Strep B Rapid Test Cassette (Swab)
Package Insert

REF WSTB-C71 | English

A rapid test for the qualitative detection of Strep B antigen in female cervical swab.
For professional in vitro diagnostic use only.

【INTENDED USE】

The Strep B Rapid Test Cassette is a rapid chromatographic immunoassay for the qualitative detection of Strep B antigens from female cervical swab specimens to aid in the diagnosis of Group B Streptococcal infection.

【SUMMARY】

Group B *Streptococci* (GBS) or *Streptococcus* agalactiae are among the most frequent causes of life-threatening infectious in neonates. Between 5% and 30% of all pregnant women are colonized with GBS. [1]Several recent studies have shown that the intrapartum treatment of GBS-colonized women significantly reduces the incidence of GBS-caused sepsis. [2-5] Therefore, screening for GBS is important and the US American authorities (Center for Disease Control and Prevention, CDC) emphasize the routine examination for the Group B streptococcus between the 35th and the 37th week of pregnancy. A CDC study results that routine examinations is 50% more effective than the use of antibiotics for pregnant women with clinical risk factors. Standard culture methods require 24 to 48 hours, and the results may not be available soon enough for efficient treatment.

The Strep B Rapid Test Cassette (Swab) is a rapid test to qualitatively detect the Strep B antigen from female cervical specimen.

【PRINCIPLE】

The Strep B Rapid Test Cassette a qualitative, lateral flow immunoassay for the detection of Strep B carbohydrate antigen in swab. In this test, antibody specific to Strep B carbohydrate antigen is coated on the test line region of the test. During testing, the extracted female cervical swab specimen reacts with an antibody to Strep B that is coated onto particles. The mixture migrates up the membrane to react with the antibody to Strep B 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.

【REAGENT】

The test contains Strep B antibody coated particles and Strep B antibody coated on the membrane.

【PRECAUTIONS】

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. The used test should be discarded according to local regulations.
6. Humidity and temperature can adversely affect results.
7. Do not use test if pouch is damaged.
8. Reagent B contains an acidic solution. If the solution contacts the skin or eye, flush with large volumes of water.
9. Do not interchange reagent bottle caps.
10. Do not interchange external control solution bottle caps.

【STORAGE AND STABILITY】

Store as packaged in the sealed pouch at room temperature or refrigerated (2-30°C). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. DO NOT FREEZE. Do not use beyond the expiration date.

【SPECIMEN COLLECTION AND PREPARATION】

- The Strep B Rapid Test Cassette (Swab) can be performed using female cervical swab.
- The quality of specimens obtained is of extreme importance. Detection of Strep B requires a vigorous and thorough collection technique that provides cellular material rather than just body fluids.
- To collect Female Cervical Swab Specimen:
  - Use the swab provided in the kit. Alternatively, any plastic-shaft swab may be use.
  - Before specimen collection, remove excess mucus from the endocervical area with a cotton ball and discard. The swab should be inserted into the endocervical canal, past the squamocolumnar junction until most of the tip is no longer visible. This will permit acquisition of columnar or cuboidal epithelial cells, which are the main reservoir of the *Strep B* organism. Firmly rotate the swab 360°in one direction (clockwise or counterclockwise), let stand for 15 seconds, then withdraw the swab. Avoid contamination from exocervical or vaginal cells. Do not use 0.9% sodium chloride to treat swabs before collection specimens.
  - If the test is to be conducted immediately, put the swab into the extraction tube.
  - It is recommended that specimens be processed as soon as possible after collection. If immediately testing is not possible, the patient swab specimens should be placed in a dry transport tube for storage or transport. The swab may be stored for 4-6 hours at room temperature (15-30℃) or 24-72 hours refrigerated (2-8℃) for 24 hours. Do not freeze. All specimens should be allow to reach the room temperature (15-30℃) before testing.

【MATERIALS】

Materials Provided

- Test Cassette
- Extraction reagent 1 (2M NaNO2)
- Extraction reagent 2 (0.027M Citric acid)
- Package insert
- Extraction tube
- Sterile female cervical swabs
- Workstation
- Dropper tip

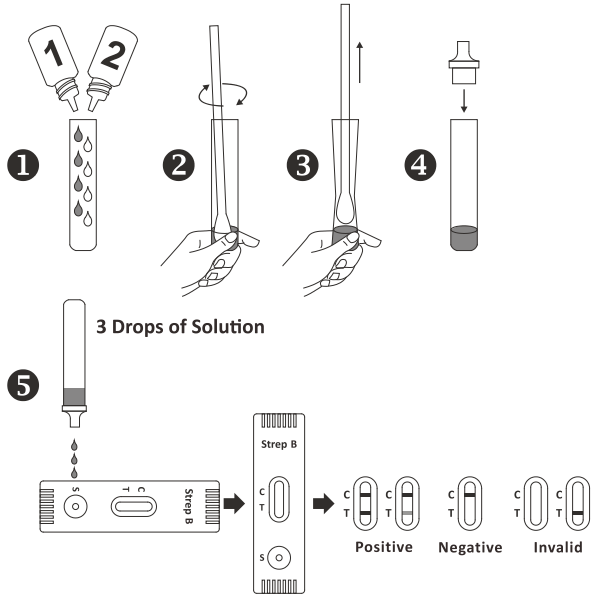
Materials Required But Not Provided

- Timer

【DIRECTIONS FOR USE】

Allow the test, reagents, female cervical swab specimen, and/or controls to reach room temperature (15-30℃) prior to testing.

