



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **QUA 18/13-12/24**

Validation decision dated: **18-12-2024**

Expiry date: **18-12-2028**

The Company:

HYGIENA LLC
941 Avenida Acaso
Camarillo, CA 93012
United-States

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):

foodproof® Salmonella plus Cronobacter Detection LyoKit for Cronobacter spp. detection

Validated for the detection of *Cronobacter* spp.

Technical sheet
reference's

foodproof® Salmonella plus Cronobacter Detection LyoKit INS-KIT230131-32-33-REVC

StarPrep® Three 8-Strip Kit Salmonella plus Cronobacter INS-KIT230187/88-5-REVA

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 19-12-2024). This NF VALIDATION certificate, included 2 pages, is valid until **December 18th, 2028**. 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



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The alternative analysis method:

foodproof® Salmonella plus Cronobacter Detection LyoKit for Cronobacter spp. detection

Validated for the detection of *Cronobacter* spp.

Manufactured by:

Hygiena Diagnostics GmbH
Hermannswerder 17,
D-17743 Potsdam
GERMANY

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	Infant formula with or without probiotics and ingredients, and industrial production environmental samples.
Restriction(s)	None.
Warning	None.
Other information	The scope includes the use of the instrument BAX® System Q7 with BAX® software versions 5.1 and higher.

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>.

CERTI F 2022.1 08/2020

Issue dated 04/03/2025

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