

STANDARD F *S.pneumoniae* Ag FIA

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PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST



EXPLANATION AND SUMMARY

[Introduction]

Streptococcus pneumoniae (*S.pneumoniae*) is a gram-positive and catalase-negative organism, also called pneumococcus since it causes the pneumococcal infection. *S.pneumoniae* is involved in upper respiratory infections such as otitis media and sinusitis and in invasive diseases such as pneumonia, bacteremia, and meningitis. *S.pneumoniae* is spread through indirect or direct contact with an *S.pneumoniae* carrier and spread of almost the whole of upper respiratory infections are due to the contaminated air by *S.pneumoniae* bacteria. Especially, rapid and reliable diagnosis of *S.pneumoniae* is so important because community acquired pneumonia (CAP) is commonly caused by *S.pneumoniae* and rapid and proper treatment of CAP is essential to reduce the risk of pneumonia. Bacterial meningitis is serious and it can be deadly. Most people recover from meningitis. However, permanent disabilities such as brain damage, hearing loss and learning disabilities can result from infection. Antibiotic treatment for bacterial meningitis, it is important to start treatment as soon as possible.

[Intended use]

STANDARD F *S.pneumoniae* Ag FIA is a fluorescence immunoassay for the qualitative detection of *S.pneumoniae* CPS Ag present in urine samples from patients with respiratory symptoms and in cerebral spinal fluid (CSF) samples from patient with meningitis. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of *S.pneumoniae* infection. It provides only an initial screening test result. Specific alternative diagnosis method should be performed in order to obtain the confirmation of *S.pneumoniae* infection.

[Test principle]

STANDARD F *S.pneumoniae* Ag FIA is based on immunofluorescence technology with STANDARD F Analyzer to detect *S.pneumoniae* antigen. STANDARD F *S.pneumoniae* Ag FIA has control line and test line which is coated with monoclonal anti-PPR and rabbit anti-*S.pneumoniae* CPS each. The patient's sample is applied into the sample well of the test device and the sample migrates through the membrane. If *S.pneumoniae* antigen is present, it will react with europium conjugated monoclonal anti-*S.pneumoniae* CPS in the conjugation pad and form antibody-antigen fluorescence particle complexes. These complexes move along to the membrane to be captured by the rabbit anti-*S.pneumoniae* CPS on the test line and make fluorescence signal. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer manufactured by SD BIOSENSOR. STANDARD F Analyzer can analyze the presence of the analyte in the clinical specimen by processing the results using pre-programmed algorithms and display the test result on the screen.

[Kit contents]

- ① Test device ② Fixed volume pipette (100µl) ③ Positive control ④ Negative control ⑤ Control extraction buffer ⑥ Instructions for use

[Materials required but not provided]

- STANDARD F Analyzer
- Timer

KIT STORAGE AND STABILITY

Store the kit at 2-30°C/36-86°F, out of direct sunlight. Kit materials are stable until expiration date printed on the outer box. Do not freeze the kit.

WARNINGS AND PRECAUTIONS

- Do not re-use the test kit.
- Use the STANDARD F *S.pneumoniae* Ag FIA at 15-32°C / 59-90°F and 10-90%RH.
- Do not use the kit if the pouch is damaged or the seal is broken.
- Do not smoke, drink or eat while handling specimen.
- Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly after you experiment.
- Clean up spills thoroughly using an appropriate disinfectant.
- Handle all specimens as if they contain infectious agents.
- Observe established precautions against microbiological hazards throughout testing procedures.
- Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and biohazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
- Silica gel in foil pouch is to absorb moisture and keep humidity from affecting products. If the moisture indicating silica gel beads change from yellow to green, the test device in the pouch should be discarded.
- The bar code of the test device is used by analyzer to identify the type of test being run and to identify the individual test device so as to prevent to a second read of the test device by the same analyzer.
- Immediately use the test device after taking out of a foil pouch.
- As the detection reagent is a fluorescent compound, no visible results will form on the test device. The STANDARD F Analyzers authorized by SD BIOSENSOR must be used for result interpretation.
- Improper specimen collection, handling or transport may yield inaccurate results.
- Do not write on the bar code or damage the bar code of the test device.
- If the test result with positive/negative control is abnormal, do not use the kit.

