

OREGON HEALTH & SCIENCE UNIVERSITY  
Hospitals and Clinics  
Point of Care

**Strep A by Acceava**

Principle

The BioStar Acceava Strep A Test is a qualitative, lateral flow immunoassay for the detection of Strep A carbohydrate antigen in a throat swab. In this test, antibody specific to Strep A carbohydrate antigen is coated on the test line region of the strip. During testing, the extracted throat swab specimen reacts with antibody specific to Strep A carbohydrate that is coated onto particles. The mixture migrates along the membrane. If the Group A Streptococcus antigen is present in the sample, it will form a complex with the anti-Group A Streptococcus antibody conjugated color particles. The complex will then be bound by the anti-Group A Streptococcus capture antibody and a visible red Test Line will appear to indicate a positive result. To serve as a procedural control, a red line will always appear in the control region if the test has been performed properly. If a red line does not appear in the control region, the test result is invalid.

Specimen Requirements

1. Pharyngeal swab collected with a sterile polyester swab provided in the test kit.
2. Specimens collected from sources other than the throat or nasopharynx are unacceptable. Take care to avoid teeth, gums, tongue, or cheek surfaces.
3. Swabs with wooden shafts, calcium alginate, or cotton tips are unacceptable.
4. Transport in Modified Stuart's liquid transport media is acceptable. Semi-solid transport media or media containing charcoal cannot be used.
5. Test the throat swab specimens as soon as possible after collection. Swabs can be stored in a clean, dry plastic tube at room temperature (15-30°C) for up to 8 hours or refrigerated (2-8°C) for up to 72 hours. Allow refrigerated swabs to reach room temperature (15-30°C) prior to testing.
6. If a culture is also required, streak the culture plate with the swab before testing, or collect two separate swabs.

Interferences

1. Poor throat swab collection technique may produce false negative results.
2. Excess blood or mucous on the swab specimen may interfere with the test performance and may yield a false positive result.
3. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collection specimens.
4. If the level of antigen present in a sample is below the sensitivity of the test, the result will be a false negative. Studies have shown that the Acceava Strep A test kit detected 96% of low and medium positive samples.
5. The Acceava Strep A Test does not differentiate between viable and nonviable Group A Streptococci.

6. This test kit does not differentiate between carriers and of Group A Streptococci and acute infection.

#### Reference Range

Negative.

#### Critical Range

N/A

#### Linearity

N/A

#### Quality Control

Built In Control Features Include:

1. *Extraction Reagent Controls*: The color of the liquid changes from red to pale yellow as you add Extraction Reagent 2 to Extraction Reagent 1. The color change means that you mixed the extraction reagents properly. The color change also means that the reagents are functioning properly.
2. *Internal Control*: The red Control Line is an internal control. The test stick must absorb the proper amount of sample and the test stick must be working properly for the red Control Line to appear. For the test stick to be working properly, the capillary flow must occur.
3. *Test Surface Control and Reference Check*: A clear background is an internal background negative control. If no interfering substances are in the specimen and the test stick is working properly, the background in the Control Line area will clear, and a discernable result will be seen.

- External Quality Control Procedure:

**Both levels of External Quality Control (QC) are to be performed when a new test kit is opened. Mark the date of QC on the outside of the box.**

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

1. Dispense 4 drops of Reagent 1 (pink to light red) and 4 drops of Reagent 2 to the Test Tube. Gently mix the liquid in the tube, the solution should turn light yellow.
2. Add 1 full drop of Positive Control from dropper bottle into the tube.

3. Place a clean swab into the tube. Rotate the swab 10 times in the tube. Leave the swab in the tube.
4. Proceed to step 3 of the Extraction Procedure below and Assay the swab as if it were a patient sample.

Repeat steps 1-4 with Negative Control added to the tube.

5. The Positive Control solution should yield a positive result. The Negative Control Solution should yield a negative result.
6. Record QC results, date, initials, lot number and expiration date of QC used, and lot number and expiration date of Strep kit used onto the QC log sheet.
7. If QC fails, repeat QC test.
8. If repeat QC fails, do not perform patient testing. Contact Technical Support or Point of Care at 4-6788. Document all action taken in the POCT QC Notebook.

#### Procedure

1. Just before testing, add 4 drops of Reagent 1 (pink to light red) and 4 drops of Reagent 2 to the Test Tube. The solution should turn light yellow.
2. Immediately insert patient's throat swab into the Test Tube of pale yellow solution. Rotate the swab 10 times in the tube. Leave the swab in the tube.
3. Let stand 1 minute.
4. Express as much liquid as possible from the swab by squeezing the sides of the tube as the swab is withdrawn.
5. Discard the swab.
6. Remove Test Stick from the container. Recap the container immediately.
7. Place the Absorbent End of the Test Stick (arrows pointing down) into the extracted sample.
9. Read the results in 5 minutes. A positive result may be read as soon as the red Test Line AND the red Control Line appear. Weak positive and negative results require the 5 minutes.

