



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

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

Extension decision dated: **15-07-2026**

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 R (all versions R covered)

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, inclusivity and exclusivity) available on the certification dedicated website <http://nf-validation.org/en>.

This certificate supersedes all previous certificates (last version dated 20-03-2025). This NF VALIDATION certificate, included 2 pages, is valid until **December 3rd, 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 of AFNOR Certification
Julien NIZRI

Issue dated 15-07-2026

Page 1/2



Validation of alternative
analysis methods

NF102 – Application to the food industry

Certificate

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

Extension decision dated: **15-07-2026**

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

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 *Cronobacter* spp.

Scope Infant formula, infant cereals, related ingredients (10, 300 and 375g test portion) and industrial production environmental samples.

Restriction(s) None.

Warning None.

Other information The scope includes both manual and automated workflows using the CyBio FeliX instrument in combination with the Applied Biosystems™ QuantStudio™ 5 PCR instrument or equivalent (same features) and Thermo Scientific™ RapidFinder™ Analysis software version 3.0 or higher. 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. Application includes the use of the Thermo Scientific™ PrecisBlue™ supplement. The Thermo Scientific™ SureClean DNA Removal kit for testing powder infant formula and related products (1-in-6 protocol), and industrial production environmental samples (BPW protocol).

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>.