Strep B (GBS) Cassette Test

RAPU014B280

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History

Resume of change :

Previous Version : 150923-1	**Current Version :** 190717-1
Ancient protocol	New protocol
LOT : 150923-1	**Version :** 190717-1
P.I. Number : 150923-1	P.I. Number cleared
No history	History added

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Rapid test for the qualitative detection of Strep B antigen in body fluid specimens

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IN VITRO DIAGNOSTIC

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INTENDED USE

The Strep B Rapid Test Cassette (Swab) is a rapid visual immunoassay for the qualitative, presumptive detection of Group B Streptococcus (GBS) antigens in specimens taken from vaginal or rectal swabs of pregnant women, or general swabs from newborn. This kit is intended for use as an aid in the diagnosis of Strep B 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.1Several recent studies have shown that the intrapartum treatment of GBS-colonized women significantly reduces the incidence of GBS-caused sepsis.2-4 The US Center for Disease Control and Prevention (CDC) recommends routine examination for Group B streptococcus between the 35th and the 37th week of pregnancy. A CDC study has shown 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. Thus, methods utilizing more rapid screening techniques are required.

PRINCIPLE

The Strep B Rapid Test Cassette (Swab) detects Group B Streptococcus antigens through visual interpretation of color development on the internal strip. Anti-Strep B antibodies are immobilized on the test region of the membrane. During testing, the specimen reacts with polyclonal anti-Strep B antibodies conjugated to colored particles and precoated onto the sample pad of the test. The mixture then migrates through the membrane by capillary action, and interacts with reagents on the membrane. If there is sufficient Strep B antigen in the specimen, a colored band will form at the test region of the membrane. The presence of this colored band indicates a positive result, while its absence indicates a negative result. The appearance of a colored band at the control region serves as a procedural control, indicating that proper volume of specimen has been added and membrane wicking has occurred.

REAGENTS

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

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- 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.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled.
- Wear protective clothing such as laboratory coats, disposable gloves and eye protection when specimens are assayed.
- Do not interchange or mix reagents from different lots. Do not mix solution bottle caps.
- Reagents 1&2 are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- Humidity and temperature can adversely affect results.

STORAGE AND STABILITY

The kit can be stored 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.

MATERIALS PROVIDED

CARD	20 Strep B Test Cassettes
EXTR BUF 1	Extraction Buffer 1, 10 ml.
EXTR BUF 2	Extraction Buffer 2, 10 ml.
EXTR TUBE	20 Test tubes
EXTR TIP	20 dropper tips
SWAB	20 swabs
WORKSTATION	1 workstation

- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

Timer

SPECIMEN COLLECTION AND PREPARATION

1. The quality of specimen obtained is of extreme importance. Collect swab specimens using standard clinical methods.
2. It is recommended that swabs 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 can be stored at room temperature up to 4 hours, or refrigerated (2-8°C) up to 24 hours. All specimens should be allowed to reach room temperature (15-30°C) before testing.
3. If a liquid transport method is desired, use Modified Stuart's Transport Media and follow the manufacturer's instructions. Do not place the swab in any transport device containing medium. Transport medium interferes with the assay, and viability of organisms is not required for the assay. Do not use transport media formulas that include charcoal or agar.
4. If a bacteria culture is desired, lightly roll the swab on a 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.

