DIACARTA

CE-MARKED

QuantiVirus™ SARS-CoV-2 Multiplex Test Kit

High throughput Detection of COVID-19 Coronavirus with Ultra Sensitivity

Since the new coronavirus (SARS-CoV-2) outbreak started in Wuhan, China, over 3,300,724 people have been infected and more than 233,693 people died of the infection. The virus has now infected people in over 212 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 30, 2020 by https://www.worldometers.info/coronavirus/*

MULTIPLEX TEST KIT KEY HIGHLIHGTS CE

- High throughput: 93 samples (96-well plate) or 381 samples (384-well plate) per run
- Detects as low as 50 copies of viral RNA /mL sample, enables early virus detection and diagnosis.
- Minimal sample input: as low as 2 µL sample needed
- Sample Type: Sputum, NP, OP, and saliva
- < 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 low throughput.
DiaCarta's QuantiVirus™ SARS-CoV-2 Multiplex Test Kit accurately detects positive subjects within 2 hours, thereby providing great value to the current outbreak.

INTRODUCTION

The QuantiVirus™ SARS-CoV-2 Multiplex Test Kit is based on Real-Time PCR (RT-PCR) technology, developed for high throughput and specific detection of SARS-CoV-2 (COVID-19) viral RNA extracted from nasopharyngeal swabs, oropharyngeal swabs, sputum and saliva. The sensitivity reaches 50 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.

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: Nasopharyngeal swabs, oropharyngeal swabs, sputum and saliva
- **Minimal Sample Input**: As low as 2 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, Oropharyngeal Swabs, Sputum and Saliva
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
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 Multiplex Test Kit	24 Reactions	DC-11-0017	DC-11-0015E
	48 Reactions	DC-11-0018	DC-11-0014E
	480 Reactions	DC-11-0019	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 or Bio-Rad CXF 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, enables early virus detection and diagnosis.** Please refer to the product IFU for analytical sensitivity data on ABI QuantStudio 5 and Bio-Rad CFX384

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 Reproductivity**: 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-CoV2 virus strains and exhibited no cross reactivity with non-SARS-CoV2 species.
- **Cross-Reactivity**: The cross reactivity with SARS-coronavirus 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 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. Sputum samples (20 samples) were contrived with non-infectious viral particles templates at 1X LoD (1x50 copies/mL), 20 samples at 2xLoD (2x50 copies/mL), 20 samples at 4xLoD (4x50 copies/mL) and 10 sputum samples were spiked with non-infectious virus at 6xLoD (300 copies/mL) and another 10 sputum samples were spiked at the concentration of 10xLoD (500 copies/mL). Viral RNA was extracted from spiked samples and tested blindly with the QuantiVirus™ SARS-CoV-2 RT-qPCR. 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. For negative control, all the 30 samples were 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 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