



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificat No.: **BIO 12/37-11/14**
Extension decision dated: 04-10-2018
Expiry date: 27-11-2022

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):

Esia™ One Day

Validated for the detection of *Cronobacter* spp.

Technical sheet
reference's

Ref. 047459 - 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 detection level...), available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last version dated 13 06 2017). This NF VALIDATION certificate, included 2 pages, is valid until 27th November 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 01-03-2019

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The alternative analysis method:

Esia™ One Day

Validated for the detection of *Cronobacter* spp.

Manufactured by:

bioMérieux
Route de Dol - BP 54
35270 Combours - 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 formula and infant cereals with or without probiotics, including ingredients, and production environmental samples.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of the VITEK MS instrument with the VITEK MS software versions 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>.

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