Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: TRA 02/12-01/09
Renewal decision dated: 11-12-2024
Expiry date: 26-01-2029

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 for *Salmonella* Tq

Validated for the detection of *Salmonella* spp.

Technical sheet reference's	20512656 **v9.0**

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 20-03-2026). This NF VALIDATION certificate, included 2 pages, is valid until **January 26th, 2029**. 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:

Assurance® GDS for *Salmonella* Tq

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Manufactured by:

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3050 Spruce Street
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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)	**NF ISO EN 6579-1** (April 2017) and its **amendment A1** (March 2020) : Microbiology of the food chain- Horizontal method for the detection, enumeration and serotyping of *Salmonella* - Part 1: Detection of *Salmonella* spp. - Amendment 1: Extension of the incubation temperature range, amendment of the status of Annex D and correction of the composition of MSRV and SC media
Scope	All human food products (by performing validation assays on a broad range of food) (excluding sprouts), milk powders, infant formula and infant cereals (375g test portion), pet food 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. Two new confirmation protocols, one of them with the use of the Pickpen ® device. The scope includes the analysis of raw and finished cocoa and chocolate products (test portion up to 375 g). 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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