Flowflex® PLUS Strep A Rapid Test Cassette

Quick Reference Instructions | IVD | Rx ONLY

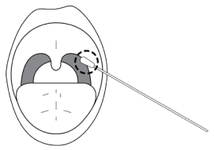
CLIA Complexity: WAIVED
For prescription use only. For *in vitro* diagnostic use.
For use with throat swab specimens.

Read the complete test procedure, including recommended QC procedures before performing the test. Refer to the package insert for complete information about the test.

A Certificate of Waiver is required to perform this test in a CLIA Waived environment. Laboratories with a Certificate of Waiver must follow the manufacturer's instructions for performing the test 42 CFR 493.15(e)(1).

Failure to follow the instructions or modifications to the test instructions will result in the test no longer meeting the requirements for waived classification (i.e., test will be high-complexity).

Collecting The Sample



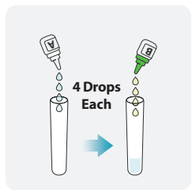
- Use the swab in the kit to collect a sample from the throat. Be careful not to touch the teeth, gums, tongue, or cheek surfaces with the swab.
- Rub the swab on the back of the throat, on the tonsils, and on any red or swollen areas.

Try to test the sample right after you collect it. If immediate testing is not possible, put the swab in a clean, dry plastic tube. You may keep samples at room temperature or in the fridge 36–46°F (2–8°C) for up to 72 hours before testing.

How To Do The Test

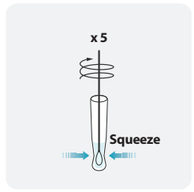
1. Remove the test cassette from the sealed pouch and use it as soon as possible. Place the test cassette on a clean, dry, level surface.

2. Hold the Reagent A bottle upside down vertically. **Add 4 full drops** into the test tube. Then do the same with the Reagent B bottle, **add 4 full drops**. Reagent B is yellow. Gently swirl the tube to mix the liquids. When Reagent B is added to Reagent A, the color changes from clear to light blue.



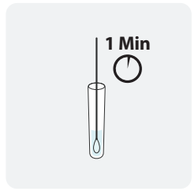
3. Immediately, put the swab into the test tube with the light blue liquid. **Rotate** it at least **5 times** while gently squeezing the tube.

⚠ Not rotating the swab 5 times can lead to an inaccurate result.

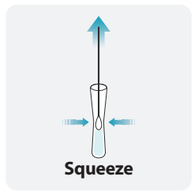


4. Leave the swab in the tube for 1 minute.

⚠ Not leaving the swab for 1 minute can lead to an inaccurate result.



5. Remove the swab while squeezing the tube to extract as much liquid as possible. Discard the swab.



6. Attach the dropper tip firmly onto the tube. Mix thoroughly by swirling or flicking the bottom of the tube.



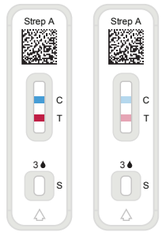
7. **Add 3 full drops** of the solution into the sample well (S) on the test cassette. Then start the timer.



8. **Read results at 5 minutes.**



How To Read The Results



Positive

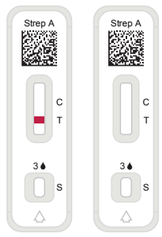
If the blue Control (C) line and the red Test (T) line are visible, the test is positive. A positive result indicates that Strep A was detected in the sample.

Note: The color of the test line may be light or dark depending on the concentration of Strep A antigen is in the sample. Any color in the test line area (T) means the result is 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 means there is no Strep A antigen 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. Not enough sample or doing the testing procedure wrong are the most likely reasons the control line does not show up. Review the procedure and repeat the test with a new swab and a new test cassette. If the problem persists, stop using the test and contact Customer Support.

Testing External Controls

Each kit has one positive control bottle and one negative control bottle. The positive control is non-infectious heat-inactivated Strep A bacteria with buffer and stabilizer. The negative control is heat-inactivated Strep C bacteria with buffer. Besides your lab's standard quality control procedure, it is recommended to test the positive and negative controls once for every new user who is not trained, and once for each new shipment of kits. Be sure to test each different lot in the shipment. This helps make sure the test cassette and steps are done correctly. Other commercial controls are not recommended.

How To Test Controls

1. Add 4 full drops of Reagent A and 4 full drops of Reagent B into a test tube. Mix the solution by gently swirling the tube.

2. Shake the control solution bottle vigorously. Hold the bottle upside down vertically. Add 1 full drop of positive or negative control solution into the test tube.

3. Place a new swab into the tube and swirl at least 5 times. 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.

4. Follow Step 4 of the "DIRECTIONS FOR USE" section.

Note: If the controls do not work as expected, do the test again or contact Customer Support.

Safety information

- Do not use the test kit beyond the expiration date printed on the pouch.
- This test is only for use in patients with symptoms of pharyngitis.
- Negative results are presumptive and should be confirmed by culture.
- Keep the test in the original sealed pouch. Store it at room temperature or in the fridge between 36–86°F (2–30°C).
- DO NOT FREEZE any of the test kit components below 32°F (0°C).

Support

If you have any questions about this product, please contact Customer Support at 1-800-838-9502.

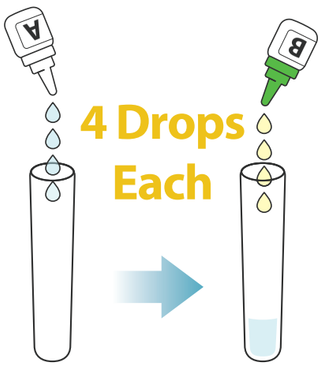
IVD | Rx ONLY | 2°C 36°F | 30°C 86°F | REP | LOT

For symbol glossary, refer to the Package Insert

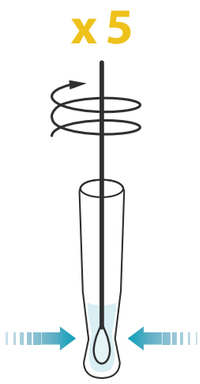
ACON®
***ACON* Laboratories, Inc.**
San Diego, CA 92121, USA
aconlabs.com
Customer Support: 1-800-838-9502

Number: 1150000694
Effective Date: 2026-10-29

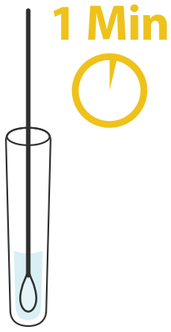
1 Prepare



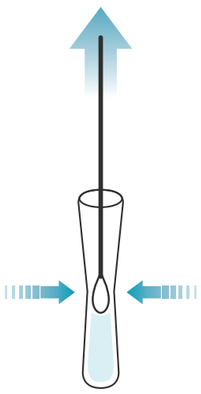
2 Mix



3 Wait



4 Remove



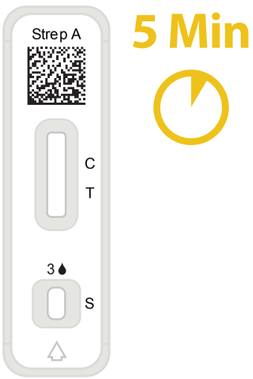
5 Cap



6 Drop



7 Wait



8 Read Results

