



Validation of alternative analysis methods

NF102 – Application to the food industry

# Certificate

Certificate No.: **BIO 12/21-12/06**

Renewal decision dated: 03-12-2018

Expiry date: 14-12-2022

The Company:

**bioMérieux**

Chemin de l'Orme

69280 –Marcy l'Etoile - France

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):

## TEMPO® EB

Validated for the enumeration of Enterobacteriaceae

Technical sheet reference's

Ref. 80 003 – 12596 version H

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 (linearity, relative accuracy...), available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last version dated 18-12-2014). This NF VALIDATION certificate, included 2 pages, is valid until December 14<sup>th</sup> 2022. 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  
Franck LEBEUGLE

Issue dated 17/07/2019

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The alternative analysis method:

## TEMPO<sup>®</sup> EB

Validated for the enumeration of Enterobacteriaceae

Manufactured by:

**bioMérieux**  
3, route du Port Michaud  
38390 La Balme Les grottes - FRANCE

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 21528-2</b> (July 2017): Microbiology of the food chain - Horizontal method for the detection and enumeration of Enterobacteriaceae - Part 2 : Colony-count technique                  |
| Scope               | In all human food products (by performing validation assays on a broad range of foods) and pet food.  |
| Restriction(s)      | None.   |
| Warning             | None.   |
| Other informations  | The scope includes as a version of SOFTWARE TEMPO: R5 and all previous versions.  |

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>.