



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **EGS 38/01-03/15**

Extension decision dated: **08-02-2024**

Expiry date: **26-03-2027**

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 *Salmonella* spp.

Validated for the detection of *Salmonella* spp.

Technical sheet
reference's

BACGene_Salmonella_spp_5123221801_10-11_V4

PREraser-BACGene_5123222301-11_V5.7

HU0060910 OT-2 for BACGene Use

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 30-10-2023). This NF VALIDATION certificate, included 2 pages, is valid until **26th March 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

Issue dated 05/03/2024

Page 1/2



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **EGS 38/01-03/15**

Extension decision dated: **08-02-2024**

Expiry date: **26-03-2027**

The alternative analysis method:

BACGene *Salmonella* spp.

Validated for the detection of *Salmonella* spp.

Manufactured by:

Gold Standard Diagnostics

Fóti út 56

building A

H-1047 Budapest HUNGARY

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 6579-1** (April 2017) **and its amendment A1** (March 2020) : Microbiology of the food chain- Horizontal method for the detection, enumeration and serotyping of *Salmonella* - Part 1: Detection of *Salmonella* spp. - Amendment 1: Extension of the incubation temperature range, amendment of the status of Annex D and correction of the composition of MSRV and SC media

Scope All human food products (by performing validation assays on a broad range of foods), feed products pet food (25g et 375g) and animal feed (25g), industrial environmental samples, milk powders, infant formula with and without probiotics (375g), heat-processed milk and dairy products (375g).

Restriction(s) The *PREraser* protocol is validated for the analysis of heat-treated milk and milk products (375g) and samples from the industrial production environment.

Warning None.

Other information The scope includes the use of AriaMx Agilent, BIO-Rad CFX96 Touch™ and Bio-Rad CFX96 Touch™ Deep Well instruments with the BACGene evaluation sheet and Fastfinder evaluation software.

The scope includes the use of the new internal evaluation software "PURE" and the use of the automation OT-2 Liquid Handler.

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>.