

# COVID-19 SP

Microfluidic Qualitative Immunoassay

Pr  
Date/Time: 2013-9-24 2:1 PM  
User ID: NANO  
Patient ID: P-2

The **FREND™ COVID-19 SP** 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. The FREND™ COVID-19 SP is a fluorescence immunoassay (FIA) using the FREND™ System intended for the qualitative detection of IgG and IgM antibodies to SARS-CoV-2. The FREND™ COVID-19 SP is intended for use as an aid in identifying individuals with an adaptive immune response to SARS-CoV-2, indicating recent or prior infection.

**Fast**



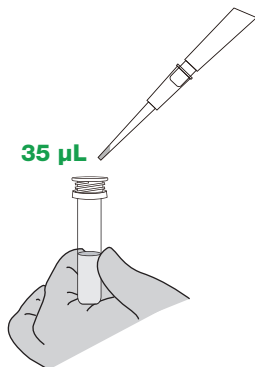
**Easy**



**Monitoring**

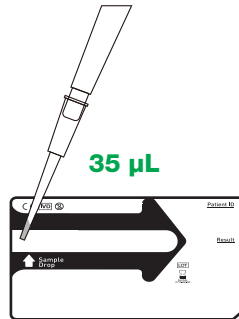


## Steps



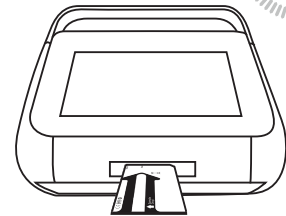
**STEP 01.**

Dilute sample.



**STEP 02.**

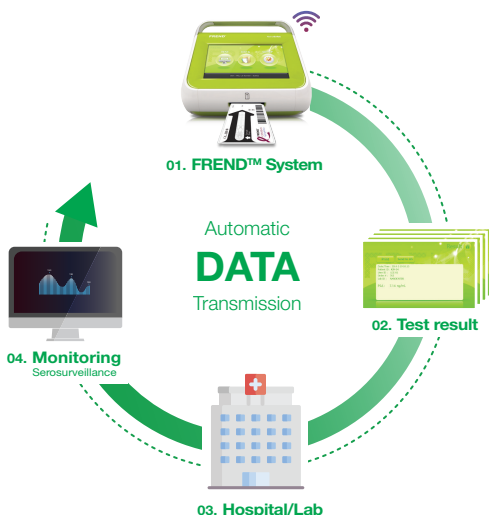
Add **35 µL** of the diluted sample.



**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<sup>(1)</sup>, the **FREND™ System** provides the following advantages:

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

## Clinical Performance Evaluation

A total of 88 clinical samples (34 positive and 54 negative) confirmed with RT-PCR were tested with the FREND™ COVID-19 SP, demonstrating 97.06% PPA\* and 96.30% NPA\* as shown below.



Method			RT-PCR confirmed	
			Positive	Negative
FREND™ COVID-19 SP	Positive	IgG(+), IgM(+)	32	0
		IgG(+), IgM(-)	1	0
		IgG(-), IgM(+)	0	2
	Negative	1	52	
Total			34	54

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

### Specification

Item	Specification
Assay principle	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 SP	FRCOS 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
FRCOD 020	COVID-19 IgG/IgM Duo	20

\*\*FDA EUA Approved



NESCT-FRCOS-001E (V.0.0)



Scan for more information.

### NanoEntek, Inc.

#### Head Office

12F, 5, Digital-ro 26-gil, Guro-gu, Seoul, 08389, Korea  
Tel: +82-2-6220-7940/Fax: +82-2-6220-7999

### NanoEntek America, Inc.

Waltham, MA, USA Tel: +1-781-472-2558

### NanoEntek Bio-Technology(Beijing) Ltd.

Fengtai District, Beijing Tel: +86-10-5920-7980

website

www.nanoentek.com

e-mail

ivdst@nanoentek.com