TOYO DIAGNOSTICS

INSTRUCTIONS FOR USE
ONE STEP TEST
Strep A (Group A *Streptococcus*) Antigen Detection in Throat Swab

Product Code: TSA01

Only for professional *in vitro* diagnostic use

Strep A Test Device detects Strep A antigen in throat swab samples.

INTENDED USE

Strep A Test Device is a rapid immunochromatographic assay for qualitative detection of Strep A antigen in throat swab samples to aid in the diagnosis of Group A *Streptococcal* infection.

BACKGROUND INFORMATION

Group A *Streptococcus* (GAS) is a bacterium often found in the throat and on the skin. People may carry Group A *Streptococci* in the throat or on the skin and have no symptoms of illness. Most GAS infections are relatively mild illnesses such as "strep throat," or impetigo. Occasionally these bacteria can cause severe and even life-threatening diseases.
These bacteria are spread through direct contact with mucus from the nose or throat of persons who are infected or through contact with infected wounds or sores on the skin.
Conventional methods used for the detection of the disease depend on the isolation and subsequent identification of the organism. These methods often require 24-48 hours to complete. Recent developments of immunological techniques which can detect Group A *Streptococcal* antigen directly from throat swabs allow physicians to diagnose and administer therapy immediately.

REAGENTS

The test contains particles coated with antibodies specific to Strep A antigen and antibodies specific to Strep A antigen immobilized on the membrane.

METHOD

Strep A Test Device is a qualitative, immunochromatographic assay for detection of Strep A carbohydrate antigen in throat swabs. There are antibodies specific to Strep A carbohydrate antigen immobilized to "T" test area of the test. While performing the test; extracted throat swab sample dropped to the sample well reacts with the particles coated with antibodies specific to Strep A antigens. This complex migrates to the other end of the membrane by capillary action. If there is Strep A antigen in the sample, they bind to antibodies specific to Strep A antigen in the "T" test area and create a visible, colored signal that means the test result is positive. If the sample does not contain Strep A antigen, colored line does not appear in the "T" test area. This means the test result is negative. As a procedural control, a colored line always appears in the "C" control area indicating that proper volume of sample has been introduced and membrane wicking has occurred.

PRECAUTIONS AND LIMITATIONS

1. For professional and *in vitro* diagnostic use only.
2. Do not use test kit beyond expiry date. The test device is single use. Do not reuse.
3. The test device should remain in its original sealed pouch until usage. Do not use the test if the seal is broken or the pouch is damaged.
4. Wear disposable gloves while performing the test.
5. Use a new dropper for each sample.
6. Sterile swabs provided with this test must be used for sample collection. Other swabs have not been validated with this test.
7. Reagent B contains an acidic solution. If the solution contacts skin or eye, flush with large volumes of water.
8. Do not interchange reagent bottle caps.
9. Excess blood or mucus on the swab sample 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 samples.
10. All patient samples should be handled as taking capable of transmitting disease into consideration. Observe established precautions against microbiological hazards throughout all procedures and follow the standard procedures for proper disposal of samples.
11. This test will indicate only the presence or absence of Strep A antigen in the sample, and should not be used as the only basis for the diagnosis of Group A Streptococcal infection.
As with all diagnostic tests, it should be kept in mind that an identification diagnosis can't be based on a single test result. Diagnosis can only be reached by an expert after the evaluation of all clinical and laboratory findings.
12. 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 this test.

STORAGE

Test device should be kept away from direct sunlight, moisture, heat and radiation sources.
Store at 4 - 30°C (39 - 86°F). Do not freeze.
The test in the original packaging retains stable until expiry date at storage conditions. The test device should be used in maximum one hour after the foil is opened.

SAMPLE COLLECTION AND PREPARATION

- Only use sterile swabs and reagents provided in the kit.
- Collect the throat swab sample with the sterile swab 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 samples have been collected. Swab samples 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 on to a Group A selective (GAS) blood agar plate before using the swab in the Strep A Test Device.

Kit components : Test devices, droppers, test tubes, steril swabs, Strep A - Reagent A (2M Sodium Nitrite), Strep A - Reagent B (0,4 M Acetic Acid), work station and instructions for use.

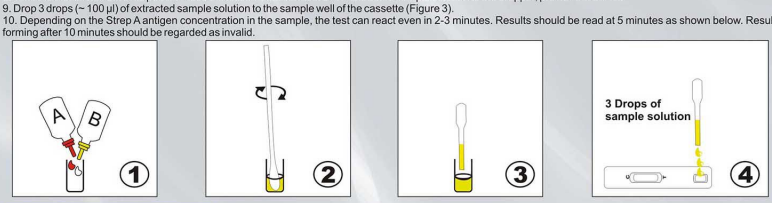
Additional materials required but not provided : Timer.

