



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **SOL 37/03-10/15**

Renewal decision dated: **07-10-2019**

Expiry date: **14-10-2023**

The Company:

**Solus Scientific (part of PerkinElmer Inc.)**  
Units 9, Mansfield Network Centre  
Millennium Business Park, Concorde Way  
Mansfield, Nottinghamshire, NG19 7JZ - United Kingdom

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):

## Solus *E. coli* O157 ELISA

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

Technical sheet reference's

Insert 38 - Issue 1.0 - January 2020

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 detection level...), 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 **14<sup>th</sup> October 2023**. 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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Renewal decision dated: **07-10-2019**

Expiry date: **14-10-2023**

The alternative analysis method:

## Solus *E. coli* O157 ELISA

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

Manufactured by:

**Solus Scientific (part of PerkinElmer Inc.)**  
Units 9, Mansfield Network Centre  
Millennium Business Park, Concorde Way  
Mansfield, Nottinghamshire, NG19 7JZ - United Kingdom

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 16654</b> (July 2001) and its <b>amendment A1</b> (June 2017): Microbiology of food and animal feeding stuffs - Horizontal method for the detection of <i>Escherichia coli</i> O157.   |
| Scope               | Raw beef meats (seasoned or not), raw milks and dairy products, vegetables products, industrial production environmental samples.   |
| Restriction(s)      | None.   |
| Warning             | None.   |
| Other informations  | Non applicable.   |

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>.