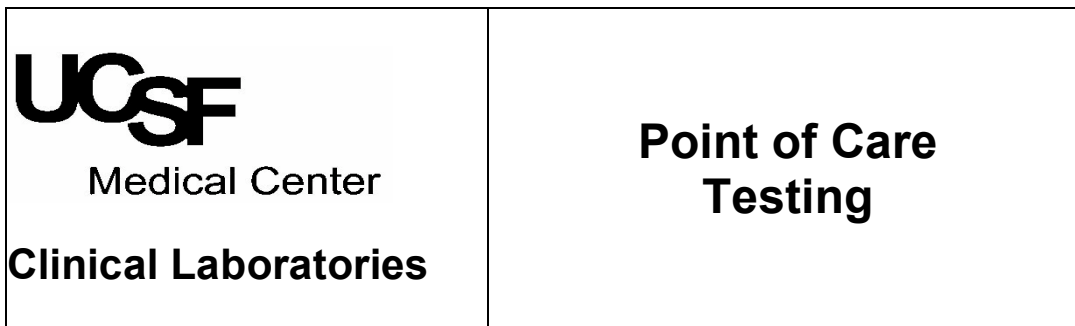


Director Approval _____ Date _____



Signify™ STREP A TEST

PURPOSE

The Signify Strep A dipstick is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab samples to aid in the diagnosis of Group A Streptococcal infection. **Negative test results require confirmatory testing.**

PRINCIPLE

The Signify Strep A Dipstick 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 sample 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.

SUPPLIES

Signify™ Group A Test Kit, 50 Test kit order number: 06595-55, Abbott Laboratories, Abbott Park, Illinois 60064

- Package Insert
- 50 Test Dipsticks (in 2 canisters, 25 each): rabbit anti-Strep A antibody
- 50 Disposable Extraction Test Tubes
- 50 Sterile Polyester Swabs
- 2 Reagent 1 (red): 2 M Sodium Nitrite
Sodium Nitrite is toxic if swallowed. If swallowed, get medical attention. Very toxic to aquatic animals; avoid release into the environment.
- 2 Reagent 2 (colourless): 0.4 M Acetic Acid
Reagent 2 contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- Positive Control (Nonviable Group A Streptococcus, 0.09% Sodium Azide)
- Negative Control (Nonviable Group C Streptococcus, 0.09% Sodium Azide)
The Positive and Negative controls contain sodium azide. Harmful if swallowed; if swallowed get medical attention. Contact with acids liberates toxic gas; dispose of in a safe way. Sodium azide may react with lead or copper plumbing; always flush plumbing with copious amounts of water to prevent azide build up.

STORAGE AND HANDLING

- The kit can be stored at room temperature 15° -30° C (59° -86 ° F).
- The test dipstick must remain in the closed canister until use. The test dipsticks (in their sealed canisters) 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 90 days.** Test dipsticks in the canisters and reagents should be tightly capped after each use.
- Do not use Test strips or reagents after expiration date.
- **Do not interchange Reagent or external Control solution bottle caps.**
- **Do not interchange or mix components from different kit lots.**

MATERIALS NEEDED BUT NOT PROVIDED

- A timer or watch.

SPECIMEN REQUIREMENTS

Collect specimens with a sterile polyester swab from the posterior pharynx, tonsils, and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab. Do not use on specimens collected from other sites, such as saliva, sputum, or urine.

Use a sterile polyester swab to collect specimens. Sterile Polyester swab supplied in the test kit is recommended.

Transport swabs containing modified Stuart's or Amies medium can also be used.

Process the swab as soon as possible after collecting the specimen. **If testing is not performed immediately by the person collecting the sample, then the sample must be labeled in the presence of the patient, using two forms of patient identification. In addition, when testing is delayed, the swab should be placed into a dry, sterile and tightly sealed plastic tube.** Specimens can be stored at room temperature for four hours prior to testing.

The swabs (specimens) and the test kit must be at room temperature before you perform the test.

QUALITY CONTROL

Internal Procedure Control

The Signify™ Strep A Test provides procedural controls with each test run. These procedural controls must be documented on the QC log, for the first patient tested each day of patient testing.

- 1) The color of the liquid changes from pink to light yellow as you add Reagent 2 to Reagent 1. This is an internal extraction reagent control. The color change means that you mixed the extraction reagents properly. The color change also means that the reagents are functioning properly
- 2) A red line appearing in the control region (C) is an internal positive procedural control. The Test dipstick must absorb the proper amount of sample and the test dipstick must be working properly for the red Control line to appear. For the Test dipstick to be working properly capillary flow must occur.
- 3) A clear background in the results area is considered an internal negative procedural control. If the reagents are working properly and the test has been performed correctly, the background in the result area should be white to light pink and not interfere with the ability to read the test result.

