



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **QUA 18/07-07/10**

Renewal decision dated: **30-06-2026**

Expiry date: **02-07-2030**

The Company:

HYGIENA LLC

941 Avenida Acaso
Camarillo, CA 93012
United-States

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 RT-PCR Assay *E. coli* O157:H7

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

Technical sheet
reference's

KIT2000 (D14203648) - INS2019 REV 07

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 04-03-2025). This NF VALIDATION certificate, included 2 pages, is valid until **July 2nd, 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

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The alternative analysis method:

BAX[®] System RT-PCR Assay *E. coli* O157:H7

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

Manufactured by:

HYGIENA L.L.C
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) and their amendments A1 (June 2017) and A2 (February 2023): Microbiology of food and animal feeding stuffs - Horizontal method for the detection of <i>Escherichia coli</i> O157 - Amendment 1 : annex B : result of interlaboratory studies. Amendment 2 : inclusion of performance testing of all culture media and reagents.
Scope	Raw beef meat and vegetable products.
Restriction(s)	None.
Warning	None.
Other information	The scope includes the use of the instrument BAX [®] System Q7 with BAX [®] software versions 5.1 and higher.

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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