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Owner	Jeanna Begay
Area	Administrative - Waived Testing
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References	WT.01.01.01, WT.04.01.01, WT.05.01.01

Acceava Rapid Strep A Test

INTENDED USE

The Acceava Strep A Test is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigen from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

SUMMARY AND EXPLANATION OF TEST

Group A *Streptococcus* is one of the most important causes of acute upper respiratory tract infection. Early diagnosis and treatment of Group A Streptococcal pharyngitis has been shown to reduce the severity of symptoms and further complications such as rheumatic fever and glomerulonephritis. Conventional identification procedures for Group A *Streptococcus* from throat swabs involve the isolation and subsequent identification of viable pathogens by techniques that require 24 to 48 hours or longer.

PRINCIPLES OF TEST

The 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 an antibody to Strep A that is coated on particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and produces a red line in the test region. The presence of this red line indicates a positive result and its absence indicates a negative 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 control line does not appear, the test result is not valid.

STORAGE

- Store test kit at room temperature or refrigerated (2°-30°C).
- The test strip must remain in the closed canister until use.
- The unopened canister of test strips and the reagents are stable through the expiration date. Once the canister is opened, the remaining test strips are stable for 12 months.
- Do not use beyond the expiration date.
- Do NOT freeze.
- Allow the test strip, reagents, and/or controls to reach room temperature (15-30°C) prior to testing.

MATERIALS REQUIRED

- Timer
- Acceava Strep A Test kit

PRECAUTIONS

- For in vitro diagnostic use.
- Personal protective equipment (disposable gloves, etc.) should be worn when specimens are assayed. Handle all specimens as if they contain infectious agents.
- Reagent 1 is harmful if swallowed or absorbed through skin. May cause eye irritation.
- Reagent 2 contains an acidic solution. If the solution comes in contact with the skin or eyes, flush with large volumes of water.
- Do not interchange reagent or external control solution bottle caps.
- Do not interchange or mix components from different kit lots.
- The positive and negative controls contain sodium azide as a preservative.

SPECIMEN COLLECTION AND PREPARATION

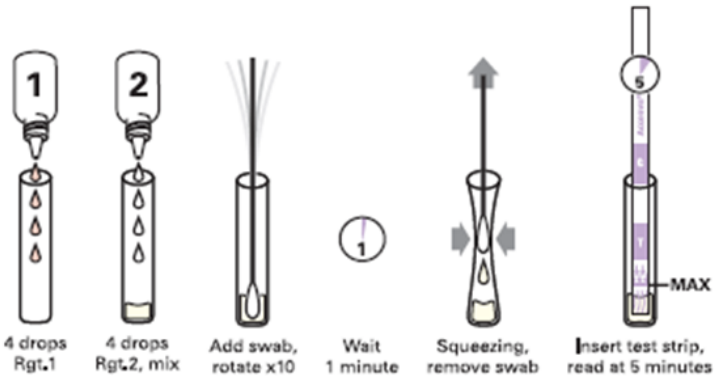
- Only use reagents provided in the kit.
- Use of sterile polyester swab supplied with the kit is recommended. Swab with transport tubes containing liquid media can also be used. Modified Stuart's or Amies Transport Media are an acceptable liquid medium. Swabs from other suppliers have not been validated. Do not use swabs that have cotton tips or wooden shafts. Do not use calcium alginate swabs. Do not use a collection system that contains charcoal or semisolid transport media.
- Two swabs must be collected, one to perform the test and the other for throat culture if test is negative. Two swabs are preferred because the extraction reagents will cause the organism to become nonviable. If only one swab is received, a culture is required to be set-up and the culture plate must be inoculated first.
- Collect specimens with a sterile swab from the posterior pharynx, tonsils, and/or other inflamed areas. Take care to avoid the tongue, cheeks and teeth with the swab.

- The swab should be tested as soon as possible after collecting the specimen. If testing is not performed immediately, swab specimens may be stored at room temperature (15-30°C) for up to 8 hours or refrigerated at 2-8 C° for up to 72 hours. Allow refrigerated swabs to reach room temperature (15-30°C) prior to testing.

DIRECTIONS FOR USE

The test strips, reagents and/or controls should be at room temperature (15-30°C) prior to testing.

1. Hold the reagent 1 bottle upright and add 4 full drops to an extraction test tube. Reagent 1 is red in color. Hold the Reagent 2 bottle upright and add 4 full drops to the tube. Reagent 2 is colorless. The addition of Reagent 2 to Reagent 1 changes the color of the solution from red to pale yellow. Tap the bottom of the tube gently to mix the liquid.
2. Immediately add the throat swab into the tube of pale 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 middle of the tube while removing the swab so that most of the liquid stays in the tube. Discard swab. See the illustration of the test procedure on the test kit box.
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. Close the canister tightly after removing the test strip. Record the 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.
5. Leave the strip in the tube and read the result at 5 minutes.
   NOTE: The result is invalid after 10 minutes.



