CE
IVD

FRENOVO

Group A Streptococcus Rapid Test Kit

PRODUCT NAME

Group A Streptococcus Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

The kit is a rapid chromatographic immunoassay for the qualitative detection of Strep A antigens from throat swab specimens to aid in the diagnosis of Group A Streptococcal infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Streptococcus pyogenes is non-motile gram-positive cocci, which contains the Lancefield group A antigens that can cause serious infections such as pharyngitis, respiratory infection, impetigo, endocarditis, meningitis, puerperal sepsis, and arthritis.1 Left untreated, these infections can lead to serious complications, including rheumatic fever and peritonsillar abscess.2 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 kit Test is a rapid test to qualitatively detect the presence of Strep A antigens in throat swab specimens, providing results within 15 minutes. 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 PROVIDED

Each kit contains:

1. Test Devices: 20 pieces test devices individually pouched.
2. Extraction Solution A: 5.0 mL in dropper bottle.
3. Extraction Solution B: 5.0 mL in dropper bottle.
4. Extraction Tubes (with Caps): 20 pieces extraction tubes (with Caps) in zipper bag.
5. Work Stations: 2 paper work stations as folded.
6. Instructions For Use: 1 piece attached.

MATERIALS REQUIRED BUT NOT PROVIDED

- Timer or stopwatch.
- Biohazard disposal waste container.
- Disposable gloves and/or protective clothing.

WARNINGS

1. Read the Instructions For Use completely before using the product. The instructions must be followed carefully as not doing so may result in inaccurate results.
2. The kit is for diagnostic use only.
3. Perform test at room temperature.

PRECAUTIONS

1. The kit Test is for professional use only.
2. The Instructions For Use must be followed to ensure optimum test performance.
3. The kit Test is intended for *in vitro* diagnostic use.
4. As with all screening assays, any results should be considered presumptive until confirmatory assays have been performed according to local practice or WHO guidelines.

Safety Precautions

1. Standard precautions for handling infectious agents should be observed when using this kit.
2. Wear protective clothing such as lab coat, safety glasses and disposable gloves when handling specimens and assay reagents.
3. Wash hands thoroughly after use.
4. In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

Bio safety Precautions

Appropriate bio safety practices should be used when handling specimens and reagents. These precautions include, but are not limited to the following:

1. Do not smoke, eat, drink, apply cosmetics or handle contact lenses in areas in which specimens are handled.
2. Dispose of all specimens, used devices and tubes as though they are capable of transmitting infection.The preferred methods of disposal are by autoclave at 121°C for a minimum of 60 minutes or by incineration. Disposable materials may be incinerated. Liquid waste may be mixed with appropriate chemical disinfectants. A solution of 10% bleach is recommended. Allow 60 minutes for effective decontamination. NOTE: Do not autoclave solutions containing bleach.
3. When disposing of extraction Solution, avoid contact with acid to prevent liberation of a toxic gas.
4. All spills should be wiped thoroughly using a suitable disinfectant such as a sodium hypochlorite solution.
5. Use a separate swab, tube and device for each specimen tested.

Handling Precautions

1. Do not use if the kit box safety seal is absent, damaged or broken.
2. Do not use any device if the pouches have been perforated.
3. Each device is for single use only.
4. Do not mix extraction solution/test devices from different kit lots.
5. Do not use the kit past the expiration date (this date is printed on the kit box).
6. Adequate lighting is required to read the test results.
7. The result should be read immediately after the end of the 15 minutes incubation time following the addition of extracted solution. Do not read results beyond 20 minutes.

STORAGE INSTRUCTIONS

1. The kit Test and extraction solution should be stored between 2-30°C and the shelf life is 24 months.
2. The Kit components are stable until the expiration date printed on the outer label, when stored as directed. The kit expiry date is determined by whichever of the components has the shortest expiry date.The kit expiry date is not impacted once the extraction solution has been opened. Do not use kit components beyond overall kit expiry date.
3. If stored refrigerated, ensure that the pouched device is brought to room temperature before opening.
4. Do not freeze the kit.

