Quick STREP A Test

Rapid test for the diagnosis of Strep A infection

INTENDED USE

Quick STREP A Test is a rapid immunoassay for the qualitative detection of Group A Streptococcus antigens in human throat swab specimens. This test is intended for use as an aid in the diagnosis of Strep A infection. Quick STREP A Test produces qualitative results and is intended only for professional use.

PERFORMANCE CHARACTERISTICS

- Specimen: throat swab.
- Accuracy: > 94.7%.
- Sensitivity: 1×10^4 organisms/swab.
- Certification: Declaration of conformity according to the directive 98/79/EC.

INTRODUCTION

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. 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 indicates that proper volume of specimen has been added and membrane wicking has occurred.

MATERIALS PROVIDED

- Quick STREP A Test individually packed.
- Reagent 1 (1.0 M sodium nitrite)
- Reagent 2 (0.4 M acetic acid)
- Positive control (Non-viable Strep A, 0.09% sodium azide).
- Sterilized swabs.
- Disposable pipettes.
- Extraction tubes.
- Package insert.

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.
**PROCEDURE**

Bring tests, specimens, reagents and/or controls to room temperature (15-30 °C) before use.

Prepare swab specimens:
1. 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;
2. 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;
3. 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.
   - 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.
   - 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.
   - Wait for the colored band(s) to appear. The result should be read at 5 minutes. Do not interpret the result after 10 minutes.

![Figure 1. Test procedure.](image)

**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). Not colored band appears in the test region (T).

Invalid
Control band fails to appear. Results from any test which has not C produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test.

![Figure 2. Interpretation of results.](image)

**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.

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QUALITY CONTROL

Good laboratory practice recommends the use of control materials to ensure proper kit performance. A positive control containing heat-killed Group A Streptococcus and a negative control containing heat-killed non-Group A Streptococcus are 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 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. Continue as described from Step 2 of the PROCEDURE section.

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 or closed canister until use.
- Do not freeze.
- The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For professional in vitro diagnostic use only. Read the entire procedure carefully prior to testing.
- 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.
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- 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 and 2 are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- The positive and negative controls 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.

LIMITATIONS OF THE TEST

1. Quick STREP A Test 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. In rare cases, test specimens heavily colonized with Staphylococcus aureus can yield false positive results. If clinical signs and symptoms are not consistent with clinical test results, a follow-up culture and grouping procedure should be performed.
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.

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CROSS-REACTIVITY

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 1×10^8 organisms/test, and all yielded negative results:

- Bordetella pertussis
- Branhamella catarrhalis
- Candida albicans
- Corynebacterium diphtheriae
- Enterococcus durans
- Enterococcus faecalis
- Hemophilus influenzae
- Klebsiella pneumoniae
- Neisseria gonorrhoea
- Neisseria meningitidis
- Neisseria sicca
- Nesseria subflava
- Pseudomonas aeruginosa
- Serratia marcescens
- Staphylococcus aureus
- Staphylococcus epidermidis
- Streptococcus canis
- Streptococcus equisimilis
- Streptococcus mutans
- Streptococcus pneumoniae
- Streptococcus sanguis
- Streptococcus oralis
- Streptococcus mitis
- Streptococcus anginosus
- Streptococcus intermedius
- Streptococcus agalactiae

REFERENCES