Strep A Rapid Test Strip (Throat Swab)

Rx Only

INTENDED USE

The Strep A Rapid Test Strip (Throat Swab) is a rapid chromatographic immunoassay for the qualitative detection of *Streptococcus pyogenes* (Group A β-hemolytic *Streptococcus*, Strep A) antigen from throat swab specimens of symptomatic patients to aid in the diagnosis of Group A *Streptococcus* bacterial infection.
All negative test results should be confirmed by bacterial culture because negative results do not preclude infection with Group A *Streptococcus* and should not be used as the sole basis for treatment.

INTRODUCTION

Streptococcus pyogenes is non-motile gram-positive coccus, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis. Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.[1] 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.[2,3]
The Strep A Rapid Test Strip (Throat Swab) is a rapid test to qualitatively detect the presence of Group A Streptococcal antigen in throat swab specimens, providing results within 5 minutes. The test utilizes specific and sensitive antibodies reactive to the Strep A antigen, is specific to group A with no cross-reactivity from other groups of Streptococci.

PRINCIPLE

The Strep A Rapid Test Strip (Throat Swab) 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. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color 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 in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS SUPPLIED

1. 25 Test strips
2. 25 Sterile swabs
3. 25 Disposable extraction tubes (one tube for each test strip)
4. 1 Reagent A (10mL; 2M Sodium Nitrite)
5. 1 Reagent B (10mL; 0.2M Acetic Acid)
6. 1 Positive control (1mL; Non-viable Strep A; 0.05% Proclin300)
7. 1 Negative control (1mL; Non-viable Strep C; 0.05% Proclin300)
8. 1 Package insert
9. 1 Workstation

MATERIAL REQUIRED BUT NOT PROVIDED

1. Clock or Timer

WARNINGS AND PRECAUTIONS

1. This kit is for professional in vitro diagnostic use only.
2. Do not use test kit beyond the expiration date printed on the pouch.
2. Do not use test kit if the pouch is punctured or not well sealed.
3. Do not interchange reagent bottle caps.
4. Do not interchange external control solution bottle caps.
5. Discard after use. The test strip cannot be used more than once.
6. The extraction tube and swab are single use items – do not use with multiple specimens.
7. Do not eat, drink or smoke in the area where the specimens and kits are handled.
8. Test strips must remain sealed in the pouch until just prior to use.
9. Reagent A and B are caustic. Avoid contact with eyes, sensitive mucous membranes, cuts, abrasions, etc. If these reagents contact the skin or eyes, flush with a large volume of water.
10. The positive and negative controls contain proclin300 as a preservative.
11. All specimens should be treated as potentially infectious diseases. Protective gloves should be worn when handling the specimen. Wash hands thoroughly afterwards.
12. Disposal of the used strip, swab and extraction tube in accordance with the local infectious disposal law or laboratory rule.

STORAGE AND STABILITY

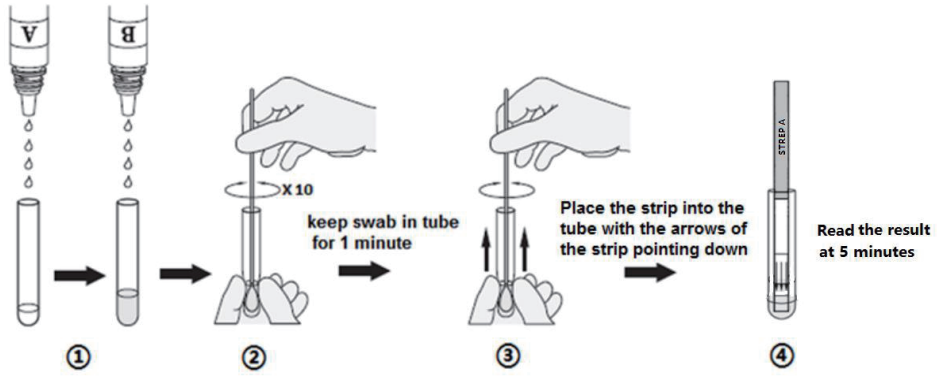
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). DO NOT FREEZE. The test strip is stable through the expiration date printed on the sealed pouch. The test strip must remain in the sealed pouch until use.

