

#### Validation of alternative analysis methods

NF102 - Application to the food industry

# Certificate

Certificate No.: BIO 12/27-02/10 Extension decision dated: 16-06-2022

Expiry date: 04-02-2026

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 Xpress (LMX)

Validated for the detection of Listeria monocytogenes

Technical sheet reference's

Ref 30123 - 050545 version 03

Ref 30123 - 050545 version 04

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 <a href="http://nf-validation.afnor.org/en">http://nf-validation.afnor.org/en</a>.

This certificate supersedes all previous certificates (last version dated 12-08-2022). This NF VALIDATION certificate, included 2 pages, is valid until **February 04<sup>th</sup>, 2026**. 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 07/06/2024



# Certificate

Certificate No.: BIO 12/27-02/10 Extension decision dated: 16-06-2022

Expiry date: 04-02-2026

The alternative analysis method:

## VIDAS® Listeria monocytogenes Xpress (LMX)

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 Listeria monocytogenes and of Listeria spp. - 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 information The scope includes the use of the following software: VIDAS version 4.10 and previous, MiniVIDAS

version 5.6, VIDAS KUBE version 1.1 and previous.

Please send any queries concerning the performances of the certified alternative method to AFNOR Certification.

You may download the validation study summarized report on <a href="http://nf-validation.afnor.org/en">http://nf-validation.afnor.org/en</a>.

