

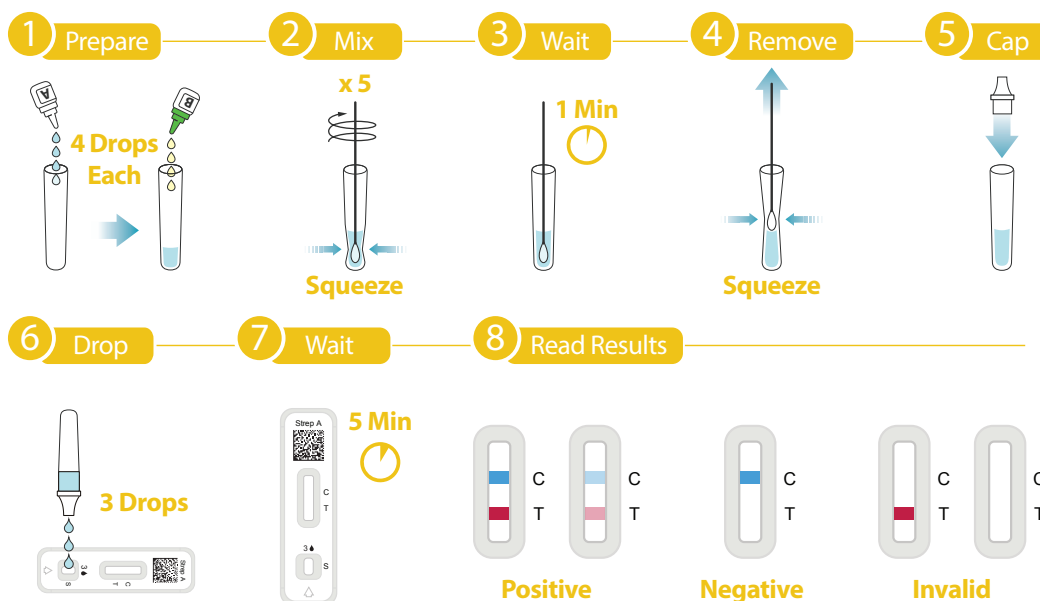
Allow the test, reagents, specimens, and/or controls to reach room temperature, 59-86°F (15-30°C), prior to testing.

Preparing The Test

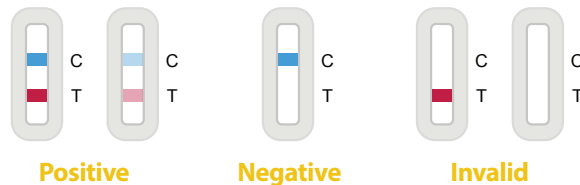
- The Flowflex Plus Strep A Rapid Test Cassette can be performed using throat swab specimens.
- For best results, testing should ideally be performed after specimen collection. If immediate testing is not possible, swab specimens may also be stored in a clean, dry plastic tube for up to 72 hours at room temperature or refrigerated, 36-46°F (2-8°C), prior to testing.
- Throat swab specimens should be collected by healthcare professionals only. Collect the throat swab specimen using the sterile swab provided in the kit. When swabbing the throat, be careful not to touch the teeth, gums, tongue, or cheek surfaces with the swab. Rub the swab on the back of the throat, on the tonsils and in any other area where there is redness or inflammation.

Performing The Test

1. Place the test cassette on a clean, dry, level surface.
2. Hold the Reagent A bottle upside down vertically and add 4 full drops (approximately 160 µL) to the test tube. Hold the Reagent B bottle upside down vertically and add 4 full drops (approximately 160 µL) of Reagent B. Reagent B is yellow in color. Mix the solution by gently swirling the tube. Adding Reagent B to Reagent A changes the color of the solution from colorless to light blue. See illustration 1.
3. Immediately place the swab into the test tube with light blue solution and rotate at least 5 times while squeezing the tube. Leave the swab in the tube for 1 minute. Remove the swab while squeezing the tube to extract as much liquid as possible. Discard the swab. See illustrations 2 to 4.
4. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube. See illustration 5.
5. Add 3 full drops of solution (approx. 90 µL) to the sample well (S) of the test cassette and then start the timer. See illustration 6.
6. Read results at 5 minutes. Do not read results after 8 minutes.



Interpreting The Results



- **POSITIVE:***

If the blue Control (C) line and the red Test (T) line are visible, the test is positive. Any visible faint red or pink test (T) line with a visible control (C) line should be read as positive. A positive result indicates that Strep A was detected in the sample.

*NOTE: The color intensity of the test line may vary depending on the concentration of the Strep A antigen present in the sample. Therefore, any shade of color in the test line region (T) should be considered positive.

- **NEGATIVE:**

If the blue Control (C) line is visible, but the red Test (T) line is not visible, the test is negative. A negative result indicates that Strep A antigen is not present in the sample or the levels of antigen in the sample were below the detectable level of the test. It is recommended that a negative patient sample be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another sample for culture.

- **INVALID:**

If the blue Control (C) line is not visible, the test is invalid. Insufficient specimen volume or incorrect procedural technique are the most likely reasons for control line failure. Review the procedure and repeat the test with a new swab and a new test cassette. If the problem persists, discontinue using the test and contact Customer Support.