



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BIO 12/37-11/14**

Renewal decision dated: **25-11-2022**

Expiry date: **27-11-2026**

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):

ESIA™ One Day

Validated for the detection of *Cronobacter* spp.

Technical sheet reference's

Ref. AEB520010 AEB150002 - 047459 Version **02**

Ref. AEB520010 AEB150002 - 047459 Version **03**

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 12-08-2022). This NF VALIDATION certificate, included 2 pages, is valid until **27th November 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 01/12/2022

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The alternative analysis method:

ESIA™ One Day

Validated for the detection of *Cronobacter* spp.

Manufactured by:

bioMérieux
4 bis Rue des Coutures
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 (Juin 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 industrial production environmental samples. |
| Restriction(s) | None. |
| Warning | None. |
| Other information | The scope includes the use of the VITEK MS software versions 3.0 and higher and VITEK® MS Prime. |

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>.