

genesig® COVID-19 assay (2019-nCoV)

Design Rationale and Inclusivity / Exclusivity Performance

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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)

Specificity Statement

This latest update of the specificity of the Primerdesign Coronavirus COVID-19 assay confirms the assay shows 100% homology with all 167 published COVID-19 sequences on the GISAID EpiFlu database.

There are several assays designed for the detection of Coronavirus COVID-19 disease (SARS-CoV-2 virus) (formerly called 2019-nCoV). Most assays for the detection of COVID-19 include a beta Coronavirus detection assay, which facilitates the use of SARS positive samples as a run control. However, for the single purpose of detecting COVID-19 these assays serve no additional purpose. The following exclusivity and inclusivity evidence indicate that the Primerdesign COVID-19 CE-IVD and RUO assays are highly specific for the detection of COVID-19.

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.

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:

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PRIMER

DESIGN

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	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 COVID-19 sequences available on the NCBI database:

select all 837 sequences selected		GenBank	Graphics	Distance tree of results		
Description	Max Score	Total Score	Query Cover	E value	Per. Ident	Accession
Wuhan seafood market pneumonia virus isolate 2019-nCoV/USA-AZ1/2020_complete genome	149	149	100%	2e-32	100.00%	MN997409.1
Wuhan seafood market pneumonia virus isolate 2019-nCoV/USA-CA2/2020_complete genome	149	149	100%	2e-32	100.00%	MN994468.1
Wuhan seafood market pneumonia virus isolate 2019-nCoV/USA-CA1/2020_complete genome	149	149	100%	2e-32	100.00%	MN994467.1
Wuhan seafood market pneumonia virus isolate 2019-nCoV_WHU02_complete genome	149	149	100%	2e-32	100.00%	MN988669.1
Wuhan seafood market pneumonia virus isolate 2019-nCoV_WHU01_complete genome	149	149	100%	2e-32	100.00%	MN988668.1
Wuhan seafood market pneumonia virus isolate 2019-nCoV/USA-IL1/2020_complete genome	149	149	100%	2e-32	100.00%	MN988713.1
Wuhan seafood market pneumonia virus isolate 2019-nCoV/USA-WA1/2020_complete genome	149	149	100%	2e-32	100.00%	MN985325.1
Wuhan seafood market pneumonia virus isolate 2019-nCoV_HKU-SZ-005b_2020_complete genome	149	149	100%	2e-32	100.00%	MN975262.1
Wuhan seafood market pneumonia virus isolate 2019-nCoV_HKU-SZ-002a_2020_complete genome	149	149	100%	2e-32	100.00%	MN938384.1
Wuhan seafood market pneumonia virus isolate Wuhan-Hu-1_complete genome	149	149	100%	2e-32	100.00%	NC_045512.2

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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