Strep A Rapid Test Cassette (Throat Swab)

IVD CE

PRODUCT CODE
RT010

INTENDED USE:
The Strep A Rapid Test Cassette (Throat Swab) 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.

CLINICALLY SIGNIFICANT:
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 Cassette (Throat Swab) is a rapid test to qualitatively detect the presence of Strep A antigen in throat swab specimens, providing results at 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 Cassette (Throat Swab) 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.

MATERIALS SUPPLIED:
1. Test Devices 2. Sterile Swab 3. Package Insert 4. Extraction Tube
5. Dropper Tip 6. Strip A Reagent A 7. Strip A Reagent B

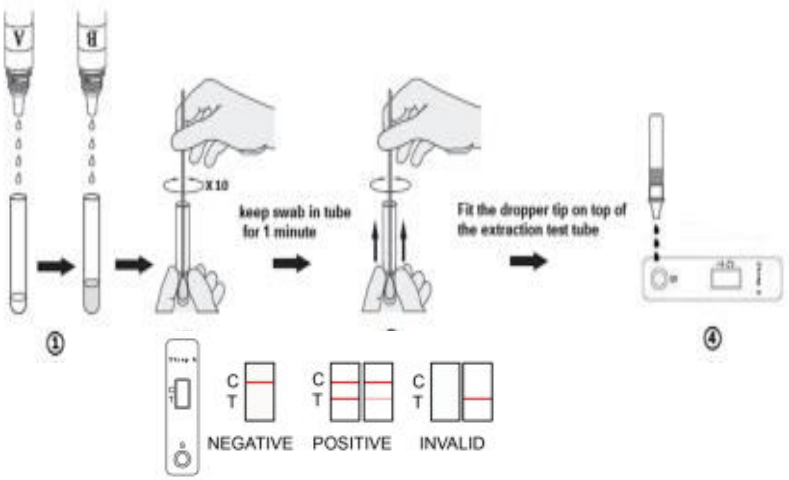
ADDITIONAL REQUIREMENTS:
1. Clock or Timer

STORAGE AND STABILITY:
Store as packaged in the sealed pouch either at room temperature or refrigerated (2-30°C). The test device is stable through the expiration date printed on the sealed pouch. The test device must remain in the sealed pouch until use.
Do Not Freeze. Do not use beyond the expiration date.

SPECIMEN AND SAMPLE PREPARATION:
1. Only use reagents and sterile swabs provided in the kit.
2. 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.
3. 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.
4. 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 Cassette (Throat Swab) TEST PROC

PRECATIONS:
1. For professional in vitro diagnostic use only. Do not use after the expiration date.
2. Do not eat, drink or smoke in the area where the specimens and kits are handled.
3. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow the standard procedures for proper disposal of specimens.
4. Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
5. Humidity and temperature can adversely affect results.
6. Do not use test if pouch is damaged.
7. Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
8. Do not interchange reagent bottle caps.
9. Do not interchange external control solution bottle caps

PROCEDURE:
1. Allow the test device, reagents, throat swab specimen, and/or controls to reach room temperature (15-30 C) prior to testing.
2. 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.
3. Hold the Reagent A bottle vertically and add 4 full drops of Reagent A to an extraction tube. Reagent A is red in color. Hold the Reagent B bottle vertically and add 4 full drops to the tube. Reagent B is colorless. Mix the solution by gently swirling the extraction tube. The addition of Reagent B to Reagent A changes the color of the solution from red to yellow.
4. Immediately add the throat swab to the extraction 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.
5. Fit the dropper tip on top of the extraction tube. Place the test device on a clean and level surface. Add 3 full drops of solution to the specimen well (S) and then start the timer.
6. Wait for the colored line(s) to appear. Read the result at 5 minutes. Do not read the result after 10 minutes



RESULTS:
Positive: Two lines appear. One coloured line should be in the control line region (C) and another apparent coloured line should be in the test line region (T).
Negative: One coloured line appears in the control line region(C). No line appears in the test line region (T).
Invalid: Control line fails to appear.
Note: Insufficient specimen volume, incorrect operation procedure, or performing expired tests are the most likely reasons for control band failure.

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 procedur-

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al 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. Procedure for External Quality Control Testing

1. Add 4 full drops of Reagent A and 4 full drops of Reagent B into an extraction 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 Test Procedure Section. If the controls do not yield the expected results, do not use the test results. Repeat the test or contact your distributor.

LIMITATION:

1. The Strep A Rapid Test Cassette (Throat Swab) 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 bacterium.
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 teeth5 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:

Clinical Sensitivity and Specificity

The Strep A Rapid Test (Throat Swab) has been evaluated with specimens obtained from patients with symptoms of pharyngitis confirmed by culture method and from normal people (no symptoms of pharyngitis) tested by commercial Strep A Test as reference device. The results show that the Strep A Rapid Test (Throat Swab) has a high overall relative accuracy.

Table 1: Orient gene Strep A Rapid Test VS. Culture method.

		Culture Method		Total Results
		+	-	
Orient gene Strep A Rapid Test	+	60	0	60
	-	5	0	5
Total Result		65	0	65

Relative Sensitivity : 92.3% (82.2%-97.1%)* *95% Confidence interval (CI)

Table 2: Orient gene Strep A Rapid Test VS. Commercial reference device.

		Commercial reference device		Total Results
		+	-	
Orient gene Strep A Rapid Test	+	0	4	4
	-	0	108	108
Total Result		0	112	112

Relative Specificity : 96.4% (90.6%-98.8%)* *95% Confidence interval (CI)

Cross-Reactivity

The following organisms were tested at 1.0 x 107 organisms per test and were all found to be negative when tested with the Strep A Rapid Test (Throat Swab). No mucoid-producing strains were tested.

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

Physician's Office Laboratory (POL) Studies

Three physicians' offices were used to conduct an evaluation of the Strep A Rapid Test (Throat Swab). 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.

SYMBOLS OB LABEL

Symbols	Signify	Symbols	Signify
REF	Catalogue Number	SIZE	Pack Size
	Expiry Date	VOL	Volume
	Storage Condition	LOT	Lot Number
	Instruction for Use	IVD	In Vitro Diagnostics
	Manufacturing Date		Manufacturer
	Number of Tests	2	For Single Use Only
EC REP	EC Representative	CE	European conformity

REFERENCE

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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

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