Brown Clinic Northridge
511 14th Ave. NE
Watertown, SD

Brown Clinic
506 First Ave. SE
Watertown, SD

BROWN CLINIC
LABORATORY PROCEDURE MANUAL

PROCEDURE: Quidel Quickvue Dipstick Strep A

PRINCIPLE:
Group A *Streptococcus* is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and serious complications such as rheumatic fever and glomerulonephritis.1 Conventional identification procedures for Group A *Streptococcus* from throat swabs involve the isolation and subsequent identification of viable pathogen techniques that require 24 to 48 hours or longer for results.2
The QuickVue Dipstick Strep A is a lateral-flow immunoassay utilizing Quidel's patented antibody-labeled particles. The test detects either viable or nonviable organisms directly from throat swabs or culture colonies within 5 minutes.
To perform the test, a throat swab specimen is collected. Antigen is extracted from the swab specimen with Reagents A and B. The Dipstick is then added to the extracted sample.
If the sample contains Strep A antigen, a pink-to-purple Test Line along with a blue procedural Control Line will appear on the Dipstick, indicating a positive result. If Strep A antigen is not present, or present at very low levels, only a blue procedural Control Line will appear.

INSTRUMENT, REAGENTS & SUPPLIES:
Each kit contains:

- Individually packaged Dipsticks (25 or 50): Dipsticks coated with rabbit polyclonal anti-Group A Streptococcus
- Extraction Reagent A (1): Contains 4 M sodium nitrite
- Extraction Reagent B (1): Contains 0.2 M acetic acid
- Sterile Throat Swabs (25 or 50)
- Tubes (25 or 50)
- Positive Control (1): Heat-inactivated Group A *Streptococcus* with 0.2% sodium azide
- Negative Control (1): Heat-inactivated Group C *Streptococcus* with 0.2% sodium azide
- Package Insert (1)
- Procedure Card (1)

STORAGE & STABILITY:
Store the kit at room temperature 59–86°F (15–30°C), out of direct sunlight. Kit contents are stable until the expiration date printed on the outer box. Do not freeze.

SPECIMEN REQUIREMENTS:

- Collect throat swab specimens by standard clinical methods. Consult standard reference procedures such as the collection method described by Miller and Holmes.5
- Depress the tongue with a tongue blade or spoon. When swabbing the throat, be careful not to touch the tongue, sides or top of the mouth with the swab.
- Rub the swab on the back of the throat, on the tonsils and in any other area where there is redness, inflammation or pus.
- Use rayon tipped swabs to collect throat specimens. Do not use calcium alginate, cotton tipped or wooden shaft swabs.

It is recommended that swab specimens be processed as soon as possible after collection. Swabs can be held in any clean, dry plastic tube or sleeve up to 72 hours at room temperature (15–30°C), or refrigerated (2–8°C) before processing. The use of charcoal or agar medium is not recommended.

If a culture is desired, lightly streak the swab on a 5% sheep blood agar plate before using the swab in the QuickVue Dipstick Strep A test.
Do not perform the QuickVue Dipstick Strep A test before streaking the swab, as the Extraction Solution will destroy the bacteria on the swab, thereby rendering the organism incapable of successful culturing. Alternatively, throat swab specimens can be obtained by dual swabs or by two sequential swabs for the culture procedure.

CONTROLS:

Built-in Control Features

The QuickVue Dipstick Strep A provides three levels of internal procedural controls with each test run. For daily quality control, Quidel recommends documenting that these internal controls were checked for the first sample tested each day.

- The color of the Extraction Reagent changes from clear to green as the reagents are mixed together. The color change is an internal extraction reagent control and is an indication that the reagents were mixed and functioning properly.
- The appearance of a blue Control Line is an internal control. The Dipstick must absorb the proper amount of sample and the Dipstick must be working properly for the blue Control Line to appear. Additionally, the appearance of the Control Line indicates that capillary flow occurred.
- A clear background is an internal background negative control. If no interfering substances are in the sample and the Dipstick is working properly, the background in the Result area should be white to light pink within 5 minutes and not interfere with the reading of the test result

External Quality Control Testing

External controls may also be used to demonstrate that the reagents and assay procedure perform properly.

