Datasheet

Coronavirus RT-PCR COVID-19 Test Kit

Product Name	Coronavirus RT-PCR COVID-19 Test Kit
Catalogue Number	PRD-Z-Path-COVID-19-CE
IVD or RUO	IVD
CE Marked	Yes
Size	1 kit

Description:

This new molecular kit has been developed for the clinical diagnosis of COVID-19. RNA extracted from patient samples can then be analysed using the Coronavirus RT-PCR COVID-19 Test Kit (validated against ABI 7500 [Applied Biosystems], CFX [Bio-Rad] and LC480 [Roche]). The detection profile of the kit displays zero cross reactivity with other related viruses and 100% homology with all published SARS-CoV-2 sequences. Our COVID-19 CE IVD kit with lyophilised reagents is available with NO cold chain shipping globally. This is the ultimate solution to sensitive, rapid and cost-effective clinical diagnosis of COVID-19.

Product Features:

Features and Benefits:

- Rapid detection of COVID-19
- Highly specific detection profile
- High priming efficiency
- Accurate controls to confirm extraction, run and reaction validity
- Supplied lyophilised with no cold chain shipping
- Validated against nasopharyngeal and oropharyngeal swabs as well as sputum
- Multi-Platform Capability

Kit controls and standards: The kit includes an Internal Control to identify possible PCR inhibition, to measure extraction purity and to confirm the integrity of PCR run. Our CE kits come combined with Oasig™ Lyophillised Master Mix providing a complete one kit diagnostic system.

Storage: Store the product at –20°C.

Regulatory/ Restrictions: For in-vitro diagnostic use only. This product is for professional use only.

Materials Supplied:

1. Primer & Probe Mix
2. Positive Control Template
3. Internal Extraction Control
4. DNase/RNase free water
5. Oasig Lyophilised qPCR Master Mix

Independent Clinical Performance Evaluations confirm Primerdesign COVID-19 assays are highly specific for the 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 the Primerdesign COVID-19 assays are highly specific for the 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 an 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

The specificity of the Primerdesign Coronavirus COVID-19 assay confirms the assay still shows 100% homology with 753 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.
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.