QuantiVirus™ Real-Time PCR Coronavirus (SARS-CoV-2) Test Clinical Evaluation

Clinical evaluation of the QuantiVirus™ Real-Time PCR Coronavirus (SARS-CoV-2) Test (CE-IVD) was conducted with contrived sputum specimens including 32 positive and 32 negative samples. 32 sputum sample were contrived with positive control témplate and 32 specimen were contrived only with the negative extraction control (NEC) témplate. The contrived clinical samples were 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 Samples			
		Positive	**Negative**	**Total**
QuantVirus™ Real-Time PCR Coronavirus (SARS-CoV-2) Test	**Test positive**	32	0	32
	Test negative	0	32	32
	Total	32	32	64

Table: Contrived Clincal Sample Evaluation

The Table Shows Assay Accuracy for the QuantVirus™ Real-Time PCR Coronavirus (SARS-CoV-2) Test

Clinical sensiti vity = 100% (95% CI, 88.6-100%)

Clinical specificity = 100% (95% CI, 88.6-100%, 95%CI)

Positive percentage agreement (PPA) =100 %

Negative percentage agreement (NPV) = 100%

Overall percentage agreement (OPV) = 100%