BoatBIO

CE IVD

StrepB Antigen Rapid Test Kit (Colloidal Gold)

Instruction for Use

A rapid test for the qualitative detection of group B Streptococcus (GBS) antigens in the specimens of human vaginal or rectal swab.
For professional in vitro diagnostic use only.

PRODUCT NAME
StrepB Antigen Rapid Test Kit (Colloidal Gold)

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

INTENDED USE
The Strep B Rapid Test is a rapid, visual immunoassay for the qualitative, presumptive detection of group B Streptococcus (GBS) antigens in specimens collected from vaginal or rectal swab. Ear or throat swabs from newborns collected directly after birth can also be used. The test is intended as an aid in diagnosing the presence of GBS in sample material that may either be a sign of colonisation or infection. This test provides epidemiological information about infections caused by GBS. The Strep B Rapid Test is designed for professional use only. The detection limit of the assay is $1x10^5$ bacteria/swab and does not depend on viability of organisms.

INTRODUCTION AND CLINICAL SIGNIFICANCE
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 and decide whether a therapy should be indicated.

TEST PRINCIPLE
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.

REAGENTS AND MATERIALS SUPPLIED
• Strep B Rapid tests (individually packaged). Each test contains coloured conjugates and reactive reagents precoated in the corresponding regions of the internal test strip.
• Reagent 1: 1.0 M sodium nitrite
• Reagent 2: 0.4 M acetic acid
• Positive Control: Non-viable GBS: 0,09% sodium azide
• Negative Control: containing heat-killed non-Group B Streptococci
• disposable pipettes: For adding specimens
• extraction tubes: For specimen preparation
• reagent holder
• package insert

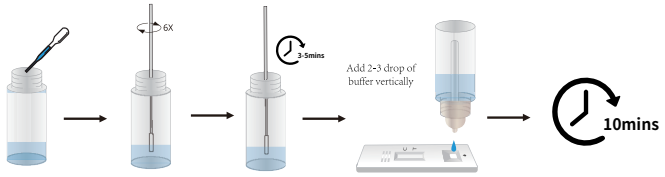
ADDITIONAL MATERIALS REQUIRED
• Timer, sterilized swabs

STORAGE & STABILITY
The test kit should be stored at 2-30°C and used before the expiry date printed on the packaging. The test cassette should remain in the sealed foil pouch until use. Do not freeze test kits. Care should be taken to protect components of the test kit from contamination. Do not use tests if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

WARNINGS AND PRECAUTIONS
• For professional in-vitro diagnostic use only.
• Carefully read through the test procedure prior to testing.
• Do not use the test beyond the expiration date indicated on the package.
• Do not use the test if the foil pouch is damaged.
• Do not reuse tests.
• Do not add samples to the reaction area (result area).
• In order to avoid contamination, do not touch the reaction area (result area).
• Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
• Do not substitute or mix components from different test kits.
• Do not swap caps between different extraction reagent bottles.
• Do not eat, drink or smoke in the area where specimens and test kits are handled.
• Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are being assayed.
• Handle all specimens as if they contain infectious agents. Observe established precautions for microbiological risks throughout all procedures and standard guidelines for the appropriate disposal of specimens.
• The test kit contains products of animal origin. Certified knowledge of the origin and/or sanitary state of the animals does not completely guarantee the absence of transmissible pathogenic agents. It is therefore recommended that these products be treated as potentially infectious, and handled in accoradance with usual safety precautions (e.g., do not ingest or inhale).
• Use the provided swabs for sample collection. Do not use calcium alginate, cottontipped or wooden-shafted swabs.
• Do not use swabs from damaged pouches.
• Reagents 1 & 2 are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
• Controls contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of this solution, always flush with copious amount of water to prevent azide build-up. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
• Humidity and temperature can adversely affect test results.
• Used testing materials should be discarded according to local regulations.

SPECIMEN COLLECTION AND PREPARATION
•The quality of specimen obtained is of extreme importance. Collect swab specimens using standard clinical methods.
• 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.
• Do not place swabs in any transport device containing liquid transport media or transport media containing agar or charcoal. Transport media may interfere with the assay and viability of organisms. If transport medium is required, we recommend using Modified Stuart's Transport Medium as outlined in the manufacture's instructions.
• If a bacterial culture is desired, lightly roll the swab on an appropriate cell culture plate before using it in the test. The extraction reagents in the test will kill bacteria on swabs and make them impossible to culture.

