NanoEntek

CE

FREND™ SYSTEM

COVID-19 IgG/IgM Duo

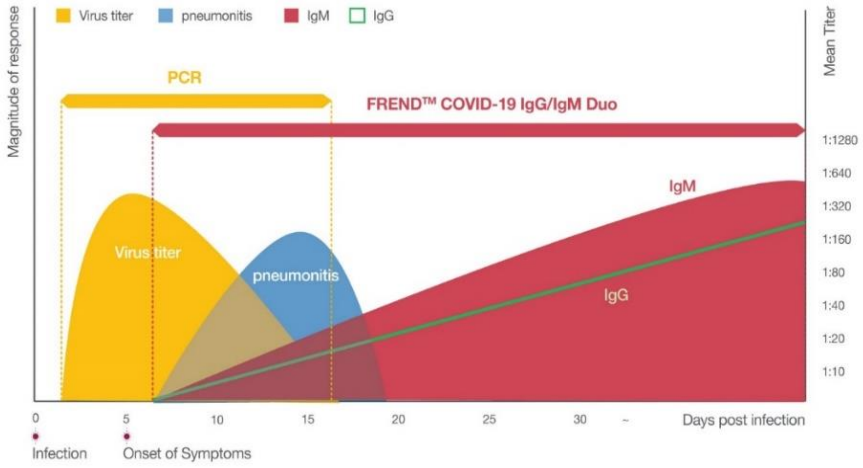
Microfluidic qualitative immunoassay for COVID-19 IgG and IgM

3 min	2 step	100 %
Fast result	Easy to use	PPA & NPA

The current PPA & NPA value could change depending on the further clinical performance evaluation.

FREND™ COVID-19 IgG/IgM Duo

According to the literatures, it is expected that IgG and IgM level will start to increase around 10 days after the onset of pneumonia symptoms. Therefore, it is recommended to use FREND™ System at minimum day 10.



Reference:
Cellular immune responses to severe acute respiratory syndrome coronavirus infection in senescent BALB/c Mice:CD4+ T cells are important in control of SARD-CoV infection. Jun Chen.
Chronological evolution of IgM, IgA, IgG and neutralisation antibodies after infection with SARS-associated coronavirus, P.-R. Hsueh.
SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients, Lirong Zou.
Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, Fei Zhou.
CDC Tests for COVID-19, centers for Disease Control and Prevention

The FREND™ COVID-19 IgG/IgM Duo is a **point-of-care testing (POCT)** which can be used to check whether patient has developed immune response to **SARS-CoV-2** using human serum or plasma. For COVID-19 IgG/IgM Duo, its measurement is based on a fluorescent immunoassay showing **QUALITATIVE** result. Originally, FREND™ System is a quantitative assay and it can be used to measure additional markers for additional studies.

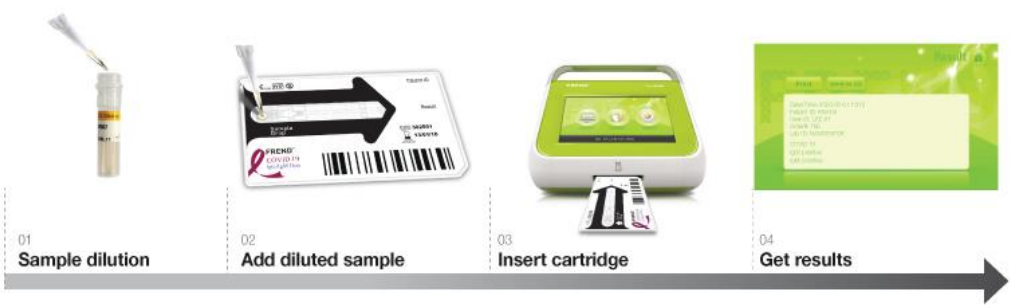
3 minutes - Fast result

2 steps - Easy to use

100% - Positive & Negative Percent Agreement

*It is currently under review by MFDS (Korea FDA).
*The current PPA & NPA value could change depending on the further clinical performance evaluation.

Instructions for Use



Preliminary Study Summary

The following table shows the preliminary study results of FREND™ COVID-19 IgG/IgM Duo when compared with PowerChek™ 2019-nCoV Real-time PCR kit (Kogene Biotech Co., Ltd.).

		2019-nCoV RT-PCR assay	
		Positive	Negative
FREND™ COVID-19 IgG/IgM Duo	Positive	8	0
	Negative	0	37
Positive Percent Agreement (PPA): 100%			
Negative Percent Agreement (NPA): 100%			

***Additional clinical performance evaluation is in progress. It will be updated soon.**

*The current PPA & NPA value could change depending on the further clinical performance evaluation.

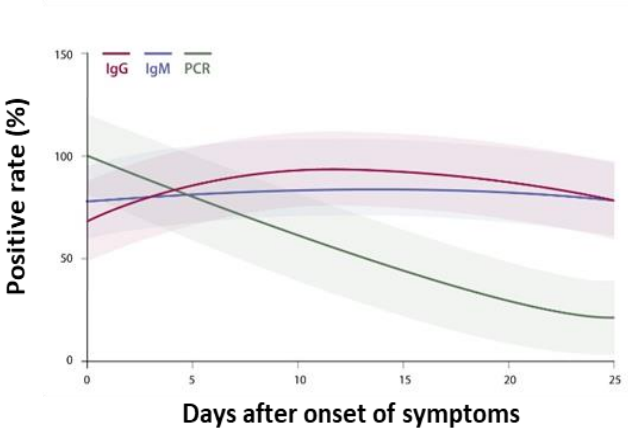
Why serological test is necessary?