1. Remove the test cassette 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.
2. Hold the Extraction Reagent 1 bottle vertically and add 4 full drops (approximately 240 µL) of Extraction Reagent 1 to an extraction tube. Extraction Reagent 1 is red in color. Hold the Extraction Reagent 2 bottle vertically and add 4 full drops (approximately 160 µL) to the tube. Extraction Reagent 2 is colorless. Mix the solution by gently swirling the extraction tube. The addition of Extraction Reagent 2 to Extraction Reagent 1 changes the color of the solution from red to yellow. See illustration 1.
3. Immediately add the swab into the extraction tube, agitate the swab vigorously 15 times. Leave the swab in the extraction test tube for 1 minute. See illustration 2.
4. Press the swab against the side of the tube and squeeze the bottom of the tube while removing the swab so that most of the liquid stays in the tube. Discard the swab. See illustration 3.
5. Fit the dropper tip on top of the extraction tube. Place the test cassette on a clean and level surface. Add three drops of the solution (approx.100ul) to the sample well and then start the timer. Read the result at 5 minutes. Do not interpret the result after 10 minutes. See illustration 4 and illustration 5.



【INTERPRETATION OF RESULTS】

(Please refer to the illustration above)

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* antigen 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* antigen 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.

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.

【QUALITY CONTROL】

A procedural control is included in the test. A colored line appearing in the control line region (C) is considered an internal procedural control. It confirms adequate membrane wicking.

Control standards are not supplied with this kit; however, it is recommended that positive and negative controls be tested as good laboratory practice to confirm the test procedure and to verify proper test performance.

【LIMITATIONS】

1. The Strep B Rapid Test Cassette is for in vitro diagnostic use only. The test should be used for the detection of Strep B antigen in the female cervical swab specimen only. Neither the quantitative value nor the rate of increase in Strep B antigen concentration can be determined by this qualitative test.
2. This test will only indicate the presence of Strep B antigen in the specimen from both viable and non-viable Group B Streptococcus bacteria.
3. A negative result should be confirmed by culture. A negative result may be obtained if the concentration of the Strep B antigen present in the female cervical swab is not adequate or is below the detectable level of the test.
4. Excess blood on the swab specimen may interfere with test performance and may yield a false positive result.
5. Therapeutic failure or success cannot be determined as antigen may persist following appropriate antimicrobial therapy..

【EXPECTED VALUES】

The Strep B Rapid Test Cassette (Swab) has been compared with another leading commercial rapid test. The correlation between this two system is 97.4%

【PERFORMANCE CHARACTERISTICS】

Sensitivity and Specificity

A total of 493 vaginal swabs were collected from patients exhibiting symptoms of Vaginal secretion. Each swab was rolled onto a sheep blood agar plate, and then tested by the Strep B Test Cassette. The plates were further streaked for isolation, and then incubated at 37°C with 5-10% CO2 and a Bacitracin disk for 18-24 hours. The negative culture plates were incubated for an additional 18-24 hours. Possible GBS colonies were subcultured and confirmed with a commercially available agglutination grouping kit.

Of the 493 total specimens, 366 were found to be negative by culture and 127 were found to be positive by culture. These swabs were tested using the Strep B Test Cassette.

Method		Culture		Total Results
Strep B Rapid Test Cassette	**Results**	Positive	Negative	
	Positive	120	7	127
	Negative	6	360	366
Total Results		126	367	493

Relative Sensitivity: 95.2% (95%CI*:89.9%-98.2%)*
Relative Specificity: 98.1% (95%CI*:96.1%-99.2%)*
Relative accuracy: 97.4% (95%CI*:95.5%-98.6%)*
* Confidence Intervals

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 B Rapid Test Cassette. No mucoid-producing strains were tested.

Acinetobacter calcoaceticus	Pseudomona aeruginosa	Proteus mirabilis
Acinetobacter spp	Neisseria meningitides	Neisseria gonnorhea
Enterococcus faecalis	Salmonella choleraesius	Group C Streptococcus
Enterococcus faecium	Candida albicans	Hemophilus influenzae
Staphylococcus aureus	Proteus vulgaris	Branhamella catarrhalis
Klebsiella pneumoniae	Gardnerella vaginalis	Group A Streptococcus

【BIBLIOGRAPHY】

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2. You, M.D., Mason, E.O., Leeds, L.J., Thompson, P.K., Clark, D.J. and Gardner, S.E.; Ampicilin prevents intrapartum transmission of group B streptococcus; JAMA 241 (12) 1245-1247 ,1979
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4. Lim, D.V., Morales, W.J., Walsh, W.J. and Kazanis, D.; Reduction of morbidity and mortility rates for neonatal group B streptococcal disease through early diagnosis and chemoprophylaxis; J. Clin.Microbiol. 23 489-492, 1986
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Index of Symbols

	Consult Instruction for use	Σ	Tests per kit	EC REP	Authorized Representative
IVD	For in vitro diagnostic use only		Use by		Do not reuse
2°C 30°C	Store between 2-30°C	LOT	Lot Number	**REF**	Catalog #
	Do not use if package is damaged				

Manufacturer BiotesT
Hangzhou Biotest Biotech Co., Ltd.
17#, Futai Road, Zhongtai Street,
Yuhang District, Hangzhou, P. R. China

EC REP
Shanghai International
Holding Corp. GmbH (Europe)
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