CE IVD

StrepA Rapid Test Kit
(Nasal Test)
Instruction for Use

Read this instruction carefully before use

A rapid test for the qualitative detection of Strep A antigen in oropharyngeal swab, nasopharyngeal swabs and Anterior nasal swab specimens.For professional medical institutions use only,Not for self testing.

PRODUCT NAME
Strep A Rapid Test Kit (Nasal Test)

SPECIFICATION
25 tests/kit;5 tests/kit;1 test/kit

INTENDED USE
The Strep A Rapid Test Kit is a lateral flow chromatographic immunoassay for the qualitative detection of Strep A in human swab (oropharyngeal swab, nasopharyngeal swabs and Anterior nasal swab). It is suitable for the auxiliary diagnosis of Group A Streptococcal infection infection.

INTRODUCTION
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 kit 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 kit 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.

COMPONENTS
Materials Provided

Components	25 tests/kit	5 tests/kit	1 tests/kit
Cassettes	25 cassettes with dependent sealed foil pouch	5 cassettes with dependent sealed foil pouch	1 cassette with dependent sealed foil pouch
Sample Diluent Solution With Dropper	5ml/bottle	1ml/bottle	300ul/tube
Cotton Swab	25 pcs	5 pcs	1 pcs
Package insert	1 pcs	1 pcs	1 pcs

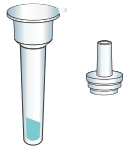
Reagents of different batch numbers cannot be used interchangeably.
Materials required but not provided
Timer for timing use

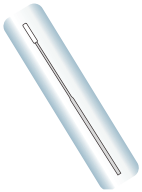
PRECAUTIONS
- Read this IFU carefully before use.
- Do not spill solution into the reaction zone.
- Do not use test if pouch is damaged.
- Do not use test kit after expiration date.
- Do not mix Sample Diluent Solution and Transfer Tubes from different lots.
- Do not open the Test Cassette foil pouch until ready to perform the test.
- Do not spill solution into the reaction zone.
- For professional use only.
- For in-vitro diagnostic use only
- Do not touch the reaction zone of the device to avoid contamination.
- Avoid cross-contamination of samples by using a new specimen collection container and specimen collection tube for each sample.
- All patient samples should be treated as if capable of transmitting disease. Observe established precautions against microbiological hazards throughout testing and follow standard procedures for proper disposal of specimens.
- Do not use more than the required amount of liquid.
- Bring all reagents to room temperature (15~30°C) before use.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when testing.
- Evaluate the test result after 20 minutes and not beyond 30 minutes.
- Store and transport the test device always at 2~30°C.

STORAGE AND STABILITY
- The kit should be stored at 2~30°C, valid for 12months.
- The test must remain in the sealed pouch until use.
- Do not freeze.
- Cares should be taken to protect components in this kit from contamination. Do not use if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

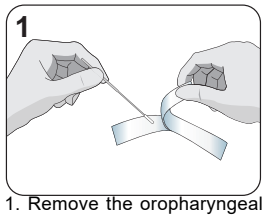
SPECIMEN COLLECTION AND HANDLING
1.Prepare Materials
Open the package,take out the StrepA Antigen test card in pouch, the Tube filled with the extraction buffer and the swab. When you are ready to proceed with the test,open the foil pouch of the StrepA Antigen test card.

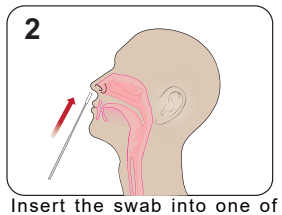

1 StrepA test card in pouch

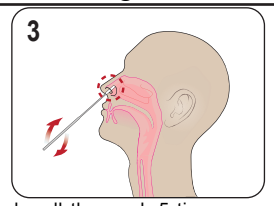

1 Sample Diluent Solution With Dropper

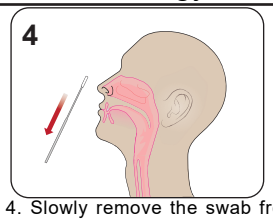

1 Swab

2.Collect Sample
2.1 Anterior Nasal Swab collection:
Note: Failure to swab properly may cause false negative results.

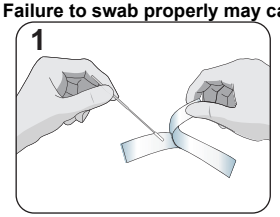

1. Remove the oropharyngeal swab from the pouch.

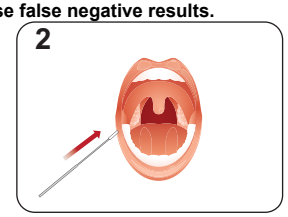

2. Insert the swab into one of patient's nostrils up to 1 inch from the edge of the nostril.

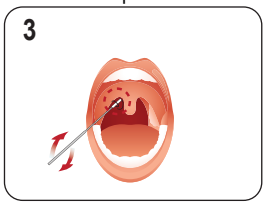

3. Slowly roll the swab 5 times over the surface of the nostril. Using the same swab repeat this collection process in the other nostril. Take approximately 15 seconds to collect the specimen.

