

# Rapid Response™

## Strep A Test Strip (Throat Swab)

### Product Insert

For professional *in vitro* diagnostic use only.

#### INTENDED USE

The Rapid Response™ Strep A Test Strip (Throat Swab) is a rapid visual immunoassay for the qualitative, presumptive detection of Group A Streptococcus antigens in human throat swab specimens. This kit is intended for use as an aid in the diagnosis of Strep A infection.

#### INTRODUCTION

Beta-hemolytic Group A Streptococcus is a major cause of upper respiratory infections such as tonsillitis, pharyngitis, and scarlet fever. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications, such as rheumatic fever and glomerulonephritis.

Conventional methods for detecting Strep A infection are dependent on isolation and subsequent identification of the organism, and often require 24-48 hours. Recent development of immunological techniques to detect Group A Streptococcal antigen directly from throat swabs allow physicians to diagnose and administer therapy immediately.

#### PRINCIPLE

The Rapid Response™ Strep A Test Strip (Throat Swab) detects Group A Streptococcus antigens through visual interpretation of color development on the internal strip. Anti-Strep A antibodies are immobilized on the test region of the membrane. During the test, the specimen reacts with polyclonal anti-Strep A antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action and interacts with reagents on the membrane. If there is sufficient Strep A antigen in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that proper volume of specimen has been added and membrane wicking has occurred.

#### MATERIALS

- 25 Strips in a canister

#### Materials Provided

Each test contains colored conjugates and reactive reagents precoated at the corresponding regions.

- 1 Procedure Card
- 1 Vial of Reagent A
- 1 Vial of Reagent B
- 1 Positive control
- 1 Negative control
- 25 Sterilized swabs
- 25 Test tubes
- 1 Workstation
- 1 Package insert

Generic procedure illustration

1.0 M sodium nitrite

0.4 M acetic acid

Non-viable Strep A; 0.09% sodium azide

Non-viable Strep C; 0.09% sodium azide

For specimen collection

For specimen preparation

Workstation

For operating instructions

#### Materials Required but Not provided

- Centrifuge
- Timer

#### PRECAUTIONS

- Do not use after the expiration date indicated on the package. Do not use the test if the canister is damaged. Do not reuse tests.
- This kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new specimen collection container for each specimen obtained.
- Read the entire procedure carefully prior to any testing.
- 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 standard procedures for proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.

- Do not interchange or mix reagents from different lots.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded in accordance with local regulations.

#### STORAGE AND STABILITY

- The kit should be stored at 36-86°F (2-30°C) until the expiry date printed on the canister. Do not freeze.
- The test must remain in the canister until use.
- Care should be taken to protect the components of the kit from contamination. 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.

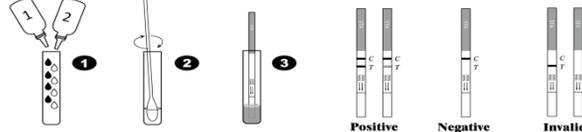
#### SPECIMEN COLLECTION AND STORAGE

- Collect throat swab specimens by standard clinical methods. Swab the posterior pharynx, tonsil, and other inflamed areas. Avoid touching the tongue, cheeks or teeth with the swab.
- It is recommended that swab specimens be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed in a sterile, dry, tightly capped tube or bottle and refrigerated. Do not freeze. Swabs can be stored at room temperature (59-86°F or 15-30°C) up to 4 hours or refrigerated (36°-46°F or 2-8°C) up to 24 hours. All specimens should be allowed to reach room temperature (59-86°F or 15-30°C) before testing.
- If a liquid transport method is desired, use Modified Stuart's Transport Media and follow the manufacturer's instructions. Do not place the swab in any transport Strip containing medium. Transport medium interferes with the assay, and viability of the organisms is not required for the assay. Do not use transport media formulas that include charcoal or agar.
- If a bacteria culture is desired, lightly roll the swab on a 5% sheep blood agar plate before using it in the test. The extraction reagents in the test will kill bacteria on the swabs and make them impossible to culture.

#### PROCEDURE

Bring tests, specimens, reagents and/or controls to room temperature (59-86°F or 15-30°C) before use.

1. Prepare swab specimens:
  - Place a clean extraction tube in the designated area of the workstation. Add 4 drops of reagent 1 to the extraction tube, then add 4 drops of reagent 2. Mix the solution by gently swirling the extraction tube. See illustration 1.
  - Immediately immerse the swab into the extraction tube. Use a circular motion to roll the swab against the side of the extraction tube so that the liquid is expressed from the swab and can reabsorb. Let stand for 1-2 minutes at room temperature, then squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Discard the swab following guidelines for handling infectious agents. See illustration 2.
2. Remove the strip from its sealed pouch. Put the strip inside the tube and let the strip remain inside for 1 minute (See illustration 3), and lay the strip on a dry and level surface. For best results, the assay should be performed within one hour. As the test begins to work, color will migrate across the membrane.
3. Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.



#### INTERPRETATION OF RESULTS

**POSITIVE:** Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

**NEGATIVE:** Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

**INVALID:** Control band fails to appear. Results from any test which has not produced a control band at the specified read 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 color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

#### QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- Good laboratory practice recommends the use of control materials to ensure proper kit performance. A positive control containing heat-killed Group A Streptococcus and a negative control containing heat-killed non-Group A Streptococcus are provided with each kit.

