Ecotest®

STB-S23 **Strep B Rapid Test Device**

INTENDED USE

The Strep B Rapid Test Device (Swab) is a rapid visual immunoassay for the qualitative, presumptive detection of Group B Streptococcus (GBS) antigens in specimens taken from vaginal or rectal swaps of pregnant women, or general swabs from newborn. This kit is intended for use as an aid in the diagnosis of Strep B infection.

INTRODUCTION

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. [2-4] 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 Device (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.

MATERIALS

Materials Provided

• Individually packed test devices	Each test contains colored conjugates and reactive reagents precoated at the corresponding regions.
• Reagent 1	1.0 M sodium nitrite
• Reagent 2	0.4 M acetic acid
• Positive control	Non-viable Strep B; 0.09% sodium azide
• Sterilized swabs	For specimen collection
• Extraction tubes & tips	For specimen preparation
• Workstation	Workstation
• Package insert	For operating instructions

Materials Required but Not provided

• Timer	For timing use

PRECAUTIONS

- For professional *in vitro* diagnostic use only.
- Do not use after the expiration date indicated on the package. Do not use the test if the foil pouch is damaged. Do not reuse tests.
- This 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 by observing usual safety precautions (e.g., do not ingest or inhale).
- Avoid cross-contamination of specimens by using a new extraction tube for each specimen obtained.
- Read the entire procedure carefully prior to testing.
- Do not eat, drink or smoke in any area where specimens and kits are handled. Handle all specimens as if they contain infectious agents. Observe established precautions against microbiological hazards throughout the procedure and follow standard procedures for the proper disposal of specimens. 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.
- Use only dacron or rayon tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped, or wooden shafted swabs.
- Reagents A & B are slightly caustic. Avoid contact with eyes or mucous membranes. In the event of accidental contact, wash thoroughly with water.
- The positive control contain sodium azide, which may react with lead or copper plumbing to form potentially explosive metal azides. When disposing of these solutions always flush with copious amounts of water to prevent azide buildup.
- Humidity and temperature can adversely affect results.
- Used testing materials should be discarded according to local regulations.

STORAGE AND STABILITY

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

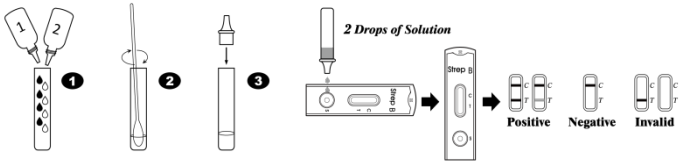
SPECIMEN COLLECTION AND STORAGE

- The quality of specimen obtained is of extreme importance. Collect swab specimens using standard clinical methods.
- Use only Dacron or Rayon tipped sterile swabs with plastic shafts such as those provided. Do not use calcium alginate, cotton tipped, or wooden shafted swabs.
- 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.
- If a liquid transport method is desired, use Modified Stuart's Transport Media and follow the manufacture'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.
- 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

Bring tests, specimens, reagents and/or controls to room temperature (15-30°C) before use.

1. Prepare swab specimens:
   - Place a clean extraction tube in the designated area of the workstation. Add 4 drops of reagent 1 to the extraction tube, then add 4 drops of reagent 2. Mix the solution by gently swirling the extraction tube.
   - Immediately immerse the swab into the extraction tube. Use a circular motion to roll the swab against the side of the extraction tube so that the liquid is expressed from the swab and can reabsorb.
   - Let stand for 3-5 minutes at room temperature, then squeeze the swab firmly against the tube to expel as much liquid as possible from the swab. Cap the extraction tube with the attached dropper tip. Discard the swab following guidelines for handling infectious agents.
2. Remove the test from its sealed pouch, and place it on a clean, level surface. Label the device with patient or control identification. For best results, the assay should be performed within one hour.
3. Add 2 drops (approximately 100 µL) of extracted solution from the extraction tube to the sample well on the test device.
   Avoid trapping air bubbles in the specimen well (S), and do not add any solution to the observation window.
   As the test begins to work, color will migrate across the membrane.
4. Wait for the colored band(s) to appear. The result should be read at 10 minutes. Do not interpret the result after 15 minutes.



INTERPRETATION OF RESULTS

POSITIVE: Two colored bands appear on the membrane. One band appears in the control region (C) and another band appears in the test region (T).

NEGATIVE: Only one colored band appears, in the control region (C). No apparent colored band appears in the test region (T).

INVALID: Control band fails to appear. Results from any test which has not produced a control band at the specified read time must be discarded. Please review the procedure and repeat with a new test. If the problem persists, discontinue using the kit immediately and contact your local distributor.

NOTE:

1. The intensity of color in the test region (T) may vary depending on the concentration of analytes present in the specimen. Therefore, any shade of color in the test region should be considered positive. Note that this is a qualitative test only, and cannot determine the concentration of analytes in the specimen.
2. Insufficient specimen volume, incorrect operating procedure or expired tests are the most likely reasons for control band failure.

QUALITY CONTROL

- Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control. It confirms sufficient specimen volume and correct procedural technique.
- Good laboratory practice recommends the use of control materials to ensure proper kit performance. A positive control containing heat-killed Group B *Streptococcus* is provided with each kit.

Operating Procedure for External Quality Control Testing
Add 2-3 drops of the provided positive directly into the specimen well of the test. Interpret results at 10 minutes. Do not interpret the result after 15 minutes.

PERFORMANCE CHARACTERISTICS

Table 1: Strep B Rapid Test vs. Culture

Sensitivity:
20/(20+2) = 90.9%
Specificity:
96/(96+2) = 97.9%
Overall Agreement:
(20+96)/(20+2+2+96)= 96.7%

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

LIMITATIONS OF THE TEST

1. The Strep B Rapid Test Device 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.

LITERATURE REFERENCES

1. Finch, R.G., French, G.L., and Phillips, I.; Group B streptococci in the female genital tract; Br. Med. J., 1 (6020) 1245-1247, 1976
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
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

GLOSSARY OF SYMBOLS

ρ	Catalog number	0	Temperature limitation
ι	Consult instructions for use	Λ	Batch code
I	In vitro diagnostic medical device	ε	Use by
µ	Manufacturer	T	Contains sufficient for <n> tests
σ	Do not reuse	A	Authorized representative in the European Community
Y	CE marking according to IVD Medical Devices Directive 98/79/EC		

Ecotest®

µ Assure Tech (Hangzhou) Co., Ltd.
2nd, Floor, Building 1, No.10. Xiyuansan RD.,
Westlake ECO. Zone, Hangzhou,
China 310030

A Wellkang Ltd.
Suite B, 29 Harley Street
LONDON, W1G 9QR, U.K.

Number: 1110009810
REV 1.0/ Effective date: 2014-05-20