

Validation of alternative analysis methods NF102 – Application to the food industry



Certificate No.: EGS 38/06-11/19 Renewal decision dated: 04-10-2023 Expiry date: 28-11-2027

The Company:

## **Gold Standard Diagnostics**

Engesserstrasse 4 Freiburg im breisgau, DE 79108 GERMANY

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):

## BACGene E. coli O157:H7

Validated for the detection of Escherichia coli O157:H7

Technical sheet reference's

BACGene\_E\_coli\_0157H7\_5123222701, 5123222711\_EN\_V2\_CB\_F

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 <a href="http://nf-validation.org/en">http://nf-validation.org/en</a>.

This certificate supersedes all previous certificates (last version dated 05-12-2019). This NF VALIDATION certificate, included 2 pages, is valid until November **28**<sup>th</sup>, **2027**. 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



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The alternative analysis method:

## BACGene E. coli O157:H7

Validated for the detection of Escherichia coli O157:H7

Manufactured by:

## **Gold Standard Diagnostics**

Fóti ùt 56 A building H-1047 Budapest HUNGARY

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>NF EN ISO 16654/A2</b> (February 2023) : Microbiology of food and animal feeding stuffs — Horizontal method for the detection of Escherichia coli O157 — Amendment 2: Inclusion of performance testing of all culture media and reagents
Scope	In raw meat, ready-to-eat and ready-to-reheat meat (except poultry), raw milk and raw milk-based products and fresh produces and fruits.
Restriction(s)	None.
Warning	None.
Other informations	Non applicable.

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.

Page 2/2

