

Validation of alternative analysis methods

NF102 - Application to the food industry



Certificate No.: BIO 12/38-06/16 Extension decision dated: 09-10-2024

Expiry date: 30-06-2028

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® Salmonella

Validated for the detection of Salmonella spp.

Technical sheet reference's

GENE-UP Salmonella (SLM): Cat. 423105 - 050555 versions 10 et previous

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 20-06-2024). This NF VALIDATION certificate, included 2 pages, is valid until **June 30th, 2028**. 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 09/10/2024



Certificate

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The alternative analysis method:

GENE-UP® 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 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 6579-1 (April 2017) and its amendment A1 (March 2020): Microbiology of the food

chain- Horizontal method for the detection, enumeration and serotyping of *Salmonella* - Part 1: Detection of *Salmonella* spp. - Amendment 1: Extension of the incubation temperature range, amendment of the status of Annex D and correction of the composition of MSRV and SC media

Scope All human food products (by performing validation assays on a broad range of foods) (37°C et

41,5°C), pet food products (37°C), industrial production environmental samples (37°C and 41.5°C),

and primary production environmental samples (37°C) (excluding drinking water).

Restriction(s) None.

Warning None.

Other informations The scope includes the use of the GENE-UP® Thermocycler with the GENE-UP® routine software

versions 4.0 and previous. 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.

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.