**Note: Do not read the results after 10 minutes.**

#### Calculations

N/A

## Results Reporting

1. *Positive Result:* A red Test Line AND a red Control Line MUST be present for a test result to be positive for the detection of Group A Streptococcus antigen. **Note:** A red line which appears uneven in color density is considered a valid result. In cases of moderate or high positive specimens, some red color behind the Test Line may be seen; as long as the Test Line and Control Line are visible, the results are valid.
2. *Negative Result:* The presence of a red Control Line but no red Test Line is a negative result.

*Invalid Result:* If no red Control Line appears or background color makes reading the red Control Line impossible, the result is invalid. If this occurs, repeat the test using a new Test Stick or contact Inverness Medical Technical Services at 800-637-3717.

3. Document test results in the patient's electronic medical record in EPIC, along with the result of the Internal Quality Control marked as 'passed'.
4. **Adult Patients (Age 16 and up):** In 2011, a survey was performed comparing results from the negative POCT rapid strep test and results from confirmatory cultures. The results for this group showed an 8% positive culture rate when the POCT screen was negative. For these patients, it is optional to perform a culture for Group A Strep if the POCT test is negative. However, If the patient has a documented history of/ or is being evaluated for, rheumatic fever, or if there is an investigation of an outbreak of Group A Strep disease, then a culture is recommended.
5. **Pediatric Patients (Age 15 and below):** In 2011, a survey was performed comparing results from the negative POCT rapid strep test and results from confirmatory cultures. The results for this group showed a 14% positive culture rate when the POCT screen was negative. For these patients, a culture for Group A Strep **should be** performed if the POCT test is negative.

## Calibration

N/A

## Reagents

1. The BioStar Acceava Strep A test kit:
  - a. Store at room temperature (15°-30°C) until the expiration on the box.
  - b. Keep Test Strips and reagents tightly capped.
  - c. Once opened strips expire after 12 months.
2. Positive Control:
  - a. Contains nonviable Group A Streptococci.
  - b. Contains 0.1% Sodium Azide.
  - c. Store at room temperature (15°-30°C) until the expiration on the box.
3. Negative Control:
  - a. Contains nonviable Group C Streptococci.
  - b. Contains 0.1% Sodium Azide.
  - c. Store at room temperature (15°-30°C) until the expiration on the box.

**Note: Sodium Azide may react with lead or copper plumbing to form potentially explosive metal azide. Large quantities of water must be used to flush discarded control material down a sink.**

4. Reagent 1:
  - a. Contains 2 M sodium Nitrite.
  - b. Store at room temperature (15°-30°C) until the expiration on the box.
5. Reagent 2:
  - a. Contains 0.3 M Acetic Acid.
  - b. If this solution comes into contact the skin or eyes, flush with large volumes of water.
  - c. Store at room temperature (15°-30°C) until the expiration on the box.

## References

1. Bisno, A.L., Stevens, D.L., Streptococcus Pyogenes, in Principles and Practice of Infectious Diseases, 5<sup>th</sup> Edition, Mandell, G.L., Bennett, J.L., Dolin, R., Churchill Livingstone, Philadelphia, PA, 2101-2117, 2000.
2. Bisno, A.L., Nonsuppurative Poststreptococcal Sequelae: Rheumatic Fever and Glomerulonephritis, in Principles and Practice of Infectious Diseases, 5<sup>th</sup> Edition, Mandell, G.L., Bennett, J.L., Dolin, R., Churchill Livingstone, Philadelphia, PA, 2117-2128, 2000.
3. American Academy of Pediatrics, Summaries of Infectious Diseases, in Pickering, L.K., ed. 2000 Red Book: Report of the Committee on Infectious Diseases, 25<sup>th</sup> ed. Elk Grove Village, IL, 526-536, 2000.
4. Thermo BioStar Acceava STREP A Test Package Insert, 12/2008.
5. CLSI Procedure provided by Medical Professional Diagnostic, Inverness Medical 10/31/2006.

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Rapid Strep A Quality Control Logsheet

Both Positive and Negative Control Solutions must be tested when a new box is opened.  
Mark and initial the box with the QC date. The solutions in the box are good until the expiration date printed on the box.

Once opened, the cylinder of strips is good for 12 months.

Mark the expiration date on the cylinder.

Date	Initials	Box Lot # Expiration Date	Quality Control Lot # Expiration Date	Result	Internal Control Area Result
			Positive:		
			Negative:		
			Positive:		
			Negative:		
			Positive:		
			Negative:		
			Positive:		
			Negative:		
			Positive:		
			Negative:		
			Positive:		
			Negative:		
			Positive:		
			Negative:		
			Positive:		
			Negative:		
			Positive:		
			Negative:		