QuickStripe™ Strep A

A rapid test for the qualitative detection of Strep A antigen in throat swab specimens. For professional in vitro diagnostic use only.

Instruction Manual

Test kit for 20 determinations
(Catalog No. 41202)

For *In Vitro* Diagnostic Use
For professional use only
Store at 2-30°C. **Do Not Freeze**

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INTENDED USE

The QuickStripe™ Strep A 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.[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 QuickStripe™ Strep A 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 QuickStripe™ Strep A is a qualitative lateral flow immunoassay which detects Group A Streptococcus carbohydrate antigens in throat swabs 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, after the test strip is immersed into a specimen tube, it reacts with polyclonal anti-Strep A antibodies conjugated to colored particles and pre-coated 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

Materials Provided

• Individually packed test strips	Each test contains colored conjugates and reactive agents pre-coated at the corresponding regions
• Strep A Reagent A (1.0M Sodium Nitrite) 	Wear protective gloves / protective clothing /eye protection /face protection IF SWALLOWED: Call a POISON CENTRE or doctor /physician if you feel unwell. IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice / attention.
• Strep A Reagent B	0.4M Acetic Acid
• Strep A Positive control	Non-viable Strep A; 0.09% sodium azide
• Sterilized Swabs	For Specimen collection
• Extraction tubes	For Specimen preparation
• Workstation	A tube stand

Materials Required But Not Provided

- Centrifuge
- Timer

PRECAUTIONS

- For professional in vitro diagnostic use only. Do not use after 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 control contains sodium azide (NaN_3) as a preservative.
- Do not interchange or mix reagents from different lots.
- Do not interchange reagent bottle caps.
- Do not interchange external control solution bottle caps.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch. **Do not freeze.**
- The test must remain in the sealed pouch 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 (15-30°C) up to 4 hours, or refrigerated (2-8°C) up to 24 hours. All specimens should be allowed to reach room temperature (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.

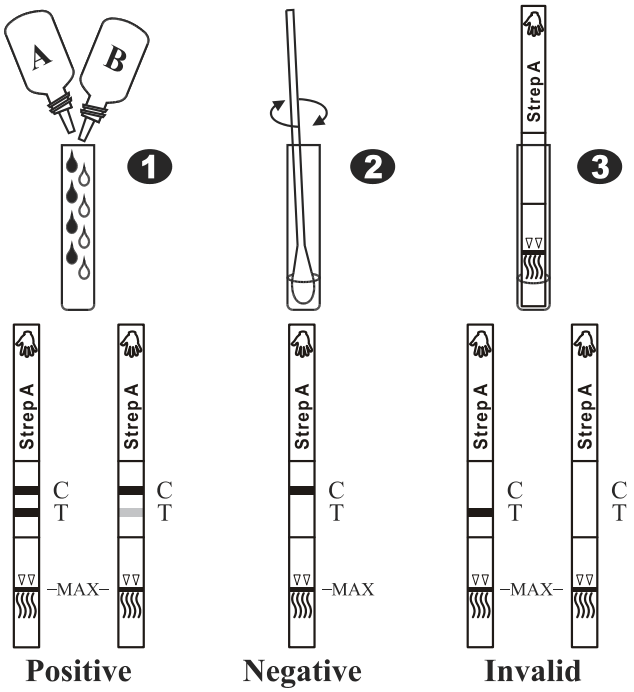
PROCEDURE

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

1. **Prepare swab specimens:**

- Place a clean extraction tube in the designated area of the workstation. Hold the reagent A bottle vertically and add 4 full drops of reagent A to the extraction tube, then add 4 drops of reagent B. 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. Alternatively, put the strip after 1 minute on a dry surface. As the test begins to work, color will migrate across the membrane. See illustration 3.
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 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 is provided with each kit.

External Quality Control- Operating Procedure for Testing.

It is recommended that a positive external control be run every 25 testes and as deemed necessary by internal laboratory procedures External Positive control is supplied within the kit.

a) Add 4 drops of reagent A and 4 drops of reagent B to an extraction tube.

b) Thoroughly mix the control by shaking the bottle vigorously. Add 1 drop of positive control to the tube.

c) Place a clean sterile swab into the tube and swirl. 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.

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 QuickStripe™ Strep A 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

Specimen correlation

A total of 244 Swabs were collected from patients exhibiting symptoms of pharyngitis. Each swab was rolled onto a sheep blood agar plate, and then tested by the QuickStripe™ Strep A. 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 244 total specimens, 160 were found to be negative by culture and 84 were found to be positive by culture. These swabs were tested using the QuickStripe™ Strep A. The results are shown as follows in Table 1:

Table: QuickStripe™ Strep A vs. Culture.

Method		Culture		Total Results
QuickStripe Strep A	Results	Positive	Negative	
	Positive	82	4	86
	Negative	2	156	158
Total Results		84	160	244

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

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

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

*** 95% Confidence Intervals**

Analytical Sensitivity

Eight different strains of Strep A were evaluated with the QuickStripe™ Strep A kit.. 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 strains showed a minimum detectable level at roughly 1×104 organisms per swab while three (3) strains showed a minimum detectable level at roughly 1×105 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

Cross-Reactivity

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 1×107 org/swab, and all yielded negative results.

Organisms	ATCC No.	Organisms	ATCC No.
Bordetella pertussis	8467	*Strep B*	12386
Branham ellacatarrhalis	25238	*Strep C*	12401
Candida albicans	1106	*Strep F*	12392
Corynebacterium diphtheriae	13812	*Strep G*	12394
Enterococcus durans	19432	*Streptococcus canis*	43496
Enterococcus faecalis	19433	*Streptococcus equisimilis*	9528
Hem ophilus influ enzae	9006	*Streptococcus equisimilis*	9542
Klebsiella pneumoniae	9987	*Streptococcus equisimilis*	12388
Neisseria gonorrhea	27633	*Streptococcus mutans*	25175
Neisseria meningitidis	13077	*Streptococcus pneumonie*	27338
Neisseria sicca	9913	*Streptococcus sanguis*	10556
Nesseria subflava	14799	*Streptococcus oralis*	9811
Pseudomonas aeruginosa	9721	*Streptococcus mitis*	903

Serratia marcescens	8100	*Streptococcus anginosus*	33397
Staphylococcus aureus	12598	*Streptococcus intermedius*	27335
Stapylococcus epidermidis	1228	*Streptococcus agalactiae*	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.

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Symbols for IVD components and Reagents			
	Manufacturer	IVD	For i*n vitro* diagnostic use only
EC REP	Authorized representative		Consult instructions for use
Σ	Tests per kit		Warning
REF	Catalogue Code	8 °C 2 °C	Temperature limitation
LOT	Lot Number		Use by
	Do not reuse		