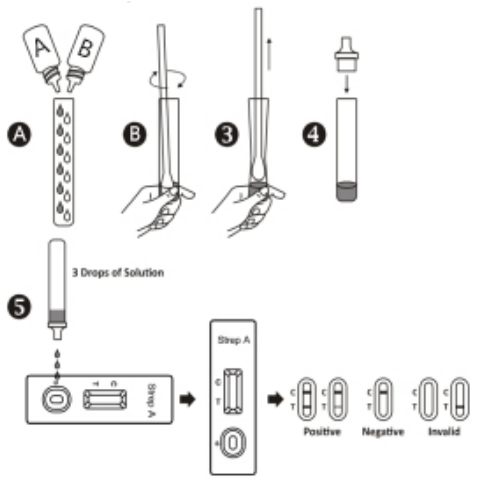
SPECIMEN COLLECTION

1. Collect the throat swab specimen with sterile swab. Swab the posterior pharynx, tonsils and other inflamed areas. Avoid touching the tongue, cheeks and teeth with the swab.
2. Testing should be performed immediately after the specimens have been collected.Swab specimens should be stored in a clean, dry plastic tube for up to 8 hours at room temperature or 72 hours at 2-8°C.

TEST PROCEDURE

Allow the test device, specimen, extraction solution to equilibrate to 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. Place the test device on a clean and level surface. Best results will be obtained if the assay is performed immediately after opening the foil pouch.
2. Place the extraction tube on the work station. Hold the Extraction solution A bottle vertically and add 6 full drops (approximately 200 µL) of Extraction solution A to the extraction tube. Extraction solution A is light blue in color. Hold the Extraction solution B bottle vertically and add 6 full drops (approximately 200 µL) to the tube. Extraction solution B is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction solution A to Extraction solution B changes the color of the solution from blue to yellow.
3. Press the swab against the side of the tube , rotate the swab for about 10 times and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Dispose of swabs according to biohazard waste disposal method.
4. Install the dropper cap on the extraction tube and leave for 1 minute, then put 3 drops (approximately 100 µL) into the specimen hole of the test card, start the timer.
5. Read the results at 15 minutes, and the results after 20 minutes are no longer valid.



INTERPRETATION OF RESULTS

POSITIVE:* Two lines appear. One colored line should be in the control line region (C) and another apparent colored line should be in the test line region (T). A positive result indicates that Strep A was detected in the specimen.

***NOTE:** The intensity of the color in the test line region (T) will vary depending on the concentration of Strep A present in the specimen. Therefore, any shade of color in the test line region (T) should be considered positive.

NEGATIVE: One colored line appears in the control line region (C). No line appears in the test line region (T). A negative result indicates that Strep A antigen is not present in the specimen, or is present below the detectable level of the test. The patient's specimen should be cultured to confirm the absence of Strep A infection. If clinical symptoms are not consistent with results, obtain another specimen for culture.

INVALID: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit immediately and contact your local distributor.

LIMITATIONS

1. The kit Test is for professional in vitro diagnostic use only. The test should be used for the detection of Strep A antigen in throat swab specimens. Neither the quantitative value nor the rate of increase in Strep A antigen concentration can be determined by this qualitative test.
2. The kit Test will only indicate the presence of Strep A antigen in the Specimen or not.
3. As with all diagnostic tests, all results must be interpreted together with other clinical information available to the physician.
4. A negative result obtained from this kit should 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.
5. Excess blood or mucus on the swab specimen may interfere with test performance and may yield a false positive result.
6. The accuracy of the test depends on the quality of the swab sample. False negatives may result from improper sample collection or storage.
7. The use of over-the-counter and prescription nasal sprays at high concentrations can interfere with results, leading to either invalid or incorrect test results.
8. A positive result for Strep A antigen does not preclude an underlying co-infection with another pathogen, therefore the possibility of an underlying bacterial infection should be considered.

PERFORMANCE CHARACTERISTICS

Cross Reaction

The following organisms were tested at $1.0x10^7$ org/ml and has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

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

INDEX OF SYBOML

IVD	In vitro diagnostic medical device		single-use,Please don't reuse it
	Use-by date		Consult instructions for use
	Cautions		Manufacturer
2°C	Temperature limit	LOT	Batch code
	Date of manufacture		Keep Dry
	Avoid overexposure to the sun		Don't use the product when the package is damaged
CE	CE mark		Biological risks

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INSTRUCTION APPROVAL AND REVISION DATE

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