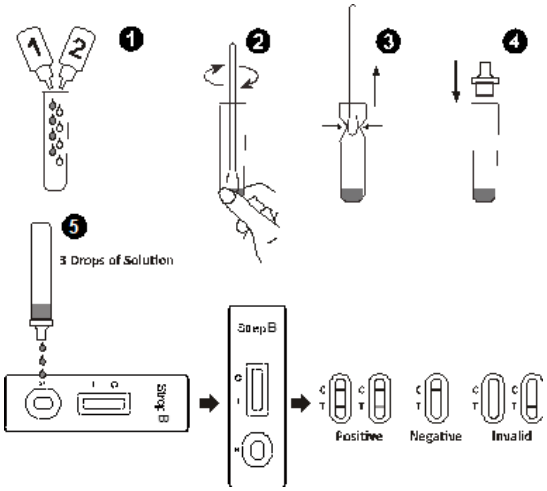
PROCEDURE OF THE TEST

Allow the test, reagents, swab specimen, and/or controls to reach room temperature (15-30°C) 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) of reagent 2 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 Insert the swab into the extraction tube, agitate the swab vigorously 15 times, leave the swab in the extraction test tube for 2 minutes. 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. See illustration 4.
6. Add 3 full drops of the extracted solution (approx. 150µl) to the specimen well of the test cassette, then start the timer. Avoid trapping air bubbles in the specimen well. Wait for the color to appear. Read the result at 10 minutes; do not interpret the result after 20 minutes. See illustration 5.
7. Note: It is suggested not to use the extraction reagents, beyond 30 days after opening the vial.



INTERPRETATION OF TEST 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 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.
Number: 145075705
Effective date: 2017-08-08
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 sufficient specimen volume, adequate membrane wicking and correct procedural technique.
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 professional *in vitro* diagnostic use, and should only be used for the qualitative detection of Group B *Streptococcus*. No meaning should be inferred from the color intensity or width of any apparent bands.
2. The accuracy of the test depends on the quality of the swab specimen. False negatives may result from improper specimen collection or storage. A negative result may also be obtained from patients at the onset of the disease due to low antigen concentration.
3. The test does not differentiate asymptomatic carriers of Group B Streptococcus from those with infection. If clinical signs and symptoms are not consistent with laboratory test results, a follow-up cell culture is recommended.
4. 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
Clinical Study
The Strep B Rapid Test Cassette (Swab) has been evaluated with specimens obtained from patients of STD clinics. Culture is used as the reference method for the Strep B Rapid Test Cassette (Swab). Specimens were considered positive if culture indicated a positive result. Specimens were considered negative if culture indicated a negative result.

Method		Culture		Total Results
Strep B Rapid Test Cassette	Results	Positive	Negative	
	Positive	100	8	108
	Negative	5	350	355
Total Results		105	358	463

Relative Sensitivity: 95.2% (95%CI:*89.6%-98.2%)
Relative Specificity: 97.8% (95%CI:*95.8%-99.0%)
Overall accuracy: 97.2% (95%CI:*95.3%-98.4%) *Confidence Intervals

Cross Reactivity
Intra/Inter-assay
Within-run and Between-run precision have been determined with three different lots by using Strep B negative; low, middle and high positive specimens. Ten replicates of each level were tested each day for 3 consecutive days. The specimens were correctly identified >99% of the time.

Cross Reactivity
Cross reactivity with other organisms has been studied using suspensions of 10^7 Colony Forming Units (CFU)/test. The following organisms were found negative when tested with the Strep B Rapid Test Cassette (Swab).

Acinetobacter calcoaceticus	Pseudomona aeruginosa	Proteus mirabilis
Acinetobacter spp	Gardnerella vaginalis	Chlamydia trachomatis
Enterococcus faecalis	Salmonella choleraesius	Group A/C Streptococcus
Enterococcus faecium	Candida albicans	Hemophilusinfluenzae
Staphylococcus aureus	Proteus vulgaris	Klebsiellapneumoniae

BIBLIOGRAPHY

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3. Boyer, K.M., and Gotoff, S.P.; Prevention of early-onset neonatal group B streptococcal disease with selective intrapartum chemotaxis; N. Eng. J. Med. 314 1665-1669, 1986
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

SYMBOLS

Consult instructions for use	Manufacturer
Storage temperature	Contains sufficient for n tests
Use by	IVD In vitro diagnostic medical device
LOT Batch code	CARD Card Test
REF Catalogue number	CONTENT Content
For single use only	Expiry date
CONTROL + Positive Control	EXTR BUF Extraction Buffer
EXTR TUBE Extraction Tubes	EXTR TIP Extraction Tip

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