

**NF VALIDATION - Validation of alternative analysis methods
Application to the food industry**

**Summary report
according to the standard EN ISO 16140-2:2016**

Qualitative method

**Thermo Scientific™ SureTect™ Cronobacter species PCR Assay
Certificate n° UNI 03/11-12/15
for the detection of *Cronobacter* spp
in infant formula, infant cereals and related ingredients
and production environmental samples**

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This report contains 91 pages including 54 pages of appendices.
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Preamble

- Protocols of validation:

- EN ISO 16140-1 and EN ISO 16140-2 (September 2016): Microbiology of the food chain — Method validation
Part 1: Vocabulary.
Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method.
- Requirements regarding comparison and interlaboratory studies for implementation of the standard EN ISO 16140-2 (version 6).

- Reference method:

- **ISO 22964 (April 2017):** Microbiology of the food chain - Horizontal method for the detection of *Cronobacter* spp.

- Application scope:

- **Infant formula (10 g and 300 g),**
- **Environmental samples (25 g or surface sampling),**
- **Infant formula, infant cereals and related ingredients (up to 375 g).**

- Certification body:

- **AFNOR Certification (<https://nf-validation.afnor.org/>).**

Definitions

- **Method comparison study**

The method comparison study is the part of the validation process that is performed in the organizing laboratory. It consists of three parts namely the following:

- A comparative study of the results of the reference method to the results of the alternative method in (naturally and/or artificially) contaminated samples (so-called sensitivity study);
- A comparative study to determine the relative level of detection (RLOD) in artificially contaminated samples (so-called RLOD study);
- An inclusivity/exclusivity study of the alternative method.

- **Sensitivity study**

The sensitivity study aims to determine the difference in sensitivity between the reference and the alternative method.

The sensitivity is the ability of the reference method or alternative method to detect the analyte.

- **Relative level of detection study**

A comparative study is conducted to evaluate the level of detection (LOD) of the alternative method against the reference method. The evaluation is based on the calculation of the relative level of detection (RLOD).

The level of detection at 50% (LOD_{50}) is the measured analyte concentration, obtained by a given measurement procedure, for which the probability of detection is 50%.

The relative level of detection level of detection at $P = 0,50$ (LOD_{50}) of the alternative method divided by the level of detection at $P = 0,50$ (LOD_{50}) of the reference method.

- **Inclusivity and exclusivity study**

The inclusivity study is a study involving pure target strains to be detected or enumerated by the alternative method.

The exclusivity study is a study involving pure non-target strains, which can be potentially cross-reactive, but are not expected to be detected or enumerated by the alternative method.

- **Interlaboratory study**

The interlaboratory study is a study performed by multiple laboratories testing identical samples at the same time, the results of which are used to estimate alternative-method performance parameters.

The aim of the interlaboratory study is to determine the difference in sensitivity between the reference and the alternative method when tested by different collaborators using identical samples (reproducibility conditions).

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Appendix A: Protocol of the alternative method

Appendix B: Protocol of the reference method

Appendix C: Artificial contaminations

Appendix D: Sensitivity study – raw results

Appendix E: Relative level of detection study – raw results

Appendix F: Inclusivity and exclusivity study – raw results

Appendix G: Interlaboratory study – raw results

1. Introduction

The SureTect Cronobacter method is validated by AFNOR Certification under the brand NF VALIDATION with the certification number UNI 03/11 – 12/15 according to the ISO 16140-2:2016 standard. The method is intended for infant formula, infant cereals and related ingredients (10 g, up to 375 g) and production environmental samples.

Table 1 summarizes the different steps of the validation that occurred since the initial validation.

Table 1: Steps of the validation AFNOR certification

Date	Study
December 2015	Initial validation study: infant formula (10 g), environmental samples - PikoReal PCR instrument
June 2016	Extension study: <ul style="list-style-type: none">- Infant formula (10 g) - 7500 Fast PCR instrument- Infant formula (300 g) - PikoReal PCR instrument, and 7500 Fast PCR instrument
April 2018	Renewal study according to the ISO 22964 (2017)
December 2018	Extension study: <ul style="list-style-type: none">- Infant formula (10 g)- Infant formula (up to 300 g)- Environmental samples QS5 PCR instrument
June 2021	Extension study: <ul style="list-style-type: none">- Infant formula, infant cereals and related ingredients (up to 375 g)

This document introduces all the results of the validation studies for the NF Validation certification of the SureTect Cronobacter™ method according to the standard ISO 16140-2:2016.

2. Protocols of the methods

2.1. Alternative method

2.1.1. Principle of the method

The PCR pellets used in the SureTect assays contain lyophilized (freeze-dried) target-specific primers and dye labelled probes. Probes are short oligonucleotides with a quencher molecule at one end that greatly reduces fluorescence from the fluorophore dye at the opposite end. The oligonucleotides target unique DNA sequences found only in the target micro-organism and use PCR technology to amplify and detect them. If present, the target DNA will be amplified, and the increasing fluorescent signal detected by the PCR instrument and software running on a connected PC.

The assays used in the Thermo Scientific SureTect System are based on Solaris™ qPCR technology. The probes have a molecule called Minor Groove Binder (MGB) attached to one end, which enhances the probe-template DNA bond and yields a better signal-to-noise ratio by lowering background fluorescence. Results are achieved in around one hour of loading the prepared sample in the PCR Instrument and are displayed on the PC screen as simple positive or negative symbols with amplification plots also easily accessible for review.

The Thermo Scientific SureTect Cronobacter spp. PCR assay targets unique DNA sequences specific to all Cronobacter species. The SureTect Cronobacter species PCR Assay includes all of the necessary reagents for bacterial DNA release and PCR. Enriched samples are simply pipetted into pre-filled Lysis Tubes, along with Proteinase K, before incubation to lyse any bacterial cells present in the sample and release their DNA. The lysate is then loaded into the SureTect Cronobacter species PCR Tubes to re-hydrate the preloaded PCR pellets which contain all of the necessary components and reagents for PCR, including a probe, primers and DNA template for the internal amplification control (IAC). The PCR Tubes are then sealed, loaded into the PCR Instrument, and the run started using the software, depending on which PCR instrument is used. After running, interpreted results will be clearly displayed and can be reported, stored, printed off and downloaded as required.

The SureTect Cronobacter species PCR kit was validated with the Thermo Scientific PikoReal PCR Instrument and Thermo Scientific SureTect Software v1.2., the Applied Biosystems™ 7500 Fast with Applied Biosystems™ RapidFinder™ Express software v2.0 (or later version), and the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Instrument using the Thermo Scientific™ RapidFinder™ Analysis Software v1.0 (or later version).

2.1.2. Protocols of the method

The workflow of the method is set out in Appendix A.

Different enrichment protocols are available depending on the categories tested. They are listed in Table 2.

