A temporary method for flu was in use throughout February, March, and April of 2018 since the usual kits were unavailable. This temporary method will no longer be used as of the end of April 2018. See Attachment 1 for policy.

XIV. Strep A Test			
Effective Date:9/08	Reviewed: 5/2019		Discontinue Date:

A. Purpose/Clinical Usage

The QuickVue In-Line Strep A test allows for the rapid detection of Group A Streptococcal antigen directly from patient throat swab specimens. The test is intended for use as an aid in the diagnosis of Group A Streptococcal infection.

B. Policy

Strep A test will be performed by designated staff that have completed annual competency and training. To provide early detection and treatment, negative Strep screen tests will be reflexed to a throat culture.

C. Clinical Significance

Group A Streptococci is an organism that typically cause illnesses such as tonsillitis, pharyngitis and scarlet fever. These infections can lead to serious complications, including rheumatic fever and acute glomerulonephritis. Rapid diagnosis and appropriate antibiotic therapy of Group A Streptococcal infections appear to be the best means of preventing these complications.

D. Test Principle

The Strep A test is a lateral-flow immunoassay utilizing antigen extraction. The test, containing a highly specific and sensitive antibody reactive to the Strep A antigen, is specific to group A with no cross-reactivity from other groups of Streptococci.

An initial chemical extraction procedure is performed to extract the antigenic component of the bacteria.

The extracted solution flows from the Swab Chamber onto the test strip by capillary action. If Streptococcal A antigens are present in the solution the antigen will bind to the rabbit polyclonal antibody producing a pink/purple test line. A blue control line should always appear. This indicates that capillary flow occurred, and the reagents were mixed and added properly in sufficient volume.

E. Specimen Type

1. Sterile swab from the tonsils or back of the throat area.
2. Specimen should be collected using green shaft swab provided with the kit.
3. A second swab must be collected and is submitted if the Strep A test is negative.

F. Specimen Rejection

1. Specimens other than throat swabs (urine, sputum, or saliva)
2. Swabs other than green shaft swabs
3. Culturettes swabs are not acceptable for the strep test.

G. Reagents and Supplies

1. Reagents or Culturettes should not be used past the expiration date.

2. Extraction Reagent
3. Individually packaged Strep A Test Cassettes (25):
4. Individually packaged sterile rayon-tipped swabs on solid green shafts (25).
5. Positive and Negative Control Swab (-) (1):
6. Culture Transport Swabs

H. Kit Storage and Stability
Kit contents are stable until the expiration date printed on the outer box when stored at room temperature (15-30°C or 59-86°F) and out of direct sunlight. Do not use kits past the expiration date printed on the kit.

I. Quality Control Rationale and Frequency
Test performance will be evaluated annually by comparison of throat cultures performed on negative test results.

Rusk State Hospital Laboratory adheres to the manufacturer's quality control guidelines. Strep A test has two types of quality control checks.

1. Internal Procedure Controls
   Internal Procedural Controls are automatically developed anytime a patient test is performed. Three internal controls, each is described in step 5 & 9 of patient testing procedure. Record observance of these controls in the Strep A test log every time a patient's test is performed.

2. External Procedural Controls
   Each kit contains one positive and negative control swab. The test swabs determine extraction reagent and test cassettes are working correctly in addition to checking the operator technique. A positive and negative swab control should be tested every 25 tests, when a new box is opened, as well as every 30 days.

   If any control does not perform as expected, do not use the results. Repeat the test or call the laboratory supervisor.

J. Patient Preparation
The person collecting the sample must identify the patient using two unique identifiers and following the National Patient Safety Goals.
Inform patient of the purpose of test and the steps involved in collection of the specimen.

K. Specimen Collection, Storage & Rejection
1. Prior to collecting the specimen, two patient identifiers must be used to accurately identify the patient. Refer to patient identification policy for acceptable identifiers.
2. Safety Precautions must be followed when collecting and handling body fluids. Wash hands. Gloves and adequate PPE should be worn at all times.
3. With the aid of a tongue depressor, use the two swabs provided in the collection kit and swab the back of the throat and tonsil area, avoiding the teeth, gums, tongue and cheek surfaces to prevent contamination of the swabs with other mouth flora.
4. Label the paper sleeve & culturettes with the patient's name, case number and the date.
5. Two (2) swabs are collected:
   a. Green Shaft Swabs (provided in kit)

1) Special swabs have green print on the paper wrapper and green shafts. Other swabs will be rejected.
2) The manufacturer recommends that processing be performed as soon as possible, but swabs can be held in any clean, dry plastic tube or sleeve up to 4 hours at room temperature (15-30 degrees C), or 24 hours refrigerated (2-8 degrees C) before processing.

b. Culturettes for reflex throat culture – check expiration date before using.

