



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BIO 12/42-03/18**
Extension decision dated: 04-10-2018
Expiry date: 23-03-2022

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[®] Cronobacter

Validated for the detection of *Cronobacter* spp.

Technical sheet reference's

Ref. 421920 - 21981 version B

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 <http://nf-validation.org/en>.

This certificate supersedes all previous certificates. This NF VALIDATION certificate, included 2 pages, is valid until 23rd March 2022. 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 27-11-2018

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The alternative analysis method:

GENE-UP[®] Cronobacter

Validated for the detection of *Cronobacter* spp.

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 22964 (June 2017): Microbiology of the food chain - Horizontal method for the detection of <i>Cronobacter</i> spp. |
| Scope | Milk powders, ingredients, infant formulas and infant cereals with and without probiotics 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 versions 2.0, and 3.0. |

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>.

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