

FREND™ COVID-19 total Ab

Microfluidics Qualitative Fluorescence Immunoassay

**Accurate
COVID-19
total Ab
Results in
3 minutes**



Nano**EnTek**

Distributed by

vidan™ diagnostics

COVID-19 total Ab

Microfluidics Qualitative Fluorescence Immunoassay



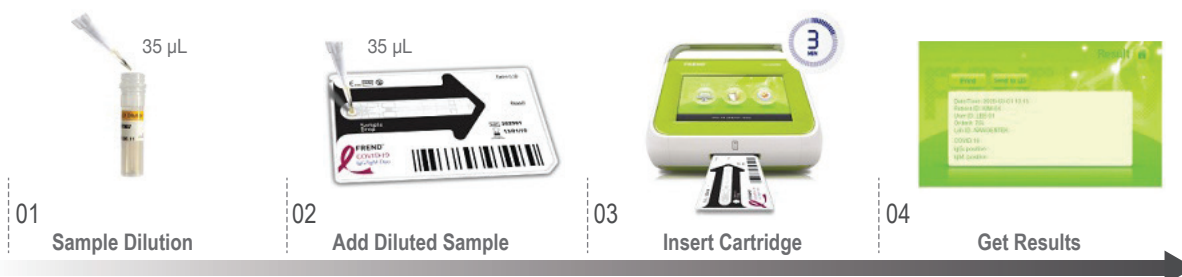
Qualitative Test for COVID-19 total Ab

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).

Key Benefits of FREND™ COVID-19 total Ab

- ✓ 3 minutes | Fast result
- ✓ 2 steps | Easy to use
- ✓ 98.6% & 99.2% | Positive & Negative Percent Agreement
- ✓ Microfluidics Qualitative Immunoassay
- ✓ LIS connectivity (data management)

Accurate Results In 3 Minutes!



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 (FNLRC) 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	

Part #	Description
F10	FREND™ System
FRCOD 020	FREND™ COVID-19 total Ab (20 tests)
	FREND™ COVID-19 Stater Pack

Test Characteristics	
Methodology	Microfluidics Qualitative Fluorescence Immunoassay
Sample Type	EDTA Plasma
Sample Volume	35 µL
Method Comparison	PPA: 98.6%, NPA: 99.2%
Time to Result	< 3 minutes
Connectivity	LIS and Printer
CPT Code	86769

Distributed by

NanoEntek


www.vidandiagnostics.com

Vidan Diagnostics, LLC
24123 Boerne Stage Rd, Ste 205
San Antonio, TX 78255
info@vidandiagnostics.com
Tel : +800-869-5992
Fax : +210-802-4684
VID-COVID19-001-10.20