Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: TRA 02/13-04/22
Renewal decision dated: 29-01-2026
Expiry date: 08-04-2030

The Company:

BioControl Systems, Inc, an affiliate of Merck KGaA, Darmstadt Germany
3050 Spruce Street
St. Louis, MO 63103
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 **v7.0**
	20764279 **v7.0**
	20764281 **v6.0**

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, inclusivity and exclusivity) available on the certification dedicated website http://nf-validation.org/en.

This certificate supersedes all previous certificates (last version dated 28-09-2026). This NF VALIDATION certificate, included 2 pages, is valid until **April 8th, 2030**. 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 of AFNOR Certification
Julien NIZRI

Issue dated 26-10-2026

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SAS au capital de 18 187 000 € - 479 076 002 RCS Bobigny - **www.afnor.org**

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The alternative analysis method:

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

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 Escherichia coli (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 Assurance® GDS Rotor-Gene® Software version 2.3.103 and previous versions. 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.

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