

#### Validation of alternative analysis methods

NF102 - Application to the food industry



Certificate No.: UNI 03/07-11/13
Extension decision dated: 04-09-2023

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™ *Salmonella* species PCR Assay

Validated for the detection of Salmonella spp.

Technical sheet reference's

MAN0026138 Rev B.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 <a href="http://nf-validation.org/en">http://nf-validation.org/en</a>.

This certificate supersedes all previous certificates. 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

ssue dated 25/09/2023



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The alternative analysis method:

# Thermo Scientific™ SureTect™ *Salmonella* species PCR Assay

Validated for the detection of Salmonella 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 6579-1/A1 (March 2020): Microbiology of the food chain- Horizontal method for the

detection, enumeration and serotyping of Salmonella - Part 1: Detection of Salmonella spp. - Amendment 1: Extension of the incubation temperature range, amendment of the status of Annex

D and correction of the composition of MSRV and SC media

Scope In all human food products (by performing validation assays on a broad range of foods) and

industrial production environmental samples.

Restriction(s) None.

Warning None.

Other information The scope includes the use of Applied Biosystems™ RapidFinder™ Express software version 2.0

or higher used with the Applied Biosystems<sup>™</sup> 7500 Fast instrument or any other equivalent instrument (same features) manufactured by Thermo Fisher Scientific and Thermo Scientific<sup>™</sup> RapidFinder<sup>™</sup> Analysis software version 1.0 or higher used with the Applied Biosystems<sup>™</sup> QuantStudio<sup>™</sup> 5 instrument or any other equivalent instrument (same features) manufactured by Thermo Fisher Scientific and/or subsidiaries. Instrument Thermo Scientific PikoReal PCR with

Thermo Scientific SureTect software version 1.2.

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

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

