SPECTRUM
MEDICAL DIAGNOSTICS

Strep A Rapid Test

QUICK REFERENCE INSTRUCTIONS

Please refer to the Package Insert for complete instructions. Read the complete test procedure before performing the test.

Before Running The Test

- Before running the test, please ensure that you have read all the information in this package insert.
- The Strep A Rapid Test Device (Swab) is intended for professional in vitro diagnostic use only.
- Follow the specimen collection and preparation instructions carefully, and make sure all materials are at room temperature before testing.

Intended Use

- The Strep A Rapid Test Device (Swab) is specifically designed for the qualitative, presumptive detection of Group A Streptococcus antigens in human throat swab specimens.
- It serves as an aid in the diagnosis of Strep A infection, allowing for early detection and timely treatment, which can reduce the severity of symptoms and prevent complications such as rheumatic fever and glomerulonephritis.
- This test is intended for point-of-care use, providing healthcare professionals with a rapid visual immunoassay that can be performed on-site, enabling immediate diagnosis and administration of appropriate therapy.

Warnings & Precautions

1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. The test should remain in the sealed pouch until ready to use. Do not use if foil is damaged.
3. This kit contains products of animal origin. Although efforts are made to ensure safety, there is still a potential risk of transmissible pathogenic agents. Treat these products as potentially infectious and handle them with appropriate safety precautions.
4. To avoid cross-contamination, use a new extraction tube for each specimen obtained.
5. Read the entire procedure carefully prior to testing.
6. Do not eat, drink, or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards and follow standard procedures for the proper disposal of specimens. Wear protective clothing such as laboratory coats, disposable gloves, and eye protection when handling specimens.
7. Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
8. Reagents 1 and 2 are slightly caustic. Avoid contact with eyes or mucous membranes. In case of accidental contact, wash thoroughly with water.
9. The positive control contains sodium azide, which can react with lead or copper plumbing to form potentially explosive metal azides. Always flush solutions containing sodium azide with copious amounts of water when disposing of them to prevent azide buildup.
10. Humidity and temperature can adversely affect test results.

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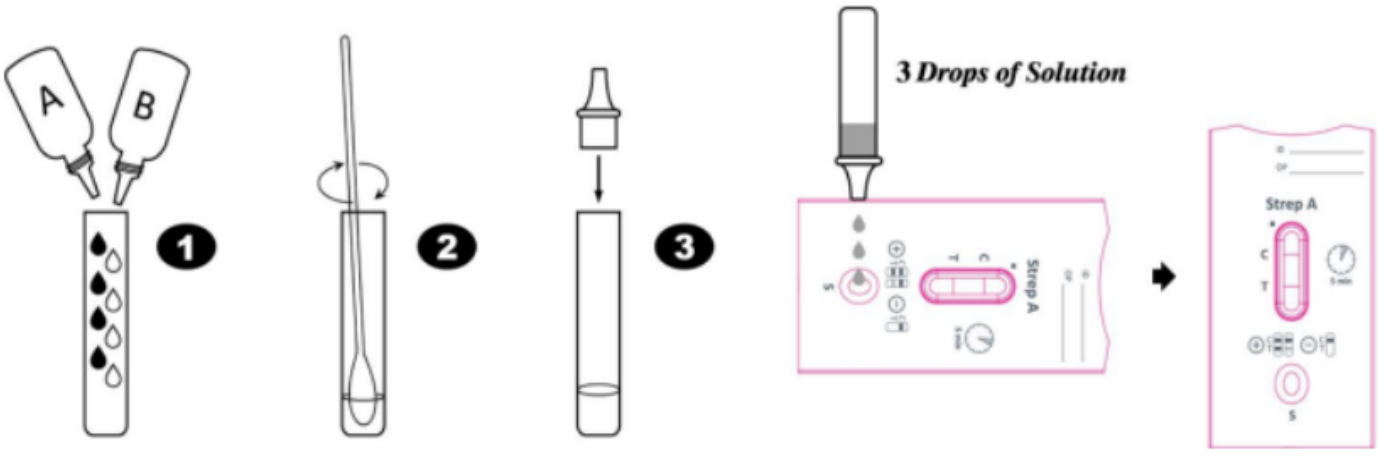
Specimen Collection

1. Instruct the patient to open their mouth wide.
2. Direct the swab tip towards the tonsillar area, avoiding contact with other areas of the mouth.
3. Rub the swab tip quickly and firmly over the tonsillar area to obtain a throat swab.
4. Remove the swab from the mouth without touching any surface.
5. If immediate processing is not possible, place the swab in a sterile, tightly capped tube or bottle and refrigerate. Do not freeze. Allow the swab to reach room temperature before testing.

Preparation of Swab Specimens

1. Place a clean extraction tube in the designated area of the tube stand. Add 4 drops of Reagent 1 (1.0 M sodium nitrite) to the extraction tube, followed by 4 drops of Reagent 2 (0.4 M acetic acid). Gently swirl the extraction tube to mix the solution.
2. Immediately immerse the swab into the extraction tube and use a circular motion to roll the swab against the side of the tube. This allows the liquid to be expressed from the swab and reabsorbed.
3. Let the swab stand for 1-2 minutes at room temperature, and then squeeze the swab firmly against the tube to expel as much liquid as possible. Discard the swab according to handling guidelines for infectious agents. Attach the nozzle onto the extraction tube.