INTERPRETATION OF RESULTS

Please see image below.

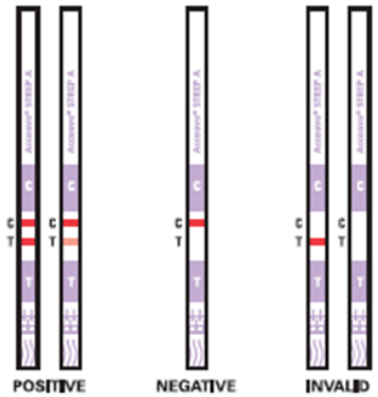
POSITIVE: Two distinct red lines appear. One line should be in the control region (C) and another line should be in the test region (T). A positive results indicates that Strep A was detected in the sample.

- **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 test.

- A NEGATIVE test result must have a throat culture ordered to confirm absence of Strep A infection.

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 the laboratory.



QUALITY CONTROL

Internal Procedural Controls

- Internal procedural controls are included in the test.
- The Acceava Strep A Test provides two levels of procedural internal controls with each test run. For daily quality control, the manufacturer recommends documenting these controls on each day of testing.
    1. The red line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
    2. A clear background is an internal negative background control. If the test is working properly, the background in the results area should be white to light pink and not interfere with the ability read the test result.

External Quality Control Testing

- *The nursing staff or laboratory must perform external quality controls on each kit before use.*
- The manufacturer recommends that positive and negative external controls be run once per kit.

- External positive and negative controls are supplied in the kit. Alternatively, other Group A and non-Group A *Streptococcus* ATCC reference strains may be used as external controls.
- Must document external and internal quality control on Quality Control Log.

QC Testing Procedure

1. Add 4 full drops of Reagent 1 and 4 full drops of Reagent 2 into an extraction test tube. Tap the bottom of the tube gently to mix the liquid.
2. Add 1 full drop of positive or negative control solution into the tube, holding the bottle upright.
3. Place a clean swab into the tube. Rotate the swab 10 times in the tube. Leave the swab in the tube for 1 minute.
4. 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 the swab.
5. Continue as you would for a patient sample starting with step 3 of the Test Procedure.

RESULTS REPORTING

Reference Range: Negative

DOCUMENTATION OF PATIENT AND PERFORMANCE CONTROL RESULTS

Results must be documented along with the initials of personnel performing the test and the date the test was performed. A functional audit trail must be maintained that allows retrieval of results.

A. Results and internal QC are to be recorded on the patient and/or QC log.
    - Must document the results of the Internal Quality Control (i.e. "Acceptable" or "Invalid").
    - **Do not report patient results unless quality control is acceptable.**
B. Document date and time the test was performed, clinical sign or symptom, medical provider, and two patient identifiers.
C. The initials of point of care testing personnel performing patient testing must be documented on log.
D. Results must be entered into E.H.R. using the POC Lab Entry button. See the "Electronic Health Record POC Lab Entry Button for Entering Point of Care Test Results Procedure" for detailed instructions.

LIMITATIONS

- The Acceava Strep A Test has been categorized as CLIA waived only for the application of qualitative detection of Group A Streptococcal Antigen from throat swabs.
- This test will only indicate the presence of Strep A antigen in the specimen from both viable and non-viable Group A *Streptococcus* bacteria.

- A negative result may be obtained if the concentration of the Strep A antigen in the throat swab is not adequate or is below the detectable level of the test.
- Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
- As with all diagnostic tests, all results must be interpreted together with other clinical information available to the medical provider.
- Manufacturer recommends that a negative rapid test be followed up with throat culture.

PERFORMANCE CHARACTERISTICS

In a multi-center evaluation, the Acceava Strep A test results were compared to culture results. The following results were obtained:
Sensitivity = 97% (91% to 99%)
Specificity = 95% (92% to 97%)

REFERENCE

Acceava® Strep A product Insert, Alere San Diego Inc.; 1155801211 © 03/2018; Phone 866-216-0094. Product No.92001.

Approval Signatures

Step Description	Approver	Date
Medical Officer Pathologist	Noelle Blue Arm: Medical Officer Pathologist	02/2024
Chief Nurse Executive	Rachel Hamblin: Chief Nurse Executive	02/2024
Lab Supervisor	Kendrick Fritz: Supervisory Medical Technologist	02/2024
Director of Quality Management	Jose Burgos: Public Health Nurse Director	02/2024
Medical Technologist	Jeanna Begay	01/2024
	Jeanna Begay	01/2024

Applicability

Hopi Health Center