Table 2: Enrichment protocols of the alternative method

Category		Sample size	Enrichment step
PIF10	Infant formula	10 g	10 g + 90 ml BPW 16 – 24 h at 34 – 38°C
ENV	Environmental samples	25 g or surface Sampling	BPW + 6 mg/l vancomycin 18 – 24h at 34 – 38°C
PIF300	Infant formula, infant cereals and related ingredients	Up to 300 g	300 g + 2 700 ml BPW + 6 mg/l vancomycin 20 – 28h at 34 – 38°C
PIF375	Infant formula, infant cereals and related ingredients	Up to 375 g	375 g + 3 375 ml BPW 6 mg/l vancomycin 20 – 28 h at 34 – 38°C

The following steps of the method are identical for all categories, they are listed below:

- Lysis step on 10 µl enrichment broth,
- PCR on 20 µl lysate,
- Confirmation tests:
 - Direct streaking on CCI Agar plates, incubated for 24 h ± 2 h at 41.5°C ± 1°C;
 - Subculture in CSB (0.1 ml + 10 ml), incubated for 24 h ± 2 h at 41.5°C ± 1°C. Streaking (10 µl) onto CCI Agar plates, incubated for 24 h ± 2 h at 41.5°C ± 1°C.

Typical colonies (blue-green) are confirmed by the tests described in the reference method.

Note: during the extension study on 375 g, characteristic colonies were directly confirmed with biochemical galleries.

According to ISO rules, it is also appropriate to use ISO 16140-6:2019 validated confirmation methods.

In order to improve the practicability, it is possible to store the enrichment broths for 72 h at 5±3°C, except for infant formula with probiotics (10 g sample size), prior to analysis with the SureTect Cronobacter species PCR Assay.

2.1.3. Restrictions

There are no restrictions on use for the SureTect Cronobacter method.

2.2. Reference method

The current version of the reference method is the ISO 22964 standard of April 2017: Microbiology of the food chain - Horizontal method for the detection of *Cronobacter* spp.

For the initial validation study and the previous extension studies, three versions of the standard were used:

- ISO/TS 22964 (February 2006),
- ISO/DIS 22964 (March 2015),
- ISO/FDIS 22964 (November 2016).

The workflow of the reference method is presented in Appendix B.

2.3. Study design

For the categories ENV, PIF300 and PIF375, the enrichment broths used for the alternative and reference methods are different, the study therefore provides unpaired data and the expression “unpaired study” is used to describe the study design.

For the category PIF10, the enrichment broth and test portion size being common, it is a “paired study”.

3. Method comparison study and extension studies results

3.1. Sensitivity study

3.1.1. Protocols applied during the extension study

- **Incubation times:**

The broths were incubated at the minimum times of the tolerance interval for each category.

- **Confirmations:**

Presumptive positive results were confirmed by direct streaking of the enriched broth on a CCI agar plate and also after a subculture in CSB, as described in §2.1.2.

- **Cold storage of the enriched broths and Petri dishes:**

Storage of the broths for 3 days at $5\pm 3^{\circ}\text{C}$ was carried out, except for infant formula with probiotics (10 g sample size). The alternative method was applied from the stored enriched broths for positive and discordant samples. Only a direct streaking on CCI was performed for confirmations.

The final results are interpreted according to ISO 16140-2: 2016, using the acceptability limits of paired or unpaired methods depending on the categories.

3.1.2. Number and nature of the samples

The sensitivity study concerned 274 samples (cf. Table 3).

Depending on the thermal cyclers that were tested, the total number of samples tested varies from 210 to 276.

Table 3: Distribution of samples tested by category, type and thermal cycler

Category	Type		Number of samples tested with the Piko Real			Number of samples tested with the 7500 Fast			Number of samples tested with the QS5		
			Positive	Negative	Total	Positive	Negative	Total	Positive	Negative	Total
PIF10	a	Infant formula without probiotics	15	15	30	15	15	30	15	15	30
	b	Infant formula with probiotics	15	19	34	15	19	34	15	19	34
	Total		30	34	64	30	34	64	30	34	64
ENV	a	Process and cleaning waters	7	13	20	7	13	20	5	13	18
	b	Dusts and wastes	8	12	20	8	12	20	8	12	20
	c	Wipe, sponges, swabs	16	13	29	16	13	29	16	13	29
	Total		31	38	69	31	38	69	29	38	67
PIF300	a	Infant formula without probiotics	21	24	45	21	24	45	21	24	45
	b	Infant formula with probiotics	16	16	32	16	16	32	16	16	32
	Total		37	40	77	37	40	77	37	40	77
PIF375	a	Infant formula & Infant cereals with probiotics	/	/	/	10	12	22	10	12	22
	b	Infant formula & Infant cereals - probiotics	/	/	/	10	13	23	10	13	23
	c	Ingredients (caseinates, lecithin, etc...)	/	/	/	10	11	21	10	11	21
	Total		/	/	/	30	36	66	30	36	66
All categories			98	112	210	128	148	276	126	148	274

3.1.3. Artificial contamination

Artificial contamination was carried out using stressed strains in accordance with the requirements of the validation standard and the AFNOR Validation Technical Board (see Appendix C).

Artificial contamination was performed by:

- Spiking protocol: the strains were stressed using various injury protocols; the injury efficiency was evaluated by comparing enumeration results onto selective and non-selective agars (respectively ESIA and TSYEA),
- Seeding protocol with lyophilized strains for dehydrated products.

Table 4 gives the distribution of the positive samples per level of contamination and per thermal cyclor used.

Table 4: distribution of the positive samples per contamination protocol and inoculation level (cl: contamination level in CFU/test portion)

Positive samples	Naturally contaminated samples	Artificially contaminated samples			
		Spiking	Seeding		
		cl ≤ 5 CFU	cl ≤ 3	3 < cl ≤ 10	cl > 10
128	6	23	79	20	0
/	4.7%	18.0%	61.7%	15.6%	0%

128 samples gave a positive result by at least one of the methods and 10% of them were naturally contaminated.

3.1.4. Results

Raw data are shown in appendix D.

Tables 5, 6 and 7 show the results of the sensitivity study for all categories, according to the thermal cyclor used.

