RAPID STREP TESTING

CLIA: Waived
Testing Personnel: CLS (tests and controls), trained lab assistant (tests only)

Principle: Medi-Lab Strep A Test-Dipstick utilizes a two-site sandwich immunoassay technology for the detection of Group A Streptococcal antigen. The test consists of a membrane strip which was pre-coated with rabbit anti-Strep A antibody on the test line region and goat anti-rabbit antibody on the control line region. A colored rabbit anti-Strep A antibody-colloidal gold conjugate pad is placed at the end of the membrane. During testing, the Strep A antigen is extracted from the throat swab using the extraction reagents. The test strip is then immersed in the extracted sample. The mixture then moves chromatographically across the membrane to the immobilized rabbit anti-Strep A antibody at the test (T) region. If Strep A antigen is present in the specimen, a colored sandwich of solid phase / Strep A antigen / gold conjugate is formed on the test region. Absence of the colored line at the test (T) region indicates a negative result. Regardless of the presence of Strep A antigen, as the extracted mixture continues to move laterally across the membrane to the immobilized goat anti-rabbit antibody control (C) region, a colored line at the control region will always appear. The presence of this colored line serves as: 1) verification that sufficient volume has been added, 2) verification that proper flow was obtained.

Materials: Medi-Lab Strep A Test-Dipstick: (McKesson.)
1) Test Packs (27) contain one test strip with pre-coated anti-Strep A antibody on the membrane and colored anti-Strep A antibody pad.
2) Disposable extraction test tubes.
3) Extraction Reagent A: 2M Sodium Nitrate (10 ml): CAUTION: May be slightly caustic, avoid contact with eyes or mucous membranes. In case of contact, wash thoroughly with water.
4) Extraction reagent B: 0.4M Acetic Acid (10 ml): CAUTION: May be slightly caustic; avoid contact with eyes or mucous membranes. In case of contact, wash thoroughly with water.
5) Positive (non-viable Group A Streptococcus) and negative (non-viable Group C Streptococcus) controls. CAUTION: 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 build-up.
6) Sterile throat swabs
7) Timer

Precautions: LATEX GLOVES MUST BE WORN WHEN PERFORMING THIS PROCEDURE
Observe all standard laboratory guidelines for handling of infectious agents and chemical reagents. Do not use after the expiration date. Dispose of all contaminated waste in biohazard bags. Do not exchange reagent bottle caps. Do not exchange external control solution bottle caps.

Specimen: Dacron-tipped sterile swab with plastic shaft is used to collect from posterior pharynx, tonsils, tonsillar fossae, or areas of inflammation and exudate. DO NOT USE CALCIUM ALGINATE OR WOODEN SHAFTED SWABS. AVOID THE LIPS AND TONGUE. Transport swabs with modified Stuart's or Aimes medium are acceptable. Swabs should be processed as soon as possible after collection. Swab specimens may be stored at room temperature (15 - 30°C) for up to 4 hours.
RAPID STREP TESTING

-2-

Procedure:

DO NOT OPEN TEST KITS UNTIL READY TO PERFORM THE ASSAY. TEST REAGENTS AND SPECIMENS SHOULD BE BROUGHT TO ROOM TEMPERATURE BEFORE TESTING. DO NOT ALLOW TIP OF REAGENT BOTTLE TO COME IN CONTACT WITH THROAT SWABS OR EXTRACTION TUBES. OPEN CANISTERS OF STRIPS ARE STABLE FOR 90 DAYS. DO NOT USE PAST EXPIRATION DATE.

1. Place the extraction tube in the workstation tray. Add four drops of Extraction Reagent A and four drops of Extraction Reagent B to the tube. Leave swab in tube 1 minute.

2. Place the throat swab specimen in the extraction tube. Rotate the swab 10 times in the tube. Squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Discard the swab.

3. Remove the test strip from the canister and use as soon as possible. Immerse the test strip into the extraction tube with the arrows pointing toward the bottom of the tube. Liquid level should be at or just below the MAX line on the strip.

4. Read results in 5 minutes. Positive results may be visible in one minute. To confirm a negative result, the complete reaction time of 5 minutes is required. DO NOT READ RESULTS AFTER TEN MINUTES.

Interpretation of Results:

POSITIVE: Two red colored lines appear, one in the test (T) region and one in the control (C) region. The color intensities of the lines may vary. Any shade of red should be considered positive. A positive result indicates that the specimen contains Strep A antigen.

NEGATIVE: Only one red colored line appears in the control (C) region. No apparent red colored line is visible in the test (T) region. A negative result indicates there is no Strep A antigen in the swab sample or that the Strep A antigen concentration is below the detection level.

INVALID: No red colored line appears in the control (C) region. An absence of the control line is an indication of procedural error or possible reagent deterioration. A new test should be performed. If the problem persists, call Applied Biotech, Inc. at (888) 578-7956 for technical assistance.

Quality Control:

A positive and negative external control must be tested every 27 tests (once per box). A procedural control is included in the test. A colored line appearing on the control (C) Region is considered an internal positive procedural control indicating proper performance. A clear background in the result area is considered an internal negative procedural control. If the reagents are working properly and the test has been performed correctly, the background will clear to give a discernible result.
Limitations:

1. The Medi-Lab Strep A Test is for *in vitro* diagnostic testing only. The test should be used for detection of the Strep A antigen in throat specimens only. The test is not quantitative.
2. A negative result may be obtained from patients due to low antigen concentration. If rapid Strep testing is negative, a follow-up culture may be indicated.
3. This test does not differentiate asymptomatic carriers of Group A Streptococcus from those with infection.
4. Excessive mucous or blood on the swab may interfere with test performance and may yield false positive results.
5. Respiratory infections, including pharyngitis, can be caused by Streptococci from serogroups other than Group A, as well as by other pathogens.
6. A definitive clinical diagnosis should not be based on the results of a single test, but should only be made by a physician after all clinical and laboratory findings have been evaluated.

Performance Characteristics:

- Sensitivity: 97%
- Specificity: 95%
- Overall Accuracy: 95%

Expected Results: The incidence of Group A beta-hemolytic Streptococcus in school aged children and adults is about 40%. Most cases occur in winter and early spring and affect males and females equally.

References:


Product insert, McKesson Medical-Surgical, Richmond, VA 23228, (866) 288-7653.