



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BIO 12/13-02/05**

Renewal decision dated: 27-01-2017

Expiry date: 04-02-2021

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[®] EC

Validated for the enumeration of *Escherichia coli*

Technical sheet reference's

Ref. 80 004 - 12597 version L or M

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

This certificate supersedes all previous certificates (last version dated 10-03-2015). This NF VALIDATION certificate, included 2 pages, is valid until 04th February 2021. 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 21-12-2017

Page 1/2



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **BIO 12/13-02/05**

Renewal decision dated: 27-01-2017

Expiry date: 04-02-2021

The alternative analysis method:

TEMPO[®] EC

Validated for the enumeration of *Escherichia coli*

Manufactured by:

bioMérieux
3, route de Port Michaud
38390 La Balme-les-Grottes - France

Has been certified according to the reference documents and for 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 ISO 16649-2 (July 2001): Microbiology of food and animal feeding stuffs. Horizontal method for the enumeration of β -glucuronidase-positive <i>Escherichia coli</i> - Part 2: colony-count technique at 44 °C using 5-bromo-4-chloro-3-indolyl β -D-glucuronate.
Scope	All human food products by performing validation assays on a broad range of foods and pet food.
Restriction(s)	None.
Warning	None.
Other information(s)	The versions of TEMPO software usable are: R5 and all prior 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>.

Issue dated 21-12-2017

Page 2/2