TEST PROCEDURE
Bring tests, specimens and reagents to room temperature (15-30°C) prior to testing.
To avoid cross contamination, do not allow the tips of the reagent bottles to come into contact with sample material.
For testing of controls refer to section "Quality Control".
1. Prepare swab specimens:
• Place a clean extraction tube onto the designated area of the reagent holder. Add 4 drops of Reagent 1 and 4 drops of Reagent 2 to the extraction tube. In order to ensure reliable drop size when adding the reagents, hold the dropper bottles vertically. Mix the solution by gently swirling the extraction tube.
• Immediately immerse the swab with the sample into the extraction tube. Using circular motions, roll the swab against the side of the extraction tube and squeeze the extraction tube tightly so that as much liquid as possible is expressed from the swab and can reabsorb. Repeat at least 5 times.
• Let the solution stand for 3-5 minutes at room temperature. Then express the liquid from the swab head by rolling the swab against the wall of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab in accordance with the guidelines for handling infectious agents.
2. Remove the test cassette from the sealed foil pouch and place it on a clean and level surface. The test cassette should be used immediately or within one hour at the latest after opening the foil pouch. Label the test cassette with the patient or control identification.
3. Transfer 3 drops (approximately 120 µL) of the extracted solution or the control with the included disposable pipette from the extraction tube to the sample well of the test cassette. Avoid trapping air bubbles in the specimen well (S) and do not add any solution to the result area. As the test begins to run, you will observe a coloured liquid migrate along the membrane.
4. Wait for the coloured line(s) to appear. The test result should be read after 10 minutes. Do not interpret the result after more than 20 minutes.



RESULT INTERPRETATION
Positive
Two coloured lines appear on the membrane. One line appears in the control line region (C) and the other line appears in the test line region (T). This indicates that streptococcus B antigen has been detected in the sample.
Negative
Only one coloured line appears in the control line region (C). No apparent coloured line appears in the test line region (T). This indicates that no streptococcus B antigen has been detected or the GBS concentration is below the detection limit.
Invalid
The control line fails to appear. Results from any test which has not produced a control line at the specified reading time must be discarded. Please review the procedure and repeat the test with a new test cassette. If the problem persists, discontinue using the test kit immediately and contact your local distributor.
Note:
The colour intensity in the test line region (T) may vary depending on the concentration of the antigen present in the specimen. Therefore, any shade of colour in the test line region should be considered positive. Note that this is a qualitative test only and it cannot determine the concentration of the antigen in the specimen.
Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for the control line failure.

Postive

Negative

Invalid

QUALITY CONTROL

An internal procedural control is included in the test cassette:
A coloured line appearing in the control line region (C) is considered an internal procedural control. It confirms sufficient specimen volume, adequate membrane wicking and correct procedural technique.
Good laboratory practice (GLP) recommends the use of control materials to ensure proper test kit performance. A positive control containing heat-killed group B streptococci and a negative control containing heat-killed non-group B streptococci are provided with each test kit.

STORAGE & STABILITY

The test kit should be stored at 2-30°C and used before the expiry date printed on the packaging. The test cassette should remain in the sealed foil pouch until use. Do not freeze test kits. Care should be taken to protect components of the test kit from contamination. Do not use tests if there is evidence of microbial contamination or precipitation. Biological contamination of dispensing equipment, containers or reagents can lead to false results.

Operating Procedure for External Quality Control Testing:
Bring tests, reagents and controls to room temperature (15-30°C) prior to testing.

1. Place a clean extraction tube onto the designated area of the reagent holder. Add 4 drops of Reagent 1 and 4 drops of Reagent 2 to the extraction tube. In order to ensure reliable drop size when adding the reagents, hold the dropper bottles vertically. Mix the solution by gently swirling the extraction tube.
2. Thoroughly mix the control solution (Positive/Negative Control) by shaking the bottle vigorously. Add 1 drop of Positive or Negative Control to the tube.
3. Place a clean sterile swab into the tube and swirl. Leave the swab in the extraction tube for 1 minute. Then express the liquid from the swab head by rolling the swab against the wall of the extraction tube and squeezing the extraction tube as the swab is withdrawn. Discard the swab.
4. Continue as described in the Step 2 of the 'Test Procedure'. If controls do not yield expected results, do not use the tests with samples. Repeat the Quality Control Testing or contact your distributor.

