



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **QUA 18/11-12/20**

Renewal decision dated: **02-10-2024**

Expiry date: **11-01-2029**

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 Assays for STEC Suite and BAX® System Real-Time PCR Assays for *E.coli* O157:H7**

Validated for the detection of shiga-toxin-producing *Escherichia coli* (O26, O103, O111, O145, and O157 serogroups)

Technical sheet reference's

Part KIT2000 (D14203648) - **INS2019 REV 06**

KIT2021/KIT2008/KIT2009 - **INS2006 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), 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 **January 11<sup>th</sup> 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  
Julien NIZRI

Issue dated 08/10/2024

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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	<b>NF EN ISO 16140-2</b> (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)	<b>Internal method based on ADRIA ISO/TS 13136</b> (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 <i>Escherichia coli</i> (STEC) and the determination of O157, O111, O26, O103 and O145 serogroups.
Scope	Raw beef meats, raw dairy products and vegetables products.
Restriction(s)	None.
Warning	None.
Other information	The scope includes the use of the instrument BAX® System Q7 with BAX® software version 5.0.

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>.