



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **UNI 03/13-10/20**

Extension decision dated: **25-02-2022**

Expiry date: **09-11-2024**

The Company:

**OXOID Ltd**  
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™ STEC Screening PCR Assay and Thermo Scientific™ SureTect™ STEC Identification PCR Assay

Validated for the detection of shiga-toxin-producing *Escherichia coli* (STEC)

Technical sheet  
reference's

MAN0018689 Rev C.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 **9<sup>th</sup> November 2024**. 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 25/10/2022

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The alternative analysis method:

## Thermo Scientific™ SureTect™ STEC Screening PCR Assay and Thermo Scientific™ SureTect™ STEC Identification PCR Assay

Validated for the detection of shiga-toxin-producing *Escherichia coli* (STEC)

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/TS 13136</b> (December 2012) : Horizontal method for the detection of Shiga toxin-producing <i>Escherichia coli</i> (STEC) and the determination of O157, O111, O26, O103 and O145 serogroups
Scope	In raw meats (excluding poultry meats) (25g et 375g test portion), dairy products (25g test portions) and vegetables including fruits(25g et 375g test portion) (excluding sprouted seeds only for 375 test portions)
Restriction(s)	None.
Warning	None.
Other informations	The scope includes 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>.