

Validation of alternative analysis methods NF102 – Application to the food industry



Certificate No.: BIO 12/11-03/04 Renewal decision dated: 06-03-2024 Expiry date: 12-03-2028

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[®] Listeria monocytogenes II (LMO2) With enrichment stage at Fraser 37°C

Validated for the detection of Listeria monocytogenes

 Technical sheet reference's
 Réf 30704 - 045204 version 05

 Réf 30704 - 045204 version 06

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 06-03-2024). This NF VALIDATION certificate, included 2 pages, is valid until **12th March 2028**. 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



Validation of alternative analysis methods NF102 – Application to the food industry



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The alternative analysis method:

VIDAS[®] Listeria monocytogenes II (LMO2) With enrichment stage at Fraser 37°C

Validated for the detection of *Listeria monocytogenes*

Manufactured by:

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

Has been certified according to the reference documents and for 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 11290-1 (July 2017) - Microbiology of the food chain. Horizontal method for the detection and enumeration of <i>Listeria monocytogenes</i> - Part 1: Detection method.
Scope	All human food products (by performing validation assays on a broad range of foods) and industrial production environmental 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, MiniVIDAS version 5.6 et 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.

Page 2/2