SPECIMEN COLLECTION AND PREPARATION

[Urine]

- Urine specimens should be collected in a clean and dry container and collected at any time of the day may be used.
- Urine specimen may be stored at room temperature for up to 24 hours or at 2-8°C / 36-46°F for up to 1 week prior to testing.
- For over 1 week storage, specimens may be frozen and stored at -40°C / -40°F.
- Frozen urine specimens should be thawed and fully mixed by vortexing before testing.
- If the specimen exhibits visible precipitates, it should be allowed to settle to obtain a clear supernatant for testing.

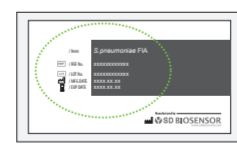
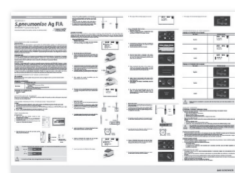
[CSF]

- CSF specimen should be collected in a dry and sterilized standard container and collected at any time of the day may be used.
- CSF specimen may be stored at room temperature for up to 24 hours prior to testing.
- When the specimen stored at 2-8°C condition, the test should be performed within anytime up to 1 week.
- If the specimen contained visible precipitates, it should be allowed to settle to obtain a clear supernatant for testing.

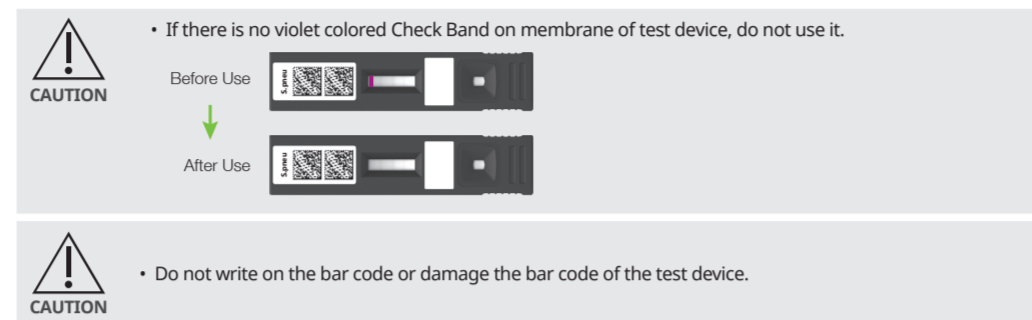
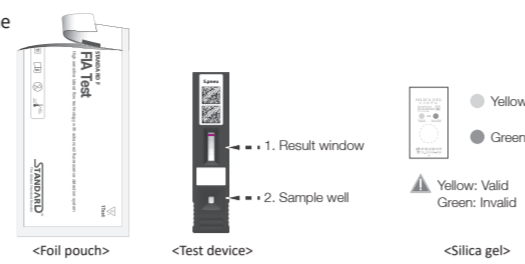
TEST PROCEDURE

[Preparation]

- Allow kit components and collected urine sample to room temperature (15-30°C / 59-86°F) a minimum of 30 minutes prior to testing.
- Carefully read instructions for using the STANDARD F *S.pneumoniae* Ag FIA.
- Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.

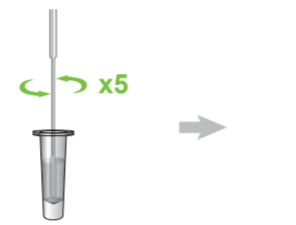


- Open the foil pouch, and check the test device and the silica gel pack in the foil pouch.



• Preparation of the positive/negative control sample

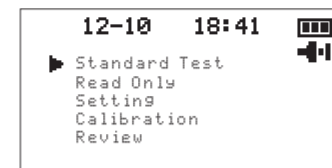
- Insert the positive/negative control swab in the kit into the control extraction buffer tube. Swirl the swab at least five times.
- Remove the swab and dispose of the used swab in accordance with your biohazard waste disposal protocol.
- To analyze of the external quality control sample, follow instructions for 'Analysis of sample' stated below.