Additional materials recommended but not provided : Micropipettes to deliver mentioned amount of sample in the test procedure, negative and positive control materials.

TEST PROCEDURE

Bring the tests, reagents and throat swab samples to room temperature.

1. Place the test tube to the work station.
2. Hold Reagent A bottle vertically and add 4 full drops (~ 240 µl) to the test tube. Reagent A has a red color (reagent with the red cap). (Figure 1).
3. Hold Reagent B bottle vertically and add 4 drops (~ 160 µl) to the test tube that includes Reagent A. Reagent B has no color (reagent with the yellow cap). (Figure 1).
4. Mix the solution gently by swirling the test tube. Addition of Reagent B to Reagent A changes the color of the solution from red to yellow (Figure 1).
5. Immediately dip the throat swab sample in the test tube that has yellow solution.
6. Agitate the swab 10 times in the tube. Leave the swab 1 minute in the tube.
7. Press the swab on the walls of the tube and try to leave as much liquid as in the tube while taking the swab out off the tube (Figure 2).
8. Take the test device out of its pouch. Place the test on a flat surface. Draw extracted sample solution to the dropper, provided in the kit.
9. Drop 3 drops (~ 100 µl) of extracted sample solution to the sample well of the cassette (Figure 3).
10. Depending on the Strep A antigen concentration in the sample, the test can react even in 2-3 minutes. Results should be read at 5 minutes as shown below. Results forming after 10 minutes should be regarded as invalid.



INTERPRETATION OF RESULTS

Negative : Only one colored line is visible in "C" area, indicating that Strep A antigen does not exist.
Positive : Two colored lines are visible in "C" and "T" areas, indicating that Strep A antigen exists.
Low concentration of Strep A antigen may cause a faint line in "T" area. Even such a faint line in "T" area should be regarded as "positive".
Invalid : No colored line is visible or only one colored line is visible in "T" area; test should be repeated using a new test device.

QUALITY CONTROL

Tests have built in procedural quality control features. When the test is complete, the user will see a colored line in the "C" area of the test on negative samples and a colored line in the "T" and "C" area on positive samples. The appearance of the control "C" line is considered as an internal procedural control. This line indicates that sufficient volume of sample was added as well as valid test result. It is recommended that a negative control and a positive control be used to verify proper test performance as an external control. Users should follow appropriate federal, state and local guidelines concerning the external quality controls.

PERFORMANCE EVALUATION

For evaluation a total of 310 throat swabs were collected from patients exhibiting symptomps of pharyngitis. Each swab was rolled onto a sheep blood agar plate and then tested by Strep A Test Device. The plates were further streaked for isolation and incubated at 37 °C with % 5 - 10 CO_2 and a Bacitracin disk for 18 - 24 hours. The negative culture plates were incubated for an additional 18 - 24 hours. Possible GAS colonies were subcultured and confirmed with a latex agglutination grouping kit as a reference method used to compare Strep A Test Device and following results are obtained.

Sensitivity: 97,3 % **Specificity: 99 %** **+ Predictive V: 98,6 %** **- Predictive V: 97,5 %**

Confidence interval : 95 %

		Reference	
		+ Result	- Result
Test	+ Result	146	4
	- Result	2	158

CROSS REACTIVITY

Cross reactivity has been tested with below samples (1,0 X 10^7 microorganism/ml), no cross reactivity was found with the Strep A Test Device.

Group B Streptococcus
Group F Streptococcus
Streptococcus pneumoniae
Streptococcus mutans
Staphylococcus aureus
Corynebacterium diphteria
Candida albicans
Pseudomonas aeruginosa
Neisseria meningtidis
Neisseria sicca
Branhamella catarrhalis
Group C Streptococcus
Group G Streptococcus
Streptococcus sanguis
Enterococcus faecalis
Staphylococcus epidermidis
Serratia marcescens
Klebsiella pneumoniae
Bordetella pertussis
Neisseria gonorrhea
Neisseria subflava
Hemophilus influenza

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SYMBOLS USED

CE

Manufacturer
EC REP Authorized European Representative
Attention, see instruction for use
Consult instruction for use
IVD *In vitro* diagnostic medical device
Σ n Number of test
For single use only
Storage temperature
LOT Lot number
REF Catalog number
Expiry date