



## PERFORMANCE CHARACTERISTICS

### Clinical Evaluation

1,636 clinical specimens are tested internally and the test result shows the 100% (36/36) sensitivity for Neutralizing Ab for serum specimen. Also, comparison result between Genscript SARS-CoV-2 sVNT Kit shows 100% correlation. The specificity is 99%(1,089/1,100) for serum and 98.8%(494/500) for EDTA plasma specimen.

### 1) Clinical sensitivity

[Serum]

		VNT (Virus Neutralization Test)		
		Pos.	Neg.	Total
STANDARD F SARS-CoV-2 nAb FIA	Pos.	36	0	36
	Neg.	0	0	0
	Total	36	0	36
Sensitivity for Neutralizing Ab : 36/36 (100%)				

[Comparison with Genscript]

		Genscript SARS-CoV-2 sVNT Kit (RUO)		
		Pos.	Neg.	Total
STANDARD F SARS-CoV-2 nAb FIA	Pos.	36	0	36
	Neg.	0	0	0
	Total	36	0	36
Sensitivity for Neutralizing Ab : 36/36 (100%)				

### 2) Clinical specificity

[Serum]

		PCR		
		Pos.	Neg.	Total
STANDARD F SARS-CoV-2 nAb FIA	Pos.	0	11	11
	Neg.	0	1,089	1,089
	Total	0	1,100	1,100
Specificity for Neutralizing Ab : 1,089/1100 (99.0%)				

[Plasma (EDTA)]

		PCR		
		Pos.	Neg.	Total
STANDARD F SARS-CoV-2 nAb FIA	Pos.	0	6	6
	Neg.	0	494	494
	Total	0	500	500
Specificity for Neutralizing Ab : 494/500 (98.8%)				

## ANALYTICAL PERFORMANCE

### 1) Limit of Detection

The limit of detection of STANDARD™ F SARS-CoV-2 nAb FIA is as follows;

[Serum/Plasma(EDTA)]

Specimen	SN titer	SN titer the detection limit
20DDV1117658	1 : 80	1 : 20
20DDV1117659	1 : 40	1 : 10
20DDV1117686	1 : 640	1 : 40
MAF4714	1 : 640	1 : 40

### 2) Cross Reactivity

None cross-reactivity was detected with potential cross reacting substance such as HCoV-229E, HCoV-NL63, HCoV-OC43, HCoV-HKU1, Anti-HBV, Anti-HCV, Anti-HIV, ANA, RSV IgG, Influenza A IgG, Influenza B IgG, Adenovirus IgG, Anti-MERS-CoV IgG, Anti-SARS-CoV IgG, Rhinovirus group A, Enterovirus group A IgG, Haemophilus, Parainfluenza virus IgG, Human Metapneumovirus IgG.

### 3) Interference

The following materials do not affect sensitivity and specificity of STANDARD™ F SARS-CoV-2 nAb FIA at the tested concentration.

Interfering substance Exogenous /Endogenous Factor	Test Concentration
Oseltamivir (Influenza)	10 mg/ml
Erythromycin (antibiotic)	81.6 uM
Ciprofloxacin (antibiotic)	31 uM
Caffeine	308 uM
Ethanol	90 mM
Biotin	300 ng/ml
Bilirubin (Unconjugate)	257 uM
Human serum albumin	20 mg/ml
Serum of pregnant women	N/A
Elevated levels of C reactive protein	19.90 ~ 179.37