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 ulti med 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 $5 \times 10^5$ organisms/ml.

MATERIALS PROVIDED
- 20 Strep B test cassettes
- Instruction (1 per kit box)
- Extraction Buffer (2 per kit box)
- Positive Control (1 per kit box)
- 20 flocked swabs
- 20 test tubes with dropper tips
- 1 Workstation

MATERIALS REQUIRED, BUT NOT PROVIDED
- Stop watch

PRECAUTIONS

The Rapid Strep B test kit may be stored at 4-30°C. 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.

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 12 drops of Extraction Buffer in the test tube with dropper tip.
2. Place the flocked swab in the test tube and rotate the flocked swab between two fingers for 10-15 seconds.
3. Discard the swab according to federal and local regulations.
4. Mix the contents of the tube by gentle swirling. The mixture is ready for testing.

IMPORTANT NOTICE

If the extraction procedure yields a viscous solution, please proceed according to the alternative testing procedure.

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 3 drops of the mixed specimen into the sample well (S).
3. As the test begins to work, you will see a purple coloured front 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.

Alternative procedure for viscous samples:

2. Hold the test tube with dropper tip above the test cassette, squeeze 1 drop of the mixed specimen into the sample well (S).
3. After the specimen drop is absorbed, add two drops of extraction buffer into the sample well (S).
4. As the test begins to work, you will see a purple coloured front move across the Result Window in the centre of the test cassette.
5. 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 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 THE TEST**

- A coloured line will appear at the left section of the result window 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 right section of the result window, this line is the Test Line.

**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 in 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.

**REFERENCES**


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**Manufacturer**

| IVD | For in vitro diagnostic use only |
| LOT | Use by |
| n | Store at |

**n** Contents sufficient for <n> tests

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