

**Document Management Number: SOP-0975**

**Document Title: Rapid Strep A Procedure**

**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 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.

**Clinical Significance:**

The early detection and treatment of Group A Streptococcus upper respiratory infections has been proven to be successful in the prevention of further complications such as rheumatic fever and glomerulonephritis.

**Specimen:**

Sterile swabs from the tonsils or the back of the throat. **Use only the sterile polyester tipped swab with a plastic shaft provided with the kit.** Culturette II® swabs are not acceptable for testing. These tend to absorb most of the liquid needed for testing during the extraction procedure of the test. Swab specimens may be store in a clean, dry plastic tube for up to 8 hours at room temperature of 72 hours at 2-8°C.

***DO NOT** use specimens taken from other sites, or use samples such as saliva, sputum or urine.*

NOTE: Hand hygiene should be observed before and after interacting with each patient. Gloves are to be worn when handling specimens and while completing all testing. Gloves should be changed between patients.

**Reagents and Supplies:**

**Provided with the Signify™ kit:**

- 50 Dipsticks
- 50 Test tubes
- 50 sterile swabs
- Reagent 1 (2 M Sodium Nitrite)
- Reagent 2 (0.3 M Acetic Acid)

**Warning:** *If Reagent 2 comes in contact with the skin or eye immediately flush with copious amounts of water.*

- Positive Control (Nonviable Group A Streptococci, 0.1% Sodium Azide)
- Negative Control (Nonviable Group C Streptococci, 0.1% Sodium Azide)

**Warning:** *The positive and negative controls contain Sodium Azide; this may react with lead or copper plumbing to form potentially explosive metal azides. Caution should be taken when discarding remaining, unused control material down a sink by flushing down with large quantities of water.*

### **Storage and Stability:**

Reagents are to be stored tightly capped at room temperature, and are stable until the manufactures expiration date. Strips are to be stored tightly capped at room temperature and are stable for one year after opening.

### **Quality Control:**

To ensure reliability, the Signify™ Strep A test system has two types of quality control checks: **Internal Controls** (onboard) and **External Controls** (Liquid) positive and negative Controls.

- **Internal (Onboard) Controls:** are automatically ‘developed’ anytime a patient test is performed. There are three internal controls and each one is described in the “Patient Testing” section of this procedure. The first is the color change of Reagents 1 and 2; after proper mixing the reagents color should change from **pink to yellow**. The second is the appearance of a **pink** colored line in the control region assures the correct test procedure was followed, indicating sufficient volume of fluid was used and that capillary flow occurred. The third control is a **clear** background in the result area is considered an internal negative procedural control. Record the observance of these controls in appropriate Rapid Strep A Reminder Dialog using a checkmark to indicate acceptable results with each patient test.
- **External (Liquid) Controls:** Each kit contains Positive and Negative Control material. These controls are bacteria based and tested like a patient sample. Liquid controls determine extraction reagent and Dipsticks are working correctly in addition to checking operator technique. A positive and negative control should be tested with each new kit before used for patient testing.

**The Ancillary Testing Coordinator will perform external Quality Control.**

### **To perform External Quality Control:**

1. Label two test tubes: one “positive” and one “negative”.
2. Into each test tube, **dispense 4 drops** of Reagent 1 and **4 drops** of Reagent 2. Observe the **Extraction Reagent Control** as the color changes from pink to yellow.

