



Validation of alternative  
analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **UNI 03/10-03/15**

Renewal decision dated: **24-02-2023**

Expiry date: **26-03-2027**

The Company:

**OXOID Ltd, Part of Thermo Fisher Scientific**

Wade 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™ *E.coli* O157:H7 PCR Assay

Validated for the detection of *E.coli* O157:H7

Technical sheet  
reference's

MAN0017804 Rev E.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. This NF VALIDATION certificate, included 2 pages, is valid until **March, 26<sup>th</sup> 2027**. 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 13/03/2023

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The alternative analysis method:

## Thermo Scientific™ SureTect™ *E.coli* O157:H7 PCR Assay

Validated for the detection of *E.coli* O157:H7

Manufactured by:

**Thermo Fisher Scientific Oy**

Ratastie 2, PO BOX 100

Vantaa 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 16654** (July 2001) and its **amendment A1** (June 2017): Microbiology of the food chain - Horizontal method for the detection of *Escherichia coli* O157

Scope Raw beef meats (25g test portion), vegetable and fruits (25g test portion).

Restriction(s) None.

Warning None.

Other informations The scope includes the use of the software Applied Biosystems™ RapidFinder™ Express version 2.0 or later used with Applied Biosystems™ 7500 Fast instrument and equivalent (same characteristics) manufactured by Thermo Fisher Scientific and the use of the software Thermo Scientific™ RapidFinder™ Analysis version 1.1 or later used with the Applied Biosystems™ QuantStudio 5 instrument and equivalent (same characteristics) manufactured by Thermo Fisher Scientific and/or subsidiaries.

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>.