Rapid Strep B Test Disk
for swab specimen
(Revised 6-5-2019)

INTENDED USE

The identification 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 Rapid Strep B test kit is a rapid test for the detection of group B streptococci from swabs or culture. The test's accuracy does not depend on the organism's viability. Instead, group B strep antigen is extracted directly from the swab and identified using antibodies specific for the group B strep carbohydrate. Its analytical sensitivity is 4500 CFU/ml of Strep B cells.

MATERIALS PROVIDED

1. Strep B test device
2. Instructions
3. Disposable sample dropper
4. Extraction Buffer
5. Swab
6. Test Tube
7. External positive and negative control

PRECAUTIONS and External Control

The Rapid Strep B test kit may be stored at room temperature 4-30ºC (40-86ºF). The test device is sensitive to humidity as well as to heat. Perform the test immediately after removing the test device from the foil pouch. Do not use it beyond the expiration date.

External controls maybe performed with the provided positive control, by adding 2 to 3 drops of the positive control directly into the specimen well of the test cassette, positive result should develop within 10 minutes.

WARNINGS

1. For in vitro diagnostic use only.
2. Do not eat or smoke while handling specimens.
3. Wear protective gloves while handling specimens. Wash hands thoroughly afterwards.
4. Avoid splashing or aerosol formation.
5. Clean up spills thoroughly using an appropriate disinfectant.
6. Decontaminate and dispose of all specimens, reaction kits and potentially contaminated materials, as if they were infectious waste, in a biohazard container.
7. Do not use the test kit if the pouch is damaged or the seal is broken.
8. Biotin can interfere and cause incorrect test results for subjects who have elevated levels of biotin in their specimen.

SPECIMEN COLLECTION

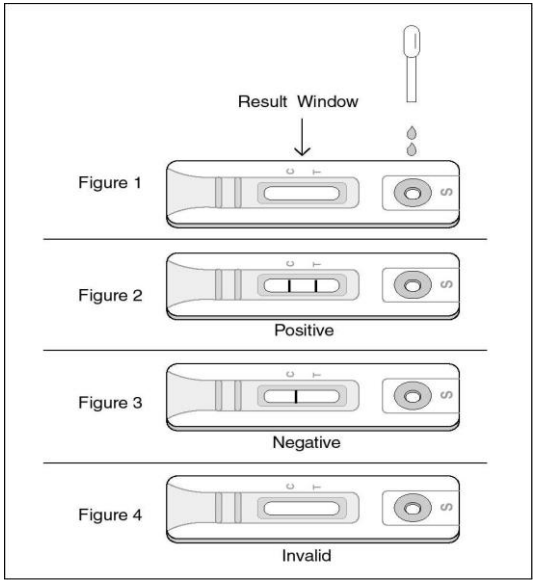
1. Swab the lower vagina (vaginal introitus), followed by the rectum (i.e., insert swab through the anal sphincter) using the same swab or two different swabs.
2. Do not use swabs with cotton or calcium alginate tips or wooden shafts. Do not use swabs impregnated with charcoal or transport media containing 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 12 drops Extraction Buffer in the test tube.
2. Place the specimen swab in the tube and swirl it vigorously to mix the reagents for about 15 seconds. Then incubate the mixture at room temperature for 10 minutes with the swab in the tube.
3. Swirl the swab vigorously for 15 seconds, then expunge as much liquid as possible from the swab by pressing and rotating the fiber portion against the wall of the tube. Discard the swab. Mix the contents of the tube by gentle swirling. The mixture is ready for testing.

PROCEDURE OF THE TEST

1. Remove the test disk from the foil packet, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk, squeeze a total of 3 drops of the mixed specimen into the sample well (Figure 1). Wait until each drop is absorbed, before adding additional drops. Note: If the drops may contain many air-bubbles, then the actual specimen volume may be less than the minimum volume required. So if there is no red-dye migrating to the Result Window in about 30 seconds, add additional drop or drops.



3. As the test begins to work, you will see purple color move across the Result Window in the center of the test disk.
4. Interpret test results at 10 minutes. Do not interpret test after 10 minutes.

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

INTERPRETATION OF THE TEST

1. A color band will appear at the left section of the result window to show that the test is working properly. This band is Control Band.
2. The right section of the result window indicates the test results. If another color band appears at the right section of the result window, this band is Test Band.

POSITIVE RESULT: TWO COLOR BANDS

The presence of two color bands ("T" band and "C" band) within the result window regardless of which band appears first indicates a positive result (Figure 2). Note: Generally, the higher the analyte level in the specimen, the stronger the "T" band color will be. When the specimen analyte level is close to but still within the sensitivity limit of the test, the color of the "T" band will be very faint.

NEGATIVE RESULT: ONE COLOR BAND

The presence of only one purple color band within the result window indicates a negative result (Figure 3).

INVALID RESULT

After performing the test and no purple color band is visible within the result window, 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 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 10 minutes.

Procedure of for External Quality Control Testing

External controls may be tested when opening a new test kit.

1. Add 2 to 3 drops of positive (provided) or negative (provided) control into the sample well of the test device. Interpret test results at 10 minutes. Do not interpret test results after 10 minutes.
2. Please see the previous section of "Interpretation of the Test" for interpreting the test results.

Strep B Relative Sensitivity and Specificity

Ameritek one step Strep B Test Kit has a relative sensitivity of 97.4% and a relative specificity of 98% with a commercially available ELISA Strep B Test Kit.

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 to be obtained. As 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 symptoms. The Rapid Strep B test is 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.

REFERENCES

1. 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.
2. 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.

ORDERING INFORMATION

mö-quick Strep B Test 25 Cassettes CAT-No.: 0230105

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