6. Remove gloves, discard, and wash hands.

L. Test Procedure Precautions

1. Do not use the extraction solution if it is green prior to breaking the ampoule.
2. Use only the green shaft swabs provided in the kit.
3. Dispose of containers and unused contents in accordance with federal, state and local requirements.
4. The test cassette must remain sealed in the protective foil pouch until prior to use.
5. The extraction solution bottle contains an acidic solution. If the solution contacts the skin or eyes, flush with large volumes of water.
6. If the extraction solution bottle is missing the glass ampoule or if the solution is green prior to the breaking of the ampoule, discard and use another extraction solution bottle.

M. Test Procedure

Follow the manufacturer's instructions for performing testing.
Three internal controls must be observed, (see steps 5 and 9) and must be documented in the Strep A Testing Log along with the patient results.

Step	Action
1.	Wash hands. Personal protective gown and gloves must be worn at all times. Check the expiration date on the kit. Do not use past the expiration date. Remove the test cassette from the foil pouch.
2.	Place on a clean, dry, level surface.
3.	Using the notch at the back of the chamber as a guide, insert the green shaft swab completely into the swab chamber.
4.	Squeeze once to cautiously break the glass ampoule inside the extraction solution bottle.
5.	Vigorously shake the bottle five times to mix the solutions. The solution should turn green (first internal control) & be used immediately.
6.	Remove the cap. Quickly fill the chamber to the rim (approximately 10 drops).
7.	Set timer for 5 minutes and begin timing. If the liquid does not move across the results window, completely remove the swab and reinsert.
8.	If the liquid still does not move across, retest with a new specimen, test cassette and extraction solution.
9.	Read results at 5 minutes. Some positive results may appear. Internal procedural controls are observed: development of a blue Control Line (second internal control) indicating the cassette is working properly and the proper amount of sample was absorbed; and the clearing of the background (third internal control) indicating no interfering substances were present in the sample. **A discernible pink to purple line**

	next to the T will appear if the cassette is working properly. Proceed to Interpretation of Results.
10.	Remove gloves, discard, and wash hands.

N. External Quality Control Testing

1. External controls should mimic that of performing a patient sample to ensure validity through method consistency.
2. Remove control swabs from foil packets and proceed with the patient's procedure starting with step one.
3. If controls do not perform as expected, contact the lab supervisor.

O. Interpretation of Results and Confirmatory Testing

1. Positive Result:
   A pink/purple line next to the letter "T" in the result window along with a blue control line next to the letter "C" means that the test is presumptive positive for Group A Streptococcus.
2. Negative Result:
   The appearance of only the blue Control Line next to the letter "C" in the result window means that the test is negative. A negative QuickVue result means that the swab is presumptive negative for Group A Streptococcus. As recommended by the manufacturer, follow up with a throat culture.
3. Invalid Result:
   If the blue control line does not appear next to the letter "C" at 5 minutes, or the background does not clear and interferes with reading the test result, the test is considered INVALID, and the test result cannot be used. A new swab must be collected from the patient if this occurs, and a new test cassette used. Notify the Lab supervisor if this occurs.

P. Expected Results

Group A Streptococci is responsible for about 19% of all upper respiratory tract infections, but the incidence varies by clinical setting. Streptococcal pharyngitis is seasonal in nature with the highest prevalence found during the winter and early spring.

Q. Limitations

1. The test is used for the qualitative detection of Group A Streptococcal antigen from throat swab specimens only.
2. Test results must always be evaluated with other data available to the provider.
3. A negative test result might occur if the level of extracted antigen in a sample is low depending on the sensitivity of the test.
4. A follow-up throat culture is recommended if the Strep A screen is negative.

Citation(s):
QuickVue In-Line Strep A Test. CLIA Complexity: Waived – Company provided pamphlet insert with test kit.