DIACARTA®

CE IVD

QuantiVirus™ SARS-CoV-2 & Flu AB Detection Test Kit

Why combining COVID-19 and Flu type A and B testing?

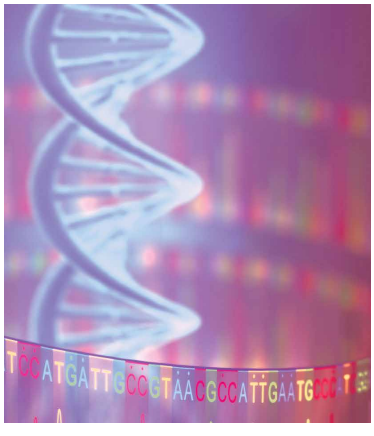
In the flu season, combining the test for Flu type A and B, the two major circulating flu viruses, with the COVID-19 test allows the screening of three viruses to be done at the same time. The three viruses cause similar symptoms such as coughing, fever, and difficulty in breathing and a person may get co-infected by both SARS-CoV-2 (the virus for COVID-19) and Flu A or B viruses. The test allows health care providers to monitor the spread of the infectious diseases and better control the spread. It may also help better target the diseases with proper treatment.

The viral RNA test vs. antigen test

Two types of COVID-19 and Flu A and B tests are available. The virus RNA test uses qualitative real-time reverse transcription PCR (RT-qPCR) to detect and differentiate each individual viral genetic material RNA and is currently the gold standard for virus testing with high sensitivity. The antigen test, on the other hand, detects the presence of virus antigens rapidly for people with the onset of symptoms, but it is less sensitive and needs to be confirmed with molecular assay for better accuracy.

QuantiVirus™ SARS-CoV-2 & Flu A&B detection test kit

QuantiVirus™ SARS-CoV-2 & Flu AB Detection Test Kit is an RT-qPCR test that can detect three types of viruses, SARS-CoV-2 (the virus that causes COVID-19), Flu A and B in one reaction. The test is intended for the qualitative detection of nucleic acid from the SARS-CoV-2 and/or Influenza viruses in nasopharyngeal (NP) swabs from individuals suspected of COVID-19 and/or Influenza by their healthcare provider. Testing is limited to laboratories certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), 42 U.S.C. §263a, to perform high complexity tests.



The assay is a multiplex RT-qPCR assay consisting of one reaction with primers and probes for all the viral targets (Orf 1ab gene for SARS-CoV-2 and Influenza A&B genes) together with internal control (human RNase P) in one tube. The multiplex assay thus provides the benefit of high throughput and ease of use.

Assay workflow

The brief procedure for performing the assay include the following steps:

1. Extract RNA from patient sample and extraction control using Thermo Fisher PureLink™ viral RNA/DNA mini kit or Qiagen QIAamp® Viral RNA Mini Kit or equivalents.
2. Set up the assay reactions using Primer/Probe Mix, and Inhibitor-Tolerant RT-qPCR Master Mix. A positive (PC), Etraction (EC) and No Template Control (NTC) must be included for every run.
3. Perform RT-qPCR using the Applied Biosystems™ QuantStudio 5 or BioRad CXF 384 Real-Time PCR Instrument.
4. Data analysis.
5. Review results and interpretation for patient samples.

Analytical performance

The assay data confirmed the multiplex assay analytical sensitivity for the three validated instruments:

ABI QuantStudio 5

SARS-CoV-2: 100 copies/mL
Influenza A: 150 copies/mL
Influenza A: 150 copies/mL

Bio-Rad CFX384

SARS-CoV-2: 300 copies/mL
Influenza A: 300 copies/mL
Influenza A: 200 copies/mL

Roche Light Cycler 480 II

SARS-CoV-2: 150 copies/mL
Influenza A: 150 copies/mL
Influenza A: 200 copies/mL

The assay precision is evaluated by both intra-assay and inter-assay reproducibility. Intra-assay %CV is established through performance of kit on reference samples run in replicates of nine. The Intra assay overall CV was <5%. Inter-assay %CV was established for same lot of reagents tested on the same instrument by the same user. Operator variability was evaluated with one lot of reagents by two operators. The overall CV for two operators is <5%.

Clinical performance

To evaluate the clinical performance of the QuantiVirus™ SARS-CoV-2 & Flu AB Detection Test Kit in detection of SARS-CoV-2 virus, COVID-19 samples determined by FDA-authorized RT-qPCR assay QuantiVirus™ SARS-CoV-2 Test (FDA EUA 200176) is tested with the COVID-19 and FLU AB combo kit. The result is summarized in Table 1.

Table 1. SARS-CoV-2 Clinical Sample Testing with QuantiVirus™ SARS-CoV-2 & Flu AB Detection Test Kit

QuantiVirus™ SARS-CoV-2	QuantiVirus™ SARS-CoV-2 & Flu AB			PPA (%)	NPA (%)
	N	Positive	Negative		
Positive	363	362	1	99.7% (95%CI: 0.98 -0.99)	99.9% (95%CI: 0.99-0.99)
Negative	997	1	996		

The clinical performance of the QuantiVirus™ SARS-CoV-2 & Flu AB Detection Test Kit towards patient samples with known Influenza infection status were assessed with the COVID-19 and Flu A and B combo kit. The status of these samples was confirmed by FDA-authorized RT-qPCR assay CDC Flu SC2 Multiplex Assay. The clinical sample testing data were summarized in Table 2.

Table 2. Influenza Clinical Sample Testing with QuantiVirus™ SARS-CoV-2 & Flu AB Detection Test Kit

CDC Flu SC2 Multiplex Assay	QuantiVirus™ SARS-CoV-2 & Flu AB Test				PPA (%)	NPA (%)
	N	Positive		Negative		
		Flu A	Flu B			
Positive	48	25	23	0	100 % (95%CI: 0.91- 1.00)	100 % (95%CI: 0.90 - 1.00)
Negative	44	0	0	44		

Note: Influenza B samples were collected in our CLIA lab around 2020-2021 and Influenza A samples were collected by iSpecimen Inc early 2022

Ordering Information

CE/IVD Marked Version (For Outside US Customer)

Product Name: QuantiVirus™ SARS-CoV-2 & Flu AB Detection Test Kit
DC-11-0084E (48 Reactions)
DC-11-0085E (480 Reactions)

Research-Use-Only Version

Product Name: QuantiVirus™ SARS-CoV-2 & Flu AB Detection Test Kit
DC-11-0084R (48 Reactions)
DC-11-0085R (480 Reactions)

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