

# STANDARD F COVID-19 Ag FIA



STANDARD F COVID-19 Ag FIA is the fluorescent immunoassay for the qualitative detection of specific nucleoprotein antigens to SARS-CoV-2 present in human nasopharynx.

- **Test time** : Within 30 mins
- **Specimen** : Nasopharyngeal swab
- **Storage temperature** : 2-30°C/36-86°F
- **Fluorescent Immunoassay (Europium)**  
: Higher sensitivity than rapid test (X 4times)
- **Result Analyzer** : F2400, F200, F100
- **Pack size** : 25Tests/kit



## >> Benefit

- Excellent sensitivity and specificity with Fluorescent**
- Easy to use**
- Fast results within 30 minutes**
- More than 4 times higher sensitivity than RDTs<sup>1</sup>**  
<sup>1</sup> Internal evaluation data
- Room temperature storage**
- Ready-to-use reagents**
- Automated platform with small POC analyzer**

## >> Performance Characteristics

### [Clinical evaluation]

Test were performed according to instructions for use of STANDARD F COVID-19 Ag FIA by using nasopharyngeal swab specimens. Positive specimen is prepared by spiking inactivated cell (SARS-CoV-2 (2019-nCoV) NCCP 43326/2020 / Korea) into nasopharyngeal swab specimens with the concentration of  $7.81 \times 10^{1.2}$  TCID<sub>50</sub>/ml,  $1.56 \times 10^{2.2}$  TCID<sub>50</sub>/ml and  $3.13 \times 10^{2.2}$  TCID<sub>50</sub>/ml. STANDARD F COVID-19 Ag FIA detect the 30 positive contrived specimens and 30 negative specimens correctly.

Specimen	Concentration	Result analysis
Positive Nasopharyngeal swab specimen	1 x Limit of Detection: $7.81 \times 10^{1.2}$ TCID <sub>50</sub> /ml	100% Sensitivity (30/30)
	2x Limit of Detection: $1.56 \times 10^{2.2}$ TCID <sub>50</sub> /ml	
	4x Limit of Detection: $3.13 \times 10^{2.2}$ TCID <sub>50</sub> /ml	
Negative Nasopharyngeal swab specimen	N/A	100% Specificity (30/30)

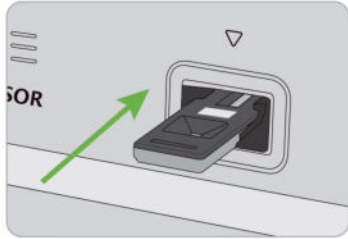


STANDARD F COVID-19 Ag FIA is designed for initial screening only for SARS-CoV-2 infection. If the antigen concentration of the specimen is below the limit of detection of STANDARD F COVID-19 Ag FIA, it may not be detected. Negative results do not rule out SARS-CoV-2 infection, particularly in those who have been in contact with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

## ➤ Test Procedure - Two modes can be used depending on the workflow requirements.

### ➤ STANDARD TEST Mode – For the single patient sample

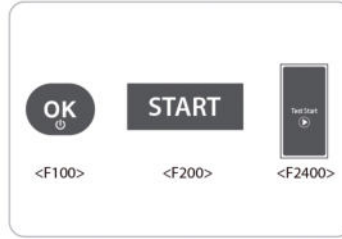
– STANDARD F100, F200 and F2400 analyzer



1 Insert the test device to the test slot of the analyzer.



2 Apply 4 drops of extracted specimen.



3 Press the 'TEST START'



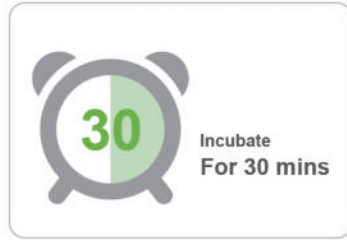
4 Result in 30 min.

### ➤ READ ONLY Mode – For the several patient samples

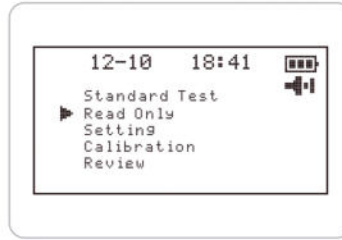
– STANDARD F100 and F200 analyzer



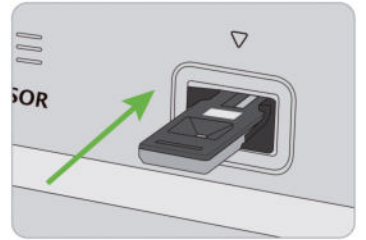
1 Apply 4 drops of extracted specimen.



3 Incubate for 30 min.



4 Set the analyzer to the **READ ONLY Mode.**



5 READ the test result.

## ➤ Specification of STANDARD F Analyzers



- **F100** : Hand-held sized & Battery-powered POC analyzer
- **F200** : Table top analyzer with maximized usability
- **F2400** : High-throughput analyzer for mass screening test

STANDARD F Analyzer is a next-generation Fluorescent Immunoassay system. It measures multiple bio-markers within a single platform, and three different models are capable of covering various medical & laboratory settings in context.

## ➤ Ordering Information

### ➤ STANDARD F Analyzers

Cat. No.	Product	Unit	Weight	Carton size (W/D/H)
10FA10	F100	1 Unit	0.7 kg	105 x 135 x 100 mm
10FA20	F200	1 Unit	2.5 kg	200 x 240 x 205 mm
10FA24	F2400	1 Unit	20 kg	510 x 566 x 297 mm

### ➤ STANDARD F COVID-19

Cat. No.	Product	Storage temperature	Tests/kit	Kits/carton	Carton size (W/D/H)
10COV30D	STANDARD F COVID-19 Ag FIA	2-30°C/36-86°F	25	30	560 x 520 x 390 mm
10COV50G	STANDARD F COVID-19 IgM/IgG Combo FIA	2-30°C/36-86°F	40	40	585 x 515 x 390 mm
10COVC10	STANDARD COVID-19 Ag Control	2-30°C/36-86°F	10	20	155 x 390 x 110 mm
10COVC20	STANDARD COVID-19 IgM/IgG Control	2-30°C/36-86°F	10	20	215 x 390 x 110 mm