Proflow™ Listeria

(for *In Vitro* Diagnostic use only)

PRODUCT CODE PL.3018 **20 Tests**

INTENDED USE

The Proflow™ Listeria test is a single use rapid membrane immunoassay for the qualitative detection of *Listeria monocytogenes* antigen in faecal samples to aid in the diagnosis of listeriosis. For *In Vitro* Diagnostic Use.

SUMMARY AND EXPLANATION

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 faecal flora of many mammals, including healthy human adults. Initial symptoms of infection include non-specific flu-like symptoms, nausea, vomiting, cramps, diarrhoea 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 mother–foetus 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.

PRINCIPLE OF THE TEST

The Proflow™ Listeria test is a single use rapid membrane immunoassay for the qualitative detection of *Listeria monocytogenes* antigen in human faecal samples.

Monoclonal antibodies to *Listeria monocytogenes* antigen are coated onto the test line region of the strip. During testing the sample migrates along the membrane by capillary action and is allowed to react with the conjugate on the test strip. In the case of a positive result the specific antibodies present on the membrane will capture the coloured conjugate. A green line should always appear in the control line region to show that sufficient volume was added, proper flow was obtained and the reagents functioned correctly. Failure of the control line to appear, whether or not test lines are present, indicates an invalid assay.

The test is interpreted by the presence or absence of visibly detectable coloured lines in the test region at 10 minutes or less depending on the concentration of antigen present.

A positive result will show a pink/red test line and a green control line, indicating that *Listeria monocytogenes* antigen is present in the sample. A negative test result, read at 10 minutes, will show only a green control line, indicating that *Listeria monocytogenes* antigen was not detectable in the sample.

MATERIALS PROVIDED

- PL.3118 Proflow™ Listeria Test Devices: 20 devices
- PL.3218 Proflow™ Listeria Sample Preparation Device: 20 devices
- Package insert

MATERIALS REQUIRED BUT NOT PROVIDED

- Sample collection container
- Timer or stopwatch
- Biohazard disposal container
- Disposable gloves

STABILITY AND STORAGE

- Store all components at 2-30ºC.
- Do not freeze or overheat.
- Do not use beyond the expiration date printed on the outer package label.
- The test kits should be kept away from direct sunlight, moisture and heat.

PRECAUTIONS

- For *In Vitro* Diagnostic Use only.
- For professional use only.
- Directions should be read and followed carefully.
- Tests are for single use only. Do not reuse.
- Reagents are provided at the necessary working strength. Do not dilute reagents.
- Do not interchange reagents between kits with different lot numbers.
- Do not use kits or reagents beyond the stated expiration dates.
- Microbial contamination of reagents may decrease the accuracy of the assay.
- Treat all materials as if they were infectious and dispose of all material in accordance with local regulation.

SAMPLE STORAGE AND COLLECTION

- Collect sufficient quantity of faeces (1-2g or mL for liquid samples).
- Faecal samples should be collected in clean and dry containers (no preservatives or transport media).
- Samples may be stored at 2-8°C for 1-2 days or at -20°C for longer periods before testing.
- Allow all samples to equilibrate to room temperature before testing.
- Freezing and thawing cycles are not recommended.

TEST PROCEDURE

Use a separate sample collection vial and test for each sample or control. Allow the tests, faecal samples and buffer to reach room temperature prior to testing.

1. Introduce the swab or stick four times into the faeces up to the thread of the stick to pick up approx. 50 mg, and put back into the sample preparation device with buffer. For liquid faecal samples, aspirate with a dropper and add 50 µL into the sample preparation device.
2. Shake the sample preparation device to ensure good sample dispersion.
3. Remove the Proflow™ Listeria test from its sealed pouch.
4. Break off the top of the vial on the sample preparation device.
5. Dispense 3 drops (100 uL) into the sample well on the test (S).
6. Read the result at 10 minutes.

QUALITY CONTROL PROCEDURE

It is recommended that a positive and negative control be used to ensure that the test is performing as expected.

The control line (C) is a procedural control and will show that the test has been performed correctly; proper flow occurred and that the test reagents functioned as expected. When a green line appears at the control line position this indicates the test has been performed correctly. The control line will appear on all valid tests, whether or not the sample is reactive or non-reactive (refer to the Interpretation of Results section).

