



Validation of alternative analysis methods

NF102 – Application to the food industry

Certificate

Certificate No.: **UNI 03/11-12/15**

Renewal decision dated: **05-10-2023**

Expiry date: **03-12-2027**

The Company:

OXOID Ltd
Thermo Fisher Scientific
Wake Road, Basingstoke
Hampshire RG24 8PW
ENGLAND

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

MAN0017960 Rev J.0

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 (last version dated 20-02-2024). This NF VALIDATION certificate, included 2 pages, is valid until **3rd December 2027**. 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 23/02/2024

Page 1/2



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The alternative analysis method:

Thermo Scientific™ SureTect™ *Cronobacter* species PCR Assay

Validated for the detection of *Cronobacter* spp.

Manufactured by:

Thermo Fisher Scientific Oy
(Microbiology Vantaa)
Ratastie 2, PO BOX 100
Vantaa, FI-01621, FINLAND

Has been certified according to the reference documents and 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 EN ISO 22964 (June 2017): Microbiology of the food chain - Horizontal method for the detection of <i>Cronobacter</i> spp. |
| Scope | Infant formula, infant cereals, related ingredients and industrial production environmental samples. |
| Restriction(s) | None. |
| Warning | None. |
| Other information | The scope includes the use of Applied Biosystems™ RapidFinder™ Express software version 2.0 or later used with Applied Biosystems™ 7500 Fast instrument and equivalent (same characteristics) manufactured by Thermo Fisher Scientific and the use of Thermo Scientific™ RapidFinder™ Analysis software version 1.0 or later used with the Applied Biosystems™ QuantStudio 5 instrument and equivalent (same characteristics) manufactured by Thermo Fisher Scientific and/or subsidiaries Instrument Thermo Scientific PikoReal PCR with Thermo Scientific SureTect software version 1.2. The scope of application includes the use of the Thermo Scientific™ PrecisBlue™ supplement. |

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>.

CERTI F 2022.1 08/2020

Issue dated 23/02/2024

Page 2/2