**PURPOSE:**

Streptococcus pyogenes is a 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. The Strep A Dipstick Rapid Test 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. Positive results are definitive in diagnosis and treatment of patients. Negative results require culture confirmation performed at the Christus Spohn Reference Microbiology Laboratory.

**PRINCIPLE:**

The Strep A Dipstick Rapid Test 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 dipstick. 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 if the test has been performed properly. If a red control line does not appear, the test result is not valid.

**SPECIMEN REQUIREMENTS:**

Collect throat swab specimens by standard clinical methods. No other specimen source can be used. Depress the tongue with a tongue blade or spoon. Be careful not to touch the tongue, sides or top of the mouth with the swab. Rub the swab on the posterior pharynx, on the tonsils, and in any other area where there is redness, inflammation or pus. Use only the Sterile Polyester Tipped Applicator supplied in the kit to collect throat specimens for testing or the BD 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 into a dry, sterile, and tightly sealed plastic tube for storage. Swab specimens can be stored at room temperature 20-30° C for 1 hour or refrigerated 2-8° C for 72 hours.

 **REAGENTS/MATERIALS:**

1. Cardinal Strep A Dipstick Kit –Positive and Negative Controls, Test Strips in Canister, and Reagent A and B.
2. Swabs
3. Timer

 **STORAGE REQUIREMENTS:**

1. The test kit is stored at room temperature or refrigerated (2–30°C). DO NOT FREEZE.
2. The test dipstick must remain in the closed canister until use. The test dipsticks (in their unopened canister) and the reagents are stable through the expiration date printed on the box. Once the canister is opened, the remaining test dipsticks are stable for 12 months.
3. Do not use beyond the expiration date.
4. Date all reagents with initials, opened and expiration date.

 **QUALITY CONTROL REQUIREMENTS:**

1. Positive and Negative QC (controls included in kit) are run every 30 days and logged into Quality Control Book
2. Parallel testing is performed on any new kit against the current kit in use and logged into Parallel QC Book.

 **TEST PROCEDURE:**

**External Controls**

1. Dispense 4 drops Reagent A and 4 drops Reagent B into each extraction tube.
2. Hold dropper bottles upright. Note: Color change of solution from red to pale yellow; gently mix liquid.
3. Add one full drop of both positive and negative control solution to respective tubes.
4. Place a clean swab into the extraction tube.
5. Rotate swab 10 times in the tube.
6. Leave swab in the tube for 1 minute.
7. Express as much liquid from the swab by squeezing the sides of the tube as swab is withdrawn. Discard swab in biohazard trash.
8. Remove the test dipstick from the closed canister, promptly replace the lid tightly on the canister and use the test dipstick as soon as possible. Best results will be obtained if the test is performed immediately after removing test dipstick from canister.
9. With arrow pointing down, place the test dipstick into the tube of solution and then start the timer. If the procedure is followed correctly, the liquid should be at or just below the maximum line (MAX) on the test dipstick. See illustration.

 10.Leave the dipstick in the tube and read the result at 5 minutes.

 11.Document the QC in the appropriate log book.

**Internal QC/Procedural QC:**

Internal procedural controls are included in the test.

1. Extraction Reagent A turns from red to pale yellow when Reagent B is added. If the color change does not occur, do not proceed. Repeat procedure. If color change does not occur, notify Point of Care immediately.
2. The appearance of a red line in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique. The test is invalid if the control line does not appear.
3. A clear background is an internal negative background control. If the test is working properly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

**PATIENT TEST PROCEDURE:**

Label extraction tube with two patient identifiers.

**(SEE TEST PROCEDURE DIAGRAM AFTER THIS)**

 Step1:

Dispense 4 drops Reagent A and 4 drops Reagent B into the extraction tube. Hold dropper bottles upright. Note: Color change of solution from red to pale yellow. Gently mix liquid.

 Step 2:

Immediately place patient swab into extraction tube.

 Rotate the swab vigorously 10 times in the tube.

 Step 3:

Place swab in the tube one minute.

Express as much liquid from the swab by squeezing the sides of the tube as it is being withdrawn. Discard swab in Red Trash Bag.

Remove the test dipstick from the closed canister, promptly replace the lid tightly on the canister and use the test dipstick as soon as possible. Best results will be obtained if the test is performed immediately after removing the dipstick from the canister.

Step 4:

With arrow pointing down, place the test dipstick into the tube of solution and then star the timer. If the procedure is followed correctly, the liquid should be at or just below the maximum line (MAX) on the test dipstick. See illustration.

Step 5:

 Leave the dipstick in the tube and read the result at 5 minutes.

  **TEST PROCEDURE INTERPRETATION OF RESULTS**



**INTERPRETATION OF RESULTS**

**(SEE DIAGRAM ABOVE)**

1. **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 (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.
2. **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 is not present in the sample, or is present below the detectable level of the test. The patient’s sample will be reflexed to a culture to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another sample for culture.
3. **INVALID**: 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 dipstick.
4. **CONFIRMATION OF A NEGATIVE**: For negative results a throat culture order for Strep A will be generated. Setup culture, streak out plate and add an “ A” disk. Place plate in incubate and submit the Culture to the Reference Laboratory .

 **REFERENCE RANGE:**

Negative: Approximately 15% of pharyngitis in children aged 3 months to 5 years is caused by Group A beta-hemolytic Streptococcus. In school-aged children and adults, the incidence of Strep throat infection is about 40%.

**PERFORMANCE CHARACTERISTICS:**

 Refer to package insert for detailed data. The manufacture states a sensitivity of 97% and a specificity of 95% when compared to culture. See package insert for more detailed information.

 **REFERENCES:**

 Cardinal Health – Strep A Dipstick, Rapid Test (catalog B1077-30)