



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **UNI 03/09-11/13**

Extension decision dated: **16-05-2025**

Expiry date: **28-11-2025**

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* species PCR Assay

Validated for the detection of *Listeria* spp.

Technical sheet
reference's

MAN0026598 Revision F (all versions F covered)

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 **November 28th, 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

Issue dated 19/05/2025

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The alternative analysis method:

Thermo Scientific™ SureTect™ *Listeria* species PCR Assay

Validated for the detection of *Listeria* spp.

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 | NF EN ISO 16140-2 (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) | NF EN ISO 11290-1 (July 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 (QS5 and 7500 Fast PCR instruments); 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 | <p>The scope includes both manual and automated workflows using the CyBio FeliX instrument in combination with the Applied Biosystems™ QuantStudio™ 5 PCR instrument or equivalent (same features) and Thermo Scientific™ RapidFinder™ Analysis software version 3.0 or higher.</p> <p>Large test portion size (125 g) for dairy products and multi-component foods. Minimum enrichment time of 20 h using Thermo Scientific™ Oxoid™ 24 <i>Listeria</i> Enrichment Broth (24 LEB). ISO-compliant Thermo Scientific™ Oxoid™ <i>Brilliance</i>™ <i>Listeria</i> Agar (ISO) media for confirmation.</p> |

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>.