DIACARTA

FDA EUA APPROVED

QuantiVirus™ SARS-CoV-2 Test Kit

Detection of COVID-19 Coronavirus

Since the new coronavirus (SARS-CoV-2) outbreak started in Wuhan, China, over 936,209 people have been infected and more than 47,249 people died of the infection. The virus has now infected people in over 203 countries.

Different from other coronaviruses that caused epidemics in the past, the SARS-CoV-2, which can be transmitted from one person to another without showing symptoms, leads to a pandemic according to the World Health Organization (WHO). It is critical to detect the virus quickly and accurately so the people who get infected can be effectively quarantined to prevent further infection.

**The numbers are calculated on April 2, 2020 by https://www.worldometers.info/coronavirus/*

Important Facts about DiaCarta's QuantiVirus™ Assay CE

- FDA Emergency Use Authorization (EUA) Approved
- CE-Marked
- Detects three genes (Orf1ab, N and E genes)
- Detects different SARS-CoV-2 virus strains
- Sensitivity is 100 copies per mL
- < 2 hours from RNA to results on most qPCR machines

WHY CHOOSE US?

Although many kits have entered the market recently, some of them suffer from low sensitivity and have misled the healthcare physicians. DiaCarta's QuantiVirus™ SARS-CoV-2 Test Kit accurately detects positive subjects within 2 hours, thereby providing great value to the current outbreak.

INTRODUCTION

The QuantiVirus™ SARS-CoV-2 Test Kit is based on Real-Time PCR (RT-PCR) technology, developed for specific detection of SARS-CoV-2 (COVID-19) viral RNA extracted from nasopharyngeal swabs, oropharyngeal swabs and sputum. The sensitivity is 100 copies per mL of SARS-CoV-2 viral with a 95% confidence. Clinical validation of the assay showed 96.7% sensitivity and a specificity of 100%, with no cross-reaction to different types of non-SARS-CoV-2 species.

ASSAY SUMMARY

Three genes of the SARS-CoV-2 including N, Orf1ab and E are targeted in the quantitative real-time PCR (qRT-PCR) assay and primers and TaqMan probes are designed in the conserved region of the SARS-CoV-2 virus specific genome region to allow sensitive and specific amplification and detection of the virus. The human Rnase P gene is used as internal and extraction control to monitor viral RNA extraction efficacy and assess amplifiable RNA/DNA in the samples to be tested.

FEATURES & ADVANTAGES

- **High Sensitivity:** The sensitivity is 100 copies per mL of SARS-CoV-2 viral with a 95% confidence.
- **Low Sample Volume:** only 2 uL viral RNA sample
- **High Accuracy:** detection of three target genes for calling positive results
- **Wide Dynamic Range:** allowing detection of from 10 million copies to single copy analyte in the linear range

PRODUCT SPECIFICATIONS

Sample Type	Nasopharyngeal Swabs, Oropharyngeal Swabs and Sputum
Pack Size	24 Reactions, 48 Reactions
Validated Machines	Thermo Fisher (ABI) QuantStudio 5 Thermo Fisher (ABI) 7500 Fast Dx Bio-Rad CFX 384
Turnaround Time	~2 hours
Stability	Stable for 12 Months at -25 °C to -15 °C

ORDERING INFORMATION

Product Name	Pack Size	Catalog Numer
QuantiVirus™ SARS-CoV-2 Test Kit	24 Reactions	DC-11-0007
	48 Reactions	DC-11-0008
	480 Reactions	DC-11-0009

QuantiVirus™ SARS-CoV-2 Test Kit Performance

The results for the QuantiVirus™ SARS-CoV-2 Test Kit performance evaluation have been generated on ABI 7500 Fast Dx and ABI QuantStudio 5 qPCR instruments. Additional tests were performed on Bio-Rad CFX 384.

