



Validation of alternative  
analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **UNI 03/08-11/13**

Extension decision dated: **06-10-2022**

Expiry date: **04-11-2025**

The Company:

**OXOID Ltd**  
**Thermo Fisher Scientific**  
Wake Road, Basingstoke  
Hampshire RG24 8PW  
ENGLAND

Is authorized to affix the NF VALIDATION mark on the alternative analysis method cited below, in accordance with the NF VALIDATION general rules and the certification rules NF102 - Validation of alternative analysis methods (Application to the food industry):

## Thermo Scientific™ SureTect™ *Listeria* *monocytogenes* PCR Assay

Validated for the detection of *Listeria monocytogenes*

Technical sheet  
reference's

**MAN0017807 Revision G.0**

This decision attests that the alternative analysis method has been assessed by AFNOR Certification and found to conform to the standards cited in page 2/2 and complementary requirements, as specified in the certification reference document. The **principal certified characteristics** are the "analytical performances" as defined in the associated validation study summarized report (sensitivity, relative level of detection), available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last version dated 21-11-2022). This NF VALIDATION certificate, included 2 pages, is valid until **4<sup>th</sup> November 2025**. It is subject to the results obtained upon regular controls carried out by AFNOR Certification. Appropriate decision is made by AFNOR Certification in accordance with the NF VALIDATION general rules and certification rules NF102 - Validation of alternative analysis methods (Application to the food industry).



Managing Director  
Julien NIZRI

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The alternative analysis method:

## Thermo Scientific™ SureTect™ *Listeria monocytogenes* PCR Assay

Validated for the detection of *Listeria monocytogenes*

Manufactured by:

**Thermo Fisher Scientific Oy**  
(Microbiology Vantaa)  
Ratastie 2, PO BOX 100  
Vantaa, FI-01621, FINLAND

Has been certified according to the reference documents and the application scope specified here after:

Validation protocol	<b>NF EN ISO 16140-2</b> (September 2016): Microbiology of the food chain. Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method.
Reference method(s)	<b>NF EN ISO 11290-1</b> (Juillet 2017) : Microbiology of the food chain - Horizontal method for the detection and enumeration of <i>Listeria monocytogenes</i> and of <i>Listeria</i> spp. - Part 1 : detection method
Scope	All human food products (by performing validation assays on a broad range of foods) and industrial production environmental samples (7500 Fast and QS5 instruments) ; in meat products, milk and dairy products, seafood and fishery products, vegetables and industrial production environmental samples (PikoReal PCR instrument)
Restriction(s)	None.
Warning	None.
Other information	New enrichment protocol using the broth 24±4 and new formulation of Brilliance™ <i>Listeria</i> Agar

Please send any queries concerning the performances of the certified alternative method to AFNOR Certification.

You may download the validation study **summarized report** on <http://nf-validation.afnor.org/en>.

CERTI F 2022.1 08/2020

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