Quality approved by SD BIOSENSOR / For *in vitro* diagnostics use only

STANDARD F
Strep A Ag FIA

REF FSRA01G

STANDARD™ F Strep A Ag FIA

PLEASE READ INSTRUCTIONS CAREFULLY BEFORE YOU PERFORM THE TEST

STANDARD™ The Global Standard Founder

EXPLANATION AND SUMMARY

[Introduction]

Group A streptococcus (GAS) is a bacterium commonly found in the respiratory, alimentary and genital tracts, as well as in the skin and mucous membrane. Group A streptococcus is spread through direct contact with nasal or throat secretions of an infected person or through contact with infected skin sores or drainage from wounds. Most group A streptococcal infections are fairly mild, such as strep throat or impetigo. On rare occasions, these bacteria can cause invasive infection and even life-threatening disease when breaks in the skin or open sores allow the bacteria to enter the tissue or when the patient has a chronic disease or compromised immune system that weakens the defenses against bacteria. Two of the most serious forms of invasive group A streptococcus disease are necrotizing fasciitis and streptococcal toxic shock syndrome (STSS). Necrotizing fasciitis rapidly destroys muscles, fat, and skin tissue. Streptococcal toxic shock syndrome causes blood pressure to drop rapidly and organs to fail. Less serious invasive diseases caused by group A streptococcus include cellulitis and pneumonia. While 10%-15% of patients with invasive Group A streptococcus (GAS) disease die from the infection, approximately 25% of patients with necrotizing fasciitis and more than 35% with streptococcal toxic shock syndrome die. Thus, correct diagnosis and treatment are primarily of importance to the prevention of invasive disease caused by group A streptococcus. STANDARD F Strep A Ag FIA, employing immunofluorescent detection system with STANDARD F analyzer, provides significantly fast, easy and accurate system to identify the target antigen from human throat specimen. The test may aid in the reliable clinical diagnosis of group A streptococcus infection and enables supportive treatment decisions.

[Intended use]

STANDARD F Strep A Ag FIA is the fluorescence immunoassay to detect group A streptococcal (Strep A) antigen present in throat specimens from patients with clinical symptoms. This test is for *in vitro* professional diagnostic use and intended as an aid to early diagnosis of group A streptococcal infection. It provides only an initial screening test result. Specific alternative diagnosis method should be performed in order to obtain the confirmation of group A streptococcal infection.

[Test principle]

STANDARD F Strep A Ag FIA is based on immunofluorescence technology with STANDARD F analyzer to detect group A streptococcal (Strep A) antigen. For extraction of the bacterial antigen, the patient's specimen is put into the extraction buffer tube containing mixed extraction buffer 1 and extraction buffer 2. After extraction, extracted specimen is applied into the sample well of the test device and specimen migrates through the membrane from the sample well. If Strep A antigen is present, it will be bound to by rabbit polyclonal anti-Strep A coupled to europium microparticle that migrates through the membrane of the test device. The fluorescent microparticle containing Strep A antigen will be captured by goat polyclonal anti-Strep A on the test line where it is detected by STANDARD F Analyzer. If Strep A antigen is not present, the europium microparticle will not be trapped by the capture antibody nor detected by STANDARD F Analyzer. The intensity of the fluorescence light generated on the membrane is scanned by the STANDARD F Analyzer. STANDARD F Analyzer can analyze the presence of the group A streptococcal (Strep A) antigen in the clinical specimen by processing the results using pre-programmed algorithms based on a pre-programmed algorithms and display the test result on the screen.

KIT CONTENTS

① Test device ② Extraction buffer 1 ③ Extraction buffer 2 ④ Disposable dropper (100µl) ⑤ Positive control ⑥ Negative control ⑦ Sterile swab (throat) ⑧ Instructions for use

