PRIMER DESIGN

Part of the Novacyt Group

genesig® COVID-19 assay (2019-nCoV)

Latest Specificity Report and Independent Clinical Performance Evaluation

Date of issue: 15th June 2020. Issue 18

Catalogue numbers

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)

The specificity of the Primerdesign Coronavirus COVID-19 assay confirms the assay still shows 100% detection with 30,833 full length, good quality SARS-CoV-2 sequences published on the GISAID EpiCoV database:

For Primerdesign COVID-19 assays to remain valid for identifying SARS-CoV-2 infectious individuals and aiding the diagnosis of coronavirus COVID-19 disease, the primers and probe must continue to detect all SARS-CoV-2 viral genomes, even when the virus mutates.

To ensure the COVID-19 primers and probe remain specific to detect SARS-CoV-2 genomes, Primerdesign's Bioinformaticians review daily the SARS-CoV-2 sequence submissions on the GISAID EpiCoV database. As of 12th June 2020, our bioinformaticians can confirm the COVID-19 assay primers and probe still show 100% detection with the 30,833 full length, good quality SARS-CoV-2 sequences published on the GISAID EpiCoV database.

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 moderate and 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.

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