Table 5: interpretation of the sensitivity study results (R+/-: reference method positive or negative, A+/-: alternative method positive or negative, PA: positive agreement, NA: negative agreement, ND: negative deviation, PD: positive deviation, PP: presumptive positive before confirmation) - Pikoreal

Category	Response	R+	R-
PIF10	A+	PA = 29	PD = 1
	A-	ND = 0 incl. 0 PPND	NA = 34 incl. 2 PPNA
ENV	A+	PA = 24	PD = 4
	A-	ND = 3 incl. 1 PPND	NA = 38 incl. 2 PPNA
PIF300	A+	PA = 23	PD = 9
	A-	ND = 5 incl. 0 PPND	NA = 40 incl. 3 PPNA
Total	A+	PA = 76	PD = 14
	A-	ND = 8 incl. 1 PPND	NA = 112 incl. 7 PPNA

Table 6: interpretation of the sensitivity study results (R+/-: reference method positive or negative, A+/-: alternative method positive or negative, PA: positive agreement, NA: negative agreement, ND: negative deviation, PD: positive deviation, PP: presumptive positive before confirmation) – 7500 Fast

Category	Response	R+	R-
PIF10	A+	PA = 29	PD = 1
	A-	ND = 0 incl. 0 PPND	NA = 34 incl. 2 PPNA
ENV	A+	PA = 24	PD = 4
	A-	ND = 3 incl. 0 PPND	NA = 38 incl. 0 PPNA
PIF300	A+	PA = 23	PD = 9
	A-	ND = 5 incl. 0 PPND	NA = 40 incl. 1 PPNA
PIF375	A+	PA = 19	PD = 7
	A-	ND = 4 incl. 0 PPND	NA = 36 incl. 4 PPNA
Total	A+	PA = 95	PD = 21
	A-	ND = 12 incl. 0 PPND	NA = 148 incl. 7 PPNA

Table 7: interpretation of the sensitivity study results (R+/-: reference method positive or negative, A+/-: alternative method positive or negative, PA: positive agreement, NA: negative agreement, ND: negative deviation, PD: positive deviation, PP: presumptive positive before confirmation) – QS5

Category	Response	R+	R-
PIF10	A+	PA = 29	PD = 1
	A-	ND = 0 incl. 0 PPND	NA = 34 incl. 2 PPNA
ENV	A+	PA = 22	PD = 4
	A-	ND = 3 incl. 0 PPND	NA = 38 incl. 1 PPNA
PIF300	A+	PA = 23	PD = 9
	A-	ND = 5 incl. 2 PPND	NA = 40 incl. 2 PPNA
PIF375	A+	PA = 19	PD = 7
	A-	ND = 4 incl. 0 PPND	NA = 36 incl. 2 PPNA
Total	A+	PA = 93	PD = 21
	A-	ND = 12 incl. 2 PPND	NA = 148 incl. 7 PPNA

3.1.5. Calculation of relative trueness (RT), sensitivity (SE) and false positive ratio (PFR)

The set of results obtained were used to calculate the relative trueness, the sensitivity and the false positive ratio for each of the categories and for all the categories, according to the formulas set out in the EN ISO 16140-2:2016 standard.

This interpretation is shown below in Table 8 for the PikoReal thermal cycler, in Table 9 for the 7500 Fast thermal cycler and in Table 10 for the Quant Studio 5 thermal cycler.

The calculations formulae of the ISO 16140-2 standard are presented below:

Sensitivity of the alternative method:

$$SE_{alt} = \frac{(PA + PD)}{(PA + ND + PD)} \times 100 \%$$

Sensitivity of the alternative method:

$$SE_{ref} = \frac{(PA + ND)}{(PA + ND + PD)} \times 100 \%$$

Relative trueness:

$$RT = \frac{(PA + NA)}{N} \times 100 \%$$

False positive ratio:

$$FPR = \frac{FP}{NA} \times 100 \%$$

Table 8: values in % of sensitivity for the two methods, relative trueness and false positive ratio for the alternative method (SE_{alt} : sensitivity for the alternative method, SE_{ref} : sensitivity for the reference method, RT: relative trueness, FPR: false positive ratio for the alternative method) – PikoReal thermal cyclor

Category	Type	PA	NA	PD	ND	N	PPND	PPNA	SE _{alt} %	SE _{ref} %	RT%	FPR %
PIF10	a Infant formula without probiotics	15	15	0	0	30	0	0	100.0%	100.0%	100.0%	0.0%
	b Infant formula with probiotics	14	19	1	0	34	0	2	100.0%	93.3%	97.1%	10.5%
	Total	29	34	1	0	64	0	2	100,0%	96.7%	98.4%	5.9%
ENV	a Process and cleaning waters	6	13	1	0	20	0	1	100.0%	85.7%	95.0%	7.7%
	b Dusts and wastes	6	12	1	1	20	0	0	87.5%	87.5%	90.0%	0.0%
	c Wipe, sponges, swabs	12	13	2	2	29	1	1	87.5%	87.5%	86.2%	15.4%
	Total	24	38	4	3	69	1	2	90,3%	87.1%	89.9%	7.9%
PIF300	a Infant formula without probiotics	11	24	6	4	45	0	1	81.0%	71.4%	77.8%	4.2%
	b Infant formula with probiotics	12	16	3	1	32	0	2	93.8%	81.3%	87.5%	12.5%
	Total	23	40	9	5	77	0	3	86.5%	75.7%	81.8%	7.5%
Total		76	112	14	8	210	1	7	91.8%	85.7%	89.5%	7.1%

Table 9: values in % of sensitivity for the two methods, relative trueness and false positive ratio for the alternative method (SE_{alt} : sensitivity for the alternative method, SE_{ref} : sensitivity for the reference method, RT: relative trueness, FPR: false positive ratio for the alternative method) – 7500 Fast thermal cyclers

Category	Type	PA	NA	PD	ND	N	PPND	PPNA	SE _{alt} %	SE _{ref} %	RT%	FPR %
PIF10	a Infant formula without probiotics	15	15	0	0	30	0	0	100.0%	100.0%	100.0%	0.0%
	b Infant formula with probiotics	14	19	1	0	34	0	2	100.0%	93.3%	97.1%	10.5%
	Total	29	34	1	0	64	0	2	100,0%	96.7%	98.4%	5.9%
ENV	a Process and cleaning waters	6	13	1	0	20	0	0	100.0%	85.7%	95.0%	0.0%
	b Dusts and wastes	6	12	1	1	20	0	0	87.5%	87.5%	90.0%	0.0%
	c Wipe, sponges, swabs	12	13	2	2	29	0	0	87.5%	87.5%	86.2%	0.0%
	Total	24	38	4	3	69	0	0	90,3%	87.1%	89.9%	0.0%
PIF300	a Infant formula without probiotics	11	24	6	4	45	0	0	81.0%	71.4%	77.8%	0.0%
	b Infant formula with probiotics	12	16	3	1	32	0	1	93.8%	81.3%	87.5%	6.3%
	Total	23	40	9	5	77	0	1	86,5%	75.7%	81.8%	2.5%
PIF375	a Infant formula & Infant cereals with probiotics	4	12	2	4	22	0	1	60.0%	80.0%	72.7%	8.3%
	b Infant formula & Infant cereals - probiotics	7	13	3	0	23	0	0	100.0%	70.0%	87.0%	0.0%
	c Ingredients (caseinates, lecithin, etc...)	8	11	2	0	21	0	1	100.0%	80.0%	90.5%	9.1%
	Total	19	36	7	4	66	0	2	86.7%	76.7%	83.3%	5.6%
Total		95	148	21	12	276	0	5	90.6%	83.6%	88.0%	3.4%

Table 10: values in % of sensitivity for the two methods, relative trueness and false positive ratio for the alternative method (SE_{alt} : sensitivity for the alternative method, SE_{ref} : sensitivity for the reference method, RT: relative trueness, FPR: false positive ratio for the alternative method) – Quant Studio 5 thermal cycler

