

Data sheet

PRImeDETECT™ *Legionella spp* Detection Kit (*Legionella spp*)

Cat. No: FP0030 (48 reactions)

Cat. No: FP0031 (96 reactions)

Introduction

Waterborne pathogens and related diseases are a major public health concern worldwide, not only by the morbidity and mortality that they cause, but by the high cost that represents their prevention and treatment. These diseases are directly related to environmental deterioration and pollution.

Legionella contamination in air conditioners and water supply systems poses a serious health concern. Canvax Biotech SL offers molecular microbiology PCR-based detection systems intended for the specific, rapid, and reliable detection of this pathogen in a user-friendly and cost-effective format.

PRImeDETECT™ *Legionella spp* Detection Kit (*Legionella spp*) is based on amplification and detection of specific DNA fragment from *Legionella spp* by the real-time PCR method.

All reagents required for qPCR are provided ready to use as 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 (*Legionella spp*), whereas the probe for the detection of IAC is labelled with the JOE 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.

Each kit contains:

- ✓ PCR Master Mix (1 vial)
- ✓ DNAREady lysis buffer (1 Bottle)
- ✓ PCR Positive Control (1 vial)
- ✓ PCR Negative Control (1 vial)

Shipping and Storage

PRImeDETECT™ *Legionella spp* Detection Kit is 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 6 months. The kit can be stored at 4°C for 1 month.

Technical features

- ✓ **Amplification limit:** 2.5 copies/reaction (95%).
- ✓ **Quantification limit:** 5 copies/reaction (95%).
- ✓ **Quantification Dynamic range:** 8 logs
- ✓ **Target:** *Legionella spp*.
- ✓ **Sample:** Environmental and Biological Samples (water, sediments, sputum, blood, serum, and urine samples).
- ✓ **Inclusivity:** 100%. Primers and probes have been tested satisfactorily in 29 strains of *Legionella*.
- ✓ **Exclusivity:** 100%. Primers and probes have been tested satisfactorily in 28 non-*Legionella* bacteria.
- ✓ **Compliance:** ISO/TS 12869:2012
- ✓ **Detection:** probe labelled with fluorescent dyes—*Legionella*: FAM-TAMRA; IAC: JOE-TAMRA.
- ✓ **Thermal cycler:** Agilent Mx3005P, Applied Biosystems 7300, 7500 and other cyclers.

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PCR cycling conditions

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

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.

PRODUCT USE LIMITATION

Not For Medical Diagnostic Use.

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