MATERIALS REQUIRED BUT NOT PROVIDED

1. STANDARD F analyzer
2. Timer

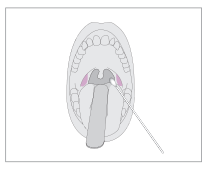
KIT STORAGE AND STABILITY

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

WARNINGS AND PRECAUTIONS

1. Do not re-use the test kit.
2. Do not use the test kit if the pouch is damaged or the seal is broken.
3. Do not use extraction buffer 1 or extraction buffer 2 of another lot.
4. Do not smoke, drink or eat while handling specimen.
5. Wear personal protective equipment, such as gloves and lab coats when handling kit reagents. Wash hands thoroughly afterwards.
6. Clean up spills thoroughly using an appropriate disinfectant.
7. Handle all specimens as if they contain infectious agents.
8. Observe established precautions against microbiological hazards throughout testing procedures.
9. Dispose of all specimens and materials used to perform the test as bio-hazard waste. Laboratory chemical and bio-hazard wastes must be handled and discarded in accordance with all local, state, and national regulations.
10. A moisture indicator with silica gel within foil pouch is to absorb moisture and keep humidity from affecting products. Check the desiccant for color change of the humidity indicator and discard the test device if the indicates shows green color.
11. 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.
12. Once a test device has been successfully scanned by analyzer, do not attempt to scan the test device again in the same analyzer.
13. 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.
14. Improper specimen collection, handling or transport may yield inaccurate results.
15. Do not write on the bar code or damage the bar code of the test device.
16. The test should be performed at least 30 minutes after brushing the teeth or gargling.
17. Never drink anything except water for 30minutes before the test. Especially do not drink coffee.

SPECIMEN COLLECTION, PREPARATION AND STORAGE



Throat Swab

- **Throat swab**
  1. Open the mouth widely.
  2. Depress the tongue with a tongue blade or spoon.
  3. Rub the swab on the back of the throat, both of the tonsils, the uvula and the posterior pharynx.
  4. Be careful not to touch the tongue, sides or top of the mouth with the swab.
  5. Swabs can be stored at room temperature for up to 24 hours or at 2-8°C/ 36-46°F for up to 48 hours after collection in a clean and dry plastic tube.
- **Specimen in transport media**
  1. Transport fresh specimens to the laboratory as rapidly as possible in a suitable liquid transport system.
  2. The BD Universal Viral Transport and Copan Universal Transport Medium have been tested and found to be compatible with STANDARD F Strep A Ag FIA.

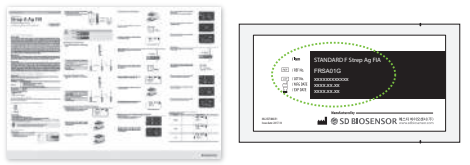
CAUTION

- Minimal dilution of the sample is recommended, as dilution may result in decreased test sensitivity.

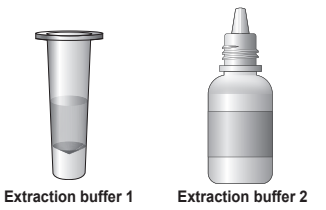
TEST PROCEDURE

[Preparation]

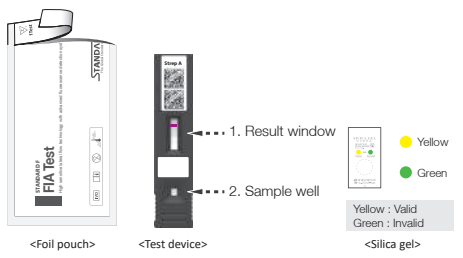
1. Allow kit components and specimen to room temperature (15-30°C/59-86°F) a minimum of 30 minutes prior to testing.
2. Carefully read instructions for using the STANDARD F Strep A Ag FIA.
3. Check the expiry date at the back of the foil pouch. Use another lot, if expiry date has passed.



4. Check the Extraction buffer1 and buffer2 as the picture on the side.



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



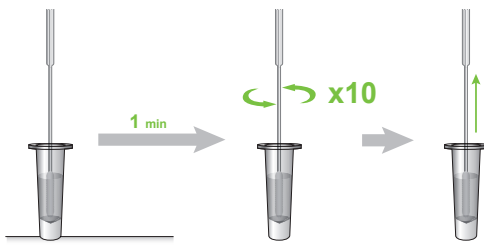
CAUTION

- If a violet colored band (check band) does not appear in the result window of the test device, do not use it.

[Positive/negative control processing]

1. Add 3 drops of extraction buffer 2 into the extraction buffer 1.

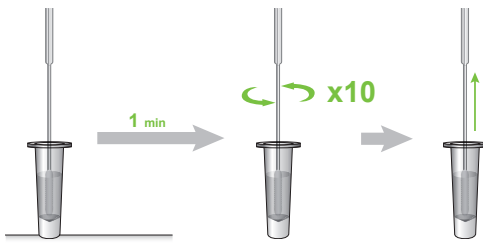
2. Put the Throat swab into the extraction buffer tube, and the incubate for about 1 minute to extract the specimen from the swab.
3. Swirl the swab at least 10 times while pressing the head against the bottom and side of the tube.
4. Roll the swab head against the inside of the test tube as you remove it.
5. Discard the swab in accordance with your biohazard waste disposal protocol.