#### Operating Procedure for External Quality Control Testing

- a) Add 4 drops of reagent A and 4 drops of reagent B to a test tube.
- b) Thoroughly mix the control by shaking the bottle vigorously. Add 1 drop of positive or negative control to the tube.
- c) Place a clean sterile swab into the tube and swirl. Leave the swab in the test tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the test tube and squeezing the test tube as the swab is withdrawn. Discard the swab.
- d) Continue as described from Step 2 of the Procedure section, above.

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

#### LIMITATIONS OF THE TEST

1. The Rapid Response™ Strep A Test Strip (Throat Swab) is for professional *in vitro* diagnostic use, and should only be used for the qualitative detection of Group A Streptococcus. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The accuracy of the test depends on the quality of the swab specimen. False negatives may result from improper specimen collection or storage. A negative result may also be obtained from patients at the onset of the disease due to low antigen concentration.
3. The test does not differentiate asymptomatic carriers of Group A Streptococcus from those with symptomatic infection. If clinical signs and symptoms are not consistent with laboratory test results, a follow-up throat culture is recommended.
4. Respiratory infections, including pharyngitis, can be caused by streptococci from serogroups other than Group A, as well as other pathogens.
5. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

#### PERFORMANCE CHARACTERISTICS

##### Correlation Study

Table 1: Strep A Rapid Test vs. Culture

Culture	Strep A Rapid Test		Total
	+	-	
	82	2	
-	4	156	160
	86	158	244

**Relative Sensitivity:**  
97.6% (91.7%-99.7%)\*

**Relative Specificity:**  
97.5% (93.7%-99.3%)\*

**Overall Agreement:**  
97.5% (94.7%-99.1%)\*

\*95% Confidence Interval

##### Sensitivity Study

Eight (8) different strains of Strep A were evaluated with the Rapid Response™ Strep A Test Strip. The minimum detectable level differed slightly depending upon the strain being tested. The detection level of all of the strains was roughly within one magnitude in concentration of each other. Five (5) strains showed a minimum detectable level at roughly  $1 \times 10^4$  organisms per swab while three (3) strains showed a minimum detectable level at roughly  $1 \times 10^5$  organisms per swab.

Strep A ATCC Number	Minimum detectable level	Strep A ATCC Number	Minimum detectable level
12202	1E+05org/swab	14289	1E+04org/swab
12203	1E+04org/swab	19615	1E+04org/swab

12204	1E+04org/swab	49399	1E+05org/swab
12365	1E+04org/swab	51399	1E+05org/swab

### Specificity Study

Cross-reactivity studies with organisms likely to be found in the respiratory tract were also performed using the test. The following organisms were tested at  $1 \times 10^8$  organisms/test, and all yielded negative results.

Organisms	ATCC No.	Organisms	ATCC No.
<i>Bordetella pertussis</i>	8467	<i>Strep B</i>	12386
<i>Branham elacatarrhialis</i>	25238	<i>Strep C</i>	12401
<i>Candida albicans</i>	1106	<i>Strep F</i>	12392
<i>Corynebacterium diphtheriae</i>	13812	<i>Strep G</i>	12394
<i>Enterococcus durans</i>	19432	<i>Streptococcus canis</i>	43496
<i>Enterococcus faecalis</i>	19433	<i>Streptococcus equisimilis</i>	9528
<i>Hemophilus influenzae</i>	9006	<i>Streptococcus equisimilis</i>	9542
<i>Klebsiella pneumoniae</i>	9987	<i>Streptococcus equisimilis</i>	12388
<i>Neisseria gonorrhoea</i>	27633	<i>Streptococcus mutans</i>	25175
<i>Neisseria meningitidis</i>	13077	<i>Streptococcus pneumoniae</i>	27338
<i>Neisseria sicca</i>	9913	<i>Streptococcus sanguis</i>	10556
<i>Neisseria subflava</i>	14799	<i>Streptococcus oralis</i>	9811
<i>Pseudomonas aeruginosa</i>	9721	<i>Streptococcus mitis</i>	903
<i>Serratia marcescens</i>	8100	<i>Streptococcus anginosus</i>	33397
<i>Staphylococcus aureus</i>	12598	<i>Streptococcus intermedius</i>	27335
<i>Staphylococcus epidermidis</i>	1228	<i>Streptococcus agalactiae</i>	13813

### POL Studies

An evaluation of the test was conducted at three physician office laboratory sites, using a panel of coded samples containing negative control, low positive and medium positive specimens. Each specimen level was tested at each site in replicates of five over a period of five days. The study showed >99.9% agreement with the expected results.

### LITERATURE REFERENCES

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4. Gupta R, Talwar GP, Gupta SK. Rapid antibody capture assay for detection of group-A streptococci using monoclonal antibody and colloidal gold-mono-specific polyvalent antibody conjugate. J Immunoassay. 1992; 13(3): 441-55.
5. Ross PW. Throat swabs and swabbing technique. Practitioner. 1971 Dec; 207(242): 791-6.
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### GLOSSARY OF SYMBOLS

#### Index of Symbols

	Consult instructions for use		Test per Kit		Authorized Representative
	For <i>In Vitro</i> diagnostics use only		Use by		Do Not Reuse
	Store between 36°F to 86°F		Lot Number	REF	Catalogue #

Manufactured for:  
 BTNX Inc.  
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