

StrepAStick (Throat Swab)

One-Step Test for Direct Determination of Group A Streptococcus

Catalog Number R-6010 (25 Determinations)

Directions for Use

SUMMARY AND EXPLANATION

Among the beta-hemolytic streptococci causing infections in humans, the A, B, C and G groups figure most prominently⁵. Group A streptococci continue to be a focus of interest not only because of their causal role in acute streptococcal pharyngitis and other pyogenic infections but also because of their association with post streptococcal sequelae, specifically acute rheumatic fever and acute glomerulonephritis^{1,2}. In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to identify the pathologic agent. For the screening of group A streptococcal infection several methods are currently used including susceptibility of the organism to a bacitracin disc placed on a sheep blood agar plate, latex agglutination and enzyme immunoassay^{3,4}.

The StrepAStick (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

The Novamed StrepAStick (Throat Swab) test is a rapid qualitative, lateral flow immunoassay for the detection of Streptococcus Group A carbohydrate antigen. The method employs a unique combination of monoclonal-dye conjugate and polyclonal solid phase antibodies to selectively identify streptococcus A with a high degree of sensitivity. As the test samples flows through the absorbent device, the labeled antibody-dye conjugate binds to the Strep A carbohydrate antigen forming an antibody-antigen complex. This complex binds to the anti-Strep A antibody in the test zone producing a pink-rose color band. In the absence of Strep A there is no line in the test zone. The reaction mixture continues flowing through the absorbent device. Unbound conjugate binds to the reagents in the control zone producing a pink-rose color band, indicating that proper volume of specimen has been added and membrane and the reagents are functioning correctly.

KIT COMPONENTS:

25 dipstick-strips StrepAStick (Throat Swab) tests in aluminum foil pouches with desiccant; 25 sterile throat swabs;
 25 empty test tubes placed in a plastic stand; 1 dropper with Extraction Reagent A ((2M Sodium Nitrite)
 1 dropper Extraction Reagent B (0.4M Acetic Acid), 1 Strep A Positive control (Non-viable Streptococcus A; 0.09% NaN₃)
 1 dropper Strep A Negative control (Non-viable Streptococcus C; 0.09% NaN₃); Instructions for Use

STORAGE AND STABILITY

StrepAStick is to be stored at room temperature (4 to 30°C) in the tightly closed tube. Do not freeze the test kit.

PRECAUTIONS

1. This test is designed for "*IN VITRO*" use only.
2. Extraction reagents are caustic and may cause irritation to skin, eyes and mucus membranes. Wash off immediately if extraction reagent came in contact with skin.
3. Read carefully instruction notice before using this test.
4. Do not use beyond expiry date that appears in the package label.

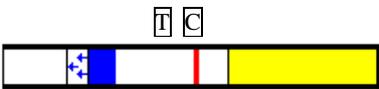
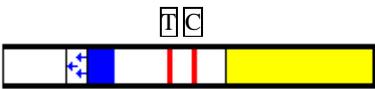
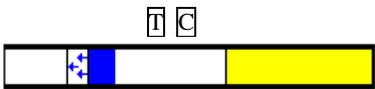
SPECIMEN COLLECTION

- 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.⁶
- 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 Amie's 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 with the StrepAStick (Throat Swab).

ASSAY PROCEDURE

1. Hold the Extraction Reagent A bottle vertically and **add 4 full drops** (approximately 240 µL) of Reagent A to an test tube. Reagent A is red in color.
2. Hold the Extraction Reagent B bottle vertically and **add 4 full drops** (approximately 160 µL) of Reagent B. Reagent B is colorless.
3. 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.
4. **Immediately add the throat swab** into the extraction test tube of yellow solution. Agitate the swab by rotating it at least 10 times. Leave the swab in the extraction test tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the tube and squeezing the tube as the swab is withdrawn. Discard the swab into hazardous waste container.
5. **Immerse** the StrepAStick (Throat Swab) test strip vertically into the extracted specimen solution with arrows pointing toward the specimen and then start the timer.
6. Leave the strip in the extraction tube and wait for the colored line(s) to appear. **Read results at 5 minutes.** Do not interpret the result after 10 minutes.

INTERPRETATION OF RESULTS

		
<p>Negative: only one pink/purple band appears in the Control window. No band is visible in the Test window.</p>	<p>Positive: in addition to the Control band a clearly distinguishable pink/purple band also appears in the Test window.</p>	<p>Inconclusive: If no control band is visible the test is inconclusive. The test should be repeated using a new device.</p>

QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A colored line appearing in the control line 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 strips 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. Mix the solution by gently swirling the extraction tube.
2. Add 1 full drop of positive or negative control solution into the extraction tube, holding the bottle vertically.
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 supplier.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

Using three medical centers for evaluation, a total of 499 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 StrepASStick (Throat Swab). The plates were further streaked for isolation, and then incubated at 37°C with 5-10% CO₂ 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 499 total specimens, 375 were confirmed to be negative and 124 were confirmed to be positive by culture. During this study, two Strep F specimens yielded positive results on the test. One of these specimens was re-cultured, 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.

StrepASStick	Method	Culture		Total Results
	Results	Positive	Negative	
	Positive	120	20	140
	Negative	4	355	359
Total Results		124	375	499

Relative Sensitivity: 97% (91%-99%)* Relative Specificity: 95% (92%-97%)* Accuracy: 95% (93%-97%)* * 95% Confidence Intervals

Positive Culture Classification	StrepASStick/Culture	% Correct
Rare	10/11	91%
1+	9/9	100%
2+	17/19	89%
3+	36/37	97%
4+	48/48	100%

Cross-Reactivity

The following organisms were tested at 1.0 x 10⁷ organisms per test and were all found to be negative when tested with the StrepASStick (Throat Swab). No mucoid-producing strains were tested.

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

LIMITATIONS OF THE TEST

- The StrepASStick (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 teeth⁶ 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.

BIBLIOGRAPHY

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