



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **QUA 18/06-07/08**

Renewal decision dated: **25-06-2024**

Expiry date: **01-07-2028**

The Company:

Hygiena LLC
941 Avenida Acaso
Camarillo, CA 93012 USA

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):

BAX® System PCR Assay Genus *Listeria* 24E

Validated for the detection of *Listeria* spp.

Technical sheet
reference's

KIT2003 (D13608135) INS2018 **Rev. 06**

KIT2024 (D15407193) INS2009 **Rev. 06**

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 08-08-2024). This NF VALIDATION certificate, included 2 pages, is valid until **July 1st, 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

Issue dated 04/03/2025

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The alternative analysis method:

BAX® System PCR Assay Genus *Listeria* 24E

Validated for the detection of *Listeria* spp.

Manufactured by:

Hygiena LLC
930 Flynn Road
Camarillo, CA 93012 USA

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 11290-1 (July 2017): Microbiology of the food chain - Horizontal method for the detection and enumeration of <i>Listeria monocytogenes</i> and of <i>Listeria</i> spp. - Part 1: detection method
Scope	All human food products (by performing validation assays on a broad range of foods) and industrial production environmental samples.
Restriction(s)	Excluding <i>Listeria grayi</i> .
Warning	None.
Other information	The scope includes the use of the BAX® System Q7 with BAX® software versions 5.1 and higher; and the BAX System X5 instrument version 1.0.

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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