

Contacts:

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Ref.: SSO/JFY/NF102/Clients/Oxoid Thermo Fisher Scientific/
Avis BT_SureTect Crono_2018-03-22_(R1).docx

Subject: NF VALIDATION mark

OXOID Ltd, Part of Thermo Fisher Scientific
Mrs. Ana-Maria LEONTE
Wade Road
RG24 8PW Basingstoke
Hampshire
United Kingdom

La Plaine Saint-Denis, March 22nd, 2018

Dear Madam,

Following the positive agreement expressed on March 22nd, 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 has been renewed** for the following alternative method:

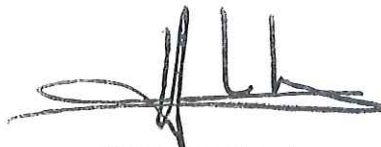
Thermo Scientific™ SureTect™ *Cronobacter* species PCR Assay

Certificate reference No. UNI 03/11-12/15, with end of validity 3rd-December-2023

The alternative method has been validated for the detection of *Cronobacter* spp. in infant formula (with and without probiotics) and production environmental samples, by comparison to the reference method NF EN ISO 22964 (2017) 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



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Ref.: SSO/JFY/NF102/Clients/Oxoid Thermo Fisher Scientific/
Avis BT_SureTect Cronobacter spp_2016-06-30_E1

Subject: NF VALIDATION mark

**Thermo Fisher Scientific
OXOID Ltd
Mr Jonathan CLOKE**
Wade Road
RG24 8PW Basingstoke
Hampshire
England, United Kingdom

La Plaine Saint-Denis, June 30th, 2016

Dear Sir,

Following the positive agreement expressed on June 30th, 2016, by the Technical Board "Food microbiology" of the NF VALIDATION mark (NF102), I beg to inform you that the **extension of NF VALIDATION certification** is granted to Oxoid Thermo Fisher Scientific Company for the following analysis method:

Thermo Scientific SureTect *Cronobacter* species PCR Assay

Certificate reference No. UNI 03/11-12/15, with end of validity 3-Dec.-2019

The alternative method is validated by comparison to the reference method ISO/TS 22964 (2006), and according to the validation protocol ISO/FDIS 16140-2 (2015). This extension allowed to validate (1) a new protocol for powdered infant formula (300g); (2) the use of ABI 7500 Fast instrument used with ABI RapidFinder Express software V2.0 for results analysis and interpretation for powdered infant formula (10g and 300g) and production environmental samples.

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.: UNI 03/11-12/15

Validation decision dated: 03-12-2015

Expiry date: 03-12-2019

The Company:

Oxoid Ltd, Part of Thermo Fisher Scientific

Wade Road, Basingstoke, Hampshire

RG24 8PW - United Kingdom

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):

Thermo Scientific™ SureTect™ Cronobacter species PCR Assay

Validated for the detection of *Cronobacter* spp.

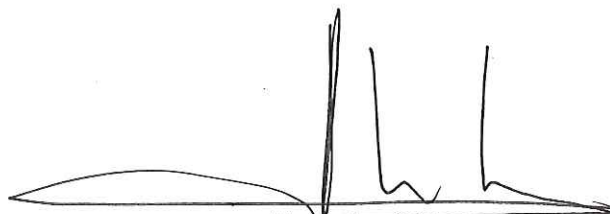
Technical sheet reference's

D14244_02

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. This NF VALIDATION certificate, included 2 pages, is valid until 03rd December 2019. 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 26-04-2016

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Certificate

Certificate No.: **UNI 03/11-12/15**
Validation decision dated: **03-12-2015**
Expiry date: **03-12-2019**

Validation of alternative analysis methods
NF102 – Application to the food industry

The alternative analysis method:

Thermo Scientific™ SureTect™ *Cronobacter species* PCR Assay

Validated for the detection of *Cronobacter* spp.

Manufactured by:

Thermo Fisher Scientific Oy
Ratastie 2, PO BOX 100
Vantaa 01621 - Finland

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

Validation protocol	ISO/FDIS 16140-2 (2015): Microbiology of the food chain. Method validation - Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method.
Reference method(s)	ISO/TS 22964 (February 2006): Milk and milk products - Detection of <i>Enterobacter sakazakii</i> .
Scope	Infant formula (with or without probiotics) and related industrial environmental samples.
Restriction(s)	None.
Warning	None.
Other informations	The scope includes the use of SureTect PikoReal PCR instrument with the SureTect Software v1.2 and its kit file version 1.0.0.20.

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>.