



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

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

Renewal decision dated: **12-10-2023**

Expiry date: **14-10-2027**

The Company:

Solus Scientific, Ltd (part of PerkinElmer Inc.)

Unit 9 Mansfield Networkcentre
Millennium Business Park - Concorde Way
Mansfield - NG18 5BR Nottinghamshire (UK)

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 ELISA

Technical sheet
reference's

Insert 38 - Issue 4.0

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 (last version dated 12-01-2023). This NF VALIDATION certificate, included 2 pages, is valid until **14th 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

Issue dated 16/10/2023

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Renewal decision dated: **12-10-2023**

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The alternative analysis method:

Solus *E.coli* O157 ELISA

Validated for the detection of *E.coli* O157 ELISA

Manufactured by:

Solus Scientific, Ltd (part of PerkinElmer Inc.)
Unit 9 Mansfield Networkcentre
Millennium Business Park - Concorde Way
Mansfield - NG18 5BR Nottinghamshire (UK)

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/A2 (February 2023) : Microbiology of food and animal feeding stuffs — Horizontal method for the detection of <i>Escherichia coli</i> O157 — Amendment 2: Inclusion of performance testing of all culture media and reagents
Scope	Human food products (by performing validation assays on a broad range of food) and industrial production environmental samples.
Restriction(s)	None.
Warning	None.
Other information	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>.

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