SAS™ *StrepAlert*™

For the presumptive qualitative detection of Group A streptococcal antigen from throat swab specimens

For *In Vitro Diagnostic* Use Only
Store at 2ºC to 30ºC

For Technical Assistance Call 800-272-2710
Outside the USA Call 210-699-8800

CLIA Complexity – Waived

SA Scientific™
4919 Golden Quail, San Antonio, Texas 78240 USA

READ ALL INSTRUCTIONS BEFORE BEGINNING THE ASSAY

INTENDED USE
SAS™ StrepAlert™ is a rapid visual test for the presumptive, qualitative detection of group A streptococcal antigen from throat swab specimens. The test is for health professional use only.

SUMMARY AND EXPLANATION
Group A streptococcus (S. pyogenes) is a principal cause of respiratory tract infection in humans. Streptococcal pharyngitis, which primarily affects children and young adults, can lead to serious complications such as rheumatic fever or acute glomerulonephritis. The rapid and accurate detection of group A streptococcus is important for the early initiation of antibiotic therapy in the treatment of streptococcal pharyngitis. Traditional diagnostic tests have relied on overnight culture together with confirmation by serological or biochemical methods.[1-3] Newer methods based on immuno-chemical detection of streptococcal antigen have been developed that do not require growth in culture of the organism, nor do these methods require viable organisms for detection of the antigen.

PRINCIPLE OF THE TEST
The SAS™ StrepAlert™ test begins with an extraction of group A streptococcal antigen from the throat swab. After the extraction has been completed, the test dipstick is placed into the extraction mixture and observed for the formation of colored lines. The specimen is absorbed and migrates via capillary action through a membrane that contains dried gold conjugated antibody that is specific for group A streptococcal antigen. If group A streptococcal antigen is present, a "half-sandwich" immuno-complex is formed. The membrane contains immobilized antibody to group A streptococcal antigen, which binds the "half sandwich" complex. Thus, in the presence of group A streptococcal antigen, a "whole sandwich" immuno-complex is formed and a visible, pink colored line develops in the specimen zone of the dipstick. In the absence of group A streptococcal antigen, a "sandwich" immuno-complex is not formed and a negative result is indicated. To serve as a procedural control, a pink colored control line will appear in the control zone regardless of the presence or absence of group A streptococcal antigen.

REAGENTS & MATERIALS PROVIDED
1. Test Dipsticks-containing gold conjugated with rabbit anti-strep antibody specific for group A streptococcal antigen
2. Reagent A (6 ml)-Sodium Nitrite (2.0 M), Phenol Red, avoid contact.
3. Reagent B (6 ml)-Acetic Acid (0.5 M), avoid contact.
4. Positive Control (1 ml)-inactivated Group A Streptococcus in solution with 0.1% Sodium Azide. Mix well before use.
5. Negative Control (1 ml)-inactivated Group B Streptococcus in solution with 0.1% Sodium Azide. Mix well before use.
6. Collection Swabs.
7. Extraction Tubes.
8. Package Insert.

MATERIALS REQUIRED BUT NOT PROVIDED
Timer.

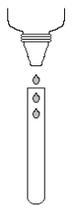
STORAGE
The kit and components can be stored at room temperature (15º - 30ºC) or refrigerated at 2º - 8ºC. If refrigerated, the components must be brought to room temperature before use.

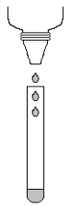
PRECAUTIONS
1. For in-vitro diagnostic use only.
2. Do not mix reagents or dipsticks from different lots.
3. Swabs form other suppliers have not been validated. Using swabs other than those provided with the kit may affect performance of the kit.
4. Do not use beyond the expiration date.
5. Reagents A & B contain a mild irritant. Avoid contact with eyes, skin or mucous membranes. If accidental contact occurs, flush thoroughly with water and seek appropriate medical attention.
6. The Test Dipsticks must remain in the closed canister or pouch until ready for use. Record the date the canister is first opened in the place provided on the label. The test strips should not be used beyond 90 days after opening the canister. Dipsticks from a pouch must be used immediately after the pouch is opened.
7. Be careful not to touch the tongue, cheeks, or lips with the swab. Sampling in these areas as well as excess saliva may affect the performance of the kit.
8. In accordance with the principles of Good Laboratory Practice, it is strongly recommended that all specimens be treated as potentially infectious and handled with all necessary precautions.
9. The Positive & Negative Controls included in the kit contain sodium azide as a preservative, which may react with lead or copper in plumbing to form potentially explosive metal azides. Upon disposal, always flush with a large volume of water to prevent azide buildup in drains.
10. If the laboratory modifies the test system instructions, then the test is considered high complexity and subject to all applicable CLIA requirements.

