



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

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

Extension decision dated: **16-06-2022**

Expiry date: **18-05-2025**

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 (ECPT)

Validated for the detection of *E.coli* O157

Technical sheet reference's

Réf 30122 - 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 level of detection), available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last version dated 14-01-2022). This NF VALIDATION certificate, included 2 pages, is valid until **18 May 2025**. 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 12/08/2022

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The alternative analysis method:

VIDAS® Up *E. coli* O157 (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 (2017) : Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Escherichia coli O157 - Amendment 1 : annex B : result of interlaboratory studies
Scope	Raw meat, raw milk and raw dairy products, raw vegetables and industrial production environmental samples.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of VIDAS version 4.7, 4.8 and 4.10, MiniVIDAS version 5.6 and VIDAS KUBE

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>.