

# Strep A Rapid Test Strip

*Immuno-chromatographic rapid test strip for qualitative detection of Strep A antigen from throat swab specimen*

Catalog #:AN1009C

## INTRODUCTION

*Streptococcus pyogenes* is non-motile gram-positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as tonsillitis, pharyngitis, scarlet fever, 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.

The Strep A Rapid Test Strip is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 10 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

## SUMMARY AND PRINCIPLE OF THE TEST

The Strep A Rapid Test Strip 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 strip. 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 red line in the test region. The presence of this red line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a red line will always appear in the control region if the test has been performed properly. If a red control line does not appear, the test result is not valid.

## REAGENTS AND MATERIALS

Test Strip	25
Swab	25
Reagent A	5ml
Reagent B	5ml
Instruction for use	1

## PRECAUTION FOR USERS

1. For in-vitro diagnostic use only.
2. Wear protective clothing (laboratory coats and disposable gloves) when assaying samples.
3. Do not eat, drink or smoke in areas where specimens and kit reagents are handled.
4. Avoid contact between hands and eyes or nose during specimen collection and testing.

## 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.
- Testing should ideally be performed immediately after the specimens have been collected. Swab specimens may be stored at room temperature for up to four hours prior to testing.

## STORAGE OF TEST KIT

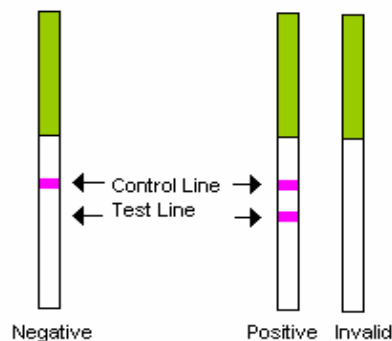
The Strep A Rapid Test Strip can be stored at any temperature between 4-30°C. **Do not freeze.** The stability of the kit under these storage conditions is 18 months. Use up the reagents as soon as possible after the kit is unpacked.

## TEST PROCEDURE

1. Remove the test strip from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the assay is performed immediately after opening the foil pouch.

2. Hold the Reagent A bottle vertically and add 4 full drops (approximately 240 ul) to an extraction test tube. Hold the Reagent B bottle vertically and add 4 full drops (approximately 160ul) of Reagent B. Mix the solution by gently swirling the extraction test tube.
3. 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.
4. With arrows pointing toward the specimen, immerse the test strip vertically into the extracted specimen solution and then start the timer. If the procedure is followed correctly, the extraction solution should not pass the maximum line (MAX) on the test strip when the strip is immersed. See the illustration below.
5. Leave the strip in the extraction tube and wait for the red line(s) to appear. Read the result at 5 minutes.  
Note: Very low concentrations of Strep A antigen might result in a weak line appearing in the test region (T) after an extended period of time; therefore, do not interpret the result after 10 minutes.

## INTERPRETATION OF RESULTS



**Negative:** Only one colored band appears on the control region. No apparent band on the test region.

**Positive:** In addition to a pink colored control band, a distinct pink colored band will also appear in the test region.

**Invalid:** A total absence of color in both regions is an indication of procedure error and/or that test reagent deterioration has occurred.

## LIMITATIONS OF THE ASSAY

1. The Strep A Rapid Test Strip 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 obtained from this kit 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 and any bleeding areas of the mouth with the swab when collecting specimens.
6. 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%. This disease usually occurs in the winter and early spring in temperate climates.

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#### PERFORMANCE

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 Strep A Rapid Test Strip. 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 499 total specimens, 375 were found to be negative by culture and 124 were found 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.

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		Culture	
		+	-
Strep A Rapid Test	+	120	20
	-	4	355

Sensitivity:	120/124 = 97% (91% to 99%)*
Specificity:	355/375 = 95% (92% to 97%)*
Accuracy:	475/499 = 95% (93% to 97%)*
PPV (+):	120/140 = 86% (79% to 91%)*
NPV (-):	355/359 = 99% (97% to 100%)*

- Denotes a 95% Confidence Interval

Positive Culture Classification	Strep A Rapid Test/ 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 10<sup>7</sup> organisms per test and were all found to be negative when tested with the Strep A Rapid Test Strip. No mucoid-producing strains were tested. 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 Strip. No mucoid-producing strains were tested.

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

#### RELATED READING MATERIALS

1. Manual of Clinical Microbiology, 6th Edition, ASM Press, p. 299-307.
2. Webb, KH. *Pediatrics* (Feb 1998), 101:2, 2.
3. Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. *Clinical Infectious Diseases* (1997), 25, 574-83.
4. Needham CA, McPherson KA, Webb KH. *Journal of Clinical Microbiology* (Dec 1998), 3468-3473.

FOR CLINICAL USE

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#### Manufacturer:

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