



# CERTIFICATION

**AOAC Research Institute**  
***Performance Tested Methods<sup>SM</sup>***

Certificate No.  
**101703**

The AOAC Research Institute hereby certifies the method known as

**Molecular Detection Assay 2 – *Cronobacter***

manufactured by

**Neogen Corporation**  
**620 Leshar Place**  
**Lansing, Michigan 48912 USA**

This method has been evaluated and certified according to the policies and procedures of the AOAC *Performance Tested Methods<sup>SM</sup>* Program. This certificate indicates an AOAC Research Institute Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Research Institute *Performance Tested Methods<sup>SM</sup>* certification mark on the above-mentioned method for the period below. Renewal may be granted by the Expiration Date under the rules stated in the licensing agreement.

A handwritten signature in black ink, appearing to read "Bradley A. Stawick".

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Bradley A. Stawick, AOAC Research Institute Senior Director

Issue Date	April 18, 2026
Expiration Date	December 31, 2026

**METHOD NAME**

Neogen<sup>®</sup> Molecular Detection Assay 2 – *Cronobacter*  
Formerly 3M<sup>™</sup> Molecular Detection Assay 2 – *Cronobacter*

**CATALOG NUMBER**

700002257/MDA2CRO96

**ORIGINAL CERTIFICATION DATE**

October 24, 2017

**PRINCIPLE OF THE METHOD**

The Neogen<sup>®</sup> Molecular Detection Assay 2 – *Cronobacter* is used with the Neogen Molecular Detection System for the rapid and specific detection of *Cronobacter* in enriched food and food process environmental samples.

The Molecular Detection Assays use loop-mediated isothermal amplification to rapidly amplify nucleic acid sequences with high specificity and sensitivity, combined with bioluminescence to detect the amplification. Presumptive positive results are reported in real-time while negative results are displayed after the assay is completed. Presumptive positive results should be confirmed using your preferred method or as specified by local regulations.

**CERTIFIED CLAIM STATEMENT:** The Molecular Detection Assay 2 – *Cronobacter* method is certified for the detection of *Cronobacter* species within the scope of Tables 1 and 2 and the modifications indicated in Table 3.

**Certified method includes:**

1. Molecular Detection System Instrument
2. Confirmation using PMAxx Free DNA Removal

**Table 1. Method performance claims**

Matrix	Test Portion	Enrichment conditions				Reference method <sup>b</sup>	Claim <sup>c</sup>
		Broth <sup>a</sup>	Volume	Temperature	Time		
Powdered infant formula with probiotics	10 g	BPW ISO	90 mL	37 ± 1°C	18-24 h	ISO/FDIS 22964:2016	NSDD
	300 g	pw BPW ISO + 10 mg/L vancomycin	2700 mL	37 ± 1°C	22-24 h	ISO/FDIS 22964:2016	NSDD
	400 g	pw BPW ISO + 10 mg/L vancomycin	3600 mL	37 ± 1°C	22-24 h	ISO 22964-1:2017	NSDD
Powdered infant formula without probiotics	400 g	pw BPW ISO	3600 mL	37 ± 1°C	18-24 h	ISO 22964-1:2017	NSDD
Powdered infant cereal without probiotics	10 g	BPW ISO	90 mL	37 ± 1°C	18-24 h	ISO/FDIS 22964:2016	NSDD
	300 g	pw BPW ISO	2700 mL	37 ± 1°C	22-24 h	ISO/FDIS 22964:2016	NSDD
Lactose powder	10 g	BPW ISO	90 mL	37 ± 1°C	18-24 h	ISO/FDIS 22964:2016	NSDD
Stainless steel	4"x4", sponge <sup>d</sup>	BPW ISO	90 mL	37 ± 1°C	18-24 h	ISO/FDIS 22964:2016	NSDD

<sup>a</sup> BPW ISO = Buffered Peptone Water ISO formulation; pw = prewarmed to 37°C

<sup>b</sup> ISO = International Organization for Standardization; FDIS = Final Draft International Standard

<sup>c</sup> NSDD = No statistical difference detected using SLV study design from OMA Appendix J (2012). The SLV qualitative method comparison study design from OMA Appendix J (2012) is not intended to demonstrate statistical equivalence. Expert opinion is that the method is appropriate for its intended use.

<sup>d</sup> Sponge was pre-moistened with 10 mL Dey/Engley neutralizing broth.

**Table 2. Method selectivity**

Broth <sup>a</sup>	Temperature	Inclusivity strains		Exclusivity strains	
		No. tested	No. positive	No. tested	No. positive
BPW ISO	37 ± 1°C	50 <sup>b</sup>	50	30 <sup>c</sup>	0
BPW ISO + 10 mg/L vancomycin	37 ± 1°C	50 <sup>b</sup>	50	30 <sup>c</sup>	0

<sup>a</sup> BPW ISO = Buffered Peptone Water ISO formulation

<sup>b</sup> Comprising *C. sakazakii*, *C. malonaticus*, *C. turicensis*, *C. muytjensii*, *C. dublinensis*, *C. universalis* and *C. condimenti*

<sup>c</sup> Comprising 30 species

**Table 3. Method history**

No.	Date	Summary	Supporting data
1	October 2017	Original certification: Included powdered infant formula with probiotics (10 g and 300 g), powdered infant cereal without probiotics (10 g and 300 g), lactose powder (10 g) and stainless steel (sponge)	Certification Report
2	2018	AOAC Official Method 2018.01: Evaluation of the 3M™ Molecular Detection Assay (MDA) 2 – <i>Cronobacter</i> for the Detection of <i>Cronobacter</i> species in Select Foods and Environmental Surfaces: Collaborative Study (First Action 2018, Final Action 2021)	OMA First Action Report
3	April 2026	Level 2 Modification: Addition of 400 g test portion size for powdered infant formula with and without probiotics and evaluation of PMAxx confirmation step	Modification 1 Report