LIMITATIONS

• 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.
• 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.
• 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.
• 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.
• 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.
• 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.

EXPECTED VALUES

Up to 30% of women carry GBS in their vaginal or rectal flora. Usually this colonisation does not cause any symptoms. However, severe infections may occur if bacteria are transmitted during birth so that GBS is a leading cause of morbiditiy and mortality amongst newborns. The incidence of early-onset neonatal disease is approximately one to two cases per 1,000 live births. Mortality rate is up to 20% in affected neonates. In heavily colonized women infection risk is increased ca. 2.5 fold if compared to lightly colonised women. Intrapartum chemoprophylaxis reduces the infection risk of early onset neonatal disease.

PERFORMANCE CHARACTERISTICS

Correlation Study
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:

		Culture		
		+	-	Total
Strep B Rapid Test	+	20	2	22
	-	2	96	98
	Total	22	98	120

Relative sensitivity: 90.9%
Relative specificity: 97.9%
Overall agreement: 96.7%

Detection limit
The detection limit of the Strep B Rapid Test was determined to be 1×105 organisms/swab. Sensitivity testing is done for each lot as part of quality control and is stated in the lot-specific Certificate of Analysis.

Prozone effect study
No adverse effect on T-line formation was recorded for streptococcus B concentration of up to 1x109 organisms/swab.

Specificity study
Cross-reactivity studies with organisms likely to be found in the vagina/rectum or with other Streptococcus species were performed using the Strep B Rapid Test. The following organisms were tested at 1×107 organisms/swab and showed negative results:

Organism	ATCC No.	Organism	ATCC No.
Candida albicans	1106	Strep C	12401
Corynebacterium diphtheriae	13812	Strep F	12392
Enterococcus durans	19432	Strep G	12394
Enterococcus faecalis	19433	Streptococcus canis	43496
Haemophilus influenzae	9006	Streptococcus equisimlis	9528
Klebsiella pneumoniae	9987	Streptococcus equisimilis	9542
Neisseria gonorrhoeae	27633	Streptococcus equisimilis	12388
Neisseria meningitidis	13077	Streptococcus mutans	25175
Neisseria sicca	9913	Streptococcus pneumoniae	27338
Neisseria subflava	14799	Streptococcus sanguis	10556
Pseudomonas aeruginosa	9721	Streptococcus oralis	9811
Serratia marcescens	8100	Streptococcus mitis	903
Staphylococcus aureus	12598	Streptococcus anginosus	33397
Stapylococcus epidermidis	1228	Streptococcus intermedius	27335
Strep A	19615		

Physician Office Laboratory (POL) Studies
An evaluation of the Strep B Rapid Test was conducted at three physicians' office laboratory sites, using a panel of coded samples containing negative control, low positive and medium positive specimens. Each specimen level was tested at each site in replicates of 30 over a period of 3 days. The study showed >99.9% agreement with the expected results.

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

Inter-lot and intra-lot variability
Three independent lots were tested with negative, low, medium and high positive controls in 10-fold determinations. No unexpected or inconsistent results were obtained, indicating that inter-lot and intra-lot variability is low.

INDEX OF SYMBOL

Symbol	Used For	Symbol	Used For
	Use-by date		Consult instructions for use
LOT	Batch code	IVD	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	Σ	Tests per kit
CE	CE Mark		Biological Risks
EC REP	Authorized representative in the European Community		

BASIC INFORMATION

Ningbo BESTest Bio-technology Co.,Ltd.
Address: No.80 building, No.777, Qing Feng Road, Cicheng Town,Jiangbei District, Ning Bo, Zhejiang, China 315033
Tel: 0086 571 2799 8736

EC REP
CMC MEDICAL DEVICES & DRUGS S.L
Address: C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain
Tel: +34951214054
Email - info@cmcmedicaldevices.com