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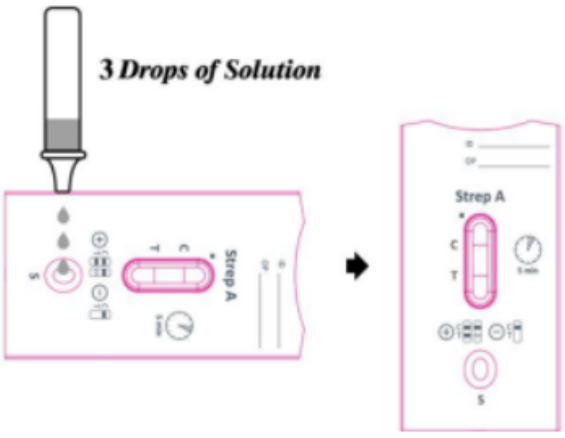
Test Procedure

1. Remove the test device from its sealed pouch and place it on a clean, level surface.
2. Label the device with patient or control identification.
3. Add 3 drops (approximately 120 µL) of the extracted solution onto the sample well on the test device. Ensure there are no air bubbles in the specimen well (S), and do not add any solution to the observation window.
4. Allow the test to work, and observe the migration of colour across the membrane.

Result Determination

1. After **5 minutes**, observe the appearance of coloured bands on the membrane.
2. A positive result is indicated by the presence of two coloured bands: one in the control region (C) and another in the test region (T).
3. A negative result is indicated by the presence of a single coloured band in the control region (C) and the absence of a coloured band in the test region (T).
4. If the control band fails to appear, the test is considered invalid, and the result must be discarded. Review the procedure and repeat the test with a new device if necessary.
5. Results should be interpreted within 5 minutes. Do not interpret the result after 10 minutes.

Note: This is a simplified overview of the test procedure. Please refer to the package insert for detailed instructions and additional information.



QUALITY CONTROL

Internal procedural controls are included in the test. A coloured band appears in the control region (C) is considered an internal positive procedural control. It generally confirms sufficient specimen volume and correct procedural technique. If controls do not yield expected results, do not use the test. Repeat the test or contact Spectrum Medical Diagnostics, Inc.

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Positive Result:

- Two coloured bands appear on the membrane: one in the control region (C) and another in the test region (T).
- The presence of both bands indicates a positive result.
- A positive result suggests the qualitative presence of Group A Streptococcus antigens in the specimen.

Negative Result:

- Only one coloured band appears in the control region (C). No apparent coloured band appears in the test region (T).
- A negative result suggests the absence or below the detectable limit of Group A Streptococcus antigens in the specimen.

Invalid Result:

- The control band fails to appear on the membrane.
- Results from any test that has not produced a control band within the specified read time must be discarded.
- An invalid result indicates an issue with procedural control and may be due to improper handling, inadequate specimen volume, or other factors.
- If the problem persists, discontinue using the test kit and contact us at (866) 287-2425 or info@spectrummdx.com

LIMITATIONS

1. The Strep A Rapid Test Device (Swab) is designed for in vitro diagnostic use and should only be used for the qualitative detection of Group A Streptococcus. It should not be used for other purposes or to determine the concentration of analytes in the specimen.
2. The accuracy of the test is dependent on the quality of the swab specimen. False negatives may result from improper specimen collection or storage. Additionally, a negative result can be obtained from patients at the onset of the disease due to low antigen concentration.
3. The test does not differentiate between asymptomatic carriers of Group A Streptococcus and those with symptomatic infection. If clinical signs and symptoms are not consistent with the laboratory test results, a follow-up throat culture is recommended.
4. Respiratory infections, including pharyngitis, can be caused by streptococci from serogroups other than Group A, as well as other pathogens. The test is specific to Group A Streptococcus and may not detect these alternative pathogens.
5. A definitive clinical diagnosis should not be based solely on the results of a single test. The physician should consider all clinical and laboratory findings before making a diagnosis.

It is important to refer to the package insert for a comprehensive understanding of the limitations and additional information regarding the test.

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Strep A Rapid Test Training Quiz

What is the intended use of the Strep A Rapid Test Device (Swab)?
a) Detection of Group B Streptococcus antigens
b) Qualitative detection of Group A Streptococcus antigens
c) Diagnosis of respiratory infections caused by Streptococcus pneumoniae
d) Confirmation of rheumatic fever

Why is early diagnosis and treatment of Group A Streptococcal pharyngitis important?
a) To reduce the severity of symptoms
b) To prevent complications like rheumatic fever and glomerulonephritis
c) To limit the spread of infection to others
d) All of the above

How does the Strep A Rapid Test Device detect Group A Streptococcus antigens?
a) By visualizing colour development on the internal strip
b) By measuring the concentration of antigens in the specimen
c) By isolating and identifying the Streptococcus organism
d) By detecting specific DNA sequences of Group A Streptococcus

What should you do if the control band fails to appear on the test device?
a) Interpret the result as positive
b) Interpret the result as negative
c) Discard the test and repeat with a new device
d) Contact the local distributor for further instructions

What is the recommended time frame for result interpretation?
a) Within 2 minutes
b) Within 5 minutes
c) Within 10 minutes
d) After 15 minutes

What is the interpretation of a positive result in the Strep A Rapid Test Device?
a) One coloured band appears in the test region (T)
b) Two coloured bands appear: one in the control region (C) and another in the test region (T)
c) No coloured bands appear in either region
d) The intensity of colour in the test region determines the result