Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: QUA 18/08-03/15
Renewal decision dated: 24-03-2023
Expiry date: 26-03-2027

The Company:

HYGIENA LLC
941 Avenida Acaso
Camarillo, CA 93012
USA

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 Assay for *Salmonella* spp.

Validated for the detection of *Salmonella* spp.

Technical sheet reference's	**KIT2006 (D14306040) INS2013 Rev 10**

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 28-11-2022). 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 29/09/2023

11 rue Francis de Pressensé - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 62 80 00 - F. +33 (0)1 49 17 90 00
SAS au capital de 18 187 000 € - 479 076 002 RCS Bobigny - **www.afnor.org**

Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **QUA 18/08-03/15**
Renewal decision dated: **24-03-2023**
Expiry date: **26-03-2027**

The alternative analysis method:

BAX® System RT-PCR Assay for *Salmonella* spp.

Validated for the detection of Salmonella spp.

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	**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.
Scope	All human food products (by performing validation assays on a broad range of foods) excluding milk powders, pet food and industrial production environmental samples.
Restriction(s)	None.
Warning	None.
Other information	The scope includes the use of the instrument BAX® System Q7 with BAX ® software version 4.0 and higher.

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.

11 rue Francis de Pressensé - 93571 La Plaine Saint-Denis Cedex - France - T. +33 (0)1 41 62 80 00 - F. +33 (0)1 49 17 90 00
SAS au capital de 18 187 000 € - 479 076 002 RCS Bobigny - **www.afnor.org**