STREPTOCOCCUS A CARD
014B055

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

INTENDED USE
The ulti med Streptococcus A Card 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]
Rapid diagnosis and early antibiotic therapy of Group A Streptococcal infection appear to be the best means of preventing medical complications and reducing the spread of the disease.[4]
The ulti med Streptococcus A Card 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

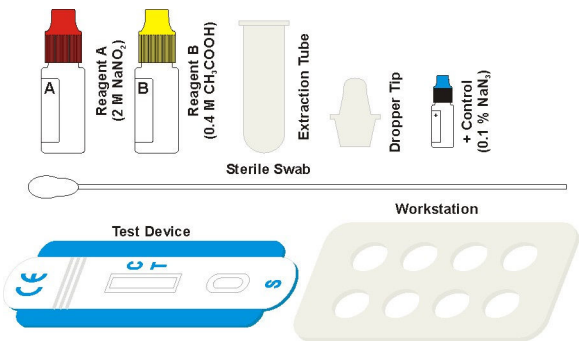

The ulti med Streptococcus A Card is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the strip. During testing, the extracted throat swab specimen 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 red line in the test region. The presence of this red line in the test region indicates a positive result, while its absence indicates a negative result. To serve as a procedural control, a red line will always appear in the control region indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS
The test utilizes both polyclonal and monoclonal antibodies to specifically identitfy Strep A antigen in throat swab specimens..

PRECAUTIONS
- For in vitro diagnostic use only.
- Do not use beyond the expiration date.
- Do not use when protective foil is damaged.
- The test device should remain in the sealed pouch until use.
- Do not eat, drink or smoke in the area where the specimens and kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed. 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.
- Humidity and temperature can adversely affect results.
- 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 reagent bottle caps.
- Do not moisten nitrocellulose membrane with urine samples.
- The used test strip should be discarded according to federal state and local regulations.

STORAGE AND STABILITY
The ulti med Streptococcus A Card can be stored at room temperature or refrigerated (2-30°C). The test device must remain in the sealed pouch until use. The test device and the reagents are stable through the expiration date printed on the box.
- Do not freeze.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION
Only use reagents and sterile swabs provided in the ulti med Streptococcus A Card. 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]

MATERIALS PROVIDED


- Test Devices
- Disposable extraction test tubes
- Dropper Tips
- Sterile Swabs (Dacron)
- Reagent A (2M Sodium Nitrite)
- Reagent B (0.4M Acetic Acid)
- Positive control (Non-viable Strep A; 0.1% NaN_3)
- Package insert
- Workstation

MATERIALS REQUIRED BUT NOT PROVIDED:
- Timer
- negative control

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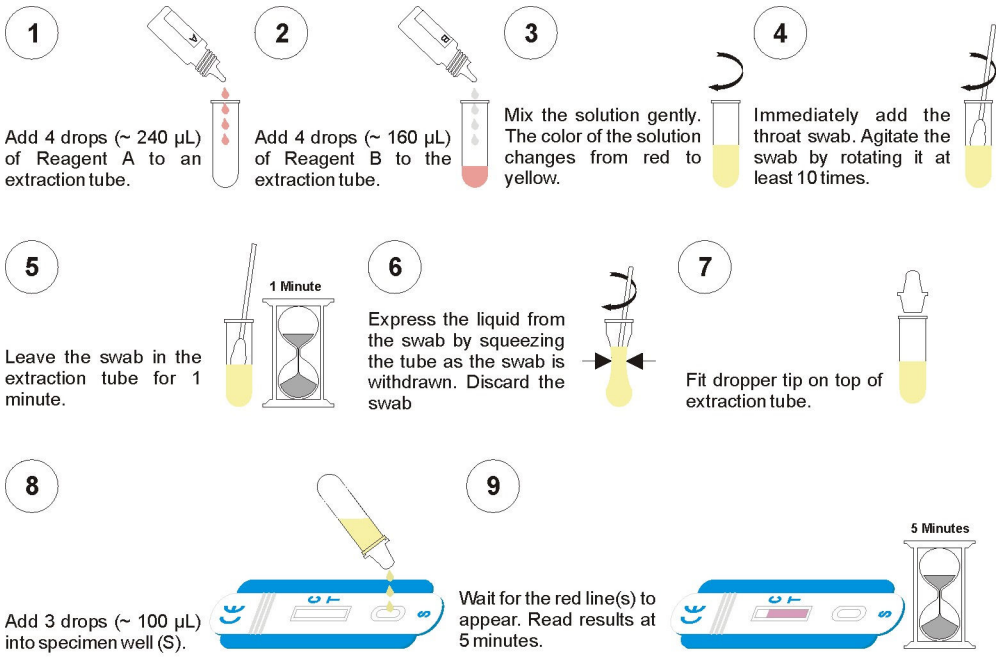
DIRECTIONS FOR USE

Allow the test device, reagents, and/or controls to reach room temperature (15-30□C) prior to testing. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.



INTERPRETATION OF RESULTS

POSITIVE:* Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). A positive result indicates that Strep A was detected in the sample.

* **NOTE**: The intensity of the red color in the test line region (T) will vary depending on the concentration of Strep A present in the sample. Therefore, any shade of red in the test region (T) should be considered positive.

