genesig® COVID-19 assay (2019-nCoV)

Clinical Performance Evaluation and Inclusivity / Exclusivity Data

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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)

Independent Clinical Performance Evaluations confirm Primerdesign COVID-19 CE-IVD and RUO assays are highly specific for detection of SARS-CoV-2 virus (previously called 2019-nCoV) and detection of coronavirus COVID-19 disease.

The following independent clinical performance evaluation studies, as well as the latest exclusivity/ inclusivity evidence, confirm Primerdesign COVID-19 CE-IVD and RUO assays are highly specific for detection of SARS-CoV-2 virus (previously called 2019-nCoV) and detection of coronavirus COVID-19 disease.

Public Health England Clinical Performance Evaluation

Evaluation of 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.

In addition, an independent clinical evaluation of the assay by a NHS clinical 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.

Specificity of the Primerdesign Coronavirus COVID-19 assay confirms the assay still shows 100% homology with 543 published SARS-CoV-2 sequences on the GISAID EpiFlu database.

Evidence of Exclusivity

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.

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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.

Evidence of Inclusivity

The bioinformatics analysis shows 100% homology with all SARS-CoV-2 sequences available on the NCBI database:

select all *52 sequences selected* GenBank Graphics Distance tree of results

Description	Max Score	Total Score	Query Cover	E value	Per. Ident	Accession
Severe acute respiratory syndrome coronavirus 2 SARS-CoV-2/Hu/DP/Kng/19-027 RNA, complete genome	152	152	100%	2e-33	100.00%	LC528233.1
Severe acute respiratory syndrome coronavirus 2 SARS-CoV-2/Hu/DP/Kng/19-020 RNA, complete genome	152	152	100%	2e-33	100.00%	LC528232.1
Severe acute respiratory syndrome-related coronavirus isolate SARS-CoV-2/IQTC03/human/2020/CHN, complete genome	152	152	100%	2e-33	100.00%	MT123293.1
Severe acute respiratory syndrome-related coronavirus isolate SARS-CoV-2/IQTC04/human/2020/CHN, complete genome	152	152	100%	2e-33	100.00%	MT123292.1
Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/IQTC02/human/2020/CHN, complete genome	152	152	100%	2e-33	100.00%	MT123291.1
Severe acute respiratory syndrome coronavirus 2 isolate SARS-CoV-2/IQTC01/human/2020/CHN, complete genome	152	152	100%	2e-33	100.00%	MT123290.1
Severe acute respiratory syndrome coronavirus 2 isolate 2019-nCoV/USA-CA9/2020, complete genome	152	152	100%	2e-33	100.00%	MT118835.1
Severe acute respiratory syndrome coronavirus 2 isolate 2019-nCoV/USA-TX1/2020, complete genome	152	152	100%	2e-33	100.00%	MT106054.1
Severe acute respiratory syndrome coronavirus 2 isolate 2019-nCoV/USA-CA8/2020, complete genome	152	152	100%	2e-33	100.00%	MT106053.1
Severe acute respiratory syndrome coronavirus 2 isolate 2019-nCoV/USA-CA7/2020, complete genome	152	152	100%	2e-33	100.00%	MT106052.1

This data is also supplemented by alignments of our assay target with whole genomes of the novel coronavirus on the GISAID EpiFlu database (data not shown), confirming 100% homology.

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