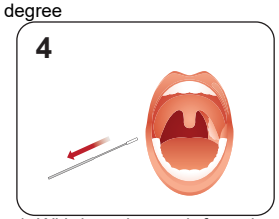

4. Slowly remove the swab from the nostril while rotating it.

2.2 Oropharyngeal Specimen collection:
Note: Failure to swab properly may cause false negative results.

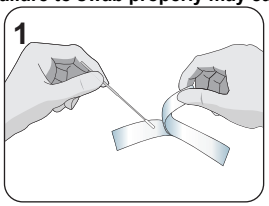

1. Remove the oropharyngeal swab from the pouch.

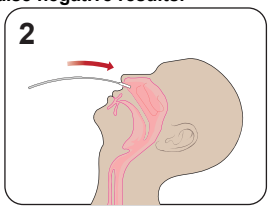

2. Tilt patient's head back 70 degree

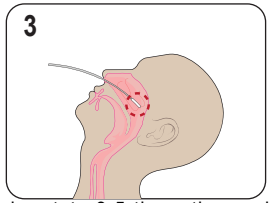

3. Insert swab into the oral cavity without touching the gums, teeth and tongue (A tongue depressor may be used.) Swab the posterior pharyngeal wall using a rotatory motion.

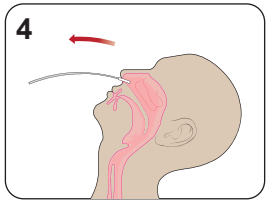

4. Withdraw the swab from the oral cavity.

2.3 Nasopharyngeal Swab collection:
Note: Failure to swab properly may cause false negative results.


1. Remove the oropharyngeal swab from the pouch.


2. Tilt patient's head back 70 degrees. Gently and slowly insert the swab into one of patient's nostrils until it reaches the posterior nasopharynx; keep insert until resistance is equivalent to that from the ear to the nostril of the patient.


3. Slowly rotate 3-5 times the swab over the surface of the posterior nasopharynx.


4. Leave swab in place for several seconds to absorb secretions. Slowly remove the swab from the nostril while rotating it.

3.Process Sample

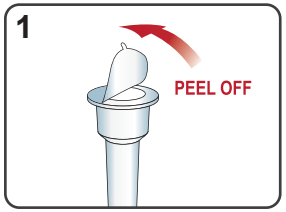
3.1Instructions must be read entirely before test, Leave the reagent and sample at room temperature for 30min before use to rewarm to room temperature.

3.2Use the cassette as soon as possible after opening the inner packing.

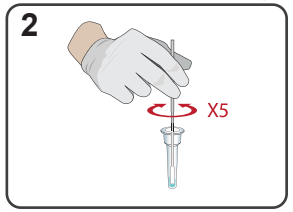
3.3Open the aluminum foil bag at the tear hole, take out the test card and lay it flat.

3.4 Apply 3 full drops of the sample diluent solution(90-100ul) vertically into the sample well of the test cassette.

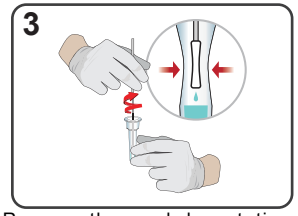
The results are observed after 20minutes and showed on clinical significance



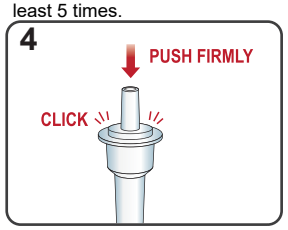
1. Peel off aluminum foil seal from the top of the extraction vial containing the extraction buffer.



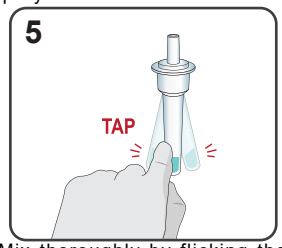
2. Place the swab into the extraction vial. Rotate the swab vigorously at least 5 times.



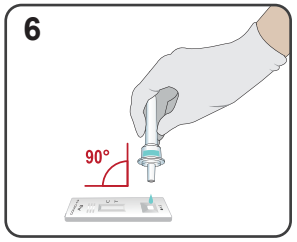
3. Remove the swab by rotating against the extraction vial while squeezing the sides of the vial to release the liquid from the swab. Properly discard the swab.



