



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BIO 12/42-03/18**

Renewal decision dated: **02-02-2022**

Expiry date: **23-03-2026**

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

Réf. 421920 - 048679 version **04**

Réf. 421920 - 048679 version **05**

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 2026**. 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 04/04/2022

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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, infant formulas and infant cereals with and without probiotics (25g and 375g sample size), ingredients (25g and 375g) and milk derivatives (375g except whey protein concentrates) and industrial production environmental samples.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of the GENE-UP [®] Thermocycler with the GENE-UP [®] routine software versions 3.0, 3.1 and 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>.