



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **QUA 18/10-01/19**  
Reconduction decision dated: **07-10-2022**  
Expiry date: **01-02-2027**

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):

## **BAX® System RT PCR Assay *Listeria monocytogenes***

Validated for the detection of *Listeria monocytogenes*

Technical sheet reference's

KIT2005 (D15134303) – INS2012 Rev 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 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 **February 1<sup>st</sup>, 2027**. 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 RT PCR Assay *Listeria monocytogenes***

Validated for the detection of *Listeria monocytogenes*

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	<b>NF EN ISO 16140-2</b> (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)	<b>NF EN ISO 11290-1</b> (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)	None.
Warning	None.
Other informations	The scope includes the use of BAX® System Q7 instrument 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>.