



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

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

Extension decision dated: 26-01-2018

Expiry date: 30-06-2020

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[®] *Salmonella*

Validated for the detection of *Salmonella* spp.

Technical sheet reference's

Ref. 414150 - 43-04319 version D or E

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 **30th June 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

Issue dated 14/02/2018

Page 1/2



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The alternative analysis method:

GENE-UP[®] *Salmonella*

Validated for the detection of *Salmonella* spp.

Manufactured by:

BioFire Defense, LLC.
79 West 4500 South
Salt Lake City, Utah 84107 - USA

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 (December 2002): Microbiology of the food chain. Horizontal method for the detection, enumeration and serotyping of <i>Salmonella</i> spp. - Part 1 : detection of <i>Salmonella</i> spp.
Scope	All human food products, by conducting validation assays on a broad range of foods, Pet food and production environmental samples (excluding environment from primary production stage).
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of the GENE-UP [®] Thermocycler with the GENE-UP [®] routine software version 1.1.2. or 2.0.

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>.

Issue dated 14/02/2018

Page 2/2