Category	Type	PA	NA	PD	ND	N	PPND	PPNA	SE _{alt} %	SE _{ref} %	RT%	FPR %
PIF10	a Infant formula without probiotics	15	15	0	0	30	0	0	100.0%	100.0%	100.0%	0.0%
	b Infant formula with probiotics	14	19	1	0	34	0	2	100.0%	93.3%	97.1%	10.5%
	Total	29	34	1	0	64	0	2	100,0%	96.7%	98.4%	5.9%
ENV	a Process and cleaning waters	4	13	1	0	18	0	0	100.0%	80.0%	94.4%	0.0%
	b Dusts and wastes	6	12	1	1	20	0	1	87.5%	87.5%	90.0%	8.3%
	c Wipe, sponges, swabs	12	13	2	2	29	0	0	87.5%	87.5%	86.2%	0.0%
	Total	22	38	4	3	67	0	1	89,7%	86.2%	89.6%	2.6%
PIF300	a Infant formula without probiotics	11	24	6	4	45	1	1	81.0%	71.4%	77.8%	8.3%
	b Infant formula with probiotics	12	16	3	1	32	1	1	93.8%	81.3%	87.5%	12.5%
	Total	23	40	9	5	77	2	2	86,5%	75.7%	81.8%	10.0%
PIF375	a Infant formula & Infant cereals with probiotics	4	12	2	4	22	0	1	60.0%	80.0%	72.7%	8.3%
	b Infant formula & Infant cereals - probiotics	7	13	3	0	23	0	0	100.0%	70.0%	87.0%	0.0%
	c Ingredients (caseinates, lecithin, etc...)	8	11	2	0	21	0	0	100.0%	80.0%	90.5%	0.0%
	Total	19	36	7	4	66	0	1	86.7%	76.7%	83.3%	2.8%
Total		93	148	21	12	274	2	6	90.5%	83.3%	88.0%	5.4%

The results for the category of the extension study and for all categories, per kind of thermal cyclers are summarized in Table 11.

Table 11: summary of the results for all categories

Parameter	Pikoreal	7500 Fast	Quant Studio 5
	All categories	All categories	All categories
Sensitivity of the alternative method (SE_{alt})	91.8%	90.6%	90.5%
Sensitivity of the reference method (SE_{ref})	85.7%	83.6%	83.3%
Relative trueness (RT)	89.5%	88.0%	88.0%
False positive ratio (FPR)	7.1%	3.4%	5.4%

3.1.6. Analysis of the discordant results

Discordant results are examined according to the standard ISO 16140-2:2016.

The discordant results for Infant formula 10 g, Infant formula in 300 g and Environmental samples are presented in Tables 12 and 13.

The discordant results for Infant formula, infant cereals and related ingredients in 375 g are listed in Table 14.

Table 12: summary of the negative deviations for the categories PIF10, ENV and PIF300

Category	Type	#	Product	Artificial contamination		ISO 22964	SureTect <i>Cronobacter</i> species						Agreement			
				Strain	Inoculation level CFU/sample		PCR result (Cq)			Confirmation	Final result Piko Real	Final result 7500 Fast	Final result QS5	Piko Real	7500 Fast	QS5
							PikoReal	7500 Fast	QS5							
ENV	b	2677	Dusts	<i>C. sakazakii</i> Ad 704	2.0	P	-	-	-	-	A	A	A	ND	ND	ND
	c	2445	Wipe	<i>C. sakazakii</i> Ad 1428	1.0	P	+(42.36) / +(47.63)	-	-	-	A	A	A	PPND	ND	ND
	c	3477	Surface sponge	<i>C. sakazakii</i> Ad 893	0.2	P	-	-	-	-	A	A	A	ND	ND	ND
PIF 300	a	3268	Infant formula without probiotics	<i>C. sakazakii</i> Ad1446	<1.0	P	-	-/-	+(44.15)	-	A	A	A	ND	ND	PPND
	a	3271	Infant formula without probiotics	<i>C. sakazakii</i> Ad940	7.5	P	-	-	-	-	A	A	A	ND	ND	ND
	a	3759	Infant formula without probiotics	<i>C. malonaticus</i> DSM18702	3.4	P	-	-	-	-	A	A	A	ND	ND	ND
	a	3761	Infant formula without probiotics	<i>C. malonaticus</i> DSM18702	3.4	P	-	-	-	-	A	A	A	ND	ND	ND
	b	1755	Infant formula with probiotics (8.4x10 ⁴ CFU/g)	<i>C. sakazakii</i> Ad916	2.8	P	-	-/(19.12)	+(22.00)	-	A	A	A	ND	ND	PPND

Table 13: summary of the positive deviations for the categories PIF10, ENV and PIF300

Cat.	Type	#	Product	Artificial contamination		ISO 22964	SureTect <i>Cronobacter</i> species						Agreement			
				Strain	Inoculation level CFU/sample		PCR result (Cq)			Confirmation	Final result Piko Real	Final result 7500 Fast	Final result QS5	Piko Real	7500 Fast	QS5
							Piko Real	7500 Fast	QS5							
PIF 10	b	2306	Infant formula milk powder with probiotics (7.0x10 ⁵ /g)	<i>C. sakazakii</i> Ad 1418	4.1	A	+(30.12)	+(28.61)	+(29.97)	+	P	P	P	PD	PD	PD
ENV	a	2053	Rinsing water	<i>C.sakazakii</i> Ad 947	2.8	A	+(21.12)	+(19.58)	+(21.85)	+	P	P	P	PD	PD	PD
	b	2682	Dusts	<i>C.sakazakii</i> Ad 831	1.4	A	+(31.71)	+(29.48)	+(30.85)	+	P	P	P	PD	PD	PD
	c	2058	Wipe	<i>C.sakazakii</i> Ad 2290	1.0	A	+(21.54)	+(19.48)	+(21.85)	+	P	P	P	PD	PD	PD
	c	2440	Wipe	<i>C.sakazakii</i> Ad 1708	0	A	+(31.27)	+(28.64)	+(31.29)	+	P	P	P	PD	PD	PD
PIF 300	a	3269	Infant formula without probiotics	<i>C.sakazakii</i> Ad940	7.5	A	+(28.06)	+(27.26)	+(30.05)	+	P	P	P	PD	PD	PD
	a	3272	Infant formula without probiotics	<i>C.sakazakii</i> Ad1420	<1.0	A	+(32.93)	+(33.00)	+(36.12)	+	P	P	P	PD	PD	PD
	a	3273	Infant formula without probiotics	<i>C.sakazakii</i> Ad1420	<1.0	A	+(30.72)	+(30.90)	+(33.02)	+	P	P	P	PD	PD	PD
	a	3483	Infant formula without probiotics	<i>C.dublinensis</i> DSM18705	1.6	A	+(26.70)	+(26.70)	+(26.64)	+	P	P	P	PD	PD	PD
	a	3754	Infant formula without probiotics	<i>C.dublinensis</i> DSM18705	0.8	A	+(30.38)	+(31.20)	+(37.52)	+	P	P	P	PD	PD	PD
	a	3758	Infant formula without probiotics	<i>C.turicensis</i> Ad1445	2.0	A	+(35.07)	+(34.23)	+(36.73)	+	P	P	P	PD	PD	PD
	b	1757	Infant formula with probiotics (2.2x10 ⁵ cfu/g)	<i>C.sakazakii</i> Ad953	<1.0	A	+(28.02)	+(27.46)	+(29.80)	+	P	P	P	PD	PD	PD
	b	1759	Infant formula with probiotics (1.0x10 ⁶ cfu/g)	<i>C.sakazakii</i> Ad953	<1.0	A	+(25.08)	+(24.00)	+(26.71)	+	P	P	P	PD	PD	PD
	b	3687	Infant formula with probiotics (<10 cfu/g)	/	/	A	+(25.22)	+(25.51)	+(27.51)	+	P	P	P	PD	PD	PD

