ONE STEP STREP B
Rapid Immunochromatographic Test for the detection of Streptococcus Group B

20 DET Ref. I4658

PRINCIPLE
Group B streptococci are most notable for their role in causing neonatal sepsis and meningitis. Two forms of neonatal infection have been recognized on clinical and epidemiological grounds:
a) Early onset disease, which usually occurs within the first 10 days after delivery.
b) Late onset disease, which usually, though not always, occurs 10 days after birth.
Late onset disease may be due to nosocomial acquisition of the organism and is rarely associated with material or obstetric complication.
Early onset disease is thought to be due to acquisition, perhaps by aspiration, of the organism from the female genital tract at the time of delivery. The incidence of Group B streptococci range from 1 to 5% live births with fatality rates from 22 to 80%. In order to properly treat the disease using antibiotic therapy, it is important to use an accurate diagnostic method to identify the pathologic agent. Different methods are currently used for detection of Group B Streptococci including cellular culture, immunofluorescence, enzyme immunoassay on latex agglutination. The Strep-B test is a rapid qualitative assay for the detection of *Streptococcus* Group B antigen from vaginal swabs specimens. The method employs an unique combination of monoclonal-dye conjugate and polyclonal solid phase antibodies to selectively identify *Streptococcus* B with a high degree of sensitivity. As the test sample flows through the absorbent device, the labelled antibody-dye conjugate binds to the Strep-B antigen forming an antibody antigen complex. This complex binds to the Anti-Strep-B antibody in the test zone producing a pink-rose colour band. In the absence of Strep-B, there is no line in the test zone. The reaction mixture continues flowing through the absorbent device. Unbound conjugate binds to the reagents in the control zone producing a pink-rose colour band, demonstrating that the reagents are functioning correctly.

One Step STREP-B KIT COMPONENTS
Each kit contains everything needed to perform 20 tests:

- Strep-B reaction devices 20
- Pipettes 20
- Swabs 20
- Extraction solution n°1 in a dropper bottle 6.5 ml
- Extraction solution n°2 in a dropper bottle 6.5 ml
- Instruction leaflet 1
- Plastic tubes 20

STORAGE AND STABILITY
1. All Strep-B kit components should be stored at room temperature (4°C to 30°C) in the sealed pouch.
2. *Do not freeze the test kit.*
3. One Step Strep-B is stable until the expiry date stated on the package label.

PRECAUTIONS
1. This test is designed for “IN VITRO” diagnostic use and for professional use only.
2. Extraction reagents are caustic and may cause irritation to skin, eyes and mucus membranes. Wash off immediately if extraction reagent came in contact with skin.
3. Read carefully instruction notice before using this test.
4. Do not use beyond expiry date which appears on the package label.
5. Do not use the test from a damaged protective wrapper.

SPECIMEN COLLECTION AND PREPARATION
To obtain the best results, specimens should be collected using standard throat swabs collection methods. Plastic shafted swabs with rayon or dacron tips may be used. Do not use swabs with cotton or calcium alginate tips, with wooden shafts or impregnated with charcoal or transport media containing agar or gelatin. Patient samples are best performed immediately following specimen collection. If immediate testing is not possible, the patient samples should be placed in a dry plastic tube and stored refrigerated at 2-8°C.

ASSAY PROCEDURE
1. Remove the test device from the pouch.
2. Place the specimen swab in a plastic tube (12 x 55 mm or comparable). Add 6 drops of extraction reagent 1 (300 µl) and 6 drops of extraction reagent 2 (300 µl). Twirl swab to mix the extraction reagents thoroughly. Incubate at room temperature for 2 min minimum and 5 min maximum.
3. At the end of incubation time, squeeze the swab firmly against the side of the tube in order to remove as much as possible liquid from the swab. Discard the swab.
4. Add 6 drops (200 µl) of the extract solution into the sample well of reaction device.
5. Read results of the test between 5 to 10 min after addition of sample on the device.

READING TEST RESULTS

**Negative:** Only 1 coloured band appears. No apparent band on the test region.

**Positive:** Two clearly distinguishable bands appear.
Inconclusive: If there is no apparent band in the control region, the test is inconclusive. In this case, it is recommended that the test be repeated or a fresh specimen be obtained and tested later.

PERFORMANCES CHARACTERISTICS
A) Accuracy: Duplicate vaginal samples were collected from pregnant women using swabs and cultured on blood agar plates immediately after collection at 37°C for 18 to 24 hours. The haemolytic colonies were then tested using the catalase test. Another cycle of culture and catalase testing was performed for all colonies showing negative results with the catalase test. Finally all colonies giving negative results with second catalase test were using a commercially available STREP B immunoassay (EIA) as confirmatory procedure in order to pool them. The study was performed on a total of 432 patients.

<table>
<thead>
<tr>
<th></th>
<th>One Step Strep B</th>
<th>Total</th>
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<tbody>
<tr>
<td>Culture</td>
<td></td>
<td></td>
</tr>
<tr>
<td>+</td>
<td>46</td>
<td>52</td>
</tr>
<tr>
<td>-</td>
<td>8</td>
<td>372</td>
</tr>
<tr>
<td>Total</td>
<td>54</td>
<td>378</td>
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</table>

From the above table, the sensitivity of One Step Strep-B is 88.4% (46/52) and the specificity is 97.9% (372/380) compared to the culture method.

B) Cross reaction: Different strain of bacteria were tested using the Strep-B-check-1 rapid test in order to determine if they may cause non specific reaction (cross-reactions). The following panel of organisms was obtained from the Center for Disease Control (CDC) and the American Type Culture Collection (ATCC).

<table>
<thead>
<tr>
<th>GROUP</th>
<th>STRAIN</th>
<th>RESULT</th>
</tr>
</thead>
<tbody>
<tr>
<td>Strep B</td>
<td>CDC-1073</td>
<td>Positive</td>
</tr>
<tr>
<td>Strep A</td>
<td>CDC-799</td>
<td>Negative</td>
</tr>
<tr>
<td>Strep C</td>
<td>CDC-660</td>
<td>Negative</td>
</tr>
<tr>
<td>S. MUTANS</td>
<td>ATCC-27351</td>
<td>Negative</td>
</tr>
<tr>
<td>Staph. Epidemitis</td>
<td>ATCC-155</td>
<td>Negative</td>
</tr>
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There was no cross-reaction with the above tested panel of organisms using the One Step Strep B rapid test.

LIMITATIONS
1– One Step Strep-B is a screening test for the presence of Group B streptococci.
2– As it is true with any diagnostic procedure, the physician should evaluate data obtained by the use of this kit in light of other clinical information, including culture, if results are inconsistent with clinical presentation.
3– When from a sample only few colonies can be isolated in culture, Group B streptococci may not be detected using one step STREP-B.

SYMBOLOG
- Read instructions for use
- In vitro medical device
- CE Mark (requirement of 98/79 regulation)
- Storing temperature limits
- Dimension / Number test
- Lot Number
- Catalog Number
- Expiry

BIBLIOGRAPHY

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