SPECIMEN COLLECTION AND PREPARATION

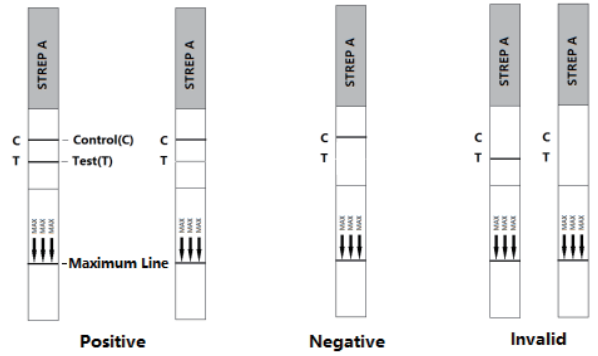
1. Only use reagents and sterile swabs provided in the kit.
2. Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.[4]
3. Testing should ideally be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 48 hours at room temperature or 72 hours at 2-8°C.
4. If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Rapid Test Strip (Throat Swab).

TEST PROCEDURE

Do not remove test strip from the foil pouch until ready to perform the assay. Allow the test strip, reagents, throat swab specimen, and/or controls to reach room temperature (15-30℃) prior to testing.
1. Hold the Reagent A bottle vertically and add 4 full drops of Reagent A to an extraction tube. Reagent A is light red in color. Hold the Reagent B bottle vertically and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube.
2. Immediately place the throat swab into the extraction tube. Agitate the swab 10 times in the tube. Leave the swab in the tube for 1 minute. Then press the swab against the side of the tube and squeeze the bottom of the tube as the swab is withdrawn. Discard the swab.
3. Remove the test strip from the foil pouch. Place the test strip into the tube with the arrows of the strip pointing down and then start the timer. Do not handle or move the strip until the test is complete and ready for reading.
4. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.



INTERPRETATION OF RESULTS



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).
Negative: One colored line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear.

NOTE: Insufficient specimen volume, incorrect operation procedure, or performing 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 color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
External Quality Control
In addition to your laboratory's standard quality control procedures, it is recommended that a positive and negative external control be tested at least once within each test kit and by each operator performing testing within a kit. This will verify that the reagents and test strips are working properly and the operator is able to correctly perform the test procedure.
Procedure for External Quality Control Testing
1. Add 4 full drops of Reagent A and 4 full drops of Reagent B into an extraction tube. Tap the bottom of the tube gently to mix the liquid.
2. Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
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 3 of **TEST PROCEDURE** Section. 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 Strep A Rapid Test Strip (Throat Swab) is for in vitro diagnostic use only. The test should be used for the detection of Group A Streptococcal antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Group A Streptococcal antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Group A Streptococcal 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 Group A Streptococcal 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. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Analytical Sensitivity
The limit of detection of the test is 7.2×10^3 CFU/mL. This was established by testing cultures of *Streptococcus pyogenes* with a known number of organisms, ATCC 19615. The organisms were serially diluted and spiked with clinical matrix and tested by Strep A Rapid Test Strip (Throat Swab).

Clinical Sensitivity and Specificity
The Strep A Rapid Test Strip (Throat Swab) was used to evaluate 368 throat swab specimens collected from three physician offices patients presenting with pharyngitis. The test result compared to the culture method. The below table summarizes the data.

