

DATA SHLL

Version: 02 Revision date: 05/06/2023 Canvax Reagents, S.L.U. Luis de Mercado Street, 19 Boecillo Technological Park 47151, Boecillo Valladolid, Spain.

Tlf: +34 983 54 85 63 info@canvaxbiotech.com

www.canvaxbiotech.com

1. Identification

Product name PRImeDETECT™ Listeria monocytogenes

Detection Kit

Cat. No FP0016 (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.

PRImeDETECT™ 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.

Include DNAready lysis buffer to extract the DNA from the sample prior to PCR detection.

3. Composition

- ✓ PCR Master Mix (1 vial)
- ✓ DNAready lysis buffer (1 bottle)
- ✓ PCR Positive Control (1 vial)
- ✓ PCR Negative Control (1 vial)

4. Features

- ✓ Amplification limit: 10 UG per reaction (100%), 2 UG per reaction (40%)
- ✓ Quantification limit: 20 UG 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 nomonocytogenes and 43 strains of non-Listeria.
- ✓ Detection: probe labelled with fluorescent dyes Listeria monocytogenes: FAM-BHQ1a; IAC: HEXBHQ1.
- ✓ Thermal cycler: Agilent Mx3005P, Applied Biosystems 7300, 7500 and other cyclers.





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5. Storage specifications

The PRImeDETECT™ Listeria monocytogenes Detection Kits 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.

6. PCR cycling conditions

Step	Time	Temperature
Initial denaturation	10 min	95°C
40 Cycles	15 sec	95°C 60°C*
	1 min	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, analyze 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.

Not For Medical Diagnostic Use.

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.

