



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **EGS 38/03-01/17**

Renewal decision dated: **13-01-2025**

Expiry date: **26-01-2029**

The Company:

Gold Standard Diagnostics

Engesserstrasse 4
Freiburg im breisgau,
DE 79108 GERMANY

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):

BACGene *Listeria monocytogenes*

Validated for the detection of *Listeria monocytogenes*

Technical sheet
reference's

BACGene Listeria monocytogenes _Cat. No 5123222001, 5123222011, 5123222010_V6.1

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 21-01-2025). This NF VALIDATION certificate, included 2 pages, is valid until **January 26th, 2029**. 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 13-02-2026

Page 1/2



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The alternative analysis method:

BACGene *Listeria monocytogenes*

Validated for the detection of *Listeria monocytogenes*

Manufactured by:

Gold Standard Diagnostics

Fóti út 56 A Building H-1047

Budapest HUNGARY

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 The scope includes the use of the new enrichment protocol with the BACGro™ Ultra *Listeria* Broth (BULB).

The scope of application also includes manual and automated workflows using the OT2 automation in combination with PCR instruments: Agilent AriaMx™, Bio-Rad CFX96 Touch (Standard and Deep Well) and CFX Opus 96 (Standard and Deep Well), and analysis software: Evaluation Sheet, Fast Finder and PURE.

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>.

Issue dated 13-02-2026

Page 2/2