



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No: **GEN 25/08-07/10**

Extension decision dated: **03-12-2018**

Expiry date: **02-07-2022**

The Company :

Pall GeneDisc Technologies

1, rue du Courtil, Centre 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 monocytogenes*

Validated for the detection of *Listeria monocytogenes*

Technical sheet reference's:

IFU	Part Numbers	Version
GeneDisc Plate <i>Listeria monocytogenes</i>	GLISMON206006 & GLISMON212006	FBIFUGDLISMONENb
GeneDisc Plate <i>Listeria</i> DUO	GLISDUO106006 & GLISDUO112006	FBIFUGDLISDUOENb

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.org/en>.

This certificate supersedes all previous certificates (last version dated 18-12-2014). This NF VALIDATION certificate, included 2 pages, is valid until **02nd 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
Franck LEBEUGLE

Issue dated 30-07-2019

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The alternative analysis method:

GeneDisc® *Listeria monocytogenes*

Validated for the detection of *Listeria monocytogenes*

Manufactured by:

Pall GeneDisc Technologies
1, rue du Courtil, Centre 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 6579-1 (April 2017): Microbiology of the food chain - Horizontal method for the detection, enumeration and serotyping of <i>Salmonella</i> - Part 1 : detection of <i>Salmonella</i> spp.
Scope	All human food products and production environment samples.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the GeneDisc Cycler v3 software 2.1.i or later softwares 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>.

