



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

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

Extension decision dated: **04-12-2018**

Expiry date: **24-11-2020**

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* 2

Validated for the detection of *Listeria monocytogenes*

Technical sheet  
reference's

Ref. 423107 - 050568 - 02

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 12-06-2017). This NF VALIDATION certificate, included 2 pages, is valid until **November 24<sup>th</sup>, 2020**. 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:

## **GENE-UP<sup>®</sup> *Listeria monocytogenes* 2**

Validated for the detection of *Listeria monocytogenes*

Manufactured by:

**bioMérieux**  
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	<b>NF EN ISO 16140-2</b> (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)	<b>NF EN ISO 11290-1</b> (July 2017) + <b>Amendment 1</b> (2005): 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 and production environmental samples.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of the GENE-UP <sup>®</sup> Thermocycler with the GENE-UP <sup>®</sup> Routine software version 3.0.

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>.