[Analysis of sample]

• Using a STANDARD F100 Analyzer

- Prepare a STANDARD F100 Analyzer and set the 'Standard Test' mode according to the analyzer's manual.



- Take the test device out of the foil pouch.
- Insert the test device to the Test Slot of the analyzer. The analyzer automatically reads the information of the bar code on the test device and releases the test device for adding sample.

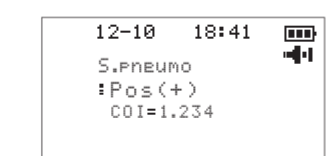
- Compress the top bulb of a fixed volume pipette (100µl) and place the tip of the pipette into the prepared sample.
- Slowly release the top bulb of the pipette dipping the tip of the pipette into the sample.
- Completely squeeze the sample into the sample well of the test device pressing hard the top bulb of the pipette.



- After applying the sample, immediately press the center button to start the test.

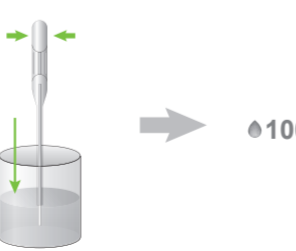


- The analyzer will automatically display the test result within 10 minutes. Strong positive results may be observed after 5 minutes.

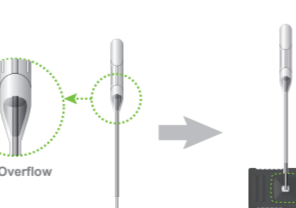


• 'Read Only' mode

- Take the test device out of the foil pouch and place it on a flat and dry surface.
- Compress the top bulb of a fixed volume pipette (100µl) and place the tip of the pipette into the prepared sample.
- Slowly release the top bulb of the pipette dipping the tip of the pipette into the sample.



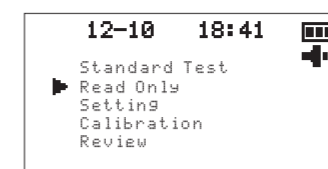
- Completely squeeze the sample into the sample well of the test device pressing hard the top bulb of the pipette.



- Leave the test device for 10 minutes. Notice that the test device should not leave for 20 more minutes.



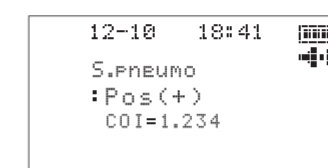
- Prepare a STANDARD F100 Analyzer and set the 'Read Only' mode according to the analyzer's manual.



- Insert the test device to the Test Slot of the analyzer.

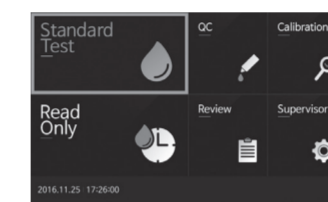


- The analyzer will automatically display the test result.

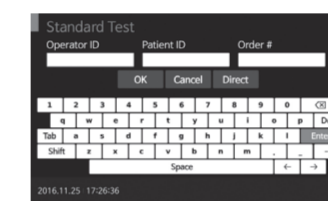


• Using a STANDARD F200 Analyzer

- Prepare a STANDARD F200 Analyzer and select the 'Standard Test' mode on the analyzer's screen.



- Input operator ID, patient ID, and order #. If patient ID is not input into the analyzer by touching the 'Direct' item, the analyzer will regard the test as that of the guest.
- Take the test device out of the foil pouch.



- Once the 'Insert Device' is displayed in the screen, insert the test device into the Test Slot of the analyzer.



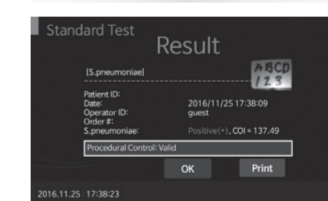
- When inserting the test device to the analyzer, the analyzer automatically reads the information of bar code on the test device and releases the test device for adding sample.



- Apply 100µl of prepared sample to the sample well in the test device with a fixed volume pipette (100µl).
- After applying the sample, immediately press the start button.

