



Validation of analysis methods
NF148 – Application to water

Certificate

Certificate No.: **GEN 25/04-12/07**
Renewal decision dated: 17-12-2015
Expiry date: 18-12-2019

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 method cited below, in accordance with the NF VALIDATION general rules and the certification rules NF148 - Validation of analysis methods (Application to water):

GeneDisc[®] *Legionella pneumophila*

Validated for the detection and the quantification of *Legionella pneumophila*

Technical sheet reference's:

IFU	Part Numbers	Version
Legionella pneumophila Standard DNA	ALEGPNE105	FBIFUGDSDNALPEN
GeneDisc Plate Legionella pneumophila	GLEGPNE106006 & GLEGPNE112006	FBIFUGDLEGPNEENa
GeneDisc Plate Legionella DUO	GLEGDUO106006	FBIFUGDLEGDUOENa
Extraction Pack Environment 01	PENVI1096	FBIFUGDEPENVENa
Extraction Pack Environment 03	PENVI3100	FBIFUGDEPENV3ENa

This decision attests that the 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 (calibration function, LOD, LOQ and positive threshold, yield...), available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last issue dated 15-10-2016). This NF VALIDATION certificate, included 2 pages, is valid until **18th December 2019**. 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 NF148 - Validation of alternative analysis methods (Application to water).



Managing Director
Franck LEBEUGLE

Issue dated 10-10-2016

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The alternative analysis method:

GeneDisc® *Legionella pneumophila*

Validated for the detection and the quantification of *Legionella pneumophila*

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 VALIDATION - Validation of analysis methods: Application to water microbiology. Validation protocol for commercial methods of detection and quantification of <i>Legionella</i> and <i>Legionella pneumophila</i> by concentration and gene amplification by polymerase chain reaction (PCR). Revision 3 (September 2015).
Reference method(s)	NF T90-471 (June 2015): Water quality. Detection and quantification of <i>Legionella</i> and/or <i>Legionella pneumophila</i> by concentration and genic amplification by real time polymerase chain reaction (qPCR). ISO/TS 12869 (November 2012): Water quality. Detection and quantification of <i>Legionella</i> spp. and/or <i>Legionella pneumophila</i> by concentration and genic amplification by quantitative polymerase chain reaction (qPCR).
Scope	Sampling all types of waters.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the GeneDisc Cyclor V2 (2.8 or later software version) and GeneDisc Cyclor V3 (2.1.21 or later software version).

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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