DIACARTA

MADE IN USA

FDA EUA Authorized & CE/IVD Marked

QuantiVirus™ SARS-CoV-2 Multiplex Test Kit

A high-throughput RT-PCR test that accurately detects all the species of COVID-19 including new Omicron BA.4 and BA.5 subvariants

Important Facts about DiaCarta's QuantiVirus™ Assay

- FDA Emergency Use Authorization (EUA) Authorized
- CE-Marked
- Detects one gene (Orf1ab)
- Detects all the species of COVID-19
- Sensitivity is 50 copies per mL
- High throughput: 93 samples (96-well plate) or 381 samples (384-well plate) per run
- Top tier among 117 tests in term of sensitivity in FDA reference panel study

INTRODUCTION

The QuantiVirus™ SARS-CoV-2 Multiplex Test Kit is based on Real-Time PCR technology, developed for specific detection of SARS-CoV-2 (COVID-19) viral RNA extracted from nasopharyngeal swabs, oropharyngeal swabs and sputum. The analytical sensitivity is 50 copies per mL of SARS-CoV-2 viral with a 95% confidence.

ASSAY SUMMARY

The multiplex RT-PCR assay consists of one reaction with primers and probes for the Orf1ab viral target and internal control both in one tube, which increases assay throughput and ease of use.

FEATURES & ADVANTAGES

- **High Sensitivity:** Detects as low as 50 copies of viral RNA /mL sample, enables early virus detection and diagnosis
- **High Throughput:** Up to 93 clinical samples can be tested on one 96-well plate; up to 381 clinical samples can be tested on one 384-well plate
- **High Specificity:** Proven by in silico analysis as well as wet lab testing
- **Intended Sample Types**: Easy sampling with Nasopharyngeal Swabs, Oropharyngeal Swabs and Sputum
- **Minimal Sample Input**: as low as 2 to 5.5 µL sample needed
- **Ease of Use**: Only one reaction mix needs to be set up per sample
- **Fast Turnaround Time**: Only 2 hours from nucleic acid extraction to results
- **Flexibility**: Assay validated on widely used qPCR instruments including ABI 7500 Fast Dx, ABI QuantStudio 5 and BioRad CFX 384
- **Precision**: Coefficient of variation (CV) < 3%, allowing reproducible test results

PRODUCT SPECIFICATIONS

Sample Type	Nasopharyngeal Swabs, Nasal Swabs, Oropharyngeal Swabs, Saliva, and Sputum
Pack Size	48 Reactions, 480 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 (FDA EUA Approved Version)	Pack Size	Catalog Numer
QuantiVirus™ SARS-CoV-2 Mutiplex Test Kit	48 Reactions	DC-11-0018
	480 Reactions	DC-11-0019

Product Name (CE/IVD Marked Version)	Pack Size	Catalog Numer
QuantiVirus™ SARS-CoV-2 Multiplex Detection Test	48 Reactions	DC-11-0014E
	480 Reactions	DC-11-0016E

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QuantiVirus™ SARS-CoV-2 Test Multiplex Kit Performance

The results for the QuantiVirus™ SARS-CoV-2 Test Kit performance evaluation have been established on the Applied Biosystems™ QuantStudio 5, 7500 Fast Dx and Bio-Rad CFX 384 Real-Time PCR instrument.

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 following data confirmed the assay detects as low as 50 copies of viral RNA /mL sample for ABI 7500 Fast Dx, enabling early virus detection and diagnosis.** Please refer to the product IFU for analytical sensitivity data on ABI QuantStudio 5 and Bio-Rad CFX 384.

Target	RNA (copy/mL)	Total	Average Ct	SD	SD	Positive	Negative	Call Rate
Orf1ab	50 copies/mL	20	34.54	0.99	0.03	19	1	95%
	100 copies/mL	20	33.35	0.63	0.02	20	0	100%

Precison

Precision studies include intra-run, inter-run, instrument and operator variability evaluation. The assay precision was assessed by the repeated testing of samples with three different template concentrations.

- **Intra-Assay Reproducibility**: Overall CV at three sample template concentrations is <3%
- **Operator Reproducibility:** Overall CV for two operators is <3%
- **Inter-Instrument Reproducibility**: Overall CV for three instruments is <3%
- **Inclusivity**: *in silico* analysis of the QuantiVirus™ SARS-CoV-2 Multiplex Test Kit assay design showed that the assay can detect all SARS-CoV-2 virus strains and exhibited no cross reactivity with non-SARS-CoV-2 species.
- **Cross-Reactivity**: The cross reactivity with other human-coronavirus such as MERS-coronavirus was tested and confirmed that it did not show any cross reactivity at 10^5 PFU/mL.

Clinical Evaluation

Clinical evaluation of the QuantiVirus™ SARS-CoV-2 Multiplex Test Kit was conducted with contrived sputum specimens including 80 positive and 30 negative samples. Sputum samples were mixed with the lysis buffer from the extraction kit at 1:1 ratio before spiking in non-infectious viral particles. 20 sputum samples were contrived with non-infectious viral particle templates at 1X LoD (1x50 copies/mL), 20 samples at 2xLoD (2x50 copies/mL), 20 samples at 4xLoD (4x50 copies/mL), 10 samples at 6xLoD (300 copies/mL), and 10 samples at 10xLoD (500 copies/mL). Viral RNA was extracted from spiked samples and tested blindly with the QuantiVirus™ SARS-CoV-2 Multiplex Test Kit. Data show that there is 95% agreement with the spiked sample at 1xLoD (1x50 copies/mL), and 100% agreement at all other concentrations including 100 copies/mL(2xLoD), 200 copies/mL (4xLoD), 300 copies/mL (6xLoD) and 500 copies/mL (10xLoD). For negative control, all 30 samples tested negative.

Specimen Type	Viral Copy Spiking	SARS-CoV-2			Performance Agreement	95% CI
		Positive	Negative	Total		
Viral RNA + Sputum	50 copies /mL (1x LoD)	19	1	20	95%	83.9-100%
	100 copies/mL (2xLoD)	20	0	20	100%	83.9-100%
	200 copies/mL (4x LoD)	20	0	20	100%	83.9-100%
	300 copies/mL (6x LoD)	10	0	10	100%	72.3-100%
	500 copies/mL (10xLoD)	10	0	10	100%	72.3-100%
H2O + Sputum	0 copy/mL	0	30	30	100%	90.6-100%

Table: Contrived clinical sample evaluation with viral particles (ABI 7500 Fast Dx). Please refer to the product IFU for clinical data on ABI QuantStudio 5 and Bio-Rad CFX384.

Third-Party Clinical Test Results

The third-party clinical test results demonstrated that DiaCarta's QuantiVirus™ SARS-CoV-2 Multiplex 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 QuantiVirus™ 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