SPECIMEN COLLECTION & PREPARATION
1. Sterile Rayon collection swabs supplied with the kit should only be used. Swabs from other suppliers have not been validated. Using swabs other than those provided with the kit may affect performance of the kit. Do not use cotton, wooden shaft or calcium alginate swabs.
2. Throat swabs should be collected by standard collection method such as outlined by Finegold and Martin.[4]
3. Depress the patient's tongue with a blade or spoon and rub the swab firmly over the back of the throat, over both tonsils, and any areas of redness. Be careful not to touch the tongue, cheeks, or lips with the swab.
4. Swabs may be transported using modified Stuart's media or equivalent. Do not use transport media containing gelatin or charcoal.
5. Test specimen swabs immediately after collection. If the swab is not to be tested immediately, it may be stored in a clean, dry, capped tube for up to 72 hours at 2º - 8ºC.
6. If culture results are required, gently streak swab on appropriate medium before performing the test. The extraction procedure will cause the bacteria to become inactive, therefore not allowing the organism to be cultured.

TEST PROCEDURE

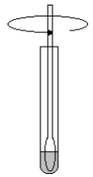
Step 1	Step 2
Add 3 drops of Reagent A to the Extraction Tube. Note: Reagent A contains a pink dye. If reagent is not pink, do not use and call Technical Assistance.	Add 3 drops of Reagent B to the Extraction Tube. Note: Color will change from pink to light yellow upon addition of Reagent B.

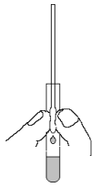




Step 3
Add the specimen swab into the extraction tube. Mix the solution thoroughly by pressing the swab against the side of the extraction tube. Keep the swab in tube for 1 minute.

Step 4
Remove all liquid from the swab by rolling and squeezing against the side of the extraction tube. Discard the swab.





Step 5
Place the dipstick into the extraction tube. Gently stir for 10-15 seconds.

Step 6
Read results after 5 minutes. Do not interpret results after 10 minutes.

INTERPRETATION OF RESULTS

Negative results

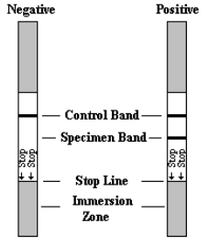
A pink Control Band and no Specimen Band is a negative result.

Positive results

Any pink colored band of any intensity in the Specimen along with a pink colored band in the control should be considered positive.

Invalid results

No pink colored band in the Control area is an invalid result. If the test is considered invalid, repeat test or call Technical Assistance.



Quality Control

Internal Controls

Each test device includes 3 levels of internal procedural controls.

- Reagent A contains a pink dye. When combined with Reagent B, the color changes from pink to light yellow. This color change is an internal extraction reagent control indicating that the two reagents have been mixed and are functioning properly.
- A pink band in the Control area is a positive procedural control. This shows that the dipstick has absorbed enough sample and that the test is functioning properly. If the colored band fails to appear in the Control area, the test result is invalid.
- A clear background is an internal negative procedural control. The background color should be white to light pink and should not interfere with the reading of the test result. An intensely red background may interfere with the ability to read the test result, therefore the test should be repeated.

External Controls

Each kit contains Positive and Negative Controls. The controls are for external quality control testing of the reagents and dipstick.

External Controls should be used according to individual laboratory procedures. If the Controls do not work as expected, repeat the test or contact Technical Assistance.

Quality Control Testing Procedure

1. Follow instructions in the Test Procedure for preparation of Extraction Reagents (steps 1 and 2).
2. Add 1 drop of Control.
3. Place a clean swab in the Test Tube.
4. Follow instructions in Test Procedure (steps 3 through 6) to complete the test.

