Dia Sure

STA-S23 Strep A Rapid Test Device (Swab)

For professional *in vitro* diagnostic use only.

INTENDED USE

The Strep A Rapid Test Device (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 Strep A Rapid Test Device (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

Materials Provided

• Individually packed test devices	Each test contains colored conjugates and reactive reagents precoated at the corresponding regions.
• Reagent 1	1.0 M sodium nitrite
• Reagent 2	0.4 M acetic acid
• Positive control	Non-viable Strep A; 0.09% sodium azide
• Negative control	Non-viable Strep C; 0.09% sodium azide
• Sterilized swabs	For specimen collection
• Disposable pipettes	For adding specimens
• Extraction tubes	For specimen preparation
• Workstation	Workstation
• Package insert	For operating instructions

Materials Required but Not provided

- Timer

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch 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 by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where 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 the 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. Do not mix solution bottle caps.
- Use only dacron or rayon tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped, or wooden shafted swabs.
- Reagents 1 & 2 are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- The positive control contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these solutions always flush with copious amounts of water to prevent azide buildup.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

- The kit should be stored at 2-30°C until the expiry date printed on the sealed pouch.
- The test must remain in the sealed pouch until use.
- **Do not freeze.**
- Care should be taken to protect components in this 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 device 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. Add 4 drops of reagent 1 to the extraction tube, and then add 4 drops of reagent 2. Mix the solution by gently swirling the extraction tube.
   - 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, and 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.
2. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
3. Add 3 drops (approximately 120 µL) of extracted solution with disposable pipettes from the extraction tube to the sample well on the test device.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the observation window.
   As the test begins to work, color will migrate across the membrane.
4. 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 is provided with each kit.

Operating Procedure for External Quality Control Testing

a) Add 4 drops of reagent 1 and 4 drops of reagent 2 to an extraction tube.
b) Thoroughly mix the control by shaking the bottle vigorously. Add 1 drop of Positive Control or Negative 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 Strep A Rapid Test Device (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: Strep A Rapid Test vs. Culture

		Culture		
		+	-	**Total**
Strep A Rapid Test	+	82	4	86
	-	2	156	158
Total		84	160	244

Relative Sensitivity: 97.6% (91.7%-99.3%)*
Relative Specificity: 97.5% (93.7%-99.0%)*
Overall Agreement: 97.5% (94.7%-98.9%)*
***95% Confidence Interval**

Sensitivity Study

Eight (8) different strains of Strep A were evaluated with The Strep A Rapid Test Device (Swab). 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 1×10^4 organisms per swab while three (3) strains showed a minimum detectable level at roughly 1×10^5 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 1×10^7 org/swab, and all yielded negative results.

Organisms	ATCC No.	Organisms	ATCC No.
Bordetella pertussis	8467	*Strep B*	12386
Branham ella catarrhalis	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 equisim ilis*	9528
Hem ophilus influ enzae	9006	*Streptococcus equisim ilis*	9542
Klebsiella pneumoniae	9987	*Streptococcus equisim ilis*	12388
Neisseria gonorrhea	27633	*Streptococcus mutans*	25175
Neisseria mening itidis	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.

LITERATURE REFERENCES

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GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
μ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

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