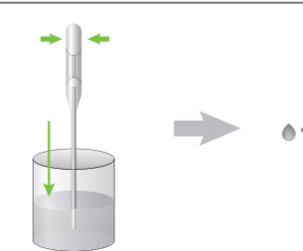


- The analyzer will automatically display the test result within 10 minutes. Strong positive results may be observed after 5 minutes.

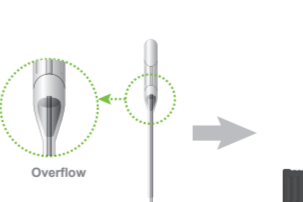


• 'Read only' mode

- Take the test device out of the foil pouch and place it on a flat and dry surface.
- Compress the top bulb of a fixed volume pipette (100µl) and place the tip of the pipette into the prepared sample.
- Slowly release the top bulb of the pipette dipping the tip of the pipette into the sample.



- Completely squeeze the sample into the sample well of the test device pressing hard the top bulb of the pipette.



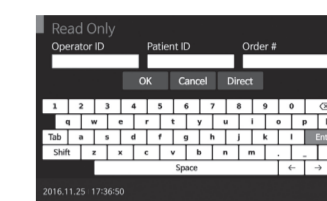
- Leave the test device for 10 minutes. Notice that the test device should not leave for 20 more minutes.



- Prepare a STANDARD F200 Analyzer and select the 'Read Only' on the analyzer's screen.



- Input operator ID, patient ID, and order #. If patient ID is not input into the analyzer by touching the 'Direct' item, the analyzer will regard the test as that of the guest.



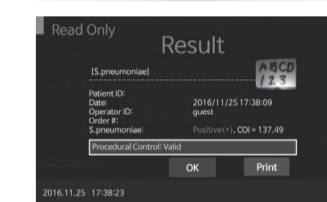
- Once the 'Insert Device' is displayed in the screen, insert the test device to the Test Slot of the analyzer.



- When inserting the test device to the analyzer, the analyzer automatically reads the information of bar code on the test device.



- The analyzer will automatically display the test result.



• The mark on the label between sample well and result window is scanned by the STANDARD F200 Analyzer and displayed on the screen.

INTERPRETATION OF TEST RESULTS

[Displays of STANDARD F100 Analyzer]

Test result	Window example
Negative	
Positive	
Invalid	

[Displays of STANDARD F200 Analyzer]

Test result	Window example
Negative	
Positive	
Invalid	



• Results should be considered in conjunction with the clinical history and other data available to the physician.



The analyzer's test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI (cutoff index) value. COI is calculated that a measured signal is divided by an appropriate cutoff value.

- Test results of a COI ≥ 1.00 are considered positive for *S.pneumoniae* Antigen.
- Test results of a COI < 1.00 are considered negative for *S.pneumoniae* Antigen.

QUALITY CONTROL

[Calibration Check Test]

The calibration set test of STANDARD F Analyzers should be conducted according to the analyzers' manual.

• When to use calibration set

1. Before using the analyzer for the first time
2. When you drop the analyzer
3. Whenever you do not agree with your result
4. When you want to check the performance of an analyzer and test device

• How to use calibration set

Calibration set test is a required function that ensures optimal performance by checking the internal analyzer optics and functions.

1. Select the 'Calibration' menu.
2. The specific calibration set is included with the analyzer.
3. Insert the CAL-1 first, and then insert the CAL-2 for UV-LED testing and the CAL-3 for RGB-LED testing in order.



• The STANDARD F Analyzers automatically calibrate and identify the optical performance through measuring the membrane of the test device whenever the test is conducted in 'Standard Test' mode. If 'EEE' message displays on the screen, it means that the analyzer has a problem, so check with CAL devices. Contact the SD BIOSENSOR local distributor if the 'EEE' message still appears.

[Internal procedural control]

1. The internal procedural control zone is on the membrane of the test device. STANDARD F Analyzers read the fluorescence signal of the internal procedural control zone and decide whether the result is valid or invalid.
2. The invalid result denotes that the fluorescence signal is not within the pre-set range. If the screen of STANDARD F Analyzer shows 'Invalid Device', turn off and turn on of the analyzer again and re-test with a new test device.

