

STANDARD F Respiratory Disease

- Influenza A/B FIA
- RSV Ag FIA
- *S.pneumoniae* Ag FIA
- Strep A Ag FIA
- *Legionella* Ag FIA



Supplied by:



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 STANDARD™



STANDARD F | Fluorescent immunoassay

➤ Rapid, Easy-to-use and Respiratory disease Diagnostics Platform for Point of Care Use



➤ Excellent sensitivity and specificity with Fluorescent immunoassay

- Proven lateral flow design enhanced with fluorescent immunoassay technology featuring Europium
- Specific antibodies selected to optimize performance in concert with fluorescence

➤ Objective test results

- Eliminate ambiguous test results as the analyzer interprets and determines the results

➤ Cut of Index (COI)

- Great reference value for medical decision-making

➤ Rapid test results

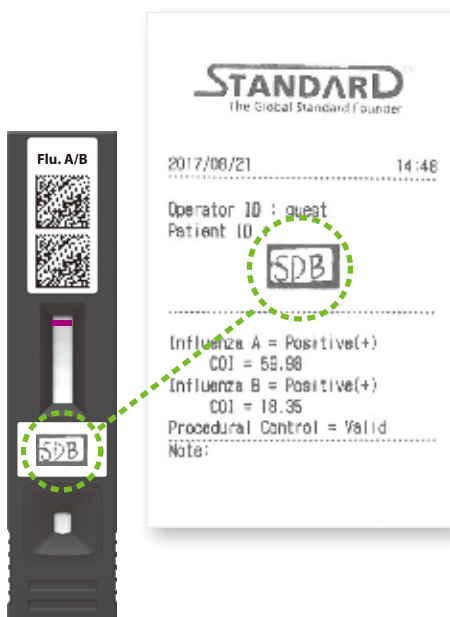
- Provides accurate, objective and automated results in just 90 seconds in case of strong positive specimen (Influenza Test)

➤ 2D barcode technology

- Auto coding procedure by recognizing 2D barcode
- Reduce time and errors associated with manually recording LOT specific information

➤ Expandable parameters

- Adenovirustest for respiratory infection is coming soon



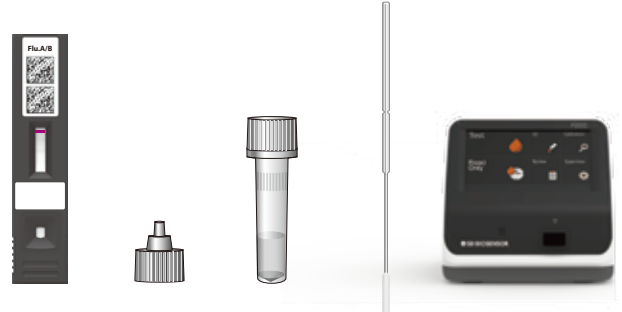
STANDARD F Influenza A/B FIA

Quick-test with reliable performance

STANDARD F Influenza A/B FIA test system (Analyzer + Test device) can be used as a commercially available rapid diagnostic tests. Moreover, it performs higher accuracy and faster test results within 1.5 – 10 minutes with the STANDARD FIA Analyzer.

Benefits

- Fast result (1.5 - 10 minutes)
- More than 200 times higher sensitive than RDTs
- Filter cap for mucoidal samples
- Great detectability
 - A type(H1N1, H1N1/2009, H3N2, H4N6, H5N1, H5N3, H6N5, H7N1, H7N2, H8N4, H9N2)
 - B type



Clinical evaluation data

Reference	Strain	Sensitivity	Specificity
Anyplex™ II RV16 Detection	A	84.48% (49/58)	100% (197/197)
	B	72.06% (49/68)	96.57% (197/204)

Reference : Guro, Korea University Hospital Clinical laboratory medicine.
* Sample : Nasal swab diluted in VTM

