



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **BIO 12/38-06/16**

Extension decision dated: **04-04-2024**

Expiry date: **30-06-2024**

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<sup>®</sup> *Salmonella*

Validated for the detection of *Salmonella* spp.

Technical sheet reference's

**GENE-UP *Salmonella* 2 (SLM 2)** : Cat. 423105 – 050555 – version **07** and **07bis**

**GENE-UP *Salmonella* (SLM)** : Cat. 423105 – 050555 – version **08** and **09**

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 16-02-2024). This NF VALIDATION certificate, included 2 pages, is valid until **June 30<sup>th</sup>, 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<sup>®</sup> *Salmonella*

Validated for the detection of *Salmonella* spp.

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	<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 6579-1</b> (April 2017) and its <b>amendment A1</b> (March 2020) : Microbiology of the food chain- Horizontal method for the detection, enumeration and serotyping of <i>Salmonella</i> - Part 1: Detection of <i>Salmonella</i> spp. - Amendment 1: Extension of the incubation temperature range, amendment of the status of Annex D and correction of the composition of MSR/V and SC media
Scope	All human food products (by conducting validation assays on a broad range of foods). Pet food products. Industrial production environmental samples and for primary production samples (excluding drinking water).
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, 3.1, et 3.2. Raw materials for chocolate industry (375g test portion size) tested with two specific protocols with the addition of the BACTBOOST supplement and using an automated protocol and a manual protocol for the lysis step. Use of a new protocol of enrichment with BACTVIAB <sup>®</sup> PMAxx <sup>™</sup> pretreatment for the analysis of dog and cat feed products (375g test portion).

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>.