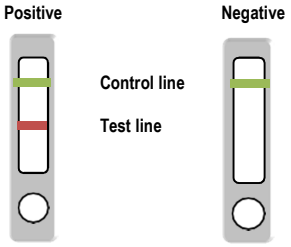
INTERPRETATION OF RESULTS

Positive

A pink/red line of any intensity appears in the test window at the test line position. This indicates a reactive result that is interpreted as positive for *Listeria monocytogenes* antigen.

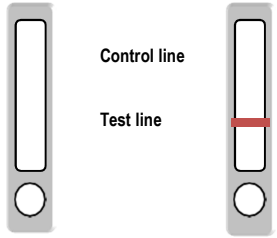
Negative

A single green line of any intensity appears in the test window at the control line position. There is no line at the test line position. This indicates a non-reactive result that is interpreted as negative for *Listeria monocytogenes* antigen.



Invalid

No line appears in the test window at the control line position. This is an invalid result and cannot be interpreted. This is irrespective of whether or not a pink/red line appears in the test window at the test line position. If either condition below occurs, the test should be repeated with a new test.



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LIMITATIONS OF THE PROCEDURE

- Proflow™ Listeria test will only indicate the presence of *Listeria monocytogenes* antigens in the sample (qualitative detection) and should be used for the detection of *Listeria monocytogenes* antigens in faeces samples only. Neither the quantitative value nor the rate of increase in *Listeria monocytogenes* antigen concentration can be determined by this test.
- An excess of sample could cause wrong results (brown bands appear). Dilute the sample with the buffer and repeat the test.
- Some faecal samples can decrease the intensity of the control line.
- The test must be carried out within 2 hours of opening the sealed bag.
- 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.
- This test provides a presumptive diagnosis of listeriosis. All results must be interpreted together with other clinical information and laboratory findings available to the clinician.

PERFORMANCE CHARACTERISTICS

EXPECTED VALUES

In some groups (immunosuppressed people, neonates, pregnant women and their unborn children), a Listeria infection can be an important cause of life-threatening bacteraemia and meningitis. Because listeriosis has a long incubation time (3-60 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 UK, and the US.

SENSITIVITY AND SPECIFICITY

An evaluation was conducted comparing the results obtained using the Proflow™ Listeria test with another commercially available membrane immunoassay. Proflow™ Listeria test showed:

Specificity >96%
Sensitivity >99%

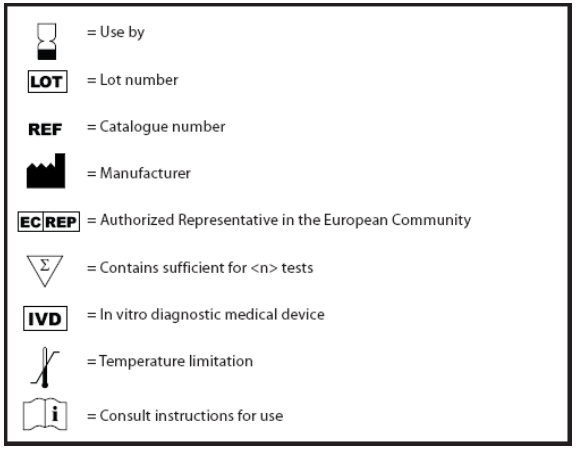
CROSS-REACTIVITY

An evaluation was performed to determine the cross-reactivity of the Proflow™ Listeria test. There was no cross-reactivity with common intestinal pathogens, other organisms and substances occasionally present in faeces:

- Adenovirus
- Astrovirus
- Campylobacter
- *Escherichia coli* O157:H7
- *Giardia lamblia*
- *Helicobacter pylori*
- Rotavirus
- Salmonella
- Shigella
- *Staphylococcus aureus*
- *Yersinia enterocolitica*

REFERENCES

- Bottledoorn N. et al. Microbiological and molecular investigation of an increase of human listeriosis in Belgium, 2006-2007. *Euro Surveill*. 2010; Vol 15, No 6:p19482.
- Bortolussi R. Listeriosis: a primer. *CMAJ*, October 2008; Vol 179, No8:, pp 795-797.



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