



Quidel Strep A Screening

CHAPTER 10: QUIDEL STREP A SCREENING

Procedure: Quidel Strep A Screening

PRINCIPLE

The Quidel 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.

The traditional means of detecting Group A Streptococcal infections involves bacterial culture. It is also possible to identify group A *Streptococci* by immunological means. The cell walls of Group A *Streptococci* share a common, group-specific, antigenic determinant. This determinant is a carbohydrate consisting of polyrhamnose chains terminating in N-acetyl glucosamine residues.³ Antibodies against this carbohydrate antigen have been used in a variety of tests to identify the group A organism. The QuickVue In-Line Strep A test is a lateral-flow immunoassay utilizing an in-the-device 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*.

To perform the test, a throat swab specimen is collected and inserted into the Swab Chamber of the Test Cassette. Strep A antigens, if present, will bind to the antibody on the pink test label which, in turn, will bind a second rabbit polyclonal anti-Strep A antibody spotted on the membrane, resulting in the formation of a pink-to-purple Test Line. If Strep A is not present, or present at very low levels, only a blue Control Line will be visible.

CLINICAL SIGNIFICANCE

Group A *Streptococci* are organisms that typically cause illnesses such as tonsillitis, pharyngitis and scarlet fever. These infections can lead to serious complications, including rheumatic fever and acute glomerulonephritis.¹ Proper diagnosis and appropriate antibiotic therapy of Group A Streptococcal infections are the best means of preventing these complications.

SPECIMEN REQUIREMENTS

The sterile rayon swabs supplied with this kit must be the only swabs used for specimen collection. These special swabs have green print on the paper wrapper and green shafts.

Depress the tongue with a tongue blade or spoon. 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.⁵

It is recommended that swab specimens be processed as soon as possible after collection. Swabs can be held in a clean, dry plastic tube or sleeve up to 4 hours at room temperature (15-30°C) or 24 hours refrigerated (2-8°C) before processing. If a culture is desired, obtain by dual swabs or two sequential swabs for the culture procedure. Do not perform the Quick Vue In-Line Strep A test before streaking the wab, as the extraction solution will destroy the bacteria, so it will not grow in culture.

REAGENTS

QuickVue In-Line Strep A test kit, 25 tests/kit:

Vendor: Quidel Corp., 10165 McKellar Court, San Diego, CA 92121

Each kit (Quidel Catalog Number 00343) contains:

- 25 Individually packaged Test Cassettes, containing a membrane coated with rabbit polyclonal antibody to Strep A.
- 25 Extraction Solution Bottles (25): 4M Sodium Nitrite (0.6 mL), and 0.2M Acetic Acid (0.65 mL) inside glass ampule.
- 25 Individually packaged sterile rayon-tipped swabs on solid green shafts. Additional swabs can be ordered through the RWJMS POCT office.
- 1 Positive Control Swab of Heat-inactivated Group A *Streptococcus*.
- 1 Negative Control Swab of Heat-inactivated Group C *Streptococcus*.
- 1 Extraction Kit of 5 Tubes and 5 Disposable Droppers for use with Proficiency Testing Samples only.

Kit contents are stable until the expiration date printed on the outer box if stored at **room temperature**, 59-86°F (15-30°C), out of direct sunlight. Do not freeze.

The Test Cassette must remain sealed in the protective foil pouch until just prior to use.

CAUTION:

- The Extraction Solution Bottle contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
- The Extraction Solution Bottle contains glass, break cautiously.
- If the Extraction Solution Bottle is missing the glass ampule, or the solution is green prior to the breaking of the ampule, discard and use another Extraction Solution Bottle.
- Containers and used contents are potentially infectious. Dispose of them in accordingly.⁴

QUALITY CONTROL

Quality Control Material

Control swabs are included with each test kit. Additional control swabs can be obtained from the RWJMS POCT office (Quidel Catalog Number 00345).

External controls also may be used to demonstrate that the reagents have not deteriorated during shipping or storage, and that the assay procedure is being performed properly. The Positive Control Swab (+) is stored in the pink-capped tube; the Negative Control Swab (-) is stored in the blue-capped tube. To test using a Positive or Negative Control Swab, remove the Control Swab from its container and insert it into the QuickVue In-Line Strep A Test Cassette Swab Chamber. Continue with the assay as instructed in the **TEST PROCEDURE** section.