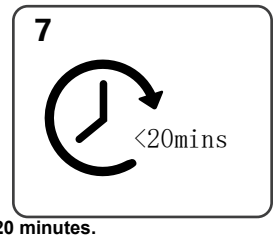
4. Close the vial by pushing the cap firmly onto the vial.



5. Mix thoroughly by flicking the bottom of the tube.



6. Invert the extraction vial and hold the sample vertically above the sample well. Squeeze the vial gently. Allow three (3) drops of sample to fall into the sample well.



7. Start the timer by clicking the "Start Timer" button, immediately after adding sample to the sample port. The result will be ready in 20 minutes.

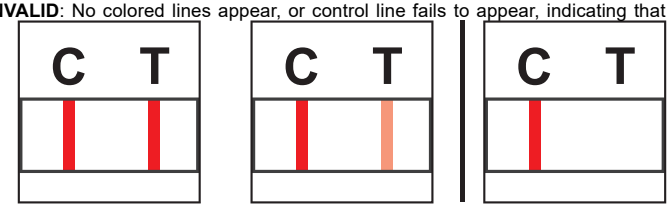
after 20 minutes.

RESULT INTERPRETATION

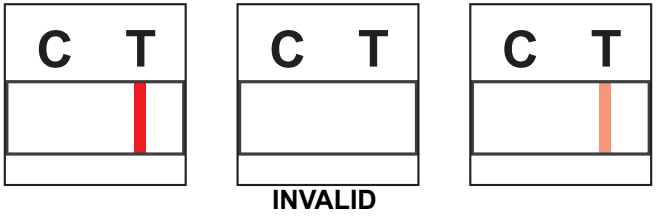
POSITIVE: Two distinct red lines appear. One line should be in the control region(C) and the other line should be in the test region(T).

NEGATIVE: One red line appears in the control region(C). No red line appears in the test region(T).The negative result does not indicate the absence of analyses in the sample, it only indicates the level of tested analyses in the sample is less than cut-off level.

INVALID: No colored lines appear, or control line fails to appear, indicating that the



operator error or reagent failure. Verify the test procedure and repeat the test with a new testing device.



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 cannot 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.

PERFORMANCE CHARACTERISTICS

1.Sensitivity, Specificity and Accuracy

A total of 560 patient samples from susceptible subjects were test by the ELISA test. Comparison for all subjects is showed in the following table:

Strep A Antigen Test	RT-PCR		
BESTest	Positive	Negative	Total
Positive	102	7	109
Negative	6	377	383
Total	108	384	492

Relative Sensitivity: 94% (88%-98%)* Relative Specificity: 98% (96%-99%)* Accuracy: 97% (96%-98%)* * 95% Confidence Intervals

2. Limit of Detection（LOD）

The limit of detection of the StrepA Antigen Rapid test has been studied.The LOD of the test to the StrepA N protein is around 10pg/ml.The LOD of the test to the StrepA virus(inactivated)is about $5*10^2$ $TCID_{50}$ /ml.

Concentration	Positive Results	Agreement Rate
10pg/ml recombinant protein	**100/100**	**100%**
$5*10^2$ $TCID_{50}$/ml	**100/100**	**100%**

3. Cross-reactivity

The following organisms were tested at 1.0 x 10^7 organisms per test and were all found to be negative when tested with the Strep A Rapid Test Device. No mucoid-producing strains were tested.

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

4.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.

QUALITY CONTROL

1.Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.

2.External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

TEST LIMITATIONS

1.The Strep A Rapid Test Kit 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 teeth5 and any bleeding areas of the mouth with the swab when collecting specimens.

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

CAUTION

1.This product is used for in vitro diagnosis only.

2.Must strictly follow the instructions for operation and interpretation of the results.

3.The product is qualitatively tested, and the result cannot be used as a quantitative basis.should be tested using reagents within the validity period.

4.The cassetes, collectors,droppers,and tubes are for single person one-time use, cannot be reused.

5.Because the sample titer is different, the red lines of the test line will show different shades of color, all of which indicate positive results. The depth of the test line color cannot be used as the basis for determining the antibody titer in the sample.

6.The samples stored at low temperature should be balanced to room temperature and fully mixed before testing.

7.Samples and waste must be treated as a potential source of infection and the desiccant in the foil bag is not edible.

SYMBOLS

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
	Batch code		In vitro diagnostic medical device
	Temperature limit		Manufacturer
	Please don't reuse it		Keep away from sunlight
	Don’t use the product when the package is damaged		Keep dry
	Date of manufacture		Tests per kit
	CE Mark		Biological Risks
	Authorized representative in the European Community		

BASIC INFORMATION

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