Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: TRA 02/06-11/95
Renewal decision dated: 20-10-2023
Expiry date: 21-11-2027

The Company:

BioControl Systems, Inc, an affiliate of Merck KGaA, Darmstadt Germany
3050 Spruce Street
St. Louis, MO 63103
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):

TRANSIA® Plate *Listeria*

Validated for the detection of *Listeria* spp.

Technical sheet reference's	20551700 **V5.0**
	20551701 **V5.0**

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, inclusivity and exclusivity), available on the certification dedicated website http://nf-validation.org/en.

This certificate supersedes all previous certificates (last version dated 23-10-2023). This NF VALIDATION certificate, included 2 pages, is valid until **November 21st, 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 of AFNOR Certification
Julien NIZRI

Issue dated 12-10-2026

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

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Certificate

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The alternative analysis method:

TRANSIA® Plate *Listeria*

Validated for the detection of *Listeria* spp.

Manufactured by:

BioControl Systems, Inc, an affiliate of Merck KGaA, Darmstadt Germany
3050 Spruce Street
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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 *Listeria monocytogenes* and of *Listeria* 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 information	Use of instruments Microplate reader (450nm); Gemini® Automated EIA System (Sigma 78000-1EA)

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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