PERFORMANCE CHARACTERISTICS

Comparison Study

A multi-site evaluation of the SAS™ StrepAlert™ test was carried out to determine the clinical performance characteristics of the test relative to another commercially available test. Two throat swabs were collected from patients presenting symptoms of pharyngitis. A total of 104 patients were tested.

SAS™ StrepAlert™ Test

		+	-	Total
Other Commercially Available Test	+	28	2	30
	–	5	69	74
Total		33	71	104

The SAS™ StrepAlert™ had an overall agreement of 93.3% to that of the other commercially available test. The four (4) samples that were found to be SAS™ StrepAlert™ positive (+) and other commercially available test negative (-) were confirmed positive (+) by culture. The sample that was other commercially available test positive (+) and SAS™ StrepAlert™ (-) was found to be positive by culture.

Correlation Study

A multi-site evaluation of the SAS™ StrepAlert™ test was carried out to determine the clinical performance characteristics of the test relative to standard culture techniques. Throat swabs were collected from patients presenting symptoms of pharyngitis. A total of 193 patients were tested. Swabs were first used to streak blood agar plates before testing. All cultures were confirmed for the presence of Group A streptococcus using serological grouping methods. Results are as follows:

SAS™ StrepAlert™ Test

		+	-	Total
Culture	+	46	1	47
	–	4	142	146
Total		50	143	193

Sensitivity: 97.9% (95% CI, 88.7% to 99.9%)
Specificity: 97.3% (95% CI, 93.1% to 99.2%)
Overall Agreement: 97.4% (95% CI, 94.1% to 99.1%)

EXPECTED VALUES

It is believed that approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci.[5] Infection is most prevalent in winter and early spring, with most cases arising in patients living in highly populated areas.

LIMITS OF DETECTION

Group A Streptococcus organisms were grown and tested at different levels. The test was capable of detecting 1.5 x 10^5 organisms per test.

SPECIFICITY

To confirm the specificity of the SAS™ StrepAlert™, bacterial cultures likely to be found in the respiratory tract were tested at 3.0x10^5 to 2.8x10^9 organisms/test and all yielded negative results. The organisms tested are listed below:

Branhamella catarrhalis	*Candida albicans*
Haemophilus influenzae	*Neisseria mucosa*
Enterococcus faecalis	*Neisseria meningitides*
Streptococcus mutans	*Group B Streptococcus*
Neisseria subflava	*Group C Streptococcus*
Streptococcus pneumoniae	*Group F Streptococcus*
Neisseria gonorrhea`	*Group G Streptococcus*
Staphylococcus aureus	*Ungrouped Streptococcus*
Pseudomonas aeruginosa	

To further confirm the specificity, the following eleven strains of Group A Streptococcus were tested and positive results were detected at 1.5 x 10^5 organisms/test.

SS-091	SS-482	SS-633	SS-635	SS-754
BRS0023A	SS-410	SS-496	SS-634	SS-721
SS-799				

Physician Office Lab Study

The SAS™ StrepAlert™ test was evaluated at three different physician's offices using a panel of five samples. Physician office personnel with diverse educational backgrounds performed the testing. The sample panel consisted of two negative, one low positive, one medium positive and one high positive. One hundred percent (100%) of the forty-five (45) samples tested produced the expected results.

Lay Person User Study

Individuals having diverse educational backgrounds evaluated the SAS™ StrepAlert™ at three different sites. Each site tested a coded panel consisting of a negative, low positive and high positive. There was greater than ninety-seven percent (97%) agreement (175/180) of the expected results.

REFERENCES

1. Levinson, M.L. and P.F. Frank. 1955. Differentiation of Group A from Other beta-hemolytic *Streptococci* with Bacitracin. J . Bacteriol. 69:284.
2. Lancefield, R.C. 1933. A Serological Differentiation of Human and Other Groups of Hemolytic *Streptococci*. J. Exp. Med. 57:571.
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4. Finegold, S.M. and Martin, W.J. 1982. Microorganisms Encountered in Respiratory Tract Infections, p. 66, Diagnostic Microbiology, 6th Edition. The C.V. Mosby Co. St. Louis.
5. Lauer, B.A., Rellar, L.B., and Mirrett, S., 1983. Effects of Atmosphere and Duration of Incubation on Primary Isolation of Group A Streptococci From Throat Cultures, Journal of Clin. Micro., 17,338.

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