Strep A Rapid Test Device
Package Insert

Cat: IST-502
Version: 02

Specimens: Swab
Effective Date: 2015-02

For professional *in vitro* diagnostic use only.

INTENDED USE

The Strep A Rapid Test Device is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

INTRODUCTION

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigen 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 Rapid Test Device is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

PRINCIPLE

The Strep A Rapid Test Device is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. 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 and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

KIT COMPONENTS

- Test devices
- Sterile swabs
- Workstation
- Strep A Reagent A (1M Sodium Nitrite)
- Strep A Reagent B (0.4M Acetic Acid)
- Test tubes
- Dropper tips
- Package insert

MATERIALS REQUIRED AND AVAILABLE FOR PURCHASE

- Strep A Positive Control (Non-viable Strep A; preservative)
- Strep A Negative Control (Non-viable Strep C; preservative)

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after the expiration date.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- 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.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Humidity and temperature can adversely affect results.
- Do not use test if pouch is damaged.
- Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use. **DO NOT FREEZE.** Do not use beyond the expiration date.

SPECIMEN COLLECTION AND STORAGE

- Only use reagents and sterile swabs provided in the kit.
- Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[5]
- 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. Transport swabs containing modified Stuart's or Amies medium can also be used with this product.
- 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 Rapid Test Device.

PROCEDURE

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

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Reagent A bottle vertically and **add 4 full drops** (approximately 240 µL) of Reagent A to an extraction test tube. Reagent A is red in color. Hold the Reagent B bottle vertically and **add 4 full drops** (approximately 160 µL) to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction test tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.
3. **Immediately add the throat swab to the extraction test tube of yellow solution.** Agitate the swab **10 times** in the tube. Leave the swab in the tube for **1 minute.** Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.
4. Fit the dropper tip on top of the extraction test tube. Place the test device on a clean and level surface. **Add 3 full drops of solution** (approx. 100 µL) to the specimen well (S) and then start the timer.
5. Wait for the colored line(s) to appear. **Read the result at 5 minutes.** Do not read the result after 10 minutes.

INTERPRETATION OF RESULTS

POSITIVE RESULT:

* A colored band appears in the control band region (C) and another colored band appears in the T band region.

NEGATIVE RESULT:

One colored band appears in the control band region (C). No band appears in the test band region (T).

INVALID RESULT:

Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.
2. Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

Internal Quality Control
Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.

External Quality Control
In addition to your laboratory's standard quality control procedures, it is recommended that a positive and negative external control be tested at least once within each test kit and by each operator performing testing within a kit. This will verify that the reagents and test devices are working properly and the operator is able to correctly perform the test procedure. External positive and negative controls are supplied in the kit.

Procedure for External Quality Control Testing

1. Add 4 full drops of Reagent A and 4 full drops of Reagent B into an extraction test tube. Tap the bottom of the tube gently to mix the liquid.
2. Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
3. Place a clean swab into this extraction tube and agitate the swab in the solution by rotating it at least 10 times. Leave the swab in the extraction tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab.
4. Continue with Step 4 of Directions For Use.

If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATIONS OF THE TEST

1. The Strep A Rapid Test Device 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 must 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. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
5. 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.

As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Strep A Rapid Test vs. PCR Test

Method		Culture		Total Results
	Results	Positive	Negative	
Strep A Rapid Test	Positive	102	7	109
	Negative	6	377	383
Total Results		108	384	492

Relative Sensitivity: 94.4% (90.1%-98.8%)*

Relative Specificity: 98.2% (96.8%-99.5%)*

Accuracy: 97.4% (95.9%-98.8%)* * 95% Confidence Intervals **Cross-Reactivity**

The following organisms were tested at 1.0 x 10^7 organisms per test and were all found to be negative when tested with the Strep A Rapid Test Device. No mucoid-producing strains were tested.

Group B Streptococcus
Group F Streptococcus
Streptococcus pneumoniae
Streptococcus mutans
Staphylococcus aureus
Corynebacterium diphtheria
Candida albicans
Pseudomonas aeruginosa
Neisseria meningitidis
Neisseria sicca
Branhamella catarrhalis
Group C Streptococcus
Group G Streptococcus
Streptococcus sanguis
Enterococcus faecalis
Staphylococcus epidermidis
Serratia marcescens
Klebsiella pneumoniae
Bordetella pertussis
Neisseria gonorrhea
Neisseria subflava
Hemophilus influenza

POL Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test Device. Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20), and medium positive (20) for three days. The results obtained had a 96% correlation with the expected results.

LITERATURE REFERENCES

1. Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C. p. 299-307.
2. Webb, KH. *Does Culture Confirmation of High-sensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis.* Pediatrics (Feb 1998), 101:2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. *Diagnosis and Management of Group A Streptococcal Pharyngitis.* Clinical Infectious Diseases (1997), 25:574-83.
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.