



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

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

Extension decision dated: **03-05-2023**

Expiry date: **04-02-2025**

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 β -glucuronidase positive *Escherichia coli*

Technical sheet
reference's

Réf. 80004 – 12597 version **M**

Réf. 80004 – 12597 version **N**

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 12-01-2022). This NF VALIDATION certificate, included 2 pages, is valid until **04th February 2025**. 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 26/06/2023

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The alternative analysis method:

TEMPO[®] EC

Validated for the enumeration of β -glucuronidase positive *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, pet food products.
Restriction(s)	The TEMPO EC method is not recommended to analyse products with a high enzymatic activity, such as raw mollusks and red offal. This restriction is lifted when applying a dilution $\geq 1/40$.
Warning	None.
Other information(s)	Non applicable

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>.