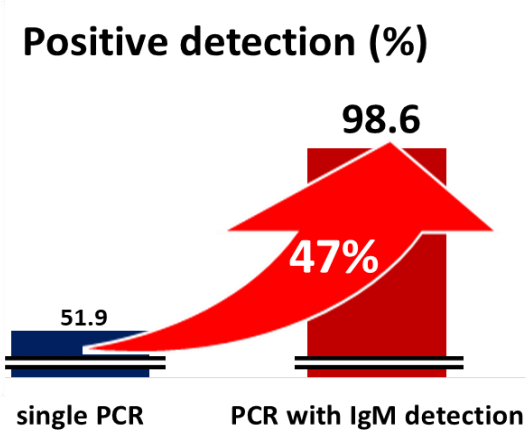
Molecular diagnostic kit such as RT-PCR is very useful in detecting the presence of viral genes. However, this cannot tell whether the person has developed an immune response to SARS-CoV-2. Therefore, **serological test** using blood samples is required to detect whether symptoms developed from infection or the infection was asymptomatic (Centers for Disease Control and Prevention is also developing its own serological test using IgG and IgM).(1)

-Serological test is required to check presence of immune response to SARS-CoV-2.

-Useful source to distinguish symptomatic and asymptomatic patient.

The following study suggests the importance of serological test.





Reference:
(1) CDC Tests for COVID-19 from Centers for Disease Control and Prevention.
(2) Profiling Early Humoral Response to Diagnose Novel Coronavirus Disease (COVID-19), Li Guo.

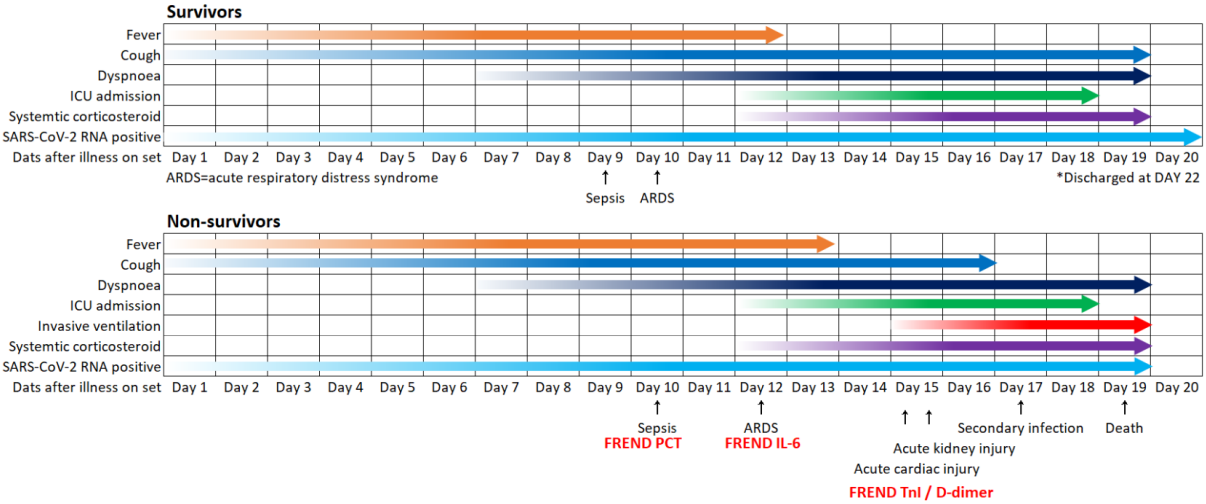
After the onset of symptoms, the sensitivity of positive PCR result showed higher than 90% from day 1 to day 3. However, it decreased below 80% and 50% in day 6 and day 14, respectively. The combination of PCR with serological test increased the positive sensitivity by 47%. (2)

Using FREND™ System for Extension Study

Most of the rapid kits only offer test on Serological Diagnostic Kits using IgG and IgM.

However, FREND™ System **<u>can also be used to manage and assess COVID-19 patient in secondary infection or comorbidities</u>** that could follow using the additional markers, D-dimer, Troponin I, PCT, IL-6, and CRP (C-reactive protein) through **QUANTITATIVE** measurement.

Suggestion from Studies



D-dimer > 1 ug/L	Associated with increased odds of death [1]
High-sensitivity cardiac Troponin I	Increase of hs-TnI found in more 50% of those who died during hospitalization [1]
PCT	A valuable additional information for early risk assessment and rule-out of bacterial coinfection in COVID-19 patients [2]
IL-6	High percentage of GM-CSF+ and IL-6+ expressions found in CD4+T cells from patients infected with 2019-nCoV in 99 both ICU and non-ICU patients compared to healthy controls. [3]
CRP	Marker used as common laboratory finding with normal/low white cell counts. [4]

Reference:

Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study, Fei Zhou.
Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China, Chaolin Huang
Aberrant pathogenic GM-CSF+ T cells and inflammatory CD14+CD16+ monocytes 1 in severe pulmonary syndrome patients of a new coronavirus, Yonggang Zhou.
A Review of Coronavirus Disease-2019 (COVID-19), Tanu Singhal.

Quantitative items

*Only 10 items are shown among total 14 items.

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