[External quality control]

1. Positive and negative controls are supplied with each kit and these controls are provided as a means of additional quality control to demonstrate a positive or negative reaction.
2. It is recommended that positive and negative controls be run:
 - once for each new lot.
 - once for each untrained operator.
 - as required by test procedures in this instructions and in accordance with local, state and federal regulations or accreditation requirements.

LIMITATION OF TEST

1. The contents of this kit are to be used the qualitative detection of *S.pneumoniae* antigen from urine and Cerebral Spinal Fluid (CSF) specimens of the symptomatic patients.
2. Failure to follow the test procedure or improper sample collection may adversely affect test performance or invalidate the test result.
3. For more accuracy of immune status, additional follow-up testing using other laboratory methods is recommended.
4. A negative test result may occur if the level of antigen in a sample is below the detection limit of the test or if the sample was collected, transported, or stored improperly.
5. Negative test results do not rule out possible other infections.
6. Positive test results do not rule out co-infection with other pathogens.
7. The collection of CSF sample should be performed by experienced personnel such as medical doctors under aseptic conditions.

PERFORMANCE CHARACTERISTICS

1. Analytical Reactivity: The serogroups of *Streptococcus pneumoniae* were tested by STANDARD F *S.pneumoniae* FIA. All of the serogroups were detected at the concentrations listed in the below table.

No.	Serotype	Limit of detection (CFU/mL)*
1	1	7.5 x 10 ³
2	2	6.0 x 10 ³
3	3	5.5 x 10 ³
4	4	6.5 x 10 ³
5	5	5.5 x 10 ³
6	6A	6.5 x 10 ³
7	6B	4.5 x 10 ³
8	8	6.0 x 10 ³
9	9V	6.5 x 10 ³
10	12F	5.5 x 10 ³
11	14	6.5 x 10 ³
12	15A	5.0 x 10 ³
13	15B	5.5 x 10 ³
14	18C	5.0 x 10 ³
15	19F	5.5 x 10 ³
16	19A	7.0 x 10 ³
17	20	5.5 x 10 ³
18	21	5.5 x 10 ³
19	23F	6.5 x 10 ³
20	27	5.5 x 10 ³

* Colony forming unit (CFU) is a unit used to estimate the number of viable bacteria in a sample.

2. Clinical sensitivity: Total 26 samples were evaluated for sensitivity. The STANDARD F *S.pneumoniae* Ag FIA Test got a high correlation with other FIA test.

Reference	STANDARD F <i>S.pneumoniae</i> Ag		Total Result	
	Positive	Negative		
FIA	Positive	25	1	26
	Negative	0	0	0
Total Result		25	1	26
Sensitivity		25/26 (96.2%)		

3. Clinical specificity: Total 40 samples were evaluated for specificity. The STANDARD F *S.pneumoniae* Ag FIA Test got a high correlation with other FIA test.

Reference	STANDARD F <i>S.pneumoniae</i> Ag		Total Result	
	Positive	Negative		
FIA	Positive	0	0	0
	Negative	0	40	40
Total Result		0	40	40
Specificity		40/40 (100%)		

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9. Infections Programs Network. Bacterial meningitis in the United States, 1998-2007. N Engl J Med. 2011;364:2016-2025.

Product Disclaimer

Whilst every precaution has been taken to ensure the diagnostic ability and accuracy of this product, the product is used outside of the control of the SD BIOSENSOR and distributor and the result may accordingly be affected by environmental factors and/or user error. A person who is the subject of the diagnosis should consult a doctor for further confirmation of the result.

Warning

The SD BIOSENSOR and distributors of this product shall not be liable for any losses, liability, claims, costs or damages whether direct or indirect of consequential arising out of or related to an incorrect diagnosis, whether positive or negative, in the use of this product.



Manufactured by SD BIOSENSOR

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L28SPN1ENR3
Issued date : 2018.03



Reference number



In vitro Diagnostics



Consult Instructions for Use



Contains Sufficient for n-Tests



Caution



Do not re-use.



To indicate the temperature limitations in which the transport package has to be kept and handled.



Use by



Batch code



Manufacturer



Date of manufacture



Note



Fulfill the requirements of Directive 98/79/EC on in vitro diagnostic medical devices