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Ref.: SSO/SSO/NF102/Clients/bioMérieux/
Avis BT_BACARA_2018-07-02_(R2).docx

bioMérieux
Mr. Jean-Louis PITTET
Chemin de l'Orme
F-69280 MARCY L'ETOILE
FRANCE

Subject: NF VALIDATION mark

La Plaine Saint-Denis, July 2nd, 2018

Dear Sir,

Following the positive agreement expressed on July 2nd, 2018, by the Technical Board of the NF VALIDATION mark (NF102), in its application to the food industry, I beg to inform you that the **NF VALIDATION certification is renewed** for the following alternative method:

BACARA®

Certificate reference No. AES 10/10-07/10, with end of validity 2nd-July-2022

The alternative method is validated for the detection of presumptive *Bacillus cereus* in all human food products (by performing validation tests on a broad range of foods) and animal food products, by comparison to the reference method NF EN ISO 7932 (2005) and following the validation protocol NF EN ISO 16140-2 (2016).

A further letter will mention full conclusions and possible reservations made by the Technical Board. If reservations are mentioned, I ask you to take them into account without any delay.

Yours Sincerely.



Managing Director
Franck LEBEUGLE





Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **AES 10/10-07/10**
Renewal decision dated: 15-05-2014
Expiry date: 02-07-2018

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):

BACARA™

Validated for the enumeration of presumptive *Bacillus cereus*

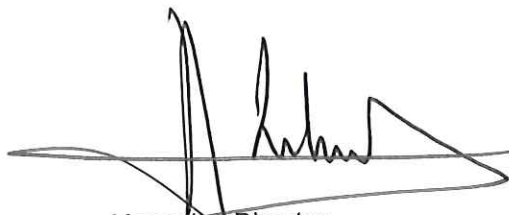
Technical sheet reference's

520100 - Versions D and E

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.afnor.org/en>.

This certificate supersedes all previous certificates (last version dated 22-01-2015). This NF VALIDATION certificate, included 2 pages, is valid until 02nd July 2018. 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 10-03-2015

Page 1/2



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **AES 10/10-07/10**
Renewal decision dated: 15-05-2014
Expiry date: 02-07-2018

The alternative analysis method:

BACARA™

Validated for the enumeration of presumptive *Bacillus cereus*

Manufactured by:

bioMérieux
Route de Dol
35270 Combourg - France

Has been certified according to the reference documents and for the application scope specified here after:

| | |
|----------------------|--|
| Validation protocol | NF EN ISO 16140 (October 2003): Microbiology of food and animal feeding stuffs. Protocol for the validation of alternative methods. |
| Reference method(s) | NF EN ISO 7932 (July 2005): Microbiology of food and animal feeding stuffs. Horizontal method for the enumeration of presumptive <i>Bacillus cereus</i> - Colony-count technique at 30 °C. |
| Scope | All human food and animal feeding stuffs. |
| Restriction(s) | None. |
| Warning | None. |
| Other information(s) | The scope includes surface and pour-plate procedures. |

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>.