Quality control is performed at a minimum:

- when a new box of reagents is put into use
- once per month if a box of reagent is still in use

If controls do not perform as expected, do not use the reagents. Return them or contact Quidel Technical Support.

The QuickVue In-Line Strep A test also contains built-in control features. If a blue Control Line next to the letter "C" does not develop within 5 minutes, the test result is invalid. If background color remains in the Result Window which interferes with reading the test result, the result is invalid. In this case, repeat the test on a fresh swab, indicate the problem on your test log, and notify the RWJMS POCT coordinator. You may also contact Quidel Technical Support.

PROFICIENCY TESTING

The RWJMS Point of Care Testing program will subscribe to the College of American Pathologists D6 Survey to satisfy the needs of sites that choose to offer Rapid Strep Antigen Detection. There are 3 challenges sent each year in February, June and October.

Proficiency Survey Test Procedure:

The testing procedure for Proficiency Survey Swab specimens is outlined below. **This procedure must be followed to ensure accuracy** because Proficiency Testing swab tips are smaller in size than the swabs provided for use with the kit.

- Place a clean tube from the Extraction Kit in a test tube rack.
- Squeeze to crush the glass ampule inside the Extraction Solution Bottle as described in the **TEST PROCEDURE** Section.
- Dispense **8 DROPS** from the Extraction Solution Bottle into the tube. Place the proficiency swab into the tube. Hold the bottom of the tube so the swab head is slightly compressed. Rotate the swab three (3) times.
- **WAIT ONE (1) MINUTE**

- Express **all** the liquid from the swab head in the Tube by rolling the swab against the inside of the tube and pressing slightly as it is withdrawn from the Tube. Discard the swab.
- Fill the Disposable Dropper **to the fill line** with the solution from the Tube and add the contents into the Test Cassette Swab Chamber.
- Read the result at 5 minutes. See **INTERPRETATION OF RESULTS** Section.

PATIENT TESTING PROCEDURE

Important :

- Gloves should be worn when handling human samples.
- Do not use the Extraction Solution if it is green prior to breaking the ampule.
- Only use the swabs provided in the kit.
- Remove the Test Cassette from foil pouch and place on a clean, dry, level surface. Label the test cassette so that you can identify the patient being tested.
- Using the notch at the back of the chamber as a guide, insert the swab **completely** into the swab chamber.
- Squeeze to crush the glass ampule inside the Extraction Solution Bottle. Vigorously shake the Bottle five times to mix the solutions. Solution should turn green after the ampule is broken. **Solution must be used immediately.**
- Remove the cap. Quickly fill the chamber to the rim (approximately 10 drops).
- **Begin Timing.**
- If liquid has not moved across the Result Window in **1 minute**, completely remove the swab and re-insert. If liquid still does not move across, retest with a new specimen, Test Cassette and Extraction Solution Bottle.
- The Test Cassette should not be moved until the assay is complete.
- **READ RESULTS AT 5 MINUTES.** SOME POSITIVE RESULTS MAY BE SEEN EARLIER.

INTERPRETATION OF RESULTS:

Positive Result :

The appearance of any pink-to-purple line next to the letter "T" in the Result Window, **along with** a blue Control Line next to the letter "C".

Negative Result :

The appearance of only the blue Control Line next to the letter "C" in the Result Window means the test is negative.

Invalid Result :

If the blue Control Line does not appear next to the letter "C" at 5 minutes, or if background color interferes with reading the "C" or "T" line, the test is INVALID and the test result cannot be used. If this occurs, retest using a fresh swab and a new QuickVue Test Cassette. Document the failed test in the testing log and notify the RWJMS POCT coordinator. You may also contact Quidel Technical Support.

LIMITATIONS:

- Respiratory infections can be caused by *Streptococcus* from serogroups other than group A as well as other pathogens.
- The QuickVue In-line Strep A test will not differentiate asymptomatic carriers of Group A *Streptococcus* from those exhibiting streptococcal infection.⁶
- In rare cases, test specimens heavily colonized with *Staphylococcus aureus* ($>10^{10}$) can yield false positive results.
- A The QuickVue In-Line Strep A test will yield positive test results with specimens containing at least 5×10^5 Group A *Streptococci* organisms per test. A negative test result might occur if the level of extracted antigen in a sample is below the sensitivity of the test. **Additional follow-up testing using the culture method is recommended if the QuickVue test result is negative.**