Quidel recommends that positive and negative controls be run once for each untrained operator, once for each new shipment of kits - provided that each different lot received in the shipment is tested - and as deemed additionally necessary by your internal quality control procedures, and in accordance with local, state, and federal regulations or accreditation requirements.

If the controls do not perform as expected, repeat the test or contact Quidel Technical

Support before testing patient specimens

Calibration:
Not applicable

PROCEDURE:
Do not remove Dipsticks from the foil pouch until ready to perform the assay.
To avoid cross contamination, do not allow the tip of the reagent bottles to come in

Important:
Gloves should be worn when handling samples.
Do not use Reagent B if the solution is green prior to mixing with Reagent A in the Tube. If this occurs, contact Technical Support.

- Just before testing, add **three (3) DROPS** of Reagent A and **three (3) DROPS** of Reagent B into a clean tube. This solution should turn **green.**
  - When adding drops, hold bottle vertically so that a complete drop forms.
- Immediately add the patient swab sample to the tube.
  - **Squeeze** the bottom of the tube so the swab head is compressed.
- Rotate the swab a **minimum of five (5) times.**
- **Keep swab in tube for one (1) minute.**
- Express **all** liquid from the swab against the inside of the tube.
- **Squeeze** the swab firmly as it is removed from the tube. Discard the swab.
- Remove the Dipstick from the foil pouch. Place the Dipstick into the tube with the arrows of the Dipstick pointing down. Do not handle or move the Dipstick until the test is complete and ready for reading.
- **Read result at five (5) minutes.** Some positive results may appear sooner.

QC TESTING PROCEDURE

- Follow the instruction procedures in the TEST PROCEDURE to dispense the Extraction Reagents into the tube (step 1)
- Vigorously mix the Control Bottles. Add one (1) drop of the Negative or Positive Control into the tube
- Place a clean swab into the tube and follow the instructions for testing the patient swab.

INTERPRETATION:

POSITIVE RESULT:
Any pink to purple Test Line along with any shade of a blue procedural Control Line is a positive result for the detection of Group A *Streptococcus* antigen.

NEGATIVE RESULT:
A blue procedural Control Line and no pink Test Line is a presumptive negative result.

INVALID RESULT:
The test result is invalid if a blue Control Line is not visible at 5 minutes. If this occurs, retest using a new sample and a new Dipstick or contact Technical Support.

REFERENCE RANGE:
Negative

REPORTING:
Report as **positive** or **negative**

LIMITATIONS:

The contents of this kit are for use in the **qualitative** detection of Group A Streptococcal antigen from throat swab specimens and culture colonies only. Failure to follow the test procedure and interpretation of test results may adversely affect performance and/or produce invalid results.

The test detects both viable and nonviable Group A *Streptococci* and may yield a positive result in the absence of living organisms.

Respiratory infections, including pharyngitis, can be caused by *Streptococcus* from serogroups other than Group A as well as other pathogens. The QuickVue Dipstick Strep A will not differentiate asymptomatic carriers of Group A *Streptococcus* from those exhibiting Streptococcal infection.

Some commercial controls may contain interfering additives and are not recommended for use in the QuickVue test.

Test results must always be evaluated with other data available to the physician. A negative test result might occur if the level of extracted antigen in a sample is below the sensitivity of the test or if a poor quality specimen is obtained. Additional follow-up testing using the culture method is recommended if the QuickVue test result is negative.

REFERENCES:

Quidel In-Line Strep A package insert

Origination Date: 5-21-12
Date of Implementation:
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Written By: ____Lori Murray MT(ASCP)_____ Date: _5-21-12_____

Approved By: ___(signature on file)_____ Date: __3/2/2018_____
Laboratory Director

REVIEW - REVISION SUMMARY DOCUMENTATION

Date	By	Revision Summary
2/20/18	Heather Hall	Updated reporting to match LIS