

## Convenient Group A Streptococcus Rapid Test Disposable Strep A Rapid Test

Our Product Introduction

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### Basic Information

- Place of Origin: China
- Brand Name: DVOT
- Certification: CE/BfArM/ PEI
- Model Number: Strep A
- Minimum Order Quantity: 1250Test
- Price: 0.28USD per Test
- Packaging Details: Each boxes 25tests
- Delivery Time: 5-8 Working days
- Payment Terms: T/T, Western Union
- Supply Ability: 1000000pcs



### Product Specification

- Product Name: Strep A Rapid Test
- Formats: Cassette
- Reaction Time: 10-15 Minutes
- Shelf Life: 24 Months At Room Temperature 4- 30 Degrees
- Others: The Kits Can Be Made According To The Customers' Artwork Or Design
- Time Of Use: Disposable
- Highlight: **Convenient Group A Streptococcus Rapid Test, Group A Streptococcus Rapid Test, Disposable Strep A Rapid Test**

## Product Description

### Rapid Detection And Convenient Use Of Group A Streptococci

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.

#### Detection 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.

#### SPECIMEN COLLECTION AND STORAGE

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.<sup>5</sup>

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.

#### PROCEDURE

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

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.

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.

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.

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 RESULT:



\* A colored band appears in the control band region (C) and another colored band appears in the T band region.

##### NEGATIVE RESULT:



One colored band appears in the control band region (C). No band appears in the test band region (T).

##### INVALID RESULT:



Control band fails to appear. Results from any test which has not produced a control band at the specified reading time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

#### NOTE:

The intensity of the color in test region (T) may vary depending on the concentration of aimed substances present in the specimen. Therefore, any shade of color in the test region should be considered positive. Besides, the substances level can not be determined by this qualitative test.

Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

#### LIMITATIONS OF THE TEST

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.

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 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.

The sterile swabs provided with this test must be used for specimen collection. Other swabs have not been validated with this test.

.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<sup>5</sup> 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.

### **KIT 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

### **MATERIALS REQUIRED BUT NOT PROVIDED**

Strep A Positive Control (Non-viable Strep A; preservative)  
Strep A Negative Control (Non-viable Strep C; preservative)



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