

1. Identification

Product name***Listeria monocytogenes* Detection Kit****Cat. No****FP0116** (96 reactions)

2. Description

Listeria monocytogenes are Gram-positive, rod-shaped ubiquitous bacteria that cause human listeriosis, a rare disease associated with high hospitalization and mortality rates—causing septicemia, meningitis, miscarriage, and stillbirth—that affects the elderly, pregnant women, newborns, and immunocompromised adults. The ingestion of contaminated food (such as meat, poultry, dairy, vegetables, and ready to eat products) is the main route of transmission to humans.

Listeria monocytogenes* Detection Kit** is based on amplification and detection of specific DNA fragments from ***Listeria monocytogenes by the real-time PCR method.

All reagents required for qPCR are provided ready to use as PCR Master Mix. The PCR Master Mix contains the appropriate amounts of buffer, dNTPs, Hot-start DNA polymerase, DNA-free water and MgCl₂ to perform the number of reactions indicated in the kit. The PCR Master Mix also includes an internal amplification control (IAC) whose detection indicates the absence of PCR inhibitors. Primers and probes for the amplification of IAC as well as for the amplification of the target gene are included in the Master Mix. The probe for the detection of target gene is labelled with the FAM, whereas the probe for the detection of IAC is labelled with the HEX fluorochrome. In addition, the kit includes positive control DNA and negative control. The positive control is supplied to demonstrate that the PCR amplification is working efficiently with the supplied components. To confirm absence of contamination, a negative control reaction should be included every time the kit is used.

3. Composition

- ✓ PCR Master Mix (1 vial)
- ✓ PCR Positive Control (1 vial)
- ✓ PCR Negative Control (1 vial)

4. Features

- ✓ **Amplification limit:** 10 genomic units per reaction (100%), 2 genomic units per reaction (40%)
- ✓ **Quantification limit:** 20 genomic units per reaction (100%).
- ✓ Quantification Dynamic range: 6 logs
- ✓ **Target:** *Listeria monocytogenes*
- ✓ **Inclusivity:** Positive in 48 reference strains of *L. monocytogenes* (serovars 1 to 7) from different collections.
- ✓ **Exclusivity:** 100% Tested with 94 nontarget strains composed of 51 strains of *Listeria nonmonocytogenes* and 43 strains of non-*Listeria*.
- ✓ **Detection:** probe labelled with fluorescent dyes ***Listeria monocytogenes***: FAM-BHQ1a; **IAC**: HEX-BHQ1.
- ✓ **Thermal cycler:** Agilent Mx3005P, Applied Biosystems 7300, 7500 and other cyclers.

5. Storage specifications

The ***Listeria monocytogenes* Detection Kit** are shipped at ambient temperature. On arrival the kit should be stored at -20°C. Avoid prolonged exposure to light. If stored correctly the kit will retain full activity for 12 months. The kit can be stored at 4°C for 1 month.



DATA SHEET

Version: 01
Revision date: 23/07/2025

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6. PCR cycling conditions

PCR reaction:

Load 5 µl of the extracted DNA samples into each PCR tube or plate well containing 15 µl of the reaction mix. Load also 5 µl of the positive controls into the appropriate tubes or plate wells. Place the PCR tubes or the plate into the real time thermal cycler. Set the fluorescence reading at the channels corresponding to the fluorochromes FAM, HEX (IAC).

Step	Time	Temperature
Initial denaturation	10 min	95°C
40 Cycles	15 sec 1 min	95°C 60°C*
Melt analysis	Refer to instrument instructions	Refer to instrument instructions

*Fluorescence measurements should be carried out during Step 2 at the end of each Annealing/Extension cycle at 60 °C

7. Analysis of results

Follow instrument software instructions to generate cycle threshold (Ct) values from the acquired data. The user may also, optionally, analyse the melt profile of each reaction.

The quantity of DNA target in each sample can be calculated by referring to the positive control template Ct value.

A result will be considered as positive whenever fluorescence corresponding to Salmonella intercepts the threshold value for detector.

A reaction will be considered negative whenever no amplification curve is produced or fluorescence does not cross the threshold and there is an amplification curve for IAC at the expected Ct.

PRECAUTIONS

- ✓ Follow ISO 22174:2024 / UNE-EN ISO 22174:2025 Microbiology of the food chain – Polymerase chain reaction (PCR) for the detection and quantification of microorganisms and viruses – Requirements and definitions
- ✓ **Good Laboratory Practice** must be observed in order to obtain reliable results with this technique. The high sensitivity of this test requires extreme care to maintain the purity of all reagents.
- ✓ Nucleic acids are very sensitive to degradation by nucleases, which are present in human skin and in surfaces that have been in contact with human skin. Wash surfaces with appropriate reagents, use powder-free examination gloves and a lab coat throughout the whole test. Wash hands thoroughly after performing the test.
- ✓ This test has been validated by using the reagents provided with **Listeria monocytogenes Detection Kit**. The use of other amplification methods or any change in the protocol may render false results. DO NOT INTERCHANGE COMPONENTS from different lots.
- ✓ Do not use **Listeria monocytogenes Detection Kit** after expiry or best before date. Store this product at the indicated temperature and conditions.
- ✓ The use of this product is limited to qualified personnel experienced in DNA extraction and amplification techniques.
- ✓ **Not For Medical Diagnostic Use**



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8. Further information

Product Use Limitations This product is developed, designed, and sold exclusively only for research purposes use. The product was not tested for use in diagnostics or for drug development, nor is it suitable for administration to humans or animals.

Safety Information When working with chemicals, always wear a suitable lab coat, disposable gloves, and protective goggles. For more information, please consult the appropriate material safety data sheets (MSDS). These are available online in convenient and compact PDF format at www.canvaxbio.com where you can find, view, and print the MSDS for each CANVAX kit.

