.6	137				
XBB.1.16.11	98				
XBB.2.3.11	116				
BA.2.86	7				

*The predicted detection of XBB.1.16.11 regarding the S gene assay is 94.0%. This is still excellent coverage, and the assay is only ever present in a kit with the ORF1ab and M assays, which provide >99.9% and >99.9% detection of XBB.1.16.11, respectively.

The primary assays described will therefore, still detect all variants and subvariants mentioned above as of 31st August 2023 and are present in the following kits developed by Novacyt:

Product name	Catalogue ref. code	Gene target
genesig™ Real-Time PCR Coronavirus COVID-19 CE IVD kit	Z-Path-COVID-19-CE	ORF1ab
genesig™ COVID-19 3G Real-Time PCR assay	D00063	ORF1ab, M & S
genesig™ SARS-CoV-2 Winterplex Real-Time PCR (CE IVD) kit	D00020	ORF1ab, M & S
PROmate™ COVID-19 (q16) 1G	D00068	ORF1ab
PROmate™ COVID-19 (q32) 1G	D00070	ORF1ab
PROmate™ COVID-19 (q32) 2G	D00074	ORF1ab & nsp16

References

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.

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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 SARSCoV-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™ assays aligns with the acceptable performance characteristics for sensitivity and specificity of the testing product. Primerdesign Ltd PROmate™ direct qRT-PCR (publishing.service.gov.uk).

**Product is CE marked but not 510(k)-cleared and not available for sale in the U.S. Availability of product in each country depends on local regulatory marketing authorization status.

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