Strep B

RAPU014B280

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LOT : 110621/1

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Rapid test for the detection of Group B Streptococcal antigen

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IN VITRO DIAGNOSTIC

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INTENDED USE

The test aids in the diagnosis of diseases caused by bacteria belonging to the genus Streptococcus and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease. For professional use only.
The DIAsource Strep B test kit permits rapid detection of group B streptococci from swabs or culture. The test's accuracy does not depend on the organism's viability. Instead, group B streptococcus antigen is extracted directly from the swab and identified using antibodies specific for the group B strep carbohydrate. The sensitivity of the test is 5700 CFU/ml of Strep B cells.

MATERIALS PROVIDED

- CARD — 20 Strep B test cassettes
- EXTR | BUF — Extraction Buffer (2 bottles), 8 ml per bottle.
- CONTROL | + — Positive control (1 bottle), 1 ml.
- EXTR | TUBE — 20 Test tubes with dropper tips
- Flocked swabs * (includes nylon fibers, swab in sterile packaged) according to 93/42/EWG

*) Micro Rheologics

- Instruction
- Workstation

MATERIALS REQUIRED BUT NOT PROVIDED

- Stop watch

PRECAUTIONS

The Rapid Strep B test kit may be stored at 4-30°C. The test cassette is sensitive to humidity as well as to heat. Perform the test immediately after removing the test cassette from the foil pouch. Do not use it beyond the expiration date.

WARNINGS

- For in vitro diagnostic use only.
- Do not eat or smoke while handling specimens.
- Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
- Avoid splashing or aerosol formation.
- Clean up spills thoroughly using an appropriate disinfectant.
- Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
- Do not use the test kit if the pouch is damaged or the seal is broken.

SPECIMEN COLLECTION

1. Swab the lower vagina (vaginal introitus), followed by the rectum (i.e., insert swab through the anal sphincter) using the same swab or two different swabs.
2. Do not use swabs with cotton or calcium alginate tips or wooden shafts. Do not use swabs impregnated with charcoal or transport media containing agar gelatin.
3. If a sample is to be stored prior to testing, it should be placed in a dry test tube, covered, and refrigerated. All samples should be tested within 5 days after collection.
4. If specimen was refrigerated, it should be brought to room temperature before testing. Avoid thawing and freezing the specimens many times before use.

SPECIMEN PREPARATION

1. Put 14 drops of Extraction Buffer in the test tube.
2. Place the flocked swab in the test tube and rotate the flocked swab between two fingers for 15 seconds.
3. Discard the swab according to federal and local regulations and close the tube with the tip.
4. Mix the contents of the tube by gentle swirling. The mixture is ready for testing.

PROCEDURE OF THE TEST

1. Remove the test cassette from the foil pouch and place it on a flat, dry surface.
2. Hold the test tube with dropper tip above the test cassette, squeeze 4 drops of the mixed specimen into the sample well (S). Wait until each drop is absorbed, before adding additional drops and if the chromatography does not start, add an additional drop.
   If after the first drop, the drop is not absorbed within 30 seconds, follow it up with 2 buffer drops directly from the buffer bottle, and require no additional specimen.
3. As the test begins to work, you will see a purple coloured line move across the Result Window in the centre of the test cassette.
4. Interpret test results at 10 minutes. Do not interpret test after more than 12 minutes.

Caution: The above interpretation time is based on reading the test results at room temperature of 15 to 30° C. If your room temperature is significantly lower than 15° C, then the interpretation time should be properly increased.

Procedure of for External Quality Control Testing

It is recommended to use positive controls when opening a new test kit.

Add 2 to 3 drops of the provided positive control directly into the specimen well (S) of the test. Interpret test results at 10 minutes. Do not interpret test results after more than 12 minutes.

Please see section "Interpretation of the Test" for interpreting the test results.

INTERPRETATION OF TEST RESULTS

- A coloured line will appear at the section of C, to show that the test is working properly. This line is the Control Line.
- The section of the result window closer to the sample well indicates the test results.
  If another coloured line appears at the result window, this line is the Test Line.

1) positive **2) negative** **3) invalid** **4) invalid**

Positive result: The presence of two coloured lines ("T" and "C" line) within the result window, regardless of which line appears first, indicates a positive result (Figure 1).

Note: Generally, the higher the analyte level in the specimen, the darker the "T" line colour will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the colour of the "T" line will be very faint.

Negative result: The presence of only the "C" line within the result window indicates a negative result (Figure 2).

Invalid result: If after performing the test, no line is visible within the result window, or only a "T" line, this result is considered invalid. The directions may not have been followed correctly or the test may have deteriorated. It is recommended that the specimen be re-tested (Figure 3 and 4).

Note: A positive result will not change once you have established your answer at 10 minutes. However, in order to prevent any incorrect results, the test result should not be interpreted after more than 12 minutes.

LIMITATIONS OF THE TEST

Although the test is very accurate in detecting Strep B, a low incidence of false results can occur. Other clinically available tests are required if questionable results are obtained. As is true with any diagnostic procedure, the physician should evaluate data obtained by the use of this kit in light of all available clinical information, including culture, if results are inconsistent with clinical symptoms. The Rapid Strep B test is a qualitative assay. The amount of Strep B present in the specimen cannot be estimated by the assay. The assay results distinguish positive from negative samples. A positive result indicates the sample contains Strep B above the cut-off concentration. 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

The following performance characteristics were conducted with polyester swabs.
Measurements with the flocked swabs showed that they didn`t show any interference with the test kit.
Furthermore measurements showed that usage of flocked swabs increases the limit of detection of the Strep B Rapid test when compared to the polyester swabs.

Sensitivity and Specificity

DIAsource rapid Strep-B test compared to the golden standard of LIM+SBM culture method.

Sensitivity: 88.8% (128/144)
Specificity: 97.8% (277/283)

Relative Sensitivity and Specificity

Clinical comparison with a commercial available ELISA test. Double blind study is carried out with 90 pregnant women about 35 weeks into their pregnancy. Two vaginal swabs (specimen) are taken from each woman, specimen are coded so that a double blind study can be carried out.

Relative Sensitivity: 97,4% (37/38)
Relative Specificity: 98.0% (51/52)

Interference Studies

Potentially interfering chemical substances such as pain medication, lipids, hemoglobin, bilirubin and glucose were supplemented to clinically defined negative normal specimen and clinically defined positive specimens. These samples were tested using the DIAsource Strep-B test by a replicate of 10. A sample was classified negative, when no purple color band was visible for the Strep-B test line but the purple color "C" control line being visible within 10 minutes. A sample was classified positive, when both the control and test line were visible within 10 minutes.

In conclusion, none of the above tested substances showed any interferences with neither a clinically defined negative nor a positive specimen. Negative specimen samples with supplementation of potentially interfering substances gave consistently negative test results, whereas specimen samples positive to Strep B scored consistently positive.

REFERENCES

- Brady K, Duff P, Schilhab JC, et al, "Reliability of a Rapid Latex Fixation Test for Detecting Group B Streptococci in the Genital Tract of Parturients at Term," Obstet Gynecol, 1989, 73(4):678-81.
- Stiller RJ, Blair E, Clark P, et al, "Rapid Detection of Vaginal Colonization With Group B Streptococci by Means of Latex Agglutination," Am J Obstet Gynecol, 1989, 160(3): 566-8.

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!

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	

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