Test Name/Equipment:	QuickVue In-Line Strep A Test

Date Initiated: 01/26/2012 Date Amended: 06/24/2019 Date Reviewed: 07/07/2022

Intended Use

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. For use by healthcare professionals.

Principle of the Test

To perform the test, a Throat Swab specimen is collected and inserted into the Swab Chamber of the test Cassette. The Extraction Solutions are mixed, resulting in a green color change, and added to the Swab in the Swab Chamber for the antigenic component of the bacteria to be extracted. Extraction begins instantaneously, after which the extracted solution flows from the Swab Chamber onto the test strip by capillary action. The extracted sample flows through a label pad consisting of a pink label containing rabbit polyclonal anti-Strep A antibody and a blue control label. If the extracted solution contains Strep A antigen, the antigen will bind to the antibody on the pink test label which, in turn, will bind a rabbit polyclonal anti-Strep A antibody spotted on the membrane, resulting in the formation of a pink-to-red Test Line. A blue Control Line will also appear next to the letter "C" on the test Cassette indicating that the reagents were mixed and added properly, proper volume of fluid entered the test Cassette and capillary flow occurred. A blue Control Line should always appear in a properly functioning test Cassette. If Strep A is not present or present at very low levels, only a blue Control Line will be visible.

Specimen collection and handling:

The sterile rayon-tipped Swabs supplied with this kit must be the only swabs used for specimen collection.

Collect Throat Swab specimens by standard clinical methods. 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. Consult standard reference procedures such as the collection method described by Facklam.4

Use **only** the rayon-tipped Swabs on green plastic shafts supplied in the kit to collect throat specimens. Other swabs, including other rayon swabs, are incompatible with this test due to their small tip size. 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 4 hours at room temperature (15°C to 30°C), or 24 hours refrigerated (2°C to 8°C) before processing.

Kit Storage and Stability:

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

TEST PROCEDURE

Important:

- Gloves should be worn when handling samples.
- Do not use the Extraction Solution if it is green prior to breaking the ampule.
- **MUST** use the Swabs provided in the kit.

Procedure instructions by step (to be completed in this order)

1. Remove the test cassette from the foil pouch and place on a clean, dry, level surface. Using the notch at the back of the chamber as a guide, insert the swab completely into the Swab Chamber.
2. Squeeze **ONCE** to break the glass ampule inside the Extraction Solution Bottle.
3. Vigorously shake the bottle five (5) times to mix the solutions. Solution should turn green after the ampule is broken. **Solution must be used immediately**
4. Remove the cap. Holding bottle vertically, quickly fill the chamber to the rim. (approximately 8 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.
5. Read results in 5 minutes. Some positive results may be seen earlier.

Interpretation of Results

- **POSITIVE RESULTS**: The appearance of any pink-to-red 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 positive for Group A Streptococcus.

  - Look closely! Even if you see a very faint, pink Test Line and a blue Control Line, you must report the results as POSITIVE. The positive test line is usually very prominent, but test line intensity can vary.

- **NEGATIVE RESULTS**: 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.

- **INVALID RESULTS**: If the blue Control Line does not appear next to the letter "C" at 5 minutes, the test is considered INVALID, and the test result cannot be used. If this occurs, retest using a fresh Swab and a new QuickVue test Cassette or contact Technical Support.

Reporting and Documentation of Results

The nurse will report the results verbally to the Telehealth provider during a consultation, document manually on the Patient Result log located in the clinic, and on the School Telehealth nurse website electronic POC Testing form.

QUALITY CONTROL

Built-in Control Features

The QuickVue In-Line Strep A Test contains built-in control features. The manufacturer's recommendation for daily quality control is to document these controls for the first sample tested each day. A control of the extraction procedure is provided by a color change from clear to green as the extraction solutions are mixed. The color change is an indication of extraction reagent integrity and is also an indication that the extraction procedure was correctly performed.

The two-color result format provides a clear-cut readout for positive and negative results. The appearance of a blue Control Line next to the letter "C" provides several forms of control. First, detection components for the specimen and internal control are processed concurrently using identical procedures; therefore, the appearance of the Control Line ensures that functional activity of the detection component is maintained. Secondly, the appearance of the Control Line also ensures that the foil pouch integrity has been maintained and the test Cassette has been stored in such a manner as not to compromise its functionality. Third, the appearance of the Control Line indicates that proper volume of fluid entered the test Cassette and capillary flow occurred. This would indicate that the test Cassette was assembled properly, by acting as a check for all membrane interfaces and proper positioning of components. If the Control Line does not develop within 5 minutes, the test result is invalid.

A negative background control is provided by the clearing of background color in the Result Window and indicates that there were no immunological interfering substances in the specimen. This area should be white to light pink within 5 minutes and not interfere with the reading of the test result. If background color remains in the Result Window which interferes with your ability to read the test result, your result may be invalid. In this case, contact Quidel Technical Support.

Positive and Negative Quality Control

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 controls do not perform as expected, do not use the test results. Repeat the test or contact Quidel Technical Support.

Limitations of the test method

See manufacturer's package insert.

Expected values, performance characteristics, clinical studies, and literature references

See manufacturer's package insert.

Warnings and Precautions

See manufacturer's package insert.

Quidel QuickVue Strep A Acknowledgement

I have read, reviewed, and certify that I am knowledgeable of the above policy and procedure. I agree to follow the steps required to perform the procedure correctly.

_____	_____
School	**District**

_____	_____	_____
Trainee Name	**Trainee Signature**	**Date**
_____	_____	_____
Trainee Name	**Trainee Signature**	**Date**
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Trainee Name	**Trainee Signature**	**Date**