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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 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. After the test strip is immersed into a specimen, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. This mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a colored line in the test line region. The presence of this colored 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 at the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

The test strip 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 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_3) 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 at room temperature or refrigerated (2-30°C). The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use. **DO NOT FREEZE**. Do not use after the expiration date.

SPECIMEN COLLECTION AND PREPARATION

- 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.[5]
- 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.
- 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 QuickStripe™ Strep A.

MATERIALS

• Test strips • Sterile swabs • Workstation	• Package insert • Test tubes
• Strep A Reagent A (2M 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% NaN_3) • Strep A Negative control (Non-viable Strep C; 0.09% NaN_3)	Safety data sheet available for professional users on request

Materials Required But Not Provided

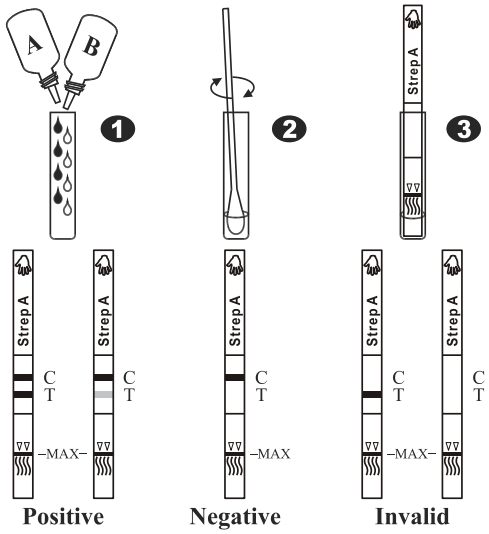
- Timer

DIRECTIONS FOR USE

Allow the test strip, reagents, throat swab specimen, and/or controls to reach room temperature (15-30°C) prior to testing.

Bring the pouch to room temperature before opening it. Remove the test strip from the sealed pouch and use it as soon as possible.

1. Hold the Reagent A bottle vertically and **add 4 full drops** (approximately 240 μL) 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 μL) of Reagent B. 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.
2. **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. See illustration 2.
3. 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 illustration 3.
4. 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

(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 antigen is 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 antigen 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 strip. If the problem persists, discontinue using the test immediately and contact your local distributor.

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

It is recommended that a positive and negative external control be run every 25 tests, and as deemed necessary by internal laboratory procedures. External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A Streptococcus reference strains may be used as external controls. Some commercial controls may contain interfering preservatives; therefore, other commercial controls are not recommended.

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

LIMITATIONS

1. The QuickStripe™ Strep A 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 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 teeth5 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.[6] In school-aged children and adults, the incidence of Strep throat infection is about 40%.[7] This disease usually occurs in the winter and early spring in temperate climates.[3]

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 QuickStripe™ Strep A. The plates were further streaked for isolation, and then incubated at 37°C with 5-10% CO_2 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.

Method		Culture		Total Results
QuickStripe Strep A	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	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 10^7 organisms per test and were all found to be negative when tested with the QuickStripe™ Strep A. No mucoid-producing strains were tested.

Group B Streptococcus	*Neisseria meningitidis*	*Serratia marcescens*
Group F Streptococcus	*Neisseria sicca*	*Klebsiella pneumoniae*
Streptococcus pneumoniae	*Branhamella catarrhalis*	*Bordetella pertussis*
Streptococcus mutans	*Group C Streptococcus*	*Neisseria gonorrhea*
Staphylococcus aureus	*Group G Streptococcus*	*Neisseria subflava*
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 QuickStripe™ Strep A. 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) specimens for three days. The results obtained had a 96% correlation with the expected results.

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Symbols for IVD components and Reagents			
	Manufacturer	IVD	For *in 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		