Table 14: summary of the positive and negative deviations for the category PIF375

#	Type	Product name (probiotic enumeration CFU/g)	Contamination	Reference method: ISO 22964			Alternative method: SureTect Cronobacter species						Agreement	
				CCI	Confirmation	Final result	PCR result (Cq)		Confirmation by direct streaking (aspect of the CCI)	Confirmation after subculture (aspect of the CCI)	Final result			
							7500 Fast	QS5			7500 Fast	QS5	7500 Fast	QS5
2034828	a	Infant formula milk powder with probiotics <i>Bifidobacterium lactis</i> 2.1x10 ⁷ CFU/g	Artificial	- (∅)	/	A	+ (19.68)	+ (19.12)	+ (AM)	+ (AM)	P	P	PD	PD
2034845	a	Infant cereals with probiotics (cocoa) Batch 2 - <i>B. lactis</i> 5.6x10 ⁶ CFU/g	Artificial	- (∅)	/	A	(+ 20.29)	+ (19.47)	+ (AM)	+ (AM)	P	P	PD	PD
2034851	b	Infant cereals w/o probiotics (vanilla)	Artificial	- (∅)	/	A	+ (20.40)	+ (18.84)	+ (AM)	+ (AL)	P	P	PD	PD
2034888	b	Infant formula milk powder 6 - 12 months batch 1	Artificial	- (∅)	/	A	+ (33.15)	+ (31.39)	+ (AL)	+ (AL)	P	P	PD	PD
2034853	b	Infant formula milk powder 6 - 12 months batch 2	Natural	- (∅)	/	A	+ (22.87)	+ (20.33)	+ (AM)	+ (AL)	P	P	PD	PD
2034838	c	Maltodextrine batch 1	Artificial	- (∅)	/	A	+ (20.38)	+ (19.44)	+ (AM)	+ (AM)	P	P	PD	PD
2055441	c	Rice flour batch 2	Natural	+ (EM)	/	A	+ (24.30)	+ (23.25)	+ (BM)	+ (BM)	P	P	PD	PD
2034824	a	Infant formula milk powder with probiotics <i>Lactobacillus reuteri</i> 5.5x10 ⁶ CFU/g	Artificial	+ (AM)	-	P	-	-	- (∅)	- (∅)	A	A	ND	ND
2034827	a	Infant formula milk powder with probiotics <i>Bifidobacterium lactis</i> 4.5x10 ⁶ CFU/g	Artificial	+ (AM)	-	P	-	-	- (∅)	- (∅)	A	A	ND	ND
2034892	a	Infant cereals with probiotics <i>B. lactis</i> 6.8x10 ⁶ CFU/g	Artificial	+ (AL)	-	P	-	-	- (EL)	- (EL)	A	A	ND	ND
2066812	a	Infant cereals with probiotics (chocolate & biscuit) - <i>B. lactis</i> 7.0x10 ⁵ CFU/g	Artificial	+ (AM)	-	P	-	-	- (EL)	- (∅)	A	A	ND	ND

Overall, twenty-one positive deviations were observed: three from naturally contaminated samples and eighteen from artificially contaminated samples.

Twelve negative deviations were also observed: all from artificially contaminated samples. The presence of *Cronobacter* in the alternative method broth was not detected, even using the additional confirmation protocol of the ISO 16140-2 standard (subculture in CSB before streaking on CCI).

In conclusion, the negative deviations and the positive deviations most probably come from the nature of the study design. In an unpaired study, because of the difference of sampling between the two methods, and the use of naturally contaminated samples or seeded samples with low levels of contamination, no cell of *Cronobacter* may have been present in the sampling of one of the two methods.

3.1.7. Confirmations

No differences were observed between the two protocols used for the confirmations (direct streaking on CCI or after a subculture in CSB) during this extension study.

Three presumed positive not confirmed results were obtained during the extension study: two with the 7500 Fast thermal cycler and one with the QS5 thermal cycler.

No negative result with the SureTect method has been confirmed after a subculture in CSB.

3.1.8. Calculation and interpretation of data

The following Tables shows the difference between negative deviations and positive deviations and the acceptability limits according to the kind of thermal cycler used:

- Table 15: PikoReal,
- Table 16: 7500 Fast,
- Table 17: Quant Studio 5.

Table 15: acceptability limits for the PikoReal thermal cycler

Category	Types	ND	PD	Paired protocol				Unpaired protocol		Combined	
				ND-PD	AL	ND+PD	AL	ND-PD	AL	ND-PD	AL
PIF10	a	0	0	0	/	0	/	/		0	/
	b	0	1	-1		1				-1	
	Total	0	1	-1	3	1	6			-1	3
ENV	a	0	1	/				-1	/	-1	/
	b	1	1					0		0	
	c	2	2					0		0	
	Total	3	4					-1		3	
PIF300	a	4	6	/				-2	/	-2	/
	b	1	3					-2		-2	
	Total	5	9					-4		3	
All categories		8	14	/	/	/	/	/	/	-6	5

Table 16: acceptability limits for the 7500 Fast thermal cycler

Category	Type	ND	PD	Paired protocol				Unpaired protocol		Combined	
				ND-PD	AL	ND+PD	AL	ND-PD	AL	ND-PD	AL
PIF10	a	0	0	0	/	0	/	/	0	/	
	b	0	1	-1		1			-1		
	Total	0	1	-1	3	1	6		-1	3	
ENV	a	0	1	/				-1	/	-1	/
	b	1	1					0		0	
	c	2	2					0		0	
	Total	3	4					-1		3	
PIF300	a	4	6	/				-2	/	-2	/
	b	1	3					-2		-2	
	Total	5	9					-4		3	
PIF375	a	4	2	/				2	/	2	/
	b	0	3					-3		-3	
	c	0	2					-2		-2	
	Total	4	7					-3		3	
All categories		12	21	/	/	/	/	/	/	-9	5