3. Thoroughly mix the positive and negative control bottles. By shaking the bottles vigorously.
4. Add 1 free falling drop of Control solution into respective Test Tube.
5. Place a clean sterile swab (provided with the kit) into each Test Tube.
6. Vigorously mix by rotating the swabs against the side of the tube at least **10 times**. This step is **critical** since mixing allows for a successful extraction of the Group A Strep antigen; a poorly extracted sample could result in a *false negative* result.
7. Allow to stand for **1 minute**.
8. Express as much liquid as possible from the swab by gently pressing the swab firmly against the side of the Test Tube. Discard the swab.
9. Remove 2 Dipsticks (one for each control level) from the container, re-cap immediately.
10. Immerse the Dipstick into the Test Tube with the arrows pointing toward the extraction sample solution. Leave the Dipstick in the Test Tube.
11. Set timer for 5 minutes.
12. Read the results in 5 minutes. Check that internal controls performed as expected: a **Pink Control Line** appears, and the **background in the Control Line is clear**. Read test result.
  - **Positive: Two Pink colored lines appear.** In addition to a pink colored line in the control region, a pink colored line will also appear in the test region. The color intensities may vary. **All lines, regardless of color intensity should be interpreted as positive. Line intensity may vary from sample to sample.** A positive result indicates that the specimen contains Strep A antigen.
  - **Negative: Only one pink colored line appears in the control region.** No apparent pink colored line is visible in the test region. A negative result indicates no Strep A antigen on the swab sample or the Strep A antigen is on the swab sample is below the detection level.
  - **Invalid: No pink colored line appears in the control region.** Absence of the control line is an indication of a procedural error or possible reagent deterioration. Repeat the sample with a new dipstick. If the problem persists, discontinue testing, and call the Ancillary Testing Coordinator at ext. 1595.
13. Document controls in the “Rapid Strep A QC Log” (External QC).

### **Test Procedure:**

### **Patient Preparation and Collection:**

Prior to testing, the patient should be informed of the purpose of the test and the steps involved in the procedure. Universal Precautions must be followed when collecting and handling body fluids. Gloves and adequate PPE should be worn at all times.

1. With the aid of a tongue depressor, swab back of throat and tonsil area with a sterile swab provided in the kit. Making sure to avoid the patient's teeth, gums, tongue, and cheek surfaces. Thus preventing contamination of the swab by other mouth flora.
2. In the patient's presence, label the sterile swab wrapper with the patient's full name, and full SSN. The patient identification must be verbally verified by the person collecting the sample with the patient.
3. The swab should be processed immediately after collection. Proceed to *Patient Testing* section.

### **Patient Testing:**

This kit contains three internal procedural controls, which must be observed at the appropriate times (see steps 3 and 10) as specified in testing procedure below.

1. Label Test Tube with patient's full name and full SSN.
2. Gently mix the Reagent bottles by inverting them 3 to 4 times. Dispense **4 drops** of Reagent 1 to the Test Tube. The solution should be pink-red in color.
3. Add **4 drops** of Reagent 2 into same Test Tube. **Observe the solutions turn from pink to light yellow.** This is the first internal procedural control.

***Note:** To avoid cross contamination do not allow the tips of the reagent bottle to come in contact with the sample swabs or the Test Tubes.*

4. Immediately, place swab in tube and mix vigorously by rotating the swabs against the side of the tube at least **10 times**. This step is **critical** since mixing allows for a successful extraction of the Group A Strep antigen; a poorly extracted sample could result in a *false negative* result.
5. Allow swab to stand in solution for **1 minute**.
6. Express as much liquid as possible from the swab by pressing the swab against the tube. Discard swab.
7. Remove Dipstick from the container; re-cap container immediately.

***Note:** Do not open the Dipstick container until ready to perform the assay.*

8. Immerse the Dipstick into the Test Tube with the arrows pointing down. Leave the Dipstick in the Test Tube.
9. Set timer for 5 minutes
10. At the end of 5 minutes, the following **internal controls** are observed: the development of a **pink Control Line** indicating the Dipstick is working properly and that it absorbed the proper amount of sample, and the **clearing of the background** indicating no interfering substances are present in the sample. If all of the **internal controls** are acceptable, the patient sample can be interpreted. Do not read test after 10 minutes, results are invalid.

## 11. Interpretation of results:

- **Positive: Two Pink colored lines appear.** In addition to a pink colored line in the control region, a pink colored line will also appear in the test region. The color intensities may vary. **All lines, regardless of color intensity should be interpreted as positive. Line intensity may vary from sample to sample.** A positive result indicates that the specimen contains Strep A antigen.
- **Negative: Only one pink colored line appears in the control region.** No apparent pink colored line is visible in the test region. A negative result indicates that there is no Strep A antigen on the swab sample or the Strep A antigen that is on the swab sample is below the detection level.

