

One Step Strep A Rapid Test Kit (Swab)

Package Insert

A rapid, one step test for the qualitative detection of group A streptococcal infection in human throat swab.

For in vitro diagnostic use only.

PRODUCT NAME

One Step Strep A Rapid Test Kit (Swab)

INTENDED USE

The Strep A Rapid Test Device 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.

Streptococcus pyogenes is non - motile gram - positive cocci, which contains the Lancefield group A antigen that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis. Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess. Traditional identification procedures for Group A Streptococci infection involve the isolation and identification of viable organisms using techniques that require 24 to 48 hours or longer.

The Strep A Rapid Test Device is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results within 5 minutes. The test utilizes antibodies specific for whole cell Lancefield Group A Streptococcus to selectively detect Strep A antigen in a throat swab specimen.

PRINCIPLE

The Strep A Rapid Test Device 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 test. During testing, the extracted throat swab specimen reacts with an antibody to Strep A that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep A on the membrane and generate a color line in the test line region. The presence of this color line in the test line region indicates a positive result, while its absence indicates a negative

result. To serve as a procedural control, a colored line will always appear in the control line region, indicating that proper volume of specimen has been added and membrane wicking has occurred.

MAIN COMPONENTS

- Test devices
- Sterile swabs
- Workstation
- Strep A Reagent A (1M Sodium Nitrite)
- Strep A Reagent B (0.4M Acetic Acid)
- Test tubes
- Dropper tips
- Package insert

STORAGE AND EXPIRY

Store as packaged in the sealed pouch at 4-30°C, avoid hot and sunshine, dry place, valid for 24 months. DO NOT FREEZE. Some protective measures should be taken in hot summer and cold winter to avoid high temperature or freeze-thaw.

SAMPLE REQUIREMENTS

Only use reagents and sterile swabs provided in the kit.

Collect the throat swab specimen with the sterile swab that is provided in the kit. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.

Testing should 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. Transport swabs containing modified Stuart's or Amies medium can also be used with this product.

If a culture is desired, lightly roll the swab tip onto a Group A selective (GAS) blood agar plate before using the swab in the Strep A Rapid Test Device.

TEST METHODS

1. *Instruction for Use* must be read carefully before taking the test. Allow the required test device, reagents, throat swab specimen to come to room temperature for 30 minutes (20°C -30°C) before use. Do not open the inner packaging (pouch) until ready, it must be used in one hour once opened (Humidity:20%~90%, Temp:10°C-50°C)

2. Test Procedure

2.1 Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.

2.2 Hold the Reagent A bottle vertically and add 4 full drops (approximately 240 µL) of Reagent A to an extraction test tube.

Reagent A is red in color. Hold the Reagent B bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction test tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.

2.3 Immediately add the throat swab to the extraction test tube of yellow solution. Agitate the swab 10 times in the tube. 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 as the swab is withdrawn. Discard the swab.

2.4 Fit the dropper tip on top of the extraction test tube. Place the test device on a clean and level surface. Add 3 full drops of solution (approx. 100 µL) to the specimen well (S) and then start the timer.

2.5 Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.

INTERPRETATION OF RESULTS

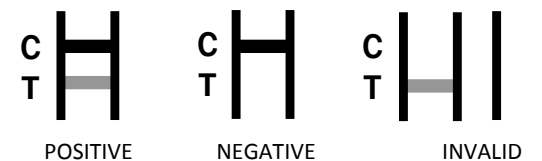
POSITIVE: Two distinct red lines appear. A red line in the control region (C), and another red line in the test region (T).

A pink to red line (T), even if it is very thin, indicates a positive result.

NEGATIVE: A red line appears in the control region(C). No line appears in the test region (T).

INVALID: No red lines appear or control line fails to appear. *Insufficient specimen volume or incorrect procedural techniques are the most likely reasons.*

Review the procedure and repeat the test with a new test device. If the problem persists, discontinue using the kit and contact your local distributor.



QUALITY CONTROL

Internal Quality Control

Internal procedural controls are included in the test. A color line appearing in the control region (C) is an internal positive procedural control. It confirms sufficient specimen volume,

adequate membrane wicking and correct procedural technique.

