Clinical Laboratory Department POLICY AND PROCEDURE

POLICY NUMBER: 1214
VERSION: 3

SUBJECT: Sure-Vue Signature Strep A Test

Purpose:

Group A streptococcus is the most significant bacterial pathogen responsible for acute upper respiratory tract infection in both children and adults. Early diagnosis and treatment of group A streptococcal infection results in more rapid resolution of the symptoms and helps to prevent further complications such as acute rheumatic fever and glomerulonephritis. Conventional identification culture results may not be available for 24 to 48 hours. The Sure-Vue Signature Strep A Test is a rapid screening assay for the qualitative detection of group A streptococcal antigen directly from throat swabs. It is intended for the qualitative detection of Group A Streptococcal antigen from both nonviable and viable organisms directly from a throat swab, providing results within 7 minutes.

Principle:

The Sure-Vue Signature Strep A test is a color immunochromatographic assay using Dual Label Technology (DLT). DLT uses antibody labeled color particles coated at two separate locations in the test device. DLT allows greater sensitivity than the conventional single label technology without sacrificing specificity. In the test procedure, a throat swab is subjected to a chemical extraction of a carbohydrate antigen unique to Group A Streptococcus. The Test Stick is then placed in the extraction mixture and the mixture migrates along the membrane. If Group A Streptococcus is present in the sample, it will form complexes with the anti-Group A Streptococcus antibody conjugated color particles located at two separate locations on the Test Stick. The complex will then be bound by the anti-Group A Streptococcus capture antibody and a visible blue Test Line will appear to indicate a positive result. A red Control Line will also appear to indicate the test is valid.
Specimen Collection:

The technique of swabbing the throat is extremely important in order to obtain an adequate specimen. Using a sterile swab, rub the tonsils and/or back of the throat and pharynx touching any areas of exudate or ulceration present. Avoid touching the teeth, gums, cheek, tongue or uvula tissues with the swab. Do not use a collection system that contains charcoal or semisolid transport media. If the same swab is to be used for routine culture, inoculate culture media first before starting the SureVue Signature Strep A Test procedure as the extraction reagents will cause the specimen to become nonviable. Alternatively a second swab may be taken for culturing. Process the swab as soon as possible after collecting the specimen. If you do not perform the SureVue Signature Strep A test immediately, store the swabs either at room temperature or refrigerated for up to 48 hours. The swabs and the test kit must be at room temperature prior to running the test. Culturing should be done as soon as possible to minimize loss of viable organisms.

Procedure:

Label a Test Tube (provided with kit) with appropriate patient/QC information.

1. Add 3 drops Reagent A (pink) and 3 drops Reagent B to the Test Tube. The solution should turn light yellow.
2. Immediately put the patient swab into the Tube.
3. Vigorously mix the solution by rotating the swab forcefully against the side of the Tube at least 10 times. Best results are obtained when the specimen is vigorously extracted in the solution.
4. Let stand for 2 minutes.
5. Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn. Discard the swab.
6. Remove Test Stick(s) from the container; re-cap the container immediately.
7. Place the Absorbent End of the Test Stick into the extracted sample.
8. Read results at 5 minutes. Positive results may be read as soon as the red Control Line appears. Negative results must be confirmed at 5 minutes.
9. Results are invalid after the read time.

Quality Control:

Internal Procedural Controls:

1. The color of the liquid changes from pink to light yellow after Reagent B is added to Reagent A and the extraction reagents are mixed. This is an internal extraction reagent control. The color change means you have mixed the extraction reagents properly. The color change also means that the reagents are functioning properly.
2. The red Control Line is an internal positive procedural control. For the Test Stick to be working properly, capillary flow must occur. The Test Stick must absorb the proper amount of sample and the Test Stick must be working properly for the red Control Line to appear. **If the red Control Line does not appear the test is invalid**.
3. A clear background is an internal background negative procedural control. If no interfering substances are in the specimen and the Test Stick is working properly, the background will clear. A discernible result will be seen. **If the background does not clear and interferes with the test result, the test is invalid.**

External Controls:
Each kit contains Positive and Negative Control material. The controls are for external quality control testing and are to be run with each new lot.

1. Label one Test Tube each for the Positive Control and the Negative Control.
2. Follow step 1 in the test procedure above to dispense Reagent A and B into the Test Tube. Vigorously mix the Positive Control material. Add 1 free falling drop of the Positive Control from the dropper bottle into the Test Tube. Place a clean swab into the Test Tube. Follow the remaining steps in the procedure above to the test swab.

Reporting Results:

A blue Test Line and a red Control Line is a positive result. A positive result means that the assay detected Group A Streptococcus antigen in the specimen. The blue line can be any shade of blue and can be lighter or darker than the external positive control.

A red Control Line but no blue Test Line is a negative result. A negative result means that no Group A Streptococcus antigen was detected, or the levels of antigen in the specimen were below the detection level of the assay.

If after 5 minutes, no red Control Line appears or the background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test using a new sample or contact Technical Service.

Note: A blue or red line that appears uneven in color density is still considered a valid line. In some cases, a trail of color may remain in the background; as long as the Test Line and Control Line are visible, the results are valid.

Using only the codes from the Microbiology Coded Response Sheet, a positive result should be reported as: **Positive for group A streptococcal antigen** and a negative result should be reported as: **Negative for group A streptococcal antigen**. An additional line stating that the Internal QC is performing as expected must be added to each result. Additionally, the QC lot information must be entered into the result using the “LOTQC” entry code. When a Negative result is reported properly, a culture order will automatically be generated by the system on the same accession number. Reprint the label, and send the specimen out for a Throat Culture.

Limitations & Precautions:

Store Test Sticks and reagents tightly capped at 15°-30°C (59°-86°F).
Do not use Test Sticks or reagents after expiration date.

Caution: Reagent A contains Sodium Nitrite and may be harmful if swallowed. Reagent B contains an acidic solution that will cause skin and eye irritation. If the solution comes in contact with the skin or eyes, flush with large volumes of water. The Positive and Negative Controls contain sodium azide which may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded control down a sink.

Do not interchange or mix components from different kit lots.

As with all diagnostic assays, the results obtained by this test yield data that must be used only as an adjunct to other information available to the physician. The following factors must be considered to obtain reliable results:

1. The Sure-Vue Signature Strep A Test is a qualitative test for the detection of Group A Streptococcal antigen. This test detects both viable and non-viable Group A Streptococci, and may yield a positive result in the absence of living organisms.
2. The quality of the test depends on the quality of the sample; proper throat swab specimens must be obtained. Negative results can occur from inadequate specimen collection or antigen level which is below the detection limit of the test.
3. The Sure-Vue Signature Strep A Test should be used only with throat swab specimens. The use of swab specimens taken from other sites or the use of other samples such as saliva, sputum or urine has not been established.
4. This test does not differentiate between carriers and acute infection.
5. Pharyngitis may be caused by viral or bacterial pathogens other than Group A Streptococcus.

6. If the test result is inconsistent with the clinical presentation, a second throat swab should be collected for repeat testing.

References:

Sure-Vue Signature Strep A Test Package Insert. Sure-Vue is a registered trademark of Fisher Scientific Company.
For technical assistance, call Technical Service at 800-332-1042

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Written By: Jill Hartenstein (CLINICAL LABORATORY SCIENTIST II)	
Distribution:	