Strep B

RAPU014B280
Strep B

Rapid test for the detection of Group B Streptococcal antigen

RAPU014B280

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.

The DIAsource 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 pouch from the packaging. After removing the test kit from the pouch, do not use it before the expiration date.

WARNINGS

• Do not use the test if the pouch is damaged or the seal is broken.
• Do not use swabs impregnated with charcoal or transport media containing agar gelatin.
• Do not use swabs with cotton or calcium alginate tips or wooden shafts. Do not use swabs with nylon fibers, swab in sterile packaged.
• Do not use the test kit if the pouch is damaged or the seal is broken.

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.

PROCEDURE OF THE TEST

1. Mix the contents of the tube by gentle swirling. The mixture is ready for testing.
2. Put 14 drops of Extraction Buffer in the test tube and rotate the flocked swab between two fingers for 15 seconds.
3. Mix the contents of the tube by gentle swirling. The mixture is ready for testing.
4. Mix the contents of the tube by gentle swirling. The mixture is ready for testing.

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). Interpret test results at 10 minutes. Do not interpret test results after more than 12 minutes.

INTERPRETATION OF TEST RESULTS

1. A coloured line will appear at the section of C, to show that the test is working properly. This line is the Control Line. If another coloured line appears at the result window, this line is the Test Line. Reproductions may vary from original!
2. The section of the result window closer to the sample well indicates the test result. After more than 12 minutes.

1. If specimen was refrigerated, it should be brought to room temperature before testing. Avoid thawing and freezing the specimens many times before use.

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.

1. 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. Reproductions may vary from original!
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)

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.

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 consistantly negative test results, whereas specimen samples positive to Strep B scored consistently positive.

REFERENCES

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