Analytical Sensitivity

To determine the limit of detection (LOD) and analytical sensitivity of the kit, the studies were performed using serial dilutions of analyte and the LOD was determined to be the lowest concentration of template that could be reliably detected with 95%-100% confidence.The LOD was confirmed by testing 3-fold dilutions of *in vitro* transcribed RNA with 20 replicates of each dilution. The LOD was determined to be the the lowest concentration (copies/uL) at which ≥95% (19/20) of the 20 replicates were tested as positive. Average Ct from 20 samples for N gene, ORF1ab and E gene were between Ct 32-36 with 95% CI. The data confirmed that the assay analytical sensivity is 1-5 copies/uL. The assay amplification showed a wide dynamic range allowing detection from 10 millon copies down to 1-5 copies of the analyte in the linear range.

Analytical Specificity

The QuantiVirus™ SARS-CoV-2 Test Kit has been designed to detect all publicly available SARS-CoV-2 viral RNA sequences. At the same time, the primers and probes were designed in the SARS-CoV-2 virus specific genome region ensuring the specific detection of the SARS-CoV-2 virus. In silico analysis of the SARS-CoV-2 assay design showed that the assay can detect different SARS-CoV-2 virus strains and exhibited no cross reactivity with non-SARS-CoV-2 species.

Inter-Instrument Reproducibility and Operator Reproducibility

Assay reactions were set up with three replicates and run on three different qPCR instruments including BioRad CFX 384, ABI QS5 and ABI 7500 Fast Dx. Coefficient of Variation (%): < 5%. The assay reactions were set up by two operators using the same lot of reagent and run on the same instrument. Coefficient of Variation (%): < 1.5%.

Clinical Evaluation

Clinical evaluation of the QuantiVirus™ SARS-CoV-2 Test Kit was conducted with contrived sputum specimens including 30 positive and 30 negative samples. 20 sputum samples were contrived with RNA (*in vitro* transcrpts) templates at 2X LOD (2X100 copies/mL) and 10 sputum samples were contrived with different higher RNA concentration (500, 1000, 5000 and 10000 copies/uL). 30 specimen were contrived only with water as negative control. The contrived clinical samples were tested blindly to generate the Positive Predictive Value (PPV), Negative Predictive Value (NPV) as a measurement of estimated diagnostic accuracy. Data shows that there is a 95% agreement with the spiking sample with 2X LOD (2x100 copies/uL), but one sample cannot be detectable. With higher concentration spiking samples (500, 1000, 5000 and 10000 copy/uL), 10 out of 10 samples were detectable. For negative control, 30 samples were negative.

Specimen Type	Viral Copy Spiking	SARS-CoV-2			Performance	
		Positive	Negative	Total		
Viral RNA + Sputum	10 copies/uL	19	1	20	95%	96.7%
	500 copies/uL	3	0	10	100%	
	1000 copies/uL	2	0	10	100%	
	5000 copies/uL	3	0	10	100%	
	10000 copies/uL	2	0	10	100%	
H2O + Sputum	0 copy/uL	0	30	30	100%	100%

Table: Contrived Clinical Sample Evaluation with *in vitro* transcribed RNA

The left table shows:

- Clinical sensitivity = 96.7% (95% CI, 81.4%-99.8%)
- Clinical specificity = 100% (95% CI, 85.4%-100%)
- Positive Predictive Value (PPV) = 100 % (95% CI, 85.8%-100%)
- Negative Predictive Value (NPV) = 96.6% (95% CI, 80.9%-99.8%)

Third-Party Clinical Test Results

The third-party clinical test results demonstrated that DiaCarta's QuantiVirus™ SARS-CoV-2 Test Kit shared the same testing results (100% match), compared with peer products, even at much lower sample concentration in some cases.

Sample ID	Abbott m2000	US CDC (Centers for Disease Control and Prevention)	DiaCarta's QunantiVirus™ Assay
A		Detected	Detected at 1:100 dilutions
B		Detected	Detected at 1:1000 dilutions
C	Not Detected	Not Detected	Not Detected
D	Not Detected	Not Detected	Not detected
E	Not Detected	Not Detected	Not detected
F	Not Detected	Not Detected	Not detected
G	Not Detected	Not Detected	Not detected
H	Not Detected	Not Detected	Not detected
I	Not Detected	Not Detected	Not detected
J	Detected	Detected	Detected
K	Detected		Detected
L	Detected		Detected
M	Detected	Detected	Detected
N	Not Detected	Not Detected	Not detected