CE IVD

FRENOVO

Strep B Rapid Test Kit

Instructions For Use

PRODUCT NAME

Strep B Rapid Test Kit

PACKAGE SPECIFICATION

20 tests/kit

INTENDED USE

The Strep B Rapid Test Kit is a rapid chromatographic immunoassay for the qualitative detection of group B Streptococcus (GBS) antigens in specimens collected from vaginal or rectal swab to aid in the diagnosis of GBS infection.

SUMMARY AND PRINCIPLES OF THE PROCEDURE

Group B Streptococci (GBS) or Streptococcus agalactiae are among the most frequent causes of life-threatening infections in neonates. Up to 30% of all pregnant women are colonised with GBS. Some recent studies have shown that the intrapartum antibiotic prophylaxis of GBS-colonised women significantly reduces the incidence of GBS-caused sepsis in newborns. Routine examination for GBS is frequently recommended between the 35th and the 37th week of pregnancy. A CDC study has shown that this screening approach is 50% more effective than the use of antibiotics for pregnant women identified by clinical risk approach. Standard culture methods require 24 to 48 hours, and the results may not be available soon enough for efficient treatment. Thus, methods utilising more rapid screening techniques are required. The Strep B Rapid Test is especially suitable if time and/or availability of culture methods are limited. It enables the detection of GBS directly from swabs, helping physicians make a presumptive diagnosis.

The Strep B Rapid Test detects group B Streptococcus antigens through visual interpretation of colour development on the internal test strip. Anti-streptococcus B antibodies are immobilised in the test line region of the membrane. During testing, the specimen reacts with further polyclonal anti-streptococcus B antibodies conjugated to coloured particles and precoated onto the conjugate pad of the internal test strip. The mixture then migrates along the membrane by capillary action and interacts with reagents on the membrane.If there are sufficient streptococcus B antigens in the specimen, a coloured line will form in the test line region of the membrane. The presence of this coloured line indicates a positive result, while its absence indicates a negative result. The appearance of a coloured line in the control line region serves as a procedural control, indicating that the 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: 20 pieces extraction tubes with 200ul .
3. Extraction Solution B: 5.0 mL in dropper bottle.
4. Swab: 20 pieces individually packed.
5. 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 is for professional use only.
2. The Instructions For Use must be followed to ensure optimum test performance.
3. The kit 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 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

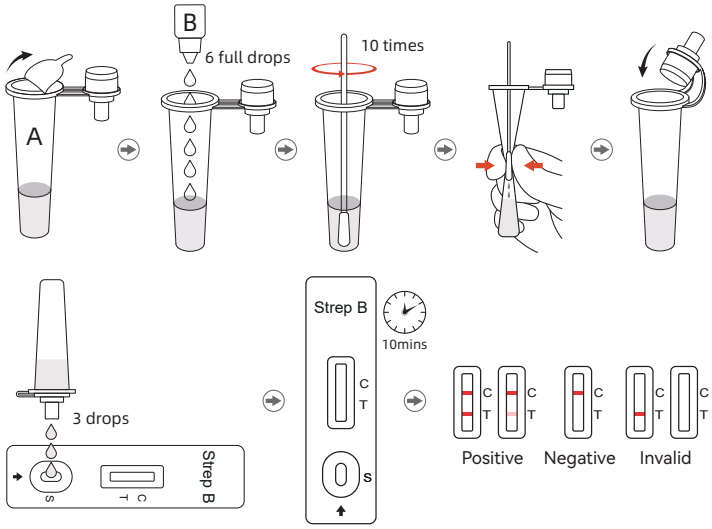
1. The quality of specimen obtained is of extreme importance. Collect swab specimens using standard clinical methods.
2. It is recommended that swab specimens be processed as soon as possible after collection. If swabs are not processed immediately, they should be placed into a sterile, dry, tightly capped tube or bottle and refrigerated. Do not freeze swabs. Swabs can be stored at room temperature (15-30°C) up to 4 hours or refrigerated (2-8°C) up to 24 hours. All specimens should be brought to room temperature (15-30°C) before testing.

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.

1. Tear off the aluminum film of Extraction Solution A tube. Hold the Extraction solution B bottle vertically and add 6 full drops (approximately 200 µL) to the tube. Mix the solution by gently swirling the extraction tube.
2. 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.
3. 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.
4. Read the results at 10 minutes, and the results after 15 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 B 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 B 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 B 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 B 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 Strep B Rapid Test is for professional in-vitro diagnostic use and should only be used for the qualitative detection of group B streptococci (GBS). No meaning should be inferred from the colour intensity or width of any apparent lines.
2. The accuracy of the test depends on the quality of the swab specimen. False negative results may occur due to improper specimen collection or storage. A negative result may also be obtained from patients with a light GBS colonization due to low antigen concentration. It is advisable to confirm negative test results with an alternative method e.g. culture.
3. Maternal colonisation with GBS can be intermittent, transient or permanent and usually does not cause any clinical symptoms. Therefore, it is usually recommended that the time point of testing should be close to birth.
4. For throat/ear swabs testing of newborns no clinical studies are available for the test. Negative results should not be used to exclude the presence of GBS because bacterial numbers may be below the detection limit. It is generally recommended to take swabs from multiple locations to increase the probability of detection.
5. The test does not differentiate asymptomatic carriers of Group B streptococci from those with infection. If clinical signs and symptoms are not consistent with laboratory test results, a follow-up culture is recommended.
6. As with all diagnostic tests, a definitive clinical diagnosis should not be based on the results of a single test, but should only be made by the physician after all clinical and laboratory findings have been evaluated.

PERFORMANCE CHARACTERISTICS

Sensitivity and Specificity

A correlation study between the Strep B Rapid Test and conventional culture was performed. Vaginal, rectal swabs were used as sample material. The results are presented in the following table:

Strep B Study		Culture		
Strep B Rapid Test Kit	Results	Positive	Negative	Total Results
	Positive	20	2	22
	Negative	2	96	98
Total Results		22	98	120

Clinical sensitivity =90.91% (70.84% ~ 98.88%)
Clinical specificity =97.96% (92.82% ~ 99.75%)
Accuracy=96.67% (91.69% ~ 99.08%)

Cross Reaction

The following organisms were tested at 1.0x107 org/ml and has no effect on the negative and positive test results of this reagent, and there is no cross-reaction.

Group A 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

Interference study

A variety of vaginal washes were tested at concentrations of 1%. None of them interfered with the generation of correct test results.

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 30°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
	Biological risks	CE	CE mark

Hangzhou Frenovo Biotech Co., Ltd.
Address: Room 401,Building 26, Room 401&301,Building 27,No.488-1,Donghu North Road, Donghu Street,LinPing District,Hangzhou City,Zhejiang Province.China.
Tel: +86-571-89170657
Email: business@frenovo.com

EC REP
CMC Medical Devices & Drugs S.L
Address: C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain
Email: info@cmcmedicaldevices.com

INSTRUCTION APPROVAL AND REVISION DATE

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