[Specimen processing]

1. Add 3 drops of extraction buffer 2 into the extraction buffer 1.

2. Put the Throat swab into the extraction buffer tube, and the incubate for about 1 minute to extract the specimen from the swab.
3. Swirl the swab at least 10 times while pressing the head against the bottom and side of the tube.
4. Roll the swab head against the inside of the test tube as you remove it.
5. Discard the swab in accordance with your biohazard waste disposal protocol.

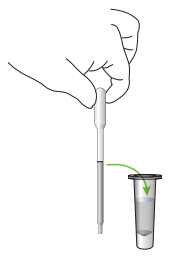


[Analysis of sample]

- **Using a 'STANDARD TEST' mode**

- **Applying of STANDARD F100, F200 and F2400 analyzer**
  1. Prepare a STANDARD F Analyzer and select the 'Standard Test' mode according to the analyzer's manual. In case of STANDARD F2400 analyzer, go to the 'Workplace' in the main screen. And select the 'Run Test'
  2. In case of STANDARD F200 and F2400 analyzer, input patient ID and/or operator ID on the analyzer.
  3. Take the test device out of the foil pouch.
  4. Insert the test device to the test slot of the analyzer. When inserting the test device to the analyzer, the analyzer will read the barcode data, and check the test device is valid.

  5. Compress the top bulb of a disposable dropper (100µl) and place the tip of the pipette into the prepared sample.



SD BIOSENSOR

6. Collect the sample until the black line of the dropper (100µl).

7. Apply 100µl of specimen mixture to the sample well of the test device.

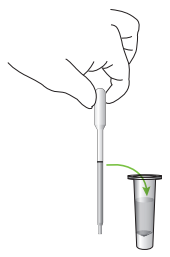
8. After applying the sample, immediately press the **'TEST START'** button.

<F100> <F200> <F2400>

9. The analyzer will automatically display the test result within 5 minutes.

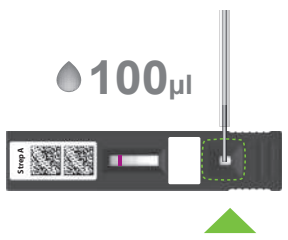
- **Using a 'READ ONLY' mode**
  - **Applying of STANDARD F100 and F200 analyzer**

1. Take the test device out of the foil pouch and place it on a flat and dry surface. Write a sample information on the label of test device.
2. Compress the top bulb of a disposable dropper (100µl) and place the tip of the pipette into the prepared sample.



3. Collect the sample until the black line of the dropper (100µl).

4. Apply 100µl of specimen mixture to the sample well of the test device.



5. Incubate the test device for 5 minutes outside of the analyzer.

6. Prepare a STANDARD F Analyzer and select the 'Read Only' mode according to the analyzer's manual.
7. Insert the test device to the test slot of the analyzer.

8. When inserting the test device to the analyzer, the analyzer will automatically scan and display the test results.

INTERPRETATION OF TEST RESULTS

Result	COI (Cutoff index) value	Interpretation
Positive	COI ≥ 1.0	Positive for Strep A antigen
Negative	COI < 1.0	Negative for Strep A antigen
Invalid	Not show the COI value	Retest should be performed

NOTE

The test result of a sample is given either as Positive(+)/Pos(+) or Negative(-)/Neg(-) with a COI (cutoff index) value. The COI is a numerical representation of the measured fluorecence signal.

QUALITY CONTROL

[Calibration]

The calibration set test of STANDARD F Analyzer should be conducted according to the analyzer's 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' in main 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.

NOTE

- The STANDARD F Analyzer 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 analyzers shows 'Invalid Device', turn off and turn on the analyzer again and re-test with a new test device.

[External quality control]

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

LIMITATION OF THE TEST

1. The contents of this kit are to be used the qualitative detection of group A streptococcal antigen from throat swab specimens of the symptomatic patients.
2. Failure to follow the test procedure and interpretation of test result 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. Respiratory infections, including pharyngitis, can be caused by streptococcus from serogroups other than group A as well as other pathogens.
5. The test will not differentiate asymptomatic carriers of group A streptococcus from those exhibiting streptococcal infection.
6. A negative test result may occur if the level of antigen in a specimen is below the detection limit of the test or if the specimen was collected, transported, or stored improperly.
7. Negative test results do not rule out possible other infections.
8. Positive test results do not rule out co-infection with other pathogens.

ANALYTICAL SPECIFICITY

1. Cross reactivity

The STANDARD F Strep A Ag FIA and STANDARD F were evaluated with a total 8 microorganism and 9 viruses.
STANDARD F Strep A Ag FIA did not show any sign of cross reactivity with microorganism or influenza viral isolates listed below in table 1.

