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CE

Rapid Listeria Cassette Test

Catalog No. R11-534

INTENDED USE

The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genus *Listeria,* and provides epidemiological information on diseases caused by these microorganisms. *Listeria monocytogenes*, the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for infants before or after birth.

PRINCIPLES OF THE PROCEDURE

Immunospec Rapid Listeria Cassette Test is a rapid, non-culture diagnostic assay that can detect the presence of this organism directly from a fecal sample. This test is comprised of colloidal gold particle-labeled anti-Listeria antibodies dried in a binding zone and immobilized antibodies in a capture zone. In this one step procedure, several drops of stool specimen is added to a cassette test. Within minutes, the test result is read. A positive result is indicated by a colored band at the test zone.

MATERIALS PROVIDED

1. Instructions.
2. Disposable Dropper.
3. Test device.

STORAGE OF KIT COMPONENTS

All kit components should be stored in a cool, dry place at room temperature of 4 to 25 degrees C.

SPECIMEN COLLECTION AND HANDLING

Specimens should be stool samples. Samples that will not be tested within 48 hours should be refrigerated at 2 to 8 degrees C.

SPECIMEN PREPARATION

Liquid Specimens: Specimen should sit undisturbed to allow large particles to settle before transferring an aliquot of specimen to begin assay procedure.

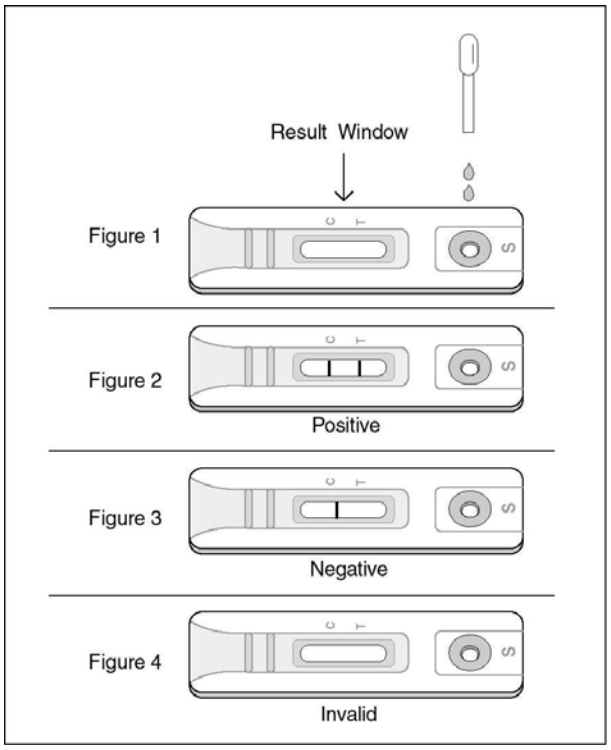
Semi-soft or Formed Specimens: Add five drops of Buffer Solution to a clean labeled tube. Using an applicator stick, transfer a small bead-sized amount of sample to the tube containing the buffer and mix vigorously. Allow large particles to settle before beginning the assay procedure. A sufficient volume of extracted sample should be present to proceed with the assay procedure.

TEST PROCEDURE

1. Remove the test disk from the foil pouch, and place it on a flat, dry surface.
2. Holding the sample dropper above the test disk, squeeze 2 to 3 drops of specimen into the sample well (Figure 1).
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 to 20 minutes. Do not interpret after 30 minutes.

INTERPRETATION OF TEST

1. As the test kit begins to work, a color band will appear at the left section of the Result Window to show that the test is working properly. This band is the Control Line.
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 the Test Line.



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 2).

Invalid result: After performing the test and no purple color band is visible within the result window, this result is considered invalid. Some causes of invalid results are: not following the directions correctly or the test is beyond the expiration date. It is recommended that the specimen be re-tested using a new test kit (Figure 2).

REFERENCES

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