Clinical Performance: Strep A Rapid Test vs. Culture

Strep A Rapid Test Strip (Throat Swab) Results	Reference Culture Results	
	Positive	Negative
Positive	200	1
Negative	6	161
Total	206	162

Sensitivity: 97.1% (200/206); 95%CI = 93.7% - 98.8%
Specificity: 99.4% (161/162); 95%CI = 96.2% - 100.0%

Clinical Performance Stratified by Age

Age	Sensitivity	Sensitivity(95%CI)	Specificity	Specificity(95%CI)
0 ~ 5	97.4%(74/76)	90.4% - 99.8%	98.1%(52/53)	89.1% - 100.0%
5+ ~ 21	96.7%(119/123)	91.7% - 99.0%	100%(88/88)	95.0% - 100.0%
21+	100%(7/7)	59.6% - 100.0%	100%(21/21)	81.8% - 100.0%
All	97.1% (200/206)	93.7% - 98.8%	99.4% (161/162)	96.2% - 100.0%

Cross-Reactivity
To confirm the cross-reactivity of Strep A Rapid Test Strip (Throat Swab), organisms likely to be found in the respiratory tract were tested and were all found to be negative when tested with the Strep A Rapid Test Strip (Throat Swab). The tested concentration of each microorganism is documented in the following table. No microbial interference was found for each microorganism at the listed concentration.

Microorganism	Concentration Tested	Microorganism	Concentration Tested
Arcanobacterium haemolyticum	2.6×10^8 CFU/mL	*Staphylococcus epidermidis*	2.1×10^8 CFU/mL
Bordetella pertussis	7.5×10^8 CFU/mL	*Staphylococcus marcescens*	1.5×10^8 CFU/mL
Candida albicans	9.5×10^8 CFU/mL	*Staphylococcus haemolyticus*	1.58×10^8 CFU/mL
Corynebacterium diphtheria	5.37×10^8 CFU/mL	*Streptococcus agalactiae* (Group B)	7.9×10^7 CFU/mL
Enterococcus faecalis	2.3×10^8 CFU/mL	*Streptococcus dysgalactiae* (Group C)	1.43×10^5CFU/mL
Enterococcus faecium	4.4×10^8 CFU/mL	*Streptococcus sp. (bovis II)* Group D	5.6×10^8 CFU/mL
Enterovirus (VR-28 Human Coxsackievirus)	1.6×10^8 $TCID_{50}$/mL	*Streptococcus sp.* Strain H60R (Group F)	1×10^6 CFU/mL
Escherichia coli	1.1×10^8 CFU/mL	*Streptococcus anginosus* (Group G)	4.2×10^7 CFU/mL
Fusobacterium necrophorum	7.3×10^8 CFU/mL	*Streptococcus pneumoniae*	4.2×10^6 CFU/mL
Haemophilus parahaemolyticus	1.3×10^8 CFU/mL	*Streptococcus salivarius*	8.7×10^8 CFU/mL
Haemophilus influenzae	4.5×10^8 CFU/mL	*Streptococcus mitis*	5.9×10^8 CFU/mL
Haemophilus parainfluenzae	1.6×10^8 CFU/mL	*Streptococcus mutans*	4.7×10^8 CFU/mL
Human metapneumovirus (HMPV-27 A2)	3.55×10^5 $TCID_{50}$/mL	*Streptococcus oralis*	6.4×10^8 CFU/mL
Human coronavirus OC43	1.7×10^5 $TCID_{50}$/mL	*Streptococcus sanguis*	1.5×10^8 CFU/mL
Klebsiella pneumoniae	3.1×10^8 CFU/mL	*Yersinia enterocolitica*	2.0×10^8 CFU/mL
Legionella pneumophila	1×10^4 bacteria/mL	*Adenovirus Type I*	3.09×10^8 $TCID_{50}$/mL
Lactobacillus sp. (Lactobacillus casei)	6.5×10^8 CFU/mL	*Adenovirus Type II*	3.9×10^7 TCID50/mL
Mycobacterium tuberculosis	1×10^3 bacteria/mL	*Adenovirus 3*	1.5×10^8 TCID50/mL
Moraxella lacunata	1.95×10^8 CFU/mL	*Adenovirus 7*	2.8×10^6 $TCID_{50}$/mL
Moraxella (Branhamella) catarrhalis	4.8×10^8 CFU/mL	*Cytomegalovirus*	1.6×10^5 $TCID_{50}$/mL
Mycobacterium tuberculosis (avirulent strain)	2.3×10^8 CFU/mL	*Epstein Barr Virus*	7.85×10^7 copies/mL
Neisseria gonorrhoeae	3.8×10^8 CFU/mL	*HSV Type 1 MacIntyre strain*	1.6×10^5 $TCID_{50}$/mL
Neisseria lactamica	1.19×10^8 CFU/mL	*Human parainfluenza Type 1*	1.6×10^5 $TCID_{50}$/mL
Neisseria meningitides	7.5×10^8 CFU/mL	*Human parainfluenza Type 2*	1.6×10^5 $TCID_{50}$/mL
Neisseria mucosa	3.25×10^8 CFU/mL	*Human parainfluenza Type 3*	1.6×10^5 $TCID_{50}$/mL
Neisseria sicca	8.5×10^8 CFU/mL	*Human rhinovirus 26*	5×10^6 TCID50/mL
Neisseria subflava	3.27×10^8 CFU/mL	*Measles Virus*	$8.9\times10^5$$TCID_{50}$/mL
Proteus vulgaris	2.9×10^8 CFU/mL	*Mumps virus*	1.38×10^7 $TCID_{50}$/mL

