STANDARD F
COVID-19 Ag FIA

Cat. No : 10COV30D (NP swab)
Cat. No : 10COV31D (NS swab)

IVD CE

- Excellent sensitivity and specificity via FIA method
- Automated platform with small POC analyzer
- Fast results (15 minutes)
- More than 4-8 times higher sensitivity than RDTs
- Room temperature storage
- Ready-to-use reagents
- Easy to use

Product specification

Specimen type	Nasal swab / Nasopharyngeal swab/ VTM
Test time	15 mins
Storage condition	2 - 30 °C / 36 – 86 °F
Result Analyzer	F2400, F200, F100
Pack size	25 Tests/kit

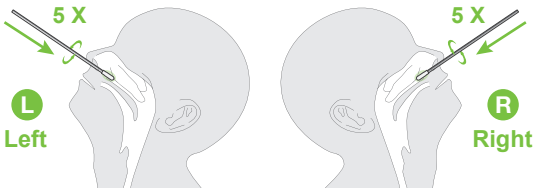
Compatible equipment

- STANDARD F100
- STANDARD F200
- STANDARD F2400

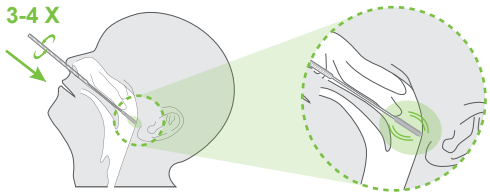
Preparation

Specimen Collection

[Nasal swab]

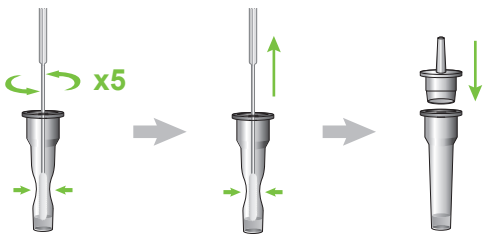


[Nasopharyngeal swab]

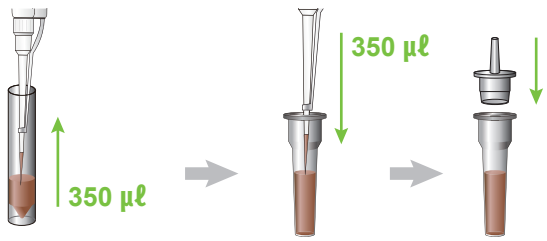


Extraction of specimen

[Nasal and Nasopharyngeal swab]



[Viral Transport Medium]

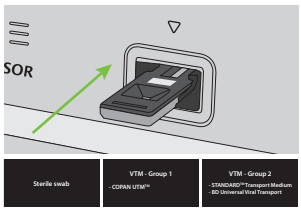


Test Procedure

Standard mode

STANDARD F100, F200 and F2400 analyzer

1 Insert the test device and select a specimen type. (Sterile swab / VTM–Group 1 / VTM-Group 2)



2 **Apply 4 drops** of extracted specimen into the specimen well.

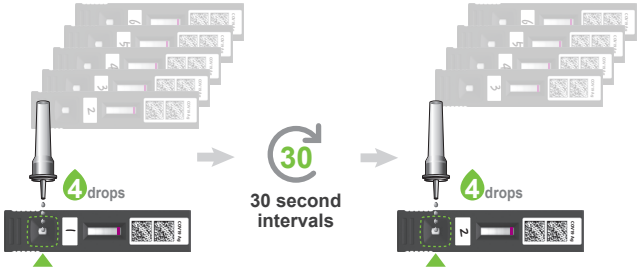
3 After applying specimen, immediately press **'START'** button.

4 The analyzer will automatically display the test result in **15 minutes.**

Read only mode

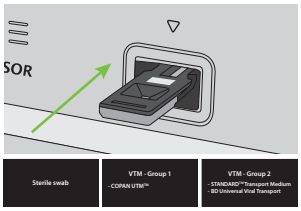
STANDARD F100 and F200 analyzer

1 **Apply 4 drops** of extracted specimen into test devices in sequence at about 30 seconds interval.



2 Incubate the test device for **15 minutes** outside of the analyzer.

3 Insert the test device and select a specimen type. (Sterile swab / VTM–Group 1 / VTM-Group 2)



Test Procedure

Clinical evaluation

Performance of STANDARD F COVID-19 Ag FIA was determined by using 663 direct nasopharyngeal specimens. Paired samples were taken for SARS-CoV-2 antigen test and RT-PCR in consecutive participants screened for COVID-19 infection to calculate the sensitivity and specificity of the test. Out of 663 patients, 125 were positive including 14 patients with RT-PCR Ct value >30 and 538 were negative by RT-PCR method.

• Clinical sensitivity in patients with RT-PCR Ct value below 30

RT-PCR Ct value	No of patients	Sensitivity(%)
Ct < 15	6	100% (6/6)
Ct 16 – 20	41	100% (41/41)
Ct 21 – 25	47	93.62% (44/47)
Ct 26 – 30	17	76.5% (13/17)
Clinical Sensitivity (Ct≤30)		**93.70% (104/111)**

• Clinical sensitivity (Ct≤30) and specificity

		STANDARD F COVID-19 Ag FIA		Total
		Positive	Negative	
Reference method (RT-PCR)	Positive	104	7	111
	Negative	2	536	538
Total		**106**	**543**	**649**
Clinical Sensitivity		**93.70%** (95% CI: 87.44 – 97.43%)		
Clinical Specificity		**99.63%** (95% CI: 98.50 – 99.96%)		

- The positive predictive value(PPV) was 98.1% (92.7, 99.7).
- The negative predictive value(NPV) was 96.4% (94.4, 97.7).
- The sensitivity including 14 patients with RT-PCR Ct value >30 was 84.00%.

Ordering Information

Cat. No.	Product	Storage temperature	Tests/kit	Kits/carton	Carton size (W/D/H)
10COV30D	STANDARD F COVID-19 Ag FIA (Nasopharyngeal)	2-30°C/36-86°F	25	30	560 x 520 x 390 mm
10COV31D	STANDARD F COVID-19 Ag FIA (Nasal)	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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