

Acceava® Strep A

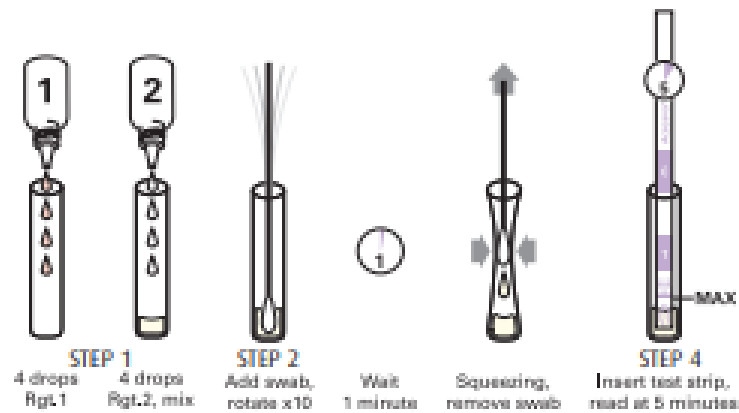
SPECIMEN COLLECTION AND PREPARATION

- Only use reagents provided in the kit.
- Use of the sterile polyester swab supplied in the test kit is recommended. Swabs from other manufacturers have not been validated.
- Rayon transport swabs containing modified Stuart's or Amies liquid medium can also be used with this product.
- Swab the posterior pharynx, tonsils, and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.⁴
- Testing should ideally be performed immediately after the specimens have been collected. Swab specimens may be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C.
- If a culture is desired, lightly roll the swab tip onto a culture plate before using the swab in the Acceava Strep A test.

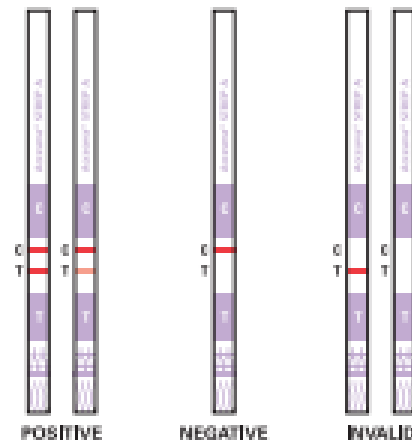
DIRECTIONS FOR USE

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

1. Hold the Reagent 1 bottle upright and add 4 full drops (approximately 240 µL) to an extraction test tube. Reagent 1 is red in color. Hold the Reagent 2 bottle upright and add 4 full drops (approximately 160 µL) to the tube. Reagent 2 is colorless. The addition of Reagent 2 to Reagent 1 changes the color of the solution from red to very faint yellow. Tap the bottom of the tube gently to mix the liquid. See step 1 in the illustration below.
2. Immediately add the throat swab into the tube of very faint yellow solution. Vigorously mix by rotating the swab forcefully against the side of the tube 10 times. Leave the swab in the tube for 1 minute. Then 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 swab. See step 2 in the illustration below.
3. Remove the test strip from the canister and use it as soon as possible. Best results will be obtained if the test is performed immediately. Immediately close the canister tightly after removing the test strip. Record initial opening date on the canister. Once opened, the remaining test strips are stable for 12 months.
4. With arrows pointing down, place the test strip into the tube of solution and then start the timer. If the procedure is followed correctly, the liquid should be at or just below the maximum line (MAX) on the test strip. See step 4 in the illustration below.
5. Leave the strip in the tube and read the result at 5 minutes. The result is invalid after 10 minutes.



INTERPRETATION OF RESULTS



POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). A positive result indicates that Strep A was detected in the sample.

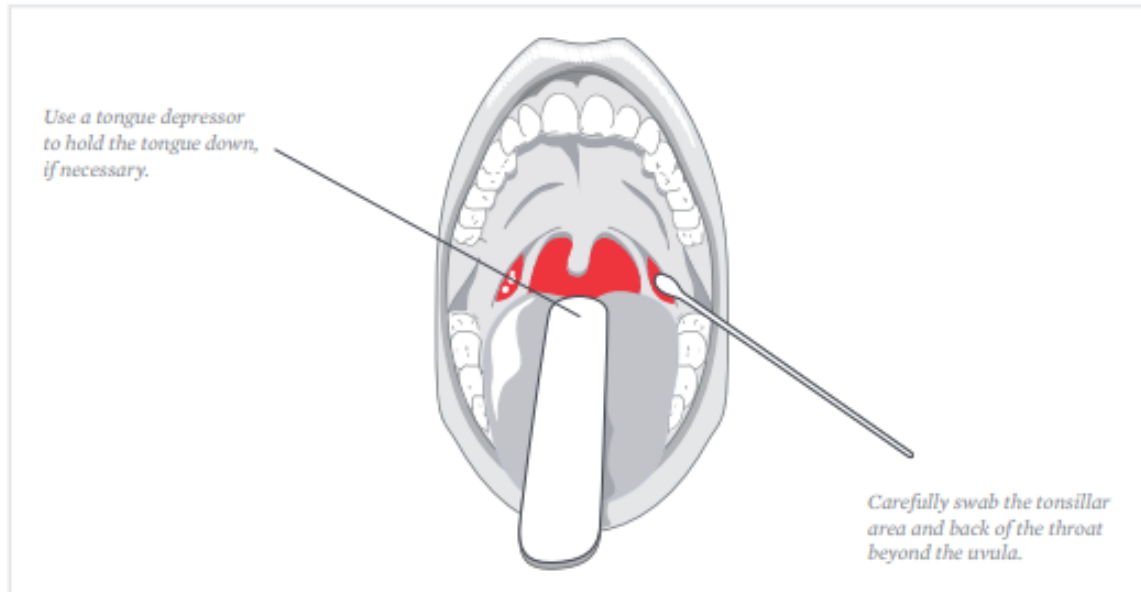
NOTE: The intensity of the red color in the test line region (T) will vary depending on the concentration of Strep A present in the sample. Therefore, any shade of red in the test region (T) should be considered positive.

NEGATIVE: One red line appears in the control region (C). No apparent red or pink line appears in the test region (T). A negative result indicates that Strep A is not present in the sample, or is present below the detectable level of the

INVALID: Control line fails to appear. 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 Alere Technical Support at 866-216-0094.

TECH TIPS

COLLECTION OF A PROPER STREP A THROAT SWAB



IMPORTANT REMINDERS

- **Swab the area with a back and forth motion – do not merely touch the area.** Swabbing is required to remove organisms adhering to the surface of the throat.
- **Aim for white patches.** Streptococcal bacteria are frequently found in white patches in the tonsillar area.
- **Avoid contact with the lips, teeth, cheek, gums, uvula and tongue.** Contact with these areas may contaminate the sample.
- **When using dual swabs, collect bacteria on both sides of the swab head and rub the two swab heads together.** Rubbing ensures even distribution of the sample.

For optimal performance, use the swabs provided in the test kit.