PRIMER DESIGN

Part of the Novacyt Group

genesig® COVID-19 assays

Latest Specificity Report and Independent Clinical Performance Evaluation

Date of issue: 25th January 2021. Issue 49

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)

Daily bioinformatic analysis of the Primerdesign Coronavirus COVID-19 ORF1ab and S gene assays confirms the assays still show 100% detection with all good quality SARS-CoV-2 sequences published on the GISAID EpiCoV database as of 22nd January 2021:

Assay Target	Number of Sequences Analysed	Detection Level
ORF1ab	278,963	100%
S gene	279,103	100%

Please note: The number of sequences analysed may differ slightly between the assays because any sequences with ambiguous bases in the assay target region were excluded from the analysis of that specific target. A sequence can have ambiguous bases in one assay target but not in the other.

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.

Primerdesign Ltd,
York House, School
Lane, Chandler's Ford,
Southampton, SO53 4DG

Tel: +44 (0) 2380 748 830
Fax: +44 (0) 8708 362 155
enquiry@primerdesign.co.uk
www.primerdesign.co.uk

Registered Office:
Unit 1 Watchmoor Point, Watchmoor Road,
Camberley, Surrey, England, GU15 3AD
Registered Number: 05228545

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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/

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