



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BIO 12/40-11/16**

Extension decision dated: **10-11-2021**

Expiry date: **24-11-2024**

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):

GENE-UP® *Listeria monocytogenes*

Validated for the detection of *Listeria monocytogenes*

Technical sheet
reference's

GENE-UP® *Listeria monocytogenes* 2 (LMO 2) : Cat. 423107-050568 version 04

GENE-UP® *Listeria monocytogenes* (LMO) : Cat. 423107-050568 version 05

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 31-01-2022). This NF VALIDATION certificate, included 2 pages, is valid until **24th November 2024**. 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 09/01/2024

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The alternative analysis method:

GENE-UP® *Listeria monocytogenes*

Validated for the detection of *Listeria monocytogenes*

Manufactured by:

bioMérieux SA
Zone Polytec
5 rue des Berges
38000 Grenoble
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 11290-1 (April 2017): Microbiology of the food chain - Horizontal method for the detection and enumeration of <i>Listeria monocytogenes</i> and of <i>Listeria</i> spp. - Part 1: detection method
Scope	All human food products (by conducting validation assays on a broad range of foods) and industrial production environmental samples.
Restriction(s)	None.
Warning	None.
Other information	The scope includes the use of the GENE-UP® Thermocycler with the GENE-UP® routine software versions 3.0, 3.1 or 3.2.

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>.

