EMERGENCY USE AUTHORIZATION
FDA

FREND™ System

COVID-19 total Ab

Microfluidic Qualitative Immunoassay

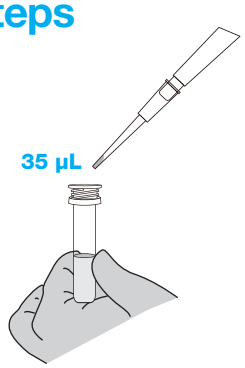
The FREND™ COVID-19 total Ab is a point-of-care testing (POCT) which can be used to check whether patient has developed immune response to the **nucleocapsid protein of SARS-CoV-2** using human plasma.
For COVID-19 total Ab, its detection is based on a fluorescent immunoassay showing qualitative result.

Fast
3 minutes

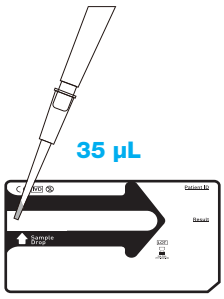
Easy
3 steps

Monitoring
LIS

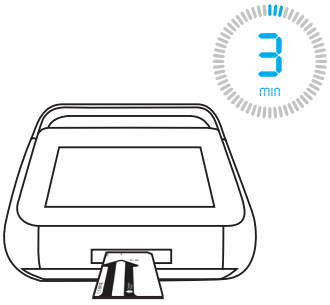
Steps



STEP 01.
Dilute sample.

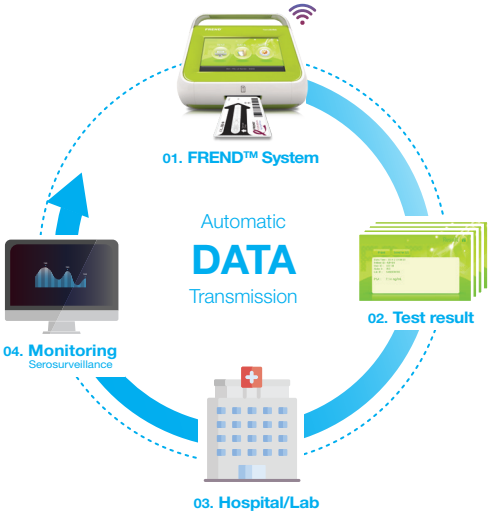


STEP 02.
Add **35 µL** of the diluted sample.



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)**

Reference

(1) Division of Laboratory Systems (DLS), Clinical Laboratory COVID-19 Response Call

Clinical Performance Evaluation

The results of the total 347 clinical samples (219 RT-PCR confirmed positive SARS-CoV-2 and 128 negative/pre-COVID-19) are presented in the table below.

Method		RT-PCR confirmed/prior to COVID-19	
		Positive	Negative
FREND™ COVID-19 total Ab	Positive	216	1
	Negative	3	127
	Total	219	128

PPA* 98.6%

NPA* 99.2%

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

Method		219 positive confirmed by RT-PCR				
		0~7 days	8~14 days	15~21 days	>21 days	UNK
FREND™ COVID-19 total Ab	Positive	34	25	13	135	9
	Negative	3	0	0	0	0
	Total	37	25	13	135	9
	PPA	(34/37) 91.9%	(25/25) 100%	(13/13) 100%	(135/135) 100%	(9/9) 100%

Independent Clinical Agreement Validation

The FREND™ COVID-19 total Ab was tested on August 19, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI). The total of 110 clinical specimens were tested.

Method		By comparator method confirmed	Collected prior to COVID-19
		Positive	Negative
FREND™ COVID-19 total Ab	Positive	29	1
	Negative	1	79
	Total	30	80

PPA 96.7%

NPA 98.8%

Specification

Item	Specification
Assay principle	Fluorescence immunoassay
Specimen	K_2- EDTA 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.	CPT Code
FREND™ System	F10	-
FREND™ COVID-19 total Ab	FRCOA 020	86769

** COVID-19 total Ab is FDA EUA approved. For US sales only.*

NanoEntek

NESCT-FRCOA-002E (V.0.0)

Scan for more information.

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