



## Strep A Rapid Test Device (Throat Swab)

A rapid test for the qualitative detection of Strep A antigen in throat swab specimens.

For professional *in vitro* diagnostic use only.

### INTENDED USE

Strep A Rapid Test Device (Throat Swab) 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.

### SUMMARY

*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. Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess. 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. Strep A Rapid Test Device (Throat Swab) 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

Strep A Rapid Test Device (Throat Swab) 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.

### REAGENTS

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

### 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.
- The positive and negative controls contain sodium azide (NaN<sub>3</sub>) as a preservative.
- 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 PREPARATION

- 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.
- 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 (Throat Swab).

### MATERIALS

#### Materials Provided

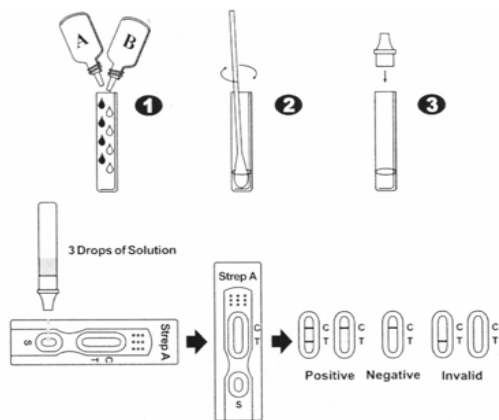
- Test devices
- Strep A Reagent A (2M Sodium Nitrite)
- Strep A Reagent B (0.4M Acetic Acid)
- Strep A Positive Control (Non-viable Strep A; 0.09%NaN<sub>3</sub>)
- Strep A Negative Control (Non-viable Strep C; 0.09%NaN<sub>3</sub>)
- Sterile swabs
- Workstation
- Test Tubes and snaps
- Package insert

#### Materials Required But Not Provided

- Timer

### DIRECTIONS FOR USE

**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  $\mu\text{L}$ ) 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  $\mu\text{L}$ ) 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. See illustration 1.
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. See illustration 2.
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  $\mu\text{L}$ ) to the specimen well (S) and then start the timer. See illustration 3.
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

(Please refer to the illustration above)

**POSITIVE:** **Two lines appear.** One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that Strep A was detected in the specimen.

**\*NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Strep A present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

**NEGATIVE:** **One colored line appears in the control line region (C).** No line appears in the test line region (T). A negative result indicates that Strep A antigen is not present in the specimen, or is present below the detectable level of the test. The patient's specimen should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another specimen for culture.

**INVALID:** **Control line fails to appear.** Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

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

## LIMITATIONS

- The Strep A Rapid Test Device (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.
- This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A Streptococcus bacteria.
- 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.
- The sterile swabs provided with this test must be used for specimen collection. Other swabs

have not been validated with this test.

- 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<sup>5</sup> 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.

### EXPECTED VALUES

Approximately 15% of pharyngitis in children ages 3 months to 5 years is caused by Group A beta-hemolytic Streptococcus. In school-aged children and adults, the incidence of Strep throat infection is about 40%.<sup>1</sup> This disease usually occurs in the winter and early spring in temperate climates.

### PERFORMANCE CHARACTERISTICS Sensitivity and Specificity

Using three medical centers for evaluation, a total of 492 throat swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate, and then tested by the Strep A Rapid Test Device (Throat Swab). The plates were further streaked for isolation, and then incubated at 37°C with 5-10% CO<sub>2</sub> and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GAS colonies were subcultured and confirmed with a commercially available latex agglutination grouping kit. Of the 492 total specimens, 384 were confirmed to be negative and 108 were confirmed to be positive by culture. During this study, two Strep F specimens yielded positive results with the Test. One of these specimens was re-cultured, then re-tested and yielded a negative result. Three additional different Strep F strains were cultured and tested for cross-reactivity and also yielded negative results.

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

Total Results	108	384	492
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Relative Sensitivity: 94% (88%-98%)  
Accuracy: 97% (96%-98%)

### Cross-Reactivity

The following organisms were tested at 1.0 x 10<sup>7</sup> organisms per test and were all found to be negative when tested with the Strep A Rapid Test Device (Throat Swab). No mucoid-producing strains were tested.

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

### POL Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test Device (Throat Swab). 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.

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