



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BIO 12/39-09/16**

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

Expiry date: **29-09-2024**

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* spp.

Validated for the detection of *Listeria* spp. (except *Listeria grayi*)

Technical sheet
reference's

GENE-UP® *Listeria* spp. 2 (LIS 2) : Cat. 423106-050567 version 04

GENE-UP® *Listeria* spp. (LIS) : Cat. 423106-050567 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 31-03-2022). This NF VALIDATION certificate, included 2 pages, is valid until **29th September 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



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The alternative analysis method:

GENE-UP[®] *Listeria* spp.

Validated for the detection of *Listeria* spp. (except *Listeria grayi*)

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 food and animal feeding stuffs. Horizontal method for the detection and enumeration of <i>Listeria monocytogenes</i> and <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) | The method does not detect <i>Listeria grayi</i> . |
| 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>.