STANDARD F

COVID-19 Ag FIA

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

CE

Cat. No : 10COV30D

SD BIOSENSOR

Product Specification

- **Test time :** Within 30 mins
- **Specimen**
  : Nasopharyngeal swab or NP swabs collected into a viral transport medium
- **Storage temperature** : 2-30℃/36-86℉
- **Fluorescent Immunoassay (Europium)**
  : Higher sensitivity than rapid test (X 4times)
- **Result Analyzer** : F2400, F200, F100
- **Pack size** : 25 Tests/kit

Benefit

- **Excellent sensitivity and specificity via FIA method**
- **Easy to use**
- **Fast results within 30 minutes**
- **More than 4 times higher sensitivity than RDTs**
- **Room temperature storage**
- **Ready-to-use reagents**
- **Automated platform with small POC analyzer**

Performance Characteristics

Clinical evaluation

This clinical evaluation of STANDARD F COVID-19 Ag FIA was conducted with using 155 patients' NP swab specimens in viral tranport media. The RT-PCR method was used as confirmatory test to reveal patients' status of SARS-CoV-2 infection.

1) Analysis by days after symptom onset

Days after symptom onset	Sensitivity	Positive	Negative	Total
≤ 7 days	89.36%	42	5	47
> 7 days	83.33%	5	1	6
asymptomatic	100.00%	2	0	2

2) Analysis by RT-PCR Ct value (RdRP gene basis)

Ct value	Sensitivity	Positive	Negative	Total
≤ 20	100.00%	11	0	11
20 < Ct ≤ 30	94.44%	34	2	36
> 30	50.00%	4	4	8

- **97.22%** Positive agreement as Ct value of RT-PCR method was below 30

3) Clinical Sensitivity & Specificity

	RT-PCR (FDA EUA approved)		Total
	Positive	Negative	
Positive	49	4	53
Negative	6	96	102
Total	**55**	**100**	**155**
Clinical Sensitivity	**89.09%** (49/55), (95% CI : 77.75% - 95.89%)		
Clinical Specificity	**96%** (96/100), (95% CI : 90.07% - 98.90%)		

Supplied by:

For Professional Use Only

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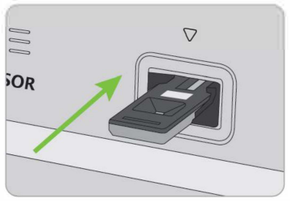
Test Procedure

'STANDARD TEST' Mode - For a single patient specimen

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 mins.

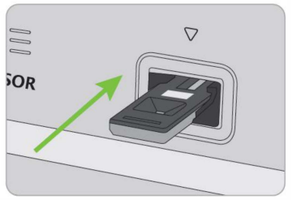
'READ ONLY' Mode - For multiple simultaneous tests

STANDARD F100 and F200 analyzer

1 Apply 4 drops of extracted specimen.

2 Incubate for 30 mins.

3 Set the analyzer to the **'Read Only'** Mode.



4 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.

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 Ag FIA

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
10COVC10	STANDARD COVID-19 Ag Control	2-30°C/36-86°F	10	20	155 x 390 x 110 mm

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