

FREND™ System

COVID-19 total Ab

Microfluidic Qualitative Immunoassay



Fast result

3
min

Easy to use

2
step

Monitoring

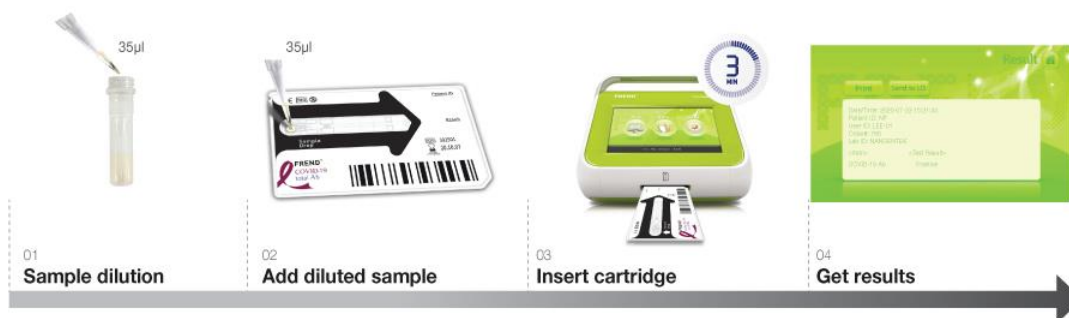
LIS



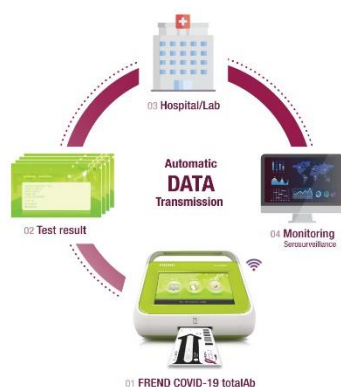
The FREND™ COVID-19 total Ab is a fluorescence immunoassay (FIA) which can be used to aid in identifying individuals with an adaptive immune response to SARS-CoV-2 using human plasma. It shows qualitative result by using [SARS-CoV-2 Nucleocapsid](#) fluorescent beads to detect total antibody (IgG and IgM).

Accurate result in 3 minutes!

With just simple steps of operation, the FREND™ system supports quick decision-making.



Laboratory Information System Connectivity



In the event of a pandemic, the management of a vast amount of clinical result is important. However, many laboratories face the challenge in arranging the essential information effectively⁽¹⁾.

- Paperless
- Time-saving
- Automatic Data Transfer & Collect
- 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
Positive percent agreement: 98.6% (216/219), 95%CI (96.05-99.53)			
Negative percent agreement: 99.2 % (127 /128), 95% CI (95.71-99.86)			

Day between		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 from NanoEntek was tested on August 19, 2020 at the Frederick National Laboratory for Cancer Research (FNLCR) sponsored by the National Cancer Institute (NCI).

	Comparator Method			Collected pre-2020		
	Antibody Positive			Antibody Negative		
FREND™ COVID-19 total Ab	IgM+, IgG+	IgM+, IgG-	IgM-, IgG+	Negative	HIV+	Total
(IgM / IgG) +	29			1		30
(IgM / IgG) -	1			69	10	80
Total	30			70	10	110

Measure	Estimate	Confidence Interval
(IgM / IgG) Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
(IgM / IgG) Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined Sensitivity	96.7% (29/30)	(83.3%; 99.4%)
Combined Specificity	98.8% (79/80)	(93.3%; 99.8%)
Combined PPV for prevalence = 5.0%	80.3%	(39.4%; 96.0%)
Combined NPV for prevalence = 5.0%	99.8%	(99.1%; 100%)
Cross-reactivity with HIV+	0.0% (0/10), not detected	

Ordering information

Item	Cat. no
FREND™ System	F10
FREND™ COVID-19 total Ab (20 tests)	FRCOA 020

Specification

Item	Specification
Specimen	EDTA Plasma
Time to result	< 3 min
Volume	35 µL

Appendix. Clinical Performance Evaluation

The total of 91 clinical samples (75 positive and 16 negative) confirmed with RT-PCR were tested with the FREND™ COVID-19 total Ab. It shows 96.0% PPA (Positive Percent Agreement) and 93.8% NPA (Negative Percent Agreement) as shown below.

Method		RT-PCR confirmed	
		Positive	Negative
FREND™ COVID-19 total Ab	Positive	72	1
	Negative	3	15
	Total	75	16
Positive percent agreement: 96.0% (72/75), 95% CI (88.89-98.63)			
Negative percent agreement: 93.8% (15/16), 95% CI (71.67-98.89)			

An additional 56 clinical samples (44 SARS-CoV-2 PCR confirmed and 12 negative, pre-COVID-19) were tested with the FREND™ COVID-19 total Ab. The results are presented in the table below.

Method		RT-PCR confirmed	Prior to COVID-19
		Positive	Negative
FREND™ COVID-19 total Ab	Positive	44	0
	Negative	0	12
	Total	44	12
Positive percent agreement: 100.0% (44/44), 95%CI (91.97-100.00)			
Negative percent agreement: 100.0% (12/12), CI (75.75-100 .00)			

An additional 200 clinical samples (100 SARS-CoV-2 PCR confirmed and 100 negative, pre-COVID-19) were tested with the FREND™ COVID-19 total Ab. The results are presented in the table below.

Method		RT-PCR confirmed	Prior to COVID-19
		Positive	Negative
FREND™ COVID-19 total Ab	Positive	100	0
	Negative	0	100
	Total	100	100
Positive percent agreement: 100.0% (100/100), 95%CI (96.30-100.00)			
Negative percent agreement: 100.0% (100/100), 95%CI (96.30-100.00)			