



Validation of alternative  
analysis methods

NF102 – Application to the food industry

# Certificate

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\_O157H7\_5123222701, 5123222711\_V3.1**

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 31-10-2023). 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 of AFNOR Certification  
Julien NIZRI

Issue dated 13-02-2026

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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 út 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</b> (January 2016) <b>and its amendment A2</b> (February 2023) : Microbiology of food and animal feeding stuffs — Horizontal method for the detection of <i>Escherichia coli</i> O157 — Amendment 2: Inclusion of performance testing of all culture media and reagents. |
| Scope               | 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 information   | The scope includes manual and automated workflows using the OT2 automation in combination with PCR instruments: Agilent AriaMx™, Bio-Rad CFX96 Touch (Standard and Deep Well) and CFX Opus 96 (Standard and Deep Well), and analysis software: Evaluation Sheet, Fast Finder and PURE.      |

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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