



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

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

Validation decision dated: **08-04-2022**

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, MPX ID for Top STEC and EHEC ID for *E. coli* O157:H7**

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

Technical sheet reference's

55410.R000.052022

55411.R000.052022

55412.R000.052022

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 NF VALIDATION certificate, included 2 pages, is valid until **8<sup>th</sup> April 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 23/06/2022

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The alternative analysis method:

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

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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 | <b>NF EN ISO 16140-2</b> (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) | <b>Internal method ADRIA (R/13136) based on NF EN ISO/TS 13136</b> (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 meat (excluding seasoned meat), raw milk and dairy products.  |
| Restriction(s)      | None.  |
| Warning             | None.  |
| Other information   | Use of the GDS Rotor-Gene® software  |

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>.