Table 17: acceptability limits for the QS5 thermal cycler

Category	Type	ND	PD	Paired protocol				Unpaired protocol		Combined	
				ND-PD	AL	ND+PD	AL	ND-PD	AL	ND-PD	AL
PIF10	a	0	0	0	/	0	/	/	0	/	
	b	0	1	-1		1			-1		
	Total	0	1	-1	3	1	6		-1	3	
ENV	a	0	1	/				-1	/	-1	/
	b	1	1					0		0	
	c	2	2					0		0	
	Total	3	4					-1		3	
PIF300	a	4	6	/				-2	/	-2	/
	b	1	3					-2		-2	
	Total	5	9					-4		3	
PIF375	a	4	2	/				2	/	2	/
	b	0	3					-3		-3	
	c	0	2					-2		-2	
	Total	4	7					-3		3	
All categories		12	21	/	/	/	/	/	/	-9	5

The observed values (ND – PD) are below the acceptability limits for each category and for all categories for the three kinds of thermal cyclers tested. The alternative method produces results comparable to the reference method.

3.1.9. Enrichment broth storage at 2 – 8°C for 72 hours

A stability study of the enriched broths stored at 5±3°C for 72 hours was performed on positive and discordant samples. After storage, the broths were reanalyzed and confirmed. The test portions of 10 g of infant formula powders (PIF10, type b) with probiotics were not covered by this study.

During the initial validation study, the conclusion changed for two samples analyzed with PikoReal and with 7500 Fast thermal cyclers and for three samples analyzed with Quant Studio 5 thermal cycler.

These samples were all belonging to the type a of the PIF300 category: Infant formula without probiotic.

They all moved from NA to PD (cf. summary report).

During the current extension study, the conclusion for only one sample changed after storage at 2-8°C for 3 days: sample 2034852, Infant cereals w/o probiotics (wheat & cocoa), which was negative just after enrichment, and became positive after the cold storage.

The concordance between the reference and the alternative method moved from NA to PD.

The interpretation of the results after cold storage is presented in the following Tables according to the kind of thermal cycler used:

- Table 18: PikoReal,
- Table 19: 7500 Fast,
- Table 20: Quant Studio 5.

Table 18: acceptability limits for the PikoReal thermal cycler after cold storage of the broths

Category	Types	ND	PD	Paired protocol				Unpaired protocol		Combined	
				ND-PD	AL	ND+PD	AL	ND-PD	AL	ND-PD	AL
PIF10	a	0	0	0	/	0	/	/	0	/	
	Total	0	0	0	3	0	6		0	3	
ENV	a	0	1	/	/	/	/	-1	/	-1	/
	b	1	1					0		0	
	c	2	2					0		0	
	Total	3	4					-1	3	-1	3
PIF300	a	4	8	/	/	/	/	-4	/	-4	/
	b	1	3					-2		-2	
	Total	5	11					-6	3	-6	3
All categories		8	15	/	/	/	/	/	/	-7	5

Table 19: acceptability limits for the 7500 Fast thermal cycler after cold storage of the broths

Category	Type	ND	PD	Paired protocol				Unpaired protocol		Combined	
				ND-PD	AL	ND+PD	AL	ND-PD	AL	ND-PD	AL
PIF10	a	0	0	0	/	0	/	/		0	/
	Total	0	0	0	3	0	6			0	3
ENV	a	0	1					-1	/	-1	/
	b	1	1					0		0	
	c	2	2					0		0	
	Total	3	4					-1		3	
PIF300	a	4	8	/				-4	/	-4	/
	b	1	3					-2		-2	
	Total	5	11					-6		3	
PIF375	a	4	2					2		2	
	b	0	4					-4		-4	
	c	0	2					-2		-2	
	Total	4	8					-4		3	
All categories		12	23	/	/	/	/	/	/	-11	5

Table 20: acceptability limits for the QS5 thermal cycler after cold storage of the broths

Category	Type	ND	PD	Paired protocol				Unpaired protocol		Combined	
				ND-PD	AL	ND+PD	AL	ND-PD	AL	ND-PD	AL
PIF10	a	0	0	0	/	0	/	/		0	/
	Total	0	0	0	3	0	6			0	3
ENV	a	0	1					-1	/	-1	/
	b	1	1					0		0	
	c	2	2					0		0	
	Total	3	4					-1		3	
PIF300	a	4	9	/				-5	/	-5	/
	b	1	3					-2		-2	
	Total	5	12					-7		3	
PIF375	a	4	2					2		2	
	b	0	4					-4		-4	
	c	0	2					-2		-2	
	Total	4	8					-4		3	
All categories		12	24	/	/	/	/	/	/	-12	5

After cold storage of the enriched broths, the observed values (ND – PD) are below the acceptability limits for each category and for all categories for the three kinds of thermal cyclers tested.

The alternative method produces results comparable to the reference method.

3.1.10. PCR inhibitions

Some inhibitions were observed during the initial validation study.

No inhibition was observed during the extension study (PIF375).

All samples on which inhibitions were observed are listed in Table 21, as well as the percentage of inhibition for each thermal cycler used with regard to the number of samples analyzed.

Table 21: PCR inhibitions (: 1/5 dilution, **: Discordant result between 7500 Fast - initial validation result - and QS5, lysates tested again with 7500 Fast in 2018)*

Sample n°	Product	PCR result		
		PikoReal	7500 Fast	QS5
2310	Infant formula milk powder with probiotics (3.6x10 ⁶ CFU/g) (10 g)	i/-*	-	-
3947	Infant formula without probiotics (300 g)	i/-* (after storage)	-/+ (37.42)**	+ 38.35
1469	Infant formula milk powder with probiotics (1.2x10 ⁷ CFU/g)	-	i/-*	-
3264	Infant formula with probiotics (3.9x10 ⁵ CFU/g)	+ (19.70)	i/+ (20.24)*	+ (21.92)
2304	Infant formula (10 g) with probiotics (5.4x10 ⁶ /g)	+ (30.57)	+ 27.53	i/+ (28.41)*
2052	Rinsing water	+ (21.15)	+ (20.16)	i/+ (24.97)*
4078	Rinsing water	-	-	i/-*
3372	Infant formula without probiotics	-	-	i/-*
% of inhibition		0,9	0,7	1,4

A 1/5th dilution was applied: 3 samples gave then a positive result and 5 samples a negative result.

The percentage of inhibition varies for 0.6 to 1.3 % depending on the thermocycles used.

3.2. Relative level of detection study

3.2.1. Matrix-strain pairs

Table 22 summarizes the matrix-strain pairs tested and the kind of thermal cyclers on which it was analyzed.

