DIACARTA

FDA EUA Approved & CE/IVD Marked

QuantiVirus™ SARS-CoV-2 Test Kit

A high-throughput RT-PCR test that accurately detects COVID-19 virus

Important Facts about DiaCarta's QuantiVirus™ Assay

- 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
- High throughput: 93 samples (96-well plate) or 381 samples (384-well plate) per run

**This product configuration image only shows the 24-reaction and 48-reaction pack size. 480-reaction pack size has 7 vials. Please refer to the product IFU for more information.*

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.

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 2-5.5 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
- **High throughput**: 93 samples (96-well plate) or 381 samples (384-well plate) per run

PRODUCT SPECIFICATIONS

Sample Type	Nasopharyngeal Swabs, Oropharyngeal Swabs and Sputum
Pack Size	24 Reactions, 48 Reactions, 480 Reactions
Validated Machines	Thermo Fisher (ABI) QuantStudio 5 Thermo Fisher (ABI) 7500 Fast Dx Bio-Rad CFX 384, Roche Light Cycler 480 II
Turnaround Time	~2 hours
Stability	Stable for 12 Months at -25 °C to -15 °C

ORDERING INFORMATION

Product Name (FDA EUA Approved Version)	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

Product Name (CE/IVD Marked Version)	Pack Size	Catalog Numer
QuantiVirus™ Real-Time PCR Coronaviru (SARS-CoV-2) Detection Test	24 Reactions	DC-11-0005E
	48 Reactions	DC-11-0004E
	480 Reactions	DC-11-0006E

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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, ABI QuantStudio 5, Bio-Rad CFX 384 and Roche Light Cycler 480 II qPCR instruments.

Analytical Sensitivity

To determine the Limit of Detection (LoD) and analytical sensitivity of the kit, studies were performed using serial dilutions of analyte and the LoD was determined to be the lowest concentration of template that could reliably be detected with 95% of all tested positive.The LOD was confirmed by testing 1xLoD of viral RNA with 20 replicates. The LoD was determined to be the lowest concentration (copies/ml) at which ≥95% (19/20) of the 20 replicates were tested as positive. **The data confirmed the assay analytical sensitivity reaches 100 copies/mL.**

Precision

- **Intra-Assay Reproductivity**: The Intra-assay overall CV was <3% and acceptable for this assay.
- **Operator Reproducibility**: Overall CV for two operators is <5% and is acceptable for this assay.
- **Inter-Instrument Reproducibility**: The results indicate that three instruments have <5% CV and is acceptable.

Inclusivity

In silico analysis of the QuantiVirus™ SARS-CoV-2 Test Kit design showed that the assay can detect all SARS-CoV2 virus strains and exhibited no cross reactivity with non-SARS-CoV2 species.

Cross-Reactivity

Our tested organisms all show negative for the three targeted genes of SARS-CoV-2, suggesting there is no cross-reactivity between SARS-CoV-2 detection and the organisms tested. The cross reactivity with SARS-coronavirus (MK062184.1) was tested and confirmed that it did not show any cross reactivity at 105 PFU/mL.

Clinical Evaluation

Clinical evaluation of the QuantiVirus™ SARS-CoV-2 Test Kit was conducted with contrived sputum specimens including 40 positive and 30 negative samples. Sputum samples (20 samples) were contrived with non-infectious viral particles templates at 1xLoD (1x200 copies/mL) and 10 sputum samples were spiked with non-infectious virus at 1.5xLoD (300 copies/mL) and another 10 sputum samples were spiked at the concentration of 2.5xLoD (500 copies/mL). Viral RNA was extracted from spiked samples and tested blindly with the QuantiVirus™ SARS-CoV-2 Test Kit.

Specimen Type	Viral Copy Spiking	SARS-CoV-2			Performance Agreeement	95% CI
		Positive	Negative	Total		
Viral RNA + Sputum	200 copies/mL (1x LoD)	20	0	20	100%	76.4-99.1%
	300 copies/mL (1.5x LoD)	10	0	10	100%	72.3-100%
	500 copies/mL (2.5x LoD)	10	0	10	100%	72.3-100%
H2O + Sputum	0 copy/uL	0	30	30	100%	90.6%-100%

Table: Contrived clinical sample evaluation with viral particles (Bio-Rad CFX 384)

Data show that there is 100% agreement with the spiked sample at 1xLoD (1x200 copies/mL), and 100% agreement at all other concentrations including 300 copies/mL and 500 copies/mL (Table 17c). For negative control, all the 30 samples were tested negative. Data was generated on Bio-Rad CFX 384.

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