External Quality Control

In addition to your laboratory's standard quality control procedures, it is recommended that a positive and negative external control be tested at least once within each test kit and by each operator performing testing within a kit. This will verify that the reagents and test devices are working properly and the operator is able to correctly perform the test procedure. External positive and negative controls are supplied in the kit.

Procedure for External Quality Control Testing

1. Add 4 full drops of Reagent A and 4 full drops of Reagent B 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 this extraction tube and agitate the swab in the solution by rotating it at least 10 times. Leave the swab in the extraction tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the inside of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab.
 4. Continue with Step 4 of Directions For Use.
- If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATIONS

1. The Strep A Rapid Test Device is for in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens only. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep A antigen in the specimen from both viable and non - viable Group A Streptococcus bacteria.
3. A negative result must be confirmed by culture. A negative result may be obtained if the concentration of the Strep A antigen present in the throat swab is not adequate or is below the detectable level of the test.
4. The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.
5. Excess blood or mucus on the swab specimen may interfere

with test performance and may yield a false positive result. Avoid touching the tongue, cheeks, and teeth and any bleeding areas of the mouth with the swab when collecting specimens.

As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.

PERFORMANCE CHARACTERISTICS

Table: Strep A Rapid Test vs. PCR Test

Method		Culture		Total Results
Strep A Rapid Test	Results	Positive	Negative	
	Positive	102	7	109
	Negative	6	377	383
Total Results		108	384	492

Relative Sensitivity: 94% (88% - 98%)

Relative Specificity: 98% (96% - 99%)

Accuracy: 97% (96% - 98%)

95% Confidence Intervals

POL Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test Device. Personnel with various educational backgrounds performed the testing. Each physician's office tested a randomly coded panel of samples consisting of negative (20), low positive (20), and medium positive (20) for three days. The results obtained had a 96% correlation with the expected results.

ATTENTIONS

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

1. Remove the test device from the sealed foil pouch and use it as soon as possible. Best results will be obtained if the test is performed immediately after opening the foil pouch.
2. Hold the Reagent A bottle vertically and add 4 full drops (approximately 240 µL) of Reagent A to an extraction test tube. Reagent A is red in color. Hold the Reagent B bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction test tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.
3. Immediately add the throat swab to the extraction test tube of yellow solution. Agitate the swab 10 times in the tube. 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 as the swab is withdrawn. Discard the swab.

4. Fit the dropper tip on top of the extraction test tube. Place the test device on a clean and level surface. Add 3 full drops of solution (approx. 100 µL) to the specimen well (S) and then start the timer.

5. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes.

BIBLIOGRAPHY

- [1] Murray, P.R., et al. Manual of Clinical Microbiology, 6th Edition, ASM Press, Washington D.C. p. 299 - 307.
- [2] Webb, KH. Does Culture Confirmation of Highsensitivity Rapid Streptococcal Tests Make Sense? A Medical Decision Analysis. Pediatrics (Feb 1998), 101:2, 2.
- [3] Bisno AL, Gerber MA, Gwaltney JM, Kaplan EL, Schwartz RH. Diagnosis and Management of Group A Streptococcal Pharyngitis. Clinical Infectious Diseases (1997), 25: 574 - 83.
- [4] Needham CA, McPherson KA, Webb KH. Streptococcal Pharyngitis: Impact of a Highsensitivity Antigen Test on Physician Outcome. Journal of Clinical Microbiology (Dec 1998), 36: 3468 - 3473.
- [5] Shea, Y.R., Specimen Collection and Transport, Clinical Microbiology Procedures Handbook, Isenberg, H.D., American Society of Microbiology, Washington D.C., 1.1.1 - 1.1.30, 1992.]
- [6] Nussinovitch, M, Finkelstein Y, Amir J, Varsano, I. Group A beta-hemolytic streptococcal pharyngitis in preschool children aged 3 months to 5 years. Clinical Pediatrics (June 1999), 38: 357 - 360.