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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