Data sheet

PRImeDETECT[™] Legionella spp Plus Detection Kit (Legionella spp & Legionella pneumophila)

Cat. No: FP0025 (48 reactions) Cat. No: FP0026 (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 Plus Detection Kit (Legionella spp & Legionella pneumophila) is based on amplification and detection of specific DNA fragments from *Legionella* spp and/or *Legionella pneumophila* by the real-time PCR method (multiplex PCR).

All reagents required for qPCR are provided ready to use as Multiplex PCR Master Mix (1 vial). The Multiplex 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 Multiplex 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) and HEX fluorochrome (L. pneumophila), whereas the probe for the detection of IAC is labelled with the CY5 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:

- \checkmark Multiplex 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 Plus 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 12 months. The kit can be stored at 4°C for 1 month.

Technical features

- Amplification limit: Legionella spp: 5 UG per reaction. L. pneumophila: 100 UG per reaction.
- \checkmark Quantification limit: Legionella spp: 50 UG/L. L. pneumophila: 1000 UG/L.
- \checkmark Quantification Dynamic range: 5 logs
- and Simultaneously detect differentiate Legionella spp. and L. pneumophila in the same tube
- ✓ Inclusivity: Primers and probes have been tested satisfactorily in 14 strains of L. pneumophila and 30 species of the genus Legionella.
- **Compliance: ISO/TS 12869:2012**
- Exclusivity: No cross-reactions with other frequent bacterial agents have been observed.
- Detection: probe labelled with fluorescent dyes-Legionella: FAM-BHQ1a; L. pneumophila: HEX-BHQ1; IAC:CY5-BHQ2.
- Thermal cycler: Agilent Mx3005P, Applied Biosystems 7300, 7500 and other cyclers.

Distributed by:



Tallaght Business Park Whitestown, Dublin 24. Ireland D24 RFK3

Tel: (01) 4523432 Fax: (01) 4523967 Web: www.labunlimited.com

Quatro House, Frimley Road, Camberley. United Kinadom **GU16 7ER**

Tel: 08452 30 40 30 Fax: 08452 30 50 30 E-mail: info@labunlimited.com E-mail: info@labunlimited.co.uk Web: www.labunlimited.co.uk

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PCR cycling conditions

Step	Time	Temperature
Initial denaturation	10 min	95°C
45 Cycles:	15 sec 1 min	95°C 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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Tel: 08452 30 40 30 Fax: 08452 30 50 30 E-mail: info@labunlimited.com E-mail: info@labunlimited.co.uk

