



Validation of analysis methods
NF148 – Application to water

Certificate

Certificate No.: **GEN 25/04-12/07**
Renewal decision dated: 09-12-2019
Expiry date: 18-12-2023

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 quantification of *Legionella pneumophila*

Technical sheet reference's

IFU	Part Numbers	Version
Legionella pneumophila Standard DNA	ALEGPNE205	FBIFUGDSDNALPENb
GeneDisc Plate Legionella pneumophila	GLEGPNE206006 and GLEGPNE212006	FBIFUGDLEGPNEENb
Extraction Pack Environment 01	PENVI1096	FBIFUGDEPENVENb
Extraction Pack Environment 03	PENVI3100	FBIFUGDEPENV3ENb
GeneDisc® Plate Legionella DUO 06	GLEGPUO206006	FBIFUGDLEGPUOENb
GeneDisc® Plate Legionella ID	GLEGOID206006 and GLEGOID212006	FBIFUGDLEGOIDENb

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 30-07-2019). This NF VALIDATION certificate, included 2 pages, is valid until 18th December 2023. 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
Julien NIZRI

Issue dated 17-07-2020

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The alternative analysis method:

GeneDisc® *Legionella pneumophila*

Validated for the detection and 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 *Legionella* and *Legionella pneumophila* 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 *Legionella* and/or *Legionella pneumophila* by concentration and genic amplification by real time polymerase chain reaction (qPCR).

ISO/TS 12869 (April 2019): Water quality - Detection and quantification of *Legionella* spp. and/or *Legionella pneumophila* 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 GeneDisc Cyclor V3 software version 2.1.i and 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>.