EXPLANATION OF THE TEST

The Listeria is a one-step coloured chromatographic immunoassay for the qualitative detection of Listeria monocytogenes in fecal samples in order to detect listeriosis in infected persons. Only for laboratory use. Listeria monocytogenes is a small, gram-positive bacillus that can grow in anaerobic or aerobic conditions. It is found widely in the environment in soil, decaying vegetation and water and may be part of the fecal flora of many mammals, including healthy human adults. Initial symptoms of infection include nonspecific flu-like symptoms, nausea, vomiting, cramps, diarrhea and fever. There are few clinical features that are unique to listeriosis. Therefore, clinicians must consider a variety of potential causes for infection, including viral infections (influenza) and other bacterial infections that may cause sepsis or meningitis. Symptoms can develop at any time from 2 to 70 days after eating contaminated food. Except for vertical mother–fetus transmission, most cases of listeriosis begin with ingestion of the organism from a food source. Most healthy adults and children who consume contaminated food experience only mild to moderate symptoms. People with poor immune function are at much higher risk of severe, life-threatening forms of listeriosis

Listeria provides a rapid detection of Listeria monocytogenes directly from fecal samples. The Listeria is a qualitative lateral flow immunoassay for the detection of Listeria monocytogenes (L. monocytogenes) antigen in fecal samples. The membrane is pre-coated with monoclonal antibodies against L. monocytogenes antigens on the test line region. During testing, the sample reacts with the particle coated with anti-L. monocytogenes antibodies which was pre-dried on the test strip. The mixture moves upward on the membrane by capillary action. In the case of a positive result the specific antibodies present on the membrane will react with the mixture conjugate and generate a coloured line. A green coloured line always appears in the control line and serves as verification that sufficient volume was added, that proper flow was obtained and as an internal control for the reagents.

MATERIALS PROVIDED

Card tests
Instructions for use
Specimen collection vials with buffer

PRECAUTIONS

For professional in vitro diagnostic use only. Do not use after expiration date. The test should remain in the sealed pouch until use. Do not use the test if pouch is damaged. Follow Good Laboratory Practices, wear protective clothing, use disposal gloves, do not eat, drink or smoke in the area. All the specimens should be considered potentially hazardous and handled in the same manner as an infectious agent. The test should be discarded in a proper biohazard container after testing. The test must be carried out within 2 hours of opening the sealed bag.

STORAGE AND STABILITY

Store as packaged in the sealed pouch either at refrigerated or room temperature (2-30°C/36-86°F). The test is stable through the expiration date printed on the sealed pouch. The test must remain in the sealed pouch until use. Do not freeze.

SPECIMEN COLLECTION AND PREPARATION

Collect sufficient quantity of feces (1-2 g or mL for liquid sample). Stool samples should be collected in clean and dry containers (no preservatives or transport media). The samples can be stored in the refrigerator (2-8°C/36-46.4°F) for 1-2 days prior to testing. For longer storage (maximum 1 year) the specimen must be kept frozen at −20°C/-4°F. In this case, the sample will be totally thawed, and brought to room temperature before testing. Freezing and thawing cycles are not recommended.

PROCEDURE OF THE TEST

To process the collected stool samples:
Use a separate specimen collection vial for each sample. Unscrew the cap of the vial and introduce the stick four times into the fecal specimen to pick up the sample (approx. 125mg). Close the vial with the buffer and stool sample. Shake the vial in order to assure good sample dispersion. For liquid stool samples, aspirate the fecal specimen with a dropper and add 125µL into the vial with buffer.

Test Procedure:
Allow the tests, stool samples and buffer to reach to room temperature (15-30°C/59-86°F) prior to testing. Do not open the pouch until ready to perform the assay.
1. Remove the Listeria from its sealed pouch and use it as soon as possible.
2. Shake the specimen collection vial to assure good sample dispersion. Break off the cap of the vial.
3. Use a separate device for each sample. Dispense exactly 4 drops into the specimen well (S). Start the timer.
4. Read the result at 10 minutes after dispensing the sample.

INTERPRETATION OF THE TEST

POSITIVE: Two lines appear across the central window, a red test line marked with the letter T and a green control line marked with the letter C.

NEGATIVE: Only one green line appears across the control line region marked with the letter C (control line).

INVALID: Total absence of the green control coloured line regardless the appearance or not of the red test line.
**Note:** Insufficient specimen volume, incorrect procedural techniques or deterioration of the reagents are the most likely reasons for control line failure. Review the procedure and repeat the test with a new test. If the problem persists, discontinue using the test kit and contact your local distributor.

**NOTES ON THE INTERPRETATION OF RESULTS:**
The intensity of the red coloured band in the result line region (T) will vary depending on the concentration of viral antigens in the specimen. However, neither the quantitative value nor the rate of increase in antigens can be determined by this qualitative test.

**EXPECTED VALUES:**
In some groups (immunosuppressed people, neonates, pregnant women and their unborn children) it can be an important cause of life-threatening bacteraemia and meningitis. Because listeriosis has a long incubation time (three to 60 days), it is often difficult to trace the source of infection. This explains why the vast majority of cases are notified as single cases. Nevertheless some well-documented outbreaks of listeriosis have been reported from Finland, France, Switzerland, the United Kingdom (UK) and United States (US).

**LIMITATIONS OF THE TEST**
Listeria will only indicate the presence of L. monocytogenes antigens in the specimen (qualitative detection) and should be used for the detection of L. monocytogenes antigens in feces specimens only. Neither the quantitative value nor the rate of increase in L. monocytogenes antigens concentration can be determined by this test.

**INTERNAL QUALITY CONTROL**
Internal procedural controls are included in the test: A green line appearing in the control line region (C). It confirms sufficient specimen volume and correct procedural technique.

**PERFORMANCES CHARACTERISTICS**
**Sensitivity and specificity**
It was studied 32 some stool samples using Listeria. For all samples, the result was confirmed by Singlepath® L’mono (Merck). The results were >99% of sensitivity and >96% of specificity.

**Cross-reactivity**
It was performed an evaluation to determine the cross-reactivity of Listeria. There is not cross-reactivity with common intestinal pathogens, other organisms and substances occasionally present in feces: Adenovirus, Astrovirus, Campylobacter, Escherichia coli O157:H7, Giardia lamblia, Helicobacter pylori, Rotavirus, Salmonella, Shigella, Staphylococcus aureus, Yersinia enterocolitica.

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2. An excess of sample could cause wrong results (brown lines appear). Dilute the sample with the buffer and repeat the test.

3. Some stool samples can decrease the intensity of the control line.

4. Freeze and thaw several times the fecal samples could cause wrong results.

5. If the test result is negative and clinical symptoms persist, additional testing using other clinical methods is recommended. A negative result does not at any time preclude the possibility of Listeria infection.

6. This test provides a presumptive diagnosis of listeriosis. All results must be interpreted together with other clinical information and laboratory findings available to the physician.

**REFERENCES**

**GRAPHICAL SYMBOLS USED**

**REV.1   09/2018**

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