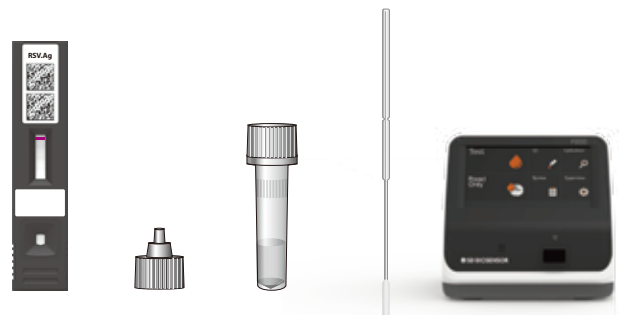
STANDARD F RSV Ag FIA

Quick-test with reliable performance

STANDARD F RSV Ag FIA test system (Analyzer + Test device) can aid in treatment decisions in clinical settings such as prescribing medications and further diagnosis.

Benefits

- Fast results in 5 - 15 minutes.
- High sensitivity and specificity
- Filter cap for mucoidal samples.



Clinical evaluation data

Reference	Strain	Sensitivity	Specificity
Anyplex™ II RV16 Detection + FIA	A	90.57% (48/53)	92.19% (118/128)

Reference : Guro, Korea University Hospital Clinical laboratory medicine.
* Sample : Nasopharyngeal swab diluted in VTM

STANDARD F

Legionella Ag FIA

Quick-test with reliable performance

STANDARD F *Legionella* Ag FIA test system (Analyzer + Test device) detects *Legionella pneumophila* serogroup 1 antigen via easily collectible urine sample. Without further sample processing, STANDARD F *Legionella* Ag FIA performs high sensitivity, and the test is not affected by Rheumatoid factor.

Benefits

- Fast results in 5 - 15 minutes.
- Urine sample, One step test
- Test not affected by Rheumatoid factor (spiked below 14.84IU/mL)



Rheumatoid Factor (IU/mL)	STANDARD F Legionella Ag FIA	
	Test with normal urine spiked with RF serum.	Test with boiled urine spiked with RF serum (100°C, 5 mins.)
14.84	Negative	Negative
7.42	Negative	Negative
3.71	Negative	Negative
1.86	Negative	Negative
0.93	Negative	Negative
0.46	Negative	Negative
0.23	Negative	Negative

Clinical evaluation data

Reference	Sensitivity	Specificity
FIA	94.9% (37/39)	100% (40/40)

Reference : Internal evaluation

STANDARD F

S.pneumoniae Ag FIA

Quick-test with reliable performance

STANDARD F *S.pneumoniae* Ag FIA test system (Analyzer + Test device) detects *S. pneumoniae* antigen in urine sample for the patients with pneumonia and in cerebral spinal fluid sample for the patients with meningitis.

Benefits

- Fast results in 5 - 10 minutes.
- Urine sample for pneumonia.
- CSF sample for meningitis.
- One step test.



Clinical evaluation data

Reference	Sensitivity	Specificity
FIA	96.2% (25/26)	100% (40/40)

Reference : Internal evaluation

STANDARD F

Strep Ag FIA

Quick-test with reliable performance

STANDARD F Strep Ag FIA test system (Analyzer + Test device) detects group A *streptococcal* (Strep A) antigen directly from throat swabs of symptomatic patients or confirmation of presumptive Group A *Streptococcal colonies* recovered from culture.

Benefits

- Fast results in 5 minutes.
- Collects and dispenses correct amount of sample via the fixed volume dropper.
- Eliminates the subjectivity of a visual result.
- Room temperature storage.



