



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: QUA 18/04-03/08

Renewal decision dated: 07-12-2023

Expiry date: 28-03-2028

The Company:

HYGIENA LLC

941 Avenida Acaso
Camarillo, CA 93012 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):

BAX[®] System PCR Assay for *E. coli* O157:H7 MP

Validated for the detection of *E. coli* O157:H7

Technical sheet reference's

KIT2004 (D12404903) - INS2025 REV 06

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 16-01-2024). This NF VALIDATION certificate, included 2 pages, is valid until **March 28th 2028**. 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



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: QUA 18/04-03/08

Renewal decision dated: 07-12-2023

Expiry date: 28-03-2028

The alternative analysis method:

BAX® System PCR Assay for *E. coli* O157:H7 MP

Validated for the detection of *E. coli* O157:H7

Manufactured by:

HYGIENA LLC
930 Flynn Road
Camarillo, CA 93012 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)	NF EN ISO 16654 (July 2001) et son amendement A1 (June 2017) : Microbiology of food products — Horizontal method for the detection of Escherichia coli O157. Amendment 1: Annex B: Result of interlaboratory studies.
Scope	Raw beef meat, raw milk, fruits and vegetables, ready-to-eat and ready-to-reheat dishes, raw pork, ovine and chicken meats.
Restriction(s)	None.
Warning	None.
Other information	The scope includes the use of the BAX® System Q7 with software version 5.0 and the BAX System X5 instrument version 1.0.

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>.

CERTI F 2022.1 08/2020

Issue dated 08/08/2024

Page 2/2