



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BIO 12/25-05/09**

Renewal decision dated: 23-11-2017

Expiry date: 18-05-2021

The Company:

bioMérieux
Chemin de l'Orme
69280 Marcy l'Etoile - France

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):

VIDAS[®] UP *E. coli* O157 including H7 (ECPT)

Validated for the detection of *E. coli* O157

Technical sheet reference's

Ref. 30 122 - 14080 version O

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.afnor.org/en>.

This certificate supersedes all previous certificates (last version dated 22-06-2017). This NF VALIDATION certificate, included 2 pages, is valid until **18th May 2021**. 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
Franck LEBEUGLE

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The alternative analysis method:

VIDAS[®] UP *E. coli* O157 including H7 (ECPT)

Validated for the detection of *E. coli* O157

Manufactured by:

bioMérieux
Chemin de l'Orme
69280 Marcy l'Etoile - France

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 food and animal feeding stuffs - Horizontal method for the detection of <i>Escherichia coli</i> O157.
Scope	Raw meat products, raw milk and raw milk products, raw vegetables and production environment samples.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of the following softwares: VIDAS versions 4.7, 4.8 and 4.10, and MiniVIDAS version 5.6.

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>.

Issue dated 29/11/2018

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