Table 1. Cross reactivity of STANDARD F Strep A Ag FIA

No	Type	Microorganism/Virus	Concentration
1	Bacteria	Escherichia coli	$2.0x10^6$ cfu/test
2		Heamophilus influenzae	$1.0x10^7$ cfu/test
3		Klebsiella pneumoniae	$1.2x10^7$ cfu/test
4		Pseudomonas aeruginosa	$1.5x10^6$ cfu/test
5		Serratia marcescens	$2.0x10^7$ cfu/test
6		Staphylococcus aureus	$2.0x10^6$ cfu/test
7		Staphylococcus epidermidis	$1.5x10^6$ cfu/test
8		Streptococcus pneumoniae	$1.0x10^6$ cfu/test
9	Viruses	Coxsackievirus A2	$1.0x10^6$ $TCID_{50}$/test
10		Coxsackievirus A3	$1.0x10^6$ $TCID_{50}$/test
11		Influenza A H1N1	$2.0x10^4$ $TCID_{50}$/test
12		Parainfluenza virus 1	$1.0x10^4$ $TCID_{50}$/test
13		Parainfluenza virus 2	$1.0x10^4$ $TCID_{50}$/test
14		Adnovirus Type 1	$1.0x10^{11}$ $TCID_{50}$/test
15		Adnovirus Type 3	$1.0x10^5$ $TCID_{50}$/test
16		Adnovirus Type 5	$2.0x10^5$ $TCID_{50}$/test
17		Adnovirus Type 11	$2.0x10^5$ $TCID_{50}$/test

2. Interfering Substances

Several over-the-counter substances, chemicals and body fluid were evaluated with STANDARD F Strep A Ag FIA and STANDARD F analyzer. There are no interfering reactions with substances below listed in Table 2.

Table 2. Non-interfering Substance

No	Potential interfering substances	Concentration of intergerent
1	Listerine cool mint	25% v/v
2	Listerine natural green tea	25% v/v
3	Mok-N Spray	25% v/v
4	Strepsils	25% v/v
5	Ibuprofen	5mg/mL
6	Acetylsalicylic acid	20mg/mL
7	Guaiacol Glyceryl Ether	20mg/mL
8	Whole blood	5% v/v
9	Budesonide	500mg/mL
10	oxymetazoline	0.01mg/mL
11	Phenylephrine	0.5mg/mL
12	Acetamidophenol	5mg/mL
13	Halls honey lemon	25% v/v
14	Halls mentholyptus	25% v/v

BIBLIOGRAPHY

1. Leung AK, Newman R, Kumar A, Davies HD. Rapid antigen detection testing in diagnosing group A beta-hemolytic streptococcal pharyngitis. Expert Rev Mol Diagn. 2006;6(5):761–766.
2. Chapin KC, Blake P, Wilson CD. Performance characteristics and utilization of rapid antigen test, DNA probe, and culture for detection of a streptococci in an acute care clinic. J Clin Microbiol. 2002;40(11):4207–4210.
3. Fox JW, Marcon MJ, Bonsu BK. Diagnosis of streptococcal pharyngitis by detection of Streptococcus pyogenes in posterior pharyngeal versus oral cavity specimens. J Clin Microbiol. 2006;44(7):2593–2594.
4. Llor C, Calviño O, Hernández S, et al. Repetition of the rapid antigen test in initially negative supposed streptococcal pharyngitis is not necessary in adults. Int J Clin Pract. 2009;63(9):1340–1344.

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.

CE

Manufactured by SD Biosensor, Inc.
Head office : C-4th&5th, 16, Deogyeong-daero 1556beon-gil, Yeongtong-gu, Suwon-si, Gyeonggi-do, 16690, REPUBLIC OF KOREA
Manufacturing site : 74, Osongsaengmyeong 4-ro, Osong-eup, Heungdeok-gu, Cheongju-si, Chungcheongbuk-do, 28161, REPUBLIC OF KOREA

EC REP **Authorized Representative**
MT Promedt Consulting GmbH
Altenhofstrasse 80 66386 St. Ingbert Germany
Phone : +49 6894 581020, Fax : +49 6894 581021

Any inquiries regarding instructions provided should be addressed to: sales@sdbiosensor.com
or you can also contact us through www.sdbiosensor.com

L28STR1ENR5
Issue date : 2019.05

REF Reference number | IVD *In vitro* Diagnostics | Consult Instructions for Use | Contains Sufficient for <n> Tests | Caution | To indicate the temperature limitations in which the transport package has to be kept and handled. | Note | Do not re-use. | Use by | LOT Batch code | Manufacturer | Date of manufacture | CE Fulfill the requirements of Directive 98/79/EC on *in vitro* diagnostic medical devices