Clinical evaluation of our Real-Time PCR Coronavirus (COVID-19) CE IVD was conducted with contrived oropharyngeal swabs (50 positive and 50 negative) in Copan universal transport medium. 50 swabs were contrived with positive control template and tested blindly to generate the Positive Percentage Agreement (PPA), Negative Percentage Agreement (NPA) and overall percentage agreement (OPA) as a measurement of estimated Diagnostic Accuracy:

		Contrived Sample Status	
		Positive	**Negative**
RealTime PCR Coronavirus (COVID-19) CE IVD	**Positive**	**49**	**0**
	Negative	**1**	**50**
		Positive Percentage Agreement (PPA)	**Negative Percentage Agreement (NPA)**
		98%	**100%**
		Overall Percentage Agreement (OPA)	
		99%	

The Real-Time Coronavirus (COVID-19) CE IVD has been designed to detect all publicly available COVID-19 viral RNA sequences. This was assessed with *in silico* sequence comparison analyses and in vitro specimen testing. Upon *in silico* analysis the genesig Real-Time PCR Coronavirus (COVID-19) CE IVD design was found to detect all COVID-19 virus strains and exhibited no cross reactivity with non-COVID-19 species.

For testing, in vitro two panels were sourced from Qnostics: the Respiratory Evaluation Panel and QCMD Past Panel from the Coronavirus EQA programme.
The results of the in vitro specimen testing are presented below

Organism	Interpreted Result*
Influenza A H1N1	COVID-19 not detected
Influenza A H3N2	COVID-19 not detected
Influenza B Victoria	COVID-19 not detected
Influenza B Yamagata	COVID-19 not detected
RSV A	COVID-19 not detected
RSV B	COVID-19 not detected
Coronavirus NL63	COVID-19 not detected
Coronavirus 229E	COVID-19 not detected
Coronavirus HKU	COVID-19 not detected
Coronavirus OC43	COVID-19 not detected