**NOTE:** A throat culture for negative results is optional. A provider may order a throat culture if he feels necessary.

- **Invalid: No pink colored line appears in the control region.** Absence of the control line is an indication of a procedural error or possible reagent deterioration. Repeat the sample with a new dipstick. If the problem persists discontinue testing, collect a throat culture, and call the Ancillary Testing Coordinator at ext. 1595.

### CLIA Waived Signify® Strep A Test Procedure



### Record results in CPRS.

- a. Log into CPRS.
- b. Click "NOTES" along bottom tab.
- c. Click "Templates" on left hand side.
- d. Click "Shared Templates".
- e. Click on "Ancillary Testing"
- f. Double click on "Group A Streptococcal Antigen" Reminder Dialog
- g. Select Location, Click "OK".
- h. Select Progress Note Title, Click "OK"
- i. Fill out reminder dialog, see example.
- j. Click "Finish".
- k. Select Primary Provider
- l. Sign Note

Reminder Dialog Template: Group A Streptococcal Antigen

Group A Streptococcal Antigen

Date and Time of Collection: \* [ ] ...

Test Result:

☐ Positive

☐ Negative

Quality Control:

☐ Positive Control Performance acceptably demonstrated

☐ Negative Control Performance acceptably demonstrated

Visit Info Finish Cancel

Group A Streptococcal Antigen

Date and Time of Collection:

Test Result:

<No encounter information entered>

\* Indicates a Required Field

Lower Sheet Problems Meds Orders Notes Consults Surgery D/C Summ Labs Reports

start Rapid Strep - Al... CPRS - Patient ... 2 Microsoft OF... 11:56 AM

### Interfering Substances:

No cross-reactivity was encountered in testing miscellaneous organisms' strains with this test. Other groups of Streptococci were found to be negative when tested with the Signify™ Strep A Test.

### Expected Results:

Approximately 19% of all upper respiratory tract infections are caused by Group A Streptococci. Group A Strep related pharyngitis displays a seasonal variation being more prevalent during the winter months and early spring. The highest incidences of this disease are found in crowded populations such as military bases and school-age children.

### Procedural Notes:

1. Do not mix kit components from different kits or lots.
2. If the Rapid Strep A kit is unavailable for testing for any reason, collect and order a Throat culture. Send specimens to laboratory.

### Limitations:

- The Signify™ Strep A does not differentiate between viable and non-viable Group A Streptococci.

- The Signify™ Strep A Test does not differentiate between carriers and acute infection. Pharyngitis may be caused by organisms other than Group A Streptococcus
- A negative result may be obtained if the specimen is inadequate or antigen (Strep) concentration is below the sensitivity of the test.
- Excess blood or mucus on the swab sample may interfere with test performance and may yield false positive result. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collecting samples.

#### References:

- Lauer, B.A. Reller, L.B., and Mirrett, S., Effect of Atmosphere and Duration of Incubation on Primary Isolation of Group A
- Streptococci from Throat Cultures, J. Clin. Microb., 17:338-340, 1983. Wannamaker, L.W., Differences Between Streptococcal Infections of the Throat and of the Skin, N. Eng. J. Med., 282:23-31, 78-85, 1970
- Youmans, G.P., Patterson, P.Y. and Sommers, H.M. Upper Respiratory Tract infection: General Considerations, in The Biology and Clinical Basis of Infectious Diseases, W.B. Saunders Co., Philadelphia, 177-183, 1980.
- Signify Strep A Dipstick package insert 2011.

#### Revision History

Section	Change	Date	Requester	Approver
Header	Update header	01/31/2017	Hung Ho	E. Hart MD
Font, Size	New Time Roman, 12	01/31/2017	Hung Ho	E. Hart MD