If the red Control Line does not appear, the test is invalid. Do not report results and repeat the test if procedural controls fail. Call the Point of Care Coordinator (353-1630) for assistance if procedural controls continue to fail.

External Quality Control

Standard precautions must be practiced when handling control materials.

Each kit contains Positive and Negative Control material; The Controls are for external quality control testing. Use the Controls to test that the reaction reagents and the Test strip are working. Also use the Controls to test that you are able to correctly perform the test procedure.

A positive and negative external control must be tested:

- When opening a new test kit, **a new bottle of reagent, or a new canister of dipsticks**

External QC Testing procedure

- Dispense 4 drops Reagent 1 and 4 drops Reagent 2 into an extraction test tube. Tap the bottom of the tube gently to mix the liquid.
- Add 1 free falling drop of Positive Control from dropper bottle.
- Place a clean swab into the tube.
- Continue as you would for a patient sample in the **PROCEDURE** section below
- Repeat using Negative Control
- Document QC on QC log sheet

PROCEDURE

Standard precautions must be practiced when performing patient testing.

1. Using two patient identifiers, verify patient identification and explain the procedure to the patient an/or family.
2. Obtain specimen
3. Check expiration dates on test dipsticks, extraction reagent vials and extraction tubes.
4. Holding dropper bottles vertically, add 4 drops Reagent 1 (red) and 4 drops Reagent 2 into the extraction tube. Solution will turn a light yellow (Reagent Control). Tap the bottom of the tube gently to mix the liquid.
5. Immediately place the throat swab specimen in the extraction tube. Rotate swab using a circular motion, so that the liquid is expressed and reabsorbed, at least ten times.
6. Let stand for one (1) minute.
7. Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.
8. Remove Test Dipsticks from the canister; re-cap canister immediately.

9. Immerse the absorbent end of the Test Dipstick into the extracted sample, with the arrow pointing to the extraction sample solution. If the procedure is followed correctly, the liquid should be at or just below the maximum line (MAX) on the test dipstick.
10. Read results at 5 minutes. Do not read after 10 minutes.
11. A Negative result must be followed up with confirmatory testing. A Specimen must be sent to the Microbiology Lab for confirmation.

INTERPRETING RESULTS

Positive Result: 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. The intensity of the red colour 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 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

Invalid Result: Control line fails to appear. Absence of the control line is an indication of procedural error, reagent deterioration or insufficient sample volume. All lines, regardless of color intensity, should be interpreted as lines. If the control line fails to appear repeat the test on a new Test strip. If the problem persists, call the Point of Care Coordinator (353-1630).

LINE CONTROL	TEST RESULT	INTERPRETATION
RED	RED	POSITIVE
RED	NO COLOR	NEGATIVE
NO COLOR	RED	DO NOT REPORT, REPEAT TEST
NO COLOR	NO COLOR	DO NOT REPORT, REPEAT TEST

Record the result in the patient's medical record.

LIMITATIONS

- The Signify Strep A Dipstick is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab samples only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
- This test will only indicate the presence of Strep A antigen in the sample from both viable and non-viable Group A Streptococcus bacteria.
- A negative result obtained from this kit should 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.
- Excess blood or mucus on the swab sample may interfere with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of

the mouth with the swab when collecting samples.

- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

REFERENCES

Inverness Medical Professional Diagnostics Signify Strep A Dipstick 2007, San Diego, CA

Manual of Clinical Microbiology, 6th Edition, ASM Press, p. 299-307

Webb, KH. *Pediatrics* (Feb 1998), 101:2, 2.

Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. *Clinical Infectious Diseases* (1997), 25, 574-83

Shea, Y.R., Specimen Collection and Transport, in *Clinical Microbiology Procedures Handbook*, Isenberg, H.D., American Society of Microbiology, Washington, D.C., 1.1.1-1.1.30, 1992.

Nussinovitch, M, Fnkelstein Y, Amir J, Varsano, I. *Clinical Pediatrics* (June 1999), 357-360.

Woods WA, Carter CT, Stack M, Connors Jr AF, Schlager TA, *Southern Medical Journal* (May 1999), 491-492

For technical assistance, call Inverness Medical Technical Support at:
1-800-637-3717