FREND™ System

COVID-19 IgG/IgM Duo

Microfluidic Qualitative Immunoassay

The FREND™ COVID-19 IgG/IgM Duo is a **point-of-care testing (POCT)** which can be used to check whether patients have developed immune responses to SARS-CoV-2 using human serum or plasma.

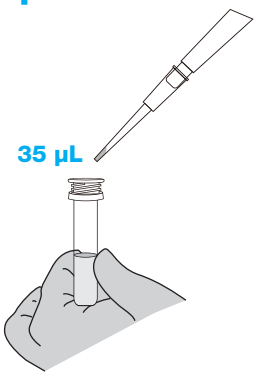
For COVID-19 IgG/IgM Duo, it provides results **qualitatively** but the principle of detection is **quantitative**.
The FREND™ System shows the test result as negative if the Cut-Off-Index (COI) is < 1.0. If the Cut-Off-Index (COI) is ≥ 1.0, then the test result will be provided as positive. The Cut-Off-Index (COI) is determined quantitatively by testing the specimens collected after day 8 from the onset of symptoms using the FREND™ System.

Fast
3 mins

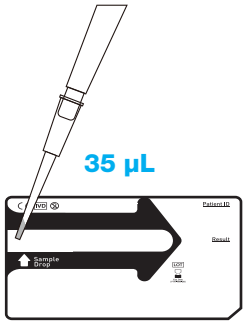
Easy
3 steps

Monitoring
LIS

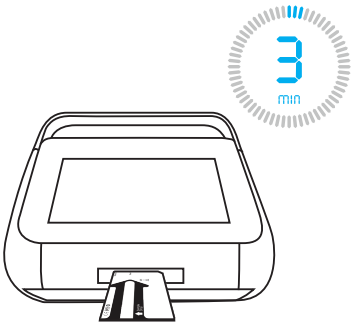
Steps



STEP 01.
Dilute sample.

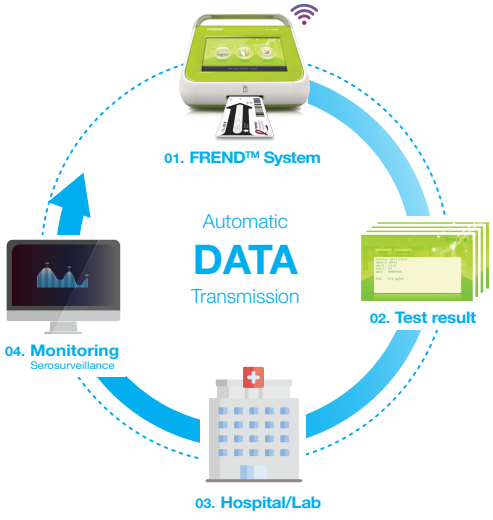


STEP 02.
Add **35 µL** of the diluted sample.



STEP 03.
Insert the cartridge and get results.

Laboratory Information System Connectivity



In the event of a pandemic, the management of a vast amount of clinical results is important. As many laboratories face challenges in effective arrangement of the essential information[1] the **FREND™ System** provides the following advantages:

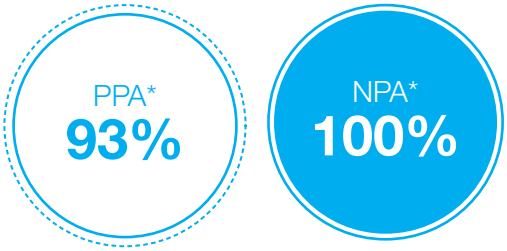
- **Paperless**
- **Time-saving**
- **Automatic Data Transfer & Collection**
- **Convenient Data Management**
- **Can help monitoring (serosurveillance)**

Clinical Performance

The total of 59 clinical specimens (43 positive and 16 negative) confirmed with RT-PCR were tested with the FREND™ COVID-19 IgG/IgM Duo.

The total result of all samples

Method			Clinically Confirmed Specimen	
			Positive	Negative
FREND™ COVID-19 IgG/IgM Duo	Positive	IgG(+), IgM(+)	14	0
		IgG(+), IgM(-)	26	0
		IgG(-), IgM(+)	0	0
	Negative		3	16
	Total		43	16

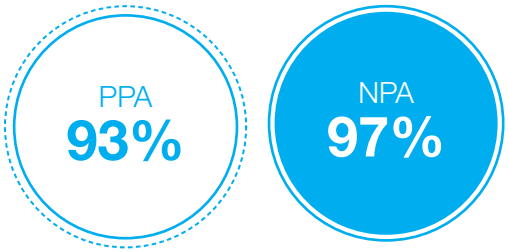


Positive Percent Agreement (PPA), Negative Percent Agreement (NPA)

The following table includes 16 negative specimens from the previous table and new 325 negative specimens, making a total of 341 negative specimens.

