STANDARD F

COVID-19 Ag FIA

CE
Cat. No : 10COV30D

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

- **Test time** : Within 30 mins
- **Specimen** : Nasopharyngeal swab
- **Storage temperature** : 2-30℃/36-86℉
- **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[1]**
  [1] 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 X $10^{1.2}$ $TCID_{50}$/ml, 1.56 X $10^{2.2}$ $TCID_{50}$/ml and 3.13 X $10^{2.2}$ $TCID_{50}$/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 X $10^{1.2}$ $TCID_{50}$/ml	100% Sensitivity (30/30)
	2x Limit of Detection: 1.56 X $10^{2.2}$ $TCID_{50}$/ml	
	4x Limit of Detection: 3.13 X $10^{2.2}$ $TCID_{50}$/ml	
Negative Nasopharyngeal swab specimen	N/A	100% Specificity (30/30)

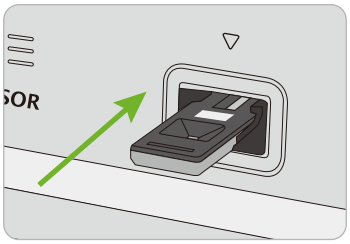
NOTE

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 contract with the virus. Follow-up testing with a molecular diagnostic should be considered to rule out infection in these individuals.

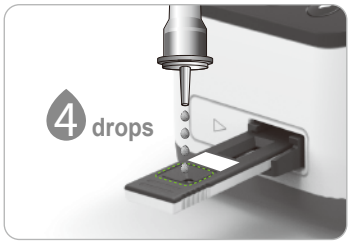
Test Procedure - Two modes can be used depending on the workflow requirements.

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.



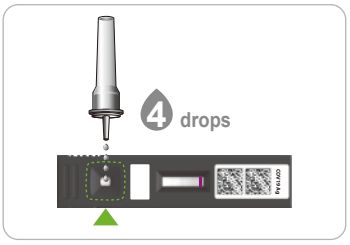
2 Apply 4 drops of extracted specimen.

3 Press the **'TEST START'**

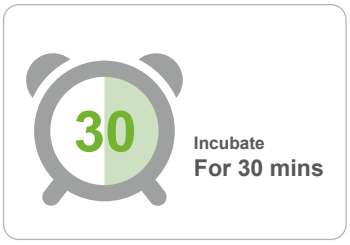
4 Result in 30 min.

READ ONLY Mode – For the several patient samples

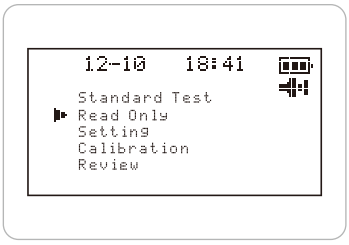
– STANDARD F100 and F200 analyzer



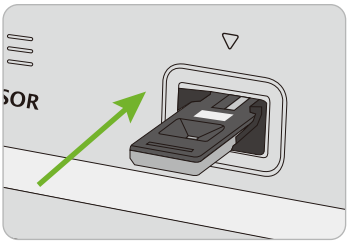
1 Apply 4 drops of extracted specimen.



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

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