Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: GEN 25/08-07/10
Renewal decision dated: 28-06-2022
Expiry date: 02-07-2026

The Company:

Pall GeneDisc Technologies
1, rue du Courtil - Centre d'affaires CICEA
35170 BRUZ
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):

GeneDisc® Listeria DUO and GeneDisc® *Listeria monocytogenes*

Validated for the detection of *Listeria monocytogenes*

Technical sheet reference's :

IFU	Part Numbers	Version
GeneDisc Plate *Listeria monocytogenes*	GLISMON206006 & GLISMON212006	**FBIFUGDLISMONENc**
GeneDisc Plate Listeria DUO	GLISDUO106006 & GLISDUO112006	**FBIFUGDLISDUOENc**

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 31-03-2021). This NF VALIDATION certificate, included 2 pages, is valid until **2nd July 2022**. 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 29/06/2022

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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:

GeneDisc® Listeria DUO and GeneDisc® *Listeria monocytogenes*

Validated for the detection of *Listeria monocytogenes*

Manufactured by:

Pall GeneDisc Technologies
1, rue du Courtil - Centre d'affaires CICEA
35170 BRUZ
FRANCE

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** (Juillet 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 GeneDisc Cycler V3 software 2.1.i or later software versions.

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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