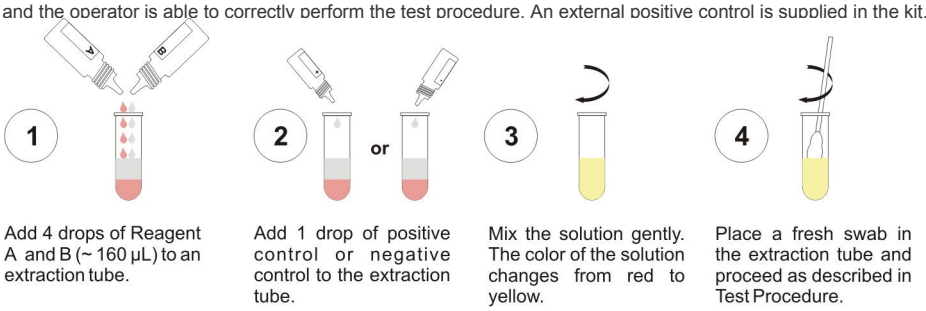
NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). A negative result indicates that Strep A antigen is not present in the sample, or is present below the detectable level of the test. The patient's sample should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another sample for culture.

I**NVALID**: Control line fails to appear. Insufficient sample 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 device. If the problem persists, discontinue using the test kit immediately and contact distributor / manufacturer.

QUALITY CONTROL

Internal procedural controls are included in the test. A red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

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 25-test kit and by each operator performing testing within a kit. This will verify that the reagents and test devices are working properly and the operator is able to correctly perform the test procedure. An external positive control is supplied in the kit.



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LIMITATIONS

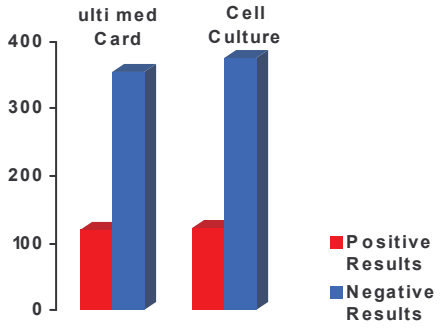
1. The ulti med Streptococcus A Card is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. 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 obtained from this kit 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 ulti med Streptococcus A Card. 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 (Group A β-hemolytic Streptococcus) were subcultured and confirmed with a commercially available latex agglutination grouping kit.
Of the 499 total specimens, 375 were found to be negative by culture and 124 were found to be positive by culture. During this study, two Strep F specimens yielded positive results with the Test. One of these specimens was re-cultured, then 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.

Sensitivity:	97 %	(120 + 4)
Specificity: ^	95 5	(20 + 335)

Minimum Detection Limit

A Strep A cell stock was diluted to 1.0 x 10^6, 1.0 x 10^7, 2.5 x 10^7, 5.0 x 10^7, and 1 x 10^8 organisms per mL. Ten µL of each was spiked on the dry dacron swab provided in the kit. The swabs were tested according to the package insert in replicates of three. The tests were rated as either positive or negative at the read time. The results demonstrated that the minimum detectable level is 1.0 x 10^5 organisms per swab.

Strep A Organism / swab	Test A	Test B	Test C
1.0 x 10^4	Negative	Negative	Negative
1.0 x 10^5	Positive	Positive	Positive
2.5 x 10^5	Positive	Positive	Positive
5.0 x 10^5	Positive	Positive	Positive
6.0 x 10^6	Positive	Positive	Positive

Dose Hook

Swabs were speiked with Strep A cells yoielding concentrations of 1.0 x 10^9, 1.0 x 10^8, and 1.0 x 10^7 organisms per swab to determine if a prozone effect, or a decrease in signal with increasing analyte, has occured in this assay. Three lots of devices were tested. The swabs were run according to the package insert in replicates of three. The results showed that the ulti med Streptococcus A Card is capable of detecting up to 10^9 organisms / swab without deleterious effect.

Strep A Organism / swab	Test A	Test B	Test C
1.0 x 10^9	Positive	Positive	Positive
1.0 x 10^8	Positive	Positive	Positive
1.0 x 10^7	Positive	Positive	Positive

Interfering Substances

Swabs were spiked with the interfering substances (cough drops, cough syrup, aseptic spray, or mouthwash) at a starting concentration of 1 %. These swabs were the spiked with either low or medium Strep A specimen levels. The swabs were tested according to the package insert in replicates of three. The tests were rated as either positive or negative at the read time. The results demonstrated that these substances do not interfere with the expected results.

Interfering Substances	Level Tested		
	Negative	Low	Medium
Cough drops A, B, C	Negative	Positive	Positive
Cough syrup A	Negative	Positive	Positive
Aseptic spray A, B	Negative	Positive	Positive
Mouthwash A, B	Negative	Positive	Positive

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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 ulti med Streptococcus A Card. No mucoid-producing strains were tested.

Bordetella pertussis
Branhamella catarrhalis
Candida albicans
Corynebacterium diptheria
Enterococcus faecalis
Group B Streptococcus
Group C Streptococcus
Group F Streptococcus
Group G Streptococcus
Hemophilus influenza
Klebsiella pneumoniae
Neisseria gonnorhea
Neisseria meningitidis
Neisseria sicca
Neisseria subflava
Pseudomonas aeruginosa
Serratia marcescens
Staphylococcus aureus
Staphylococcus epidermidis
Streptococcus mutans
Streptococcus pneumoniae
Streptococcus sanguis

Field Study
Three physicians' offices were used to conduct an evaluation of the ulti med Streptococcus A Card. 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) for three days. The results obtained had a 96% correlation with the expected results.

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