



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BRD 07/15-06/08**

Extension decision dated: **08-12-2022**

Expiry date: **30-06-2024**

The Company:

BIO-RAD

3 Boulevard Raymond Poincaré
92430 Marnes La Coquette – France

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):

iQ-Check *E.coli* O157 :H7

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

Technical sheet
reference's

Cat. 10000131517 **Ver B**

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 detection level...), available on the certification dedicated website <http://nf-validation.afnor.org/en>.

This certificate supersedes all previous certificates (last version dated 29-03-2021). This NF VALIDATION certificate, included 2 pages, is valid until **June 30th 2024**. 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 17/04/2023

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The alternative analysis method:

iQ-Check *E.coli* O157 :H7

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

Manufactured by:

BIO-RAD Laboratories, Inc
2000 Alfred Nobel Drive
California 94547 Hercules - USA

Has been certified according to the reference documents and for 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 its amendment A1 (June 2017): Food Microbiology - Horizontal method for the detection of <i>Escherichia coli</i> O157 - Amendment 1 : annex B : result of interlaboratory studies
Scope	Raw meats excluding poultry meats (with 25g and 375g samples sizes)
Restriction(s)	None.
Warning	None.
Other information(s)	Scope includes use of CFX96 Touch, CFX96 Touch Deep well and CFX OPUS Deepwell real-time PCR instruments with CFX Manager IDE v3.1 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>.

CERTIF 2022.1 08/2020

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