Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: BRD 07/10-04/05
Extension decision dated: 08-12-2022
Expiry date: 07-04-2025

The Company:

BIO-RAD
3 Boulevard Raymond Poincaré
92430 Marnes La Coquette - 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):

iQ-Check® *Listeria monocytogenes II*

Validated for the detection of *Listeria monocytogenes*

Technical sheet reference's	Cat. 10000123535 **Ver C**

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.afnor.org/en.

This certificate supersedes all previous certificates (last version dated 18-10-2021). This NF VALIDATION certificate, included 2 pages, is valid until **07th April 2025**. 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 17/04/2023

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SAS au capital de 18 187 000 € - 479 076 002 RCS Bobigny - **www.afnor.org**

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Certificate

Certificate No.: **BRD 07/10-04/05**
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The alternative analysis method:

iQ-Check® *Listeria monocytogenes II*

Validated for the detection of *Listeria monocytogenes*

Manufactured by:

BIO-RAD Laboratories, Inc
2000 Alfred Nobel Drive
California 94547 Hercules - USA

Has been certified according to the reference documents and for 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 *Listeria monocytogenes* - Part 1: detection method.
Scope	All human products (by performing validation assays on a broad range of foods) and industrial production environment samples.
Restriction(s)	None.
Warning	None.
Other information(s)	Scope includes use of CFX96 Touch, CFX96 Touch Deep well and CFX OPUS Deepwell real-time PCR instruments with CFX Manager IDE v3.1 software

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

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