

Validation of alternative analysis methods NF102 – Application to the food industry



Certificate No.: BIO 12/44-02/23 Validation decision dated: 02-02-2023 Expiry date: 02-02-2027

The Company:

bioMérieux SA 376 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 Enteritidis & Salmonella Typhimurium (SEST)

Validated for the detection of Salmonella Enteritidis & Salmonella Typhimurium

Technical sheet reference's

Réf 423127 – 057566 version 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 NF VALIDATION certificate, included 2 pages, is valid until 2nd February 2027. 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® Salmonella Enteritidis & Salmonella Typhimurium (SEST)

Validated for the detection of Salmonella Enteritidis & Salmonella Typhimurium

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	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 <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 MSRV and SC media
	ISO/TR 6579-3 (July 2014) : Microbiology of the food chain- Horizontal method for the detection, enumeration and serotyping of Salmonella – Part 3 : Guidelines for serotyping of Salmonella spp.
Scope	Pork and poultry meat products and egg products
Restriction(s)	None.
Warning	None.
Other information	The scope includes the use of GENE-UP® thermocycler with the GENE-UP® routine software 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.

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