



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **GEN 25/09-03/19**

validation decision dated: **21-03-2019**

Expiry date: **21-03-2023**

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 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 STEC

Validated for the detection of shiga-toxin-producing *Escherichia coli* (O157, O111, O26, O103 and O145 serogroups)

Technical sheet reference's:

IFU	Part Numbers	Version
GeneDisc Plate EHEC 5 ID	GEHECID106006	FBIFUGDEHECENC
GeneDisc Plate Pathogenic <i>E. coli</i> O157	GECO157106006 & GECO157112006	FBIFUGDECO157ENC
GeneDisc Plate STEC	GSTEHEC106006 & GSTEHEC112006	FBIFUGDSTECENC
GeneDisc Plate Pathogenic <i>E. coli</i> O157 & <i>Salmonella</i> spp.	GECOSLM206006 & GECOSLM212006	FBIFUGDECO157SSPPENC
GeneDisc Plate STEC Top 7	GTOP7EC106006 & GTO7EC103012	FBIFUGDDTEC7END
GeneDisc STEC Method	-	FBIFUGDSTECMENA
GeneDisc STEC & <i>Salmonella</i> spp.	GSTECSL206006 & GSTECSL212006	FBIFUGDSTECSSPPENC

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 05-03-2020). This NF VALIDATION certificate, included 2 pages, is valid until **21st March 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 NF102 - Validation of alternative analysis methods (Application to the food industry).



Managing Director
Franck LEBEUGLE

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Page 1/2



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The alternative analysis method:

GeneDisc STEC

Validated for the detection of shiga-toxin-producing *Escherichia coli*
(O157, O111, O26, O103 and O145 serogroups)

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 food and animal feeding stuffs. Protocol for the validation of alternative methods.
Reference method(s)	Internal method ADRIA (R/13136) based on NF EN ISO/TS 13136 (November 2012): Microbiology of food and animal feed. Horizontal method for the detection of Shiga toxin-producing <i>Escherichia coli</i> (STEC) and the determination of O157, O111, O26, O103 and O145 serogroups -
Scope	Raw beef meats, raw dairy products and vegetables products.
Restriction(s)	None.
Warning	None.
Other informations	Non applicable.

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>.