Clinical evaluation data

Reference	Sensitivity	Specificity
Bacterial culture	93.3%(28/30)	95%(38/40)

Reference : Internal evaluation

Ordering Information

STANDARD F Analyzers

Products	Cat. No.	Printer	Unit	Weight	Carton size(W/L/H)
F100	10FA10	External	1 unit	0.7 kg	105 x 135 x 100
F200	10FA20	Built-in	1 unit	2.5 kg	200 x 240 x 205

STANDARD F Tests

Products	Cat. No.	Storage temperature	Shelf life	Pack size	Qty/Carton	Carton size(W/L/H)
Influenza A/B FIA	10INF10D	2~30°C/36-86°F	18M	25T/Kit	15	525 x 325 x 420
RSV Ag FIA	10RSV10D	2~30°C/36-86°F	18M	25T/Kit	15	525 x 325 x 420
<i>S. pneumoniae</i> Ag FIA	10SPN10D	2~30°C/36-86°F	18M	25T/Kit	45	515 x 465 x 420
<i>Legionella</i> Ag FIA	10LEG10D	2~30°C/36-86°F	18M	25T/Kit	45	515 x 465 x 420
Strep A Ag FIA	10STR10D	2~30°C/36-86°F	18M	25T/Kit	30	515 x 465 x 420

How to use the STANDARD F respiratory test kits

STANDARD F Influenza A/B FIA & RSV FIA

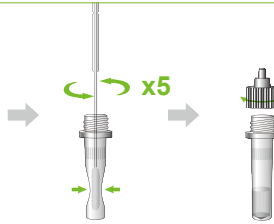
STANDARD Test Mode



Select the STANDARD TEST mode



Insert Test device into the F Analyzer

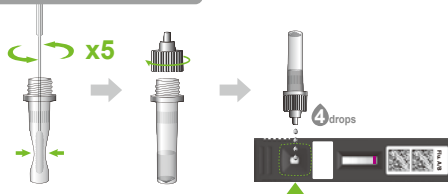


Press **START** button after apply sample



Check the test result.

Ready Only Test Mode



- Influenza **10min.**
- RSV **15min.**



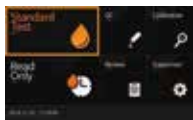
Select the READ ONLY mode and insert test device into the F Analyzer.



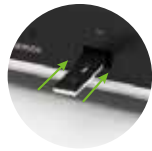
Check the test result.

STANDARD F *S.pneumoniae* Ag FIA & *Legionella* Ag FIA

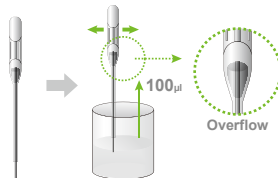
STANDARD Test Mode



Select the STANDARD TEST mode



Insert Test device into the F Analyzer

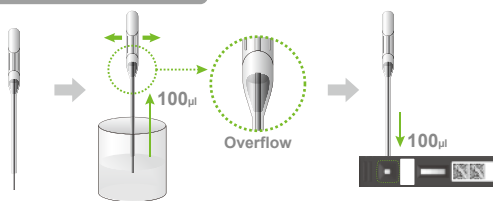


Press **START** button after apply sample



Check the test result.

Ready Only Test Mode



15min.



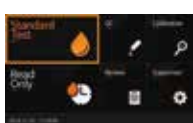
Select the READ ONLY mode and insert test device into the F Analyzer.



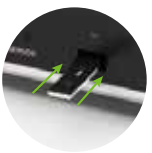
Check the test result.

STANDARD F Strep A Ag FIA

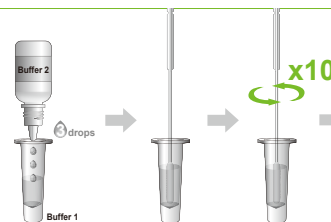
STANDARD Test Mode



Select the STANDARD TEST mode



Insert Test device into the F Analyzer

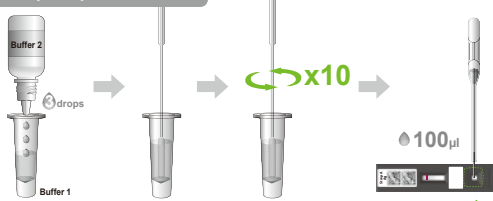


Press **START** button after apply sample



Check the test result.

Ready Only Test Mode



5min.



Select the READ ONLY mode and insert test device into the F Analyzer.



Check the test result.

SD BIOSENSOR

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