



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: TRA 02/13-04/22

Extension decision dated: 05-05-2025

Expiry date: 08-04-2026

The Company:

Millipore Sigma
12822 SE 32nd Street
Bellevue 98005
WA, USA

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):

Assurance[®] GDS MPX for Top 7 STEC, Assurance[®] MPX ID for STEC and Assurance[®] GDS EHEC ID for *E. coli* O157:H7 Tq

Validated for the detection of shiga-toxin-producing *Escherichia coli* (STEC)

Technical sheet
reference's

20764278 v5.0

20764279 v6.0

20764281 v5.0

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 23-05-2025). This NF VALIDATION certificate, included 2 pages, is valid until **April 8th, 2026**. 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 22/07/2025

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Manufactured by:

Millipore Sigma
12822 SE 32nd Street
Bellevue 98005
WA, USA

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)	Internal method ADRIA (R/13136) based on ISO/TS 13136 (November 2012): Microbiology of food and animal feed - Real-time polymerase chain reaction (PCR)-based method for the detection of food-borne pathogens - 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 meat (excluding seasoned meat for 375g test portion); raw and ready-to-cook meat; raw poultry meat, ready-to-cook, ready-to-heat and ready-to-eat; raw milk and dairy products and industrial production environmental samples.
Restriction(s)	None.
Warning	None.
Other information	Use of the GDS Rotor-Gene® software The validated scope of application includes an enrichment protocol with short and long times of up to 72 hours, as described in the manufacturer's instructions for defined weights and matrices. The scope includes the automated workflow using Assurance® GDS PickPen® PipetMax® (PPMX).

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>.