

Test Procedure

Allow the test strip, reagents, and/or controls to reach room temperature

(15-30°C) prior to use. Do not remove the test strip from the foil pouch until ready to perform the assay.

1. Hold the **Reagent A** (red solution) bottle upright and add **four (4)** full drops (approximately 240 µL) to a disposable extraction tube provided. Hold the **Reagent B** (colorless solution) bottle upright and add **four (4)** full drops (approximately 160 µL) to the same disposable extraction tube. The addition of **Reagent B** to **Reagent A** changes the color of the solution from **red** to **pale yellow**. Tap the bottom of the extraction tube gently to mix the two liquids.
2. Immediately add the patient throat swab into the tube of pale yellow solution. Rotate the swab vigorously **ten (10)** times in the tube. Leave the swab in the tube for **one (1)** minute.
3. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the used swab.
4. Remove the QuStick™ Strep A test strip from the sealed foil pouch, place the QuStick™ Strep A test strip into the tube of solution with arrows pointed down and then start the timer. If the procedure is followed correctly, the solution should be at or just below the maximum line (MAX) on the test strip.
5. Leave the QuStick™ Strep A test strip in the tube and read the result at **five (5)** minutes. Some positive results may appear sooner.

Results

POSITIVE*: **Two (2) distinct red lines appear.** One line should be in the control (C) area and another line should be in the specimen (S) area. A positive result indicates that Strep A was detected in the sample. **ANY shade of red in the specimen (S) area should be considered positive.**

NEGATIVE: **One (1) red line appears in the control (C) area.** No apparent red or pink line appears in the specimen (S) area. A negative result indicates that Strep A is not present in the sample, or is present below the detectable level of the test. It is recommended that a negative patient sample be confirmed by culture to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another sample for culture.

INVALID: **Control line fails to appear in control (C) area.** Insufficient sample volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test strip. If the problem persists, discontinue using the test kit immediately and contact Stanbio's Technical Service Department at 1-800-531-5535.