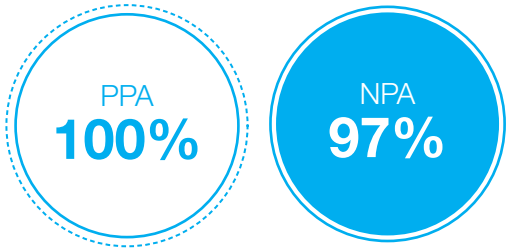
The total result of all samples

Method		Clinically Confirmed Specimen	
		Positive	Negative
FREND™ COVID-19 IgG/IgM Duo	Positive	40	10
	Negative	3	331
	Total	43	341



The test result collected specimens after 8 days from symptom onset

Method		Clinically Confirmed Specimen	
		Positive	Negative
FREND™ COVID-19 IgG/IgM Duo	Positive	40	10
	Negative	0	331
	Total	40	341



* The table shows result of specimens collected after 8 days from symptom onset.
Three specimens were excluded in the original data.

Reference:
(1) Division of Laboratory Systems (DLS), Clinical Laboratory COVID-19 Response Call
(2) CDC Tests for COVID-19 from Centers for Disease Control and Prevention.
(3) Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19), Li Guo.
(4) Purpose and Options for Testing for SARS-Cov2 (the COVID-19 Virus): Considerations for World Bank Task Teams Managing COVID-19 Fast Track Facility Operations, The World Bank
(5) Cellular immune responses to severe acute respiratory syndrome coronavirus infection in senescent BALB/c Mice:CD4+ T cells are important in control of SARS-CoV infection. Jun Chen.
(6) Chronological evolution of IgM, IgA, IgG and neutralisation antibodies after infection with SARS-associated coronavirus, P.-R. Hsueh.
(7) SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients, Lirong Zou.
(8) Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, Fei Zhou.

Why serological test is necessary?

The serological test using blood samples is required to detect whether symptoms developed from infection or the infection was asymptomatic[2]. After the onset of symptoms, the IgM starts to increase and then the IgG production begins from the next 7 days. Therefore, it is recommended to use the FREND™ System at a minimum day 8 (Fig. 1)[3-7]. After the onset of symptoms, the sensitivity of positive PCR decreased below 80% and 50% on day 6 and day 14, respectively.
The combination of PCR with serological test increased the positive sensitivity by 47% (Fig. 2)[8].

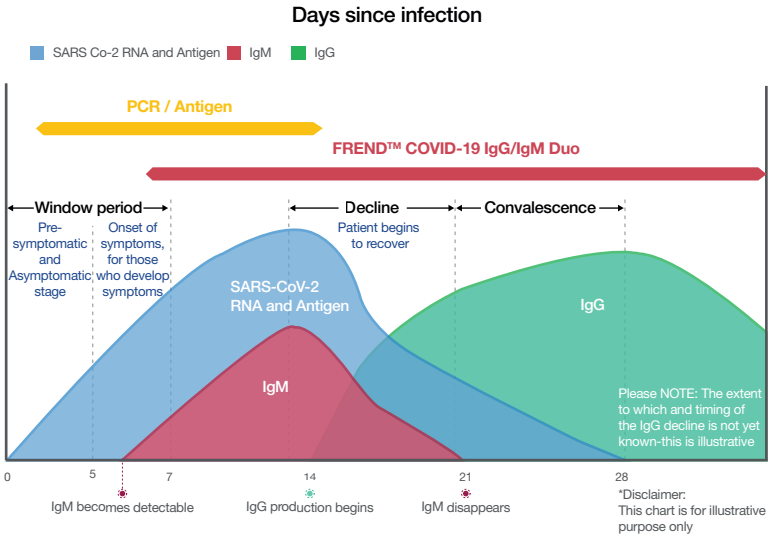


Fig. 1

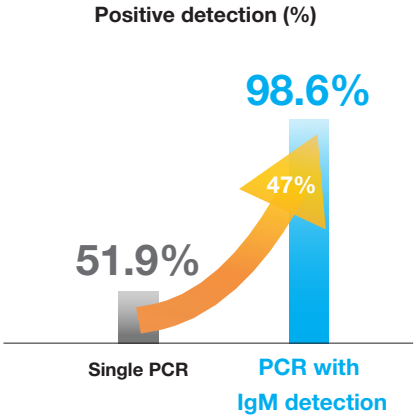


Fig. 2

Specification

Item	Specification
Assay method	Fluorescence immunoassay
Specimen	Serum or Plasma
Sample volume	35 µL
Reaction time	< 3 min
Quantity	20 tests/kit
Storage condition	2 ~ 8 °C (35 ~ 46 °F)

Ordering Information

Product	Cat. No.
FREND™ System	F10
FREND™ COVID-19 IgG/IgM Duo	FRCOD 020

Related Products

Cat. No.	Product	Quantity (tests/kit)
EPCO19 100	COVID-19 RT-PCR Kit	100
FRCOG 020P	COVID-19 Ag	20
FRCGFL 020	COVID-19 Ag+FLU A&B	20
FRCOA 020	COVID-19 total Ab**	20
FRCOS 020	COVID-19 SP	20

***FDA EUA Approved*

NanoEntek
NESCT-FRCOD-001E (V.0.0)

Scan for more information.

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