Strep A Test Cassette
(Throat Swab)
Package Insert

REF FI-STA-502	English

A Fluorescence Immunoassay test kit for the qualitative detection of Strep A Antigen in throat Swab specimens with the use of FIATEST™ Fluorescence Immunoassay Analyzer.

For professional in vitro diagnostic use only

【INTENDED USE】

The Strep A Test Cassette （Throat swab） is intended for *in vitro* detection of strep A antigens in throat swab specimens. It is intended to aid in the rapid differential diagnosis of strep A viral infections.

【SUMMARY】

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.[1] Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[2] Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.[3,4]

The Strep A Test Cassette is a test to qualitatively detect the presence of Strep A antigens in throat swab specimens, providing results within 15 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigens in a throat swab specimen.

【PRINCIPLE】

The Strep A Test Cassette (Throat Swab) detects Strep A carbohydrate antigen in a throat swab based on Fluorescence Immunoassay. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane. If the specimen contains Strep A antigen, it attaches to the fluorescent microspheres-conjugated Strep A antibodies. Then the complex will be captured by the capture antibodies coated on the nitrocellulose membrane (Test line). The concentration of Strep A in the sample correlates with the fluorescence signal intensity captured on the T line , which can be scanned by FIATEST™ Fluorescence Immunoassay Analyzer. The testing result of Strep A will display on the FIATEST™ Fluorescence Immunoassay Analyzer screen.

【REAGENT】

The test contains Strep A antibody coated particles and Strep A antibodies coated on the membrane.

【PRECAUTIONS】

1. For professional *in vitro* diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye
5. protection when specimens are assayed.
6. The used test should be discarded according to local regulations.
7. Humidity and temperature can adversely affect results.
8. Do not use test if pouch is damaged.
9. Reagent 2 contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
10. Do not interchange reagent bottle caps.
11. Do not interchange external control solution bottle caps.
12. Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
13. Read the entire procedure carefully prior to any testing.
14. The Strep A Test Cassette is only operational in the Analyzer. And tests should be applied by professionally trained staff working in certified laboratories at some remove from the patient and clinic at which the sample(s) is taken by qualified medical personnel

【STORAGE AND STABILITY】

1. The kit should be stored at 4-30°C until the expiry date printed on the sealed pouch.
2. The test must remain in the sealed pouch until use.
3. **Do not freeze.**
4. Care should be taken to protect the components of the kit from contamination.
5. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

【SPECIMEN COLLECTION AND PREPARATION】

1. Collect the throat swab specimen with the sterile swab that is provided in the kit. Transport swabs containing modified Stuart's or Amies medium can also be used with this product. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[5]
2. Testing should be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C.
3. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Test Cassette (Throat Swab).

【MATERIALS】

Materials Provided

- Test Cassettes
- Extraction Tubes
- Sterile Swabs
- Workstation
- Package Insert
- Dropper tips
- Extraction Reagent 1 (2M NaNO2)
- Extraction Reagent 2 (0.027M Citric acid)
- ID Card

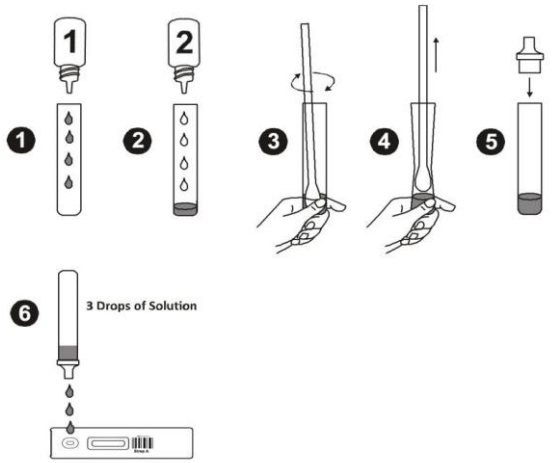
Materials Required But Not Provided

- Timer
- Pipette
- Fluorescence Immunoassay Analyzer

【DIRECTIONS FOR USE】

Allow the test, reagents, throat swab specimen, and/or controls to reach room temperature (15-30℃) prior to testing.

1. Remove the test cassette from the sealed foil pouch and use it within one hour. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Extraction Reagent 1 bottle vertically and add **4 full drops (approximately 240 µL) of Extraction Reagent 1** to an extraction tube. Extraction Reagent 1 is red in color. Hold the **Extraction Reagent 2** bottle vertically and add 4 full drops **(approximately 160 µL)** to the tube. Extraction Reagent 2 is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the color of the solution from red to yellow.
3. Immediately add the swab into the extraction tube, agitate the swab vigorously **15 times**, and leave the swab in the extraction test tube for **1 minute**.
4. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab.
5. Place the test cassette on a clean and level surface. Add **three drops of the solution (approx.120ul)** to the sample well. Start the timer at the same time.
6. There are two test modes for Fluorescence Immunoassay Analyzer, **Standard Test** mode and **Quick Test** mode. Please refer to the user manual of Fluorescence Immunoassay Analyzer for details.
   "**Quick test**" mode: After **15 minutes** of adding sample，Insert the test cassette into the Analyzer, click "**QUICK TEST**", fill the test information and click "**NEW TEST**" immediately. The Analyzer will automatically give the test result after a few seconds.
   "**Standard test**" mode: Insert the test cassette into the Analyzer immediately after adding specimen, click "**STANDARD TEST**", fill the test information and click "**NEW TEST**" at the same time, The Analyzer will automatically countdown **15 minutes**. After the countdown, the Analyzer will give the result at once.



【INTERPRETATION OF RESULTS】

Results read by FIATEST™ Fluorescence Immunoassay Analyzer.

The result of tests for Strep A is calculated by FIATEST™ Fluorescence Immunoassay Analyzer and display the result on the screen. For additional information, please refer to the user manual of FIATEST™ Fluorescence Immunoassay Analyzer..

NOTE: The test result of each specimen is given as Pos (+) or Neg (-) with a Reference Value. This Value is calculated that a measured signal is divided by an appropriate cutoff value.

- Test results of a Value ≥ 1.00 are considered positive.

- Test results of a Value < 1.00 are considered negative.

【QUALITY CONTROL】

Each FIATEST™ Strep A Test Cassette contains internal control that satisfies routine quality control requirements. This internal control is performed each time a patient sample is tested. This control indicates that the test device was inserted and read properly by FIATEST™ Fluorescence Immunoassay Analyzer. An invalid result from the internal control causes an error message on FIATEST™ Fluorescence Immunoassay Analyzer indicating that the test should be repeated. An invalid result from the internal control causes an "N/A" message on FIATEST™ Fluorescence Immunoassay Analyzer. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

【LIMITATIONS】

1. The Strep A Test Cassette (Throat Swab) is for *in vitro* diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
3. A negative result should be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
4. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth[5] and any bleeding areas of the mouth with the swab when collecting specimens.
5. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

【EXPECTED VALUES】

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A beta hemolytic Streptococcus.[6] In school-aged children and adults, the incidence of Strep throat infection is about 40%.[7] This disease usually occurs in the winter and early spring in temperate climates.[3]

【BIBLIOGRAPHY】

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4. Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a High-sensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468-3473.
5. Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
6. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
7. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

Index of Symbols

	Consult Instructions for Use		Tests per kit	EC REP	Authorized Representative
IVD	For *in vitro* diagnostic use only		Use by		Do not reuse
4°C 30°C	Store between 4-30°C	LOT	Lot Number	REF	Catalog #
	Do not use if package is damaged		Manufacturer		

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