Table 22: matrix-strain pairs for the determination of the RLOD

Category	Matrix	Inoculated strain	Storage conditions before analysis	Thermal cycler tested
Infant formula (10 g sample size) PIF10	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad1418	2 weeks at room temperature	PikoReal 7500 Fast
	Infant formula with probiotics	<i>Cronobacter sakazakii</i> Ad1418	2 weeks at room temperature	
Production environmental samples ENV	Process water	<i>Cronobacter turicensis</i> Ad1445	4°C, 48 - 72 h	PikoReal 7500 Fast
Infant formula (up to 300 g sample size) PIF300	Infant formula with probiotics	<i>Cronobacter sakazakii</i> Ad1446	2 weeks at room temperature	PikoReal 7500 Fast QS5
Infant formula, infant cereals and related ingredients (up to 375 g sample size) PIF375	Infant cereals with probiotics	<i>Cronobacter dublinensis</i> GVV828, wild strain isolated from a milk powder	Lyophilized strain with stabilization after inoculation for 2 weeks at room temperature	7500 Fast QS5

3.2.2. Contamination protocol

Three levels of contamination were prepared consisting of a negative control level, a low level, and a higher level.

The negative control level shall not produce positive results. Five replicates were tested for this level. The low level shall be the theoretical detection level, it was contaminated at 0.7 - 1 CFU per test portion to obtain fractional recovery results. Twenty replicates were tested for this level.

The higher level shall be just above the theoretical detection level, it was contaminated at 2 - 3 CFU per test portion. Five replicates were tested for this level.

3.2.3. Results

The detailed results table is set out in Appendix E for the category PIF375 tested during the extension study. Data from the previous validation studies are available in the summary report of the method.

The RLOD is defined as the ratio of the LODs of the alternative method and the reference method:
 $RLOD = \frac{LOD_{alt}}{LOD_{ref}}$.

The RLODs calculations were performed according to the standard ISO 16140-2: 2016 using the Excel spreadsheet available for download at <http://standards.iso.org/iso/16140>, with unknown concentrations. Values of the RLODs are set out in Tables 23, 24 and 25 according to the kind of thermal cycler used for the tests.

Table 23: RLODs values for all categories with the PikoReal thermal cycler (RLOD: the estimated relative level of detection value, RLODU: the upper limit of the 95% confidence interval for RLOD, RLODL: the lower limit of the 95% confidence interval for RLOD)

Name	RLOD	RLODL	RLODU	AL
Infant formula (10g) with probiotics/C.sakazakii Ad1418	1.148	0.485	2.713	1.5
Infant formula (10g) without probiotics/C.sakazakii Ad1418	1.000	0.478	2.092	1.5
Process water/C.turicensis Ad1445	1.038	0.449	2.399	2.5
Infant formula (300g) with probiotics/C.sakazakii Ad1446	1.482	0.704	3.118	2.5
Combined	1.166	0.801	1.700	/

Table 24: RLODs values for all categories with the 7500 Fast thermal cycler (RLOD: the estimated relative level of detection value, RLODU: the upper limit of the 95% confidence interval for RLOD, RLODL: the lower limit of the 95% confidence interval for RLOD)

Name	RLOD	RLODL	RLODU	AL
Infant formula (10g) with probiotics / C.sakazakii Ad1418	1.000	0.457	2.187	1.5
Infant formula (10g) without probiotics / C.sakazakii Ad1418	1.000	0.478	2.092	1.5
Process water / C.turicensis Ad1445	1.038	0.449	2.399	2.5
Infant formula (300g) with probiotics / C.sakazakii Ad1446	1.482	0.704	3.118	2.5
Infant cereals (375 g) with probiotics / C. dublinensis GVV828	1.146	0.498	2.636	2.5
Combined	1.140	0.814	1.595	/

Table 25: RLODs values for all categories with the Quant Studio 5 thermal cycler (RLOD: the estimated relative level of detection value, RLODU: the upper limit of the 95% confidence interval for RLOD, RLODL: the lower limit of the 95% confidence interval for RLOD)

Name	RLOD	RLODL	RLODU	AL
Infant formula (300g) with probiotics / C.sakazakii Ad1446	1.482	0.704	3.118	2.5
Infant cereals (375 g) with probiotics / C. dublinensis GVV828	1.146	0.498	2.636	2.5
Combined	1.342	0.789	2.281	/

3.2.4. Interpretation and conclusion

The RLODs values are below the acceptability limit set at 2.5 for “unpaired” categories and 1.5 for “paired” categories, meaning that, as stated in ISO 16140-2:2016, the maximum increase in LOD of the alternative versus the reference method is not considered as relevant in consideration of the fitness for purpose of the method.

In conclusion, alternative and reference methods show similar LODs values for the detection of *Cronobacter* spp in the categories tested.

3.2.5. Expression of the LOD values

The LOD₅₀ calculations according to Wilrich & Wilrich POD-LOD calculation program - version 9, are given in Table 26.

Table 26: LOD50% for the alternative and reference method in CFU/test portion

Categories	Reference method ISO 22964	Alternative method		
		PikoReal	7500 Fast	Quant Studio 5
PIF10 with probiotics	2.735	3.053	2.735	/
PIF10 without probiotics	1.677	1.677	1.677	/
ENV	0.911	0.959	0.959	/
PIF300	0.902	1.379	1.379	1.379
PIF375	1.254	/	1.410	1.410

3.3. Inclusivity and exclusivity study

Inclusivity and exclusivity were tested only on PikoReal PCR Instrument during the initial validation study.

The inclusivity and exclusivity studies were not performed on 7500 Fast and QS5 Instrument during the extension studies in 2016, 2018 and 2021 with the agreement of the Technical Board.

3.3.1. Test protocols

- **Inclusivity**

Fifty-seven *Cronobacter* spp. isolates were cultured in BHI Broth at 37°C. Dilutions were done in order to inoculate 10 to 100 cells/225 ml of BPW + vancomycin (6 mg/l). The enrichment broth was then incubated for 18 h at 37°C and the alternative method protocol was applied.

- **Exclusivity**

Negative strain cultures were performed in BHI Broth at 37°C. Dilutions were realised in order to inoculate 10⁵ cells/ml of BPW. The alternative protocol was then performed after an enrichment time of 24 hours at 37°C.

3.3.2. Results

Raw data are given in Appendix F.

- **Inclusivity**

All 57 *Cronobacter* spp. isolates gave a positive PCR result and positive confirmation tests using the PikoReal instrument.

- **Exclusivity**

All the 31 negative strain cultures gave a negative PCR result using the PikoReal.

3.3.3. Conclusion

The alternative method is specific and selective.

3.4. Practicability

The alternative method practicability was evaluated according to the AFNOR criteria relative to method comparison study.

- **Storage conditions of the kit**

The reagents remain stable until the expiry date stated on the packaging.

The complete box and contents should be stored at 2 - 8 °C when not in use.

- **Storage conditions after first utilization**

Do not use the reagent after the expiration date indicated on the label.

For SureTect PCR strips, unused materials must be returned to the refrigerator after a short time.

- **Time-to-result**

See table 27 below.

