genesig® COVID-19 assay (2019-nCoV)

Latest Specificity Report and Independent Clinical Performance Evaluation

Date of issue: 11th May 2020. Issue 13

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 11,547 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 7th May 2020, our bioinformaticians can confirm the COVID-19 assay primers and probe still show 100% detection with the 11,547 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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Independent Clinical Performance:

The following independent clinical performance evaluation studies confirm Primerdesign COVID-19 assays are 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.

Evidence of Exclusivity

In addition, sequence mismatches are a major indicator to predict assay specificity. They describe the degree to which a set of primers and probe will bind to unintended sequence targets and produce a false positive result.

The following table shows the primers and probe of the Primerdesign COVID-19 assay are predicted to provide greater specificity and therefore, unlikely to produce false positive results when exposed to SARS-CoV and Bat Coronavirus sequences, compared to other assays:

	Number of mismatches when compared to incorrect template	
	SARS Coronavirus (SARS-CoV)	Bat Coronavirus
Primerdesign Assay	11	9
US CDC N Assay*	12	7
WHO RdRP Assay**	3	2
CFDA approved Assay***	0	1

*US CDC assay comprises 3 designs, this number is based upon the design with highest number of mismatches

**Corman VM, Landt O, Kaiser M, Molenkamp R, Meijer A, Chu DK, Bleicker T,Brünink S, Schneider J, Schmidt ML, Mulders DG, Haagmans BL, van der Veer B, van den Brink S, Wijsman L, Goderski G, Romette JL, Ellis J, Zambon M, Peiris M, Goossens H, Reusken C, Koopmans MP, Drosten C, 2020. Detection of 2019 novel coronavirus (2019-nCoV) by real-time RT-PCR. Euro Surveillance.

*** Huang, C., Wang, Y., Li, X., Ren, L., Zhao, J., Hu, Y., Zhang, L., Fan, G., Xu, J., Gu, X. and Cheng, Z., 2020. Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet.

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