Staphylococcus aureus	3.2×10^8 CFU/mL		

Interference Substances

The following substances, naturally present in respiratory specimens or that may be artificially introduced into the upper respiratory tract, were evaluated with the Strep A Rapid Test Strip (Throat Swab) at the concentrations listed below and were found not to affect test performance.

Substance	Concentration Tested	Substance	Concentration Tested
Endogenous			
Blood (human)	20% (vol/vol)	Mucin	1 mg/mL
OTC Mouthwashes			
Colgate Total Pro-Shield, Spearmint	20%(vol/vol)	Crest Pro-Health Clean Mint	20%(vol/vol)
Crest Pro Health Multi Protection Clean Mint	20%(vol/vol)	Listerine Antiseptic Cool Mint	20%(vol/vol)
OTC Lozenges			
Cepacol Extra Strength Sore Throat & Cough Drop Lozenges, Cherry	5 mg/mL	Sucrets Sore Throat Lozenges Cherry	5 mg/mL
Halls Mentho-Lyptus Drops Cherry	5 mg/mL	Sucrets Sore Throat & Cough Lozenges, Honey Lemon,	5 mg/mL
Halls Cough Suppressant Cherry Triple Soothing Action	5 mg/mL		
OTC Throat Sprays			
Cepacol Dual Relief	20%(vol/vol)	Chloraseptic Max	20%(vol/vol)
OTC Cough Syrups			
Basic Care Tussin DM, Cough Suppressant & Expectorant	10%(vol/vol)	Robitussin Nighttime Cough	10%(vol/vol)
Children's Dimetapp Cold & Flu	10%(vol/vol)	Robitussin (Guaifenesin Syrup)	10%(vol/vol)
Children's Dimetapp Cold & Cough	10%(vol/vol)	Tylenol Cough and Sore Throat	10%(vol/vol)
Active Ingredients			
Acetaminophen (Tylenol)	5 mg/mL	Doxylamine Succinate	5 mg/mL
Brompheniramine Maleate	5 mg/mL	Guaifenesin (Guaiacol Glyceryl)	5 mg/mL
Chlorpheniramine Maleate	5 mg/mL	Ibuprofen (Advil)	5 mg/mL
Dextromethorphan HBr	5 mg/mL	Phenylephrine HCl	5 mg/mL
Diphenhydramine HCl	5 mg/mL		

REFERENCE

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4. Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1-1.1.30, 1992.
5. Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to 5 years. Clinical Pediatrics (June 1999), 38: 357-360.
6. Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA. Group A Streptococcal Pharyngitis in Adults 30 to 65 years of age. Southern Medical Journal (May 1999), 491-492.

INDEX OF SYMBOLS


Keep away from sunlight

Store between 2°C and 30°C


Keep dry


Do not re-use

Healgen Scientific LLC

3818 Fuqua Street, Houston, TX 77047

Manufacturer Tel: 713.733.8088

Fax: 713.733.8848

Web: www.Healgen.com

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