Table 27: time-to-result of the alternative method, compared to the reference method

Steps	Reference method	Alternative method
Negative samples		
Sampling	Day 0	Day 0
Extraction / PCR	/	Day 1
Subculture	Day 3	/
Final negative result	Day 3	Day 1
Presumptive samples or positive samples		
Confirmation	Day 5	Day 2 or Day 3

- **Common step with the reference method**

The enrichment step is common with the reference method only for the infant formula.

4. Interlaboratory study

4.1. Study organization

Samples were sent to 15 laboratories. This study was done with probiotic infant formula inoculated with *Cronobacter sakazakii* Ad 940 strain. In order to facilitate the study, infant formula was first homogenized in sterile water.

Samples were inoculated on Monday 19 October 2015; as described below:

- 24 blind coded samples (10 ml) for *Cronobacter* spp. detection by the Thermo Scientific™ SureTect™ Cronobacter species PCR Assay and the ISO/TS 22964 (2006) reference method;
- 1 sample (labelled “Sample for anaerobic lactic flora”) for anaerobic lactic flora enumeration in MRS agar,
- 1 water flask labelled “Temperature Control” with a temperature probe for temperature control during transport and storage in the laboratory until the beginning of the analysis.

The targeted inoculation levels were the following:

- Level 0: 0 CFU/g,
- Level 1: 1 CFU/10 g,
- Level 2: 10 CFU/10 g.

Each laboratory received 24 samples of 10 g, i.e. 8 samples per inoculation level and method. Furthermore, one non-inoculated sample was added to the package for lactic microflora enumeration.

Blind coded samples were placed in isothermal boxes, which contained cooling blocks, and express-shipped to the different laboratories.

A temperature control flask containing a sensor was added to the package in order to register the temperature profile during the transport, the package delivery and storage until analysis.

Samples were shipped within 24 h to 48 h to each of the participating laboratories. The temperature conditions had to stay lower or equal to 8°C during transport, and between 0°C – 8°C on arrival at each of the labs.

Collaborators and the expert laboratory carried out the analysis at Day 1 or Day 2 with the alternative and reference methods.

In order to evaluate the *Cronobacter* spp. strain stability during transport, *Cronobacter* spp. enumerations were performed at different times, i.e. inoculation time, after 24 h and 48 h of storage at 2°C.

4.2. Experimental control parameters

4.2.1. Strain stability and background microflora stability

In order to detect *Cronobacter* spp., the reference method was performed on nine portions (10 g) before the inoculation. All the results were negative.

Three samples inoculated at a high level were tested for enumeration after 24 h and 48 h storage. Three samples inoculated at a low level were tested for detection after 48 h storage (See Table 28).

Table 28: *Cronobacter sakazakii* stability in the matrix

Day of analysis	<i>Cronobacter sakazakii</i> enumeration		Lactic flora enumeration (cfu/g)
	ESIA (CFU/g)	ISO/TS 22964	
Day 0	1 100	+	100 000
	1 200	-	
	1 200	+	
Day 1	1 200	/	/
	1 000	/	
	890	/	
Day 2	640	+	57 000
	750	+	
	760	+	

The enumeration of *Cronobacter sakazakii* decreases slightly after storage for 48 h at 2 - 8°C.

4.2.2. Contamination levels

The contamination levels and the sample codifications were the following (See Table 29).

Table 29: Contamination levels and sample codifications

Level	Samples	Theoretical target level	True level (CFU/10 g sample)	Low limit / CFU/10 g sample	High limit / CFU/10 g sample
Level 0	2 - 6 - 8 - 11 - 15 - 19 - 22 - 23	0	/	/	/
Low level	3 - 7 - 9 - 13 16 - 18 21 - 24	1	1.0	0.8	1.3
High level	1 - 4 - 5 - 10 - 12 - 14 17 - 20	10	8.6	7.0	10.7

4.2.3. Logistic conditions

The temperatures measured on reception by the labs and those registered by the thermo-probes, along with the receipt dates are given in Table 30 below.

All the samples were delivered in appropriate conditions. Temperatures during shipment and at receipt were all correct. Two labs measured a temperature at receipt above 8.4°C, but the curves show clearly that the samples arrived at the expected temperature. Some leaks were mentioned for 5 Labs (A, F, H, I and J).

Table 30: Sample temperatures at receipt

Collaborator	Temperature measured by the probe (°C)	Temperature measured at receipt (°C)	Receipt date and time	Analysis date
A	3.5	5.0	20/10/2015 14h00	20/10/2015
B	6.5	7.2	21/10/2015 13h55	21/10/2015
C	3.0	4.2	20/10/2015 12h15	/
D	Probe discarded	4.0	20/10/2015 11h00	20/10/2015
E	3.5	3.4	20/10/2015 11h05	20/10/2015
F	3.0	3.5	20/10/2015 09h45	20/10/2015
G	Not received yet	11.2	21/10/2015	21/10/2015
H	3.5	7.4	20/10/2015 11h45	20/10/2015
I	3.5	8.8	20/10/2015 13h41	20/10/2015
J	2.0	6.0	20/10/2015 12h10	21/10/2015
K	4.0	8.1	20/10/2015 11h15	20/10/2015
L	3.5	4.5	20/10/2015 11h10	20/10/2015
M	3.0	4.6	20/10/2015 11h15	/
N	3.5	6.2	20/10/2015 14h30	/
O	3.0	4.1	20/10/2015 12h00	21/10/2015

4.3. Summary of the results

The raw data are given in Appendix G.

4.3.1. Expert laboratory results

The results obtained by the Expert Lab are given in Table 31.

Table 31: Results obtained by the expert Lab

Level	Reference method	Alternative method
L_0	0/8	0/8
L_1	2/8	2/8
L_2	8/8	8/8

4.3.2. Collaborators results

- **Aerobic mesophilic flora**

The enumeration of the aerobic mesophilic flora varied from 1.9×10^4 to 1.5×10^5 CFU/g.

- **Cronobacter spp detection**

Fifteen collaborators participated to the study. The results obtained are provided in Table 32 for reference and alternative methods.

Table 32: Positive results of reference and alternative methods (P_x : number of positive results for the reference method and number of presumed positive results for the alternative method, CP_x : number of confirmed positive results for the alternative method)

Lab	Contamination level											
	Reference method results			Alternative method results								
	L_0	L_1	L_2	L_0			L_1			L_2		
				PCR	Conf.	Final	PCR	Conf.	Final	PCR	Conf.	Final
A	0	7	8	0	0	0	7	7	7	8	8	8
B	0	5	8	0	0	0	5	5	5	8	8	8
C	0	4	8	0	0	0	4	4	4	8	8	8
D	2	6	8	2	2	0	6	5	5	8	8	8
E	0	5	8	1	0	0	5	5	5	8	8	8
F	0	5	8	0	0	0	5	5	5	8	8	8
G	1	4	8	0	0	0	5	5	5	8	8	8
H	0	4	8	0	0	0	4	4	4	8	8	8
I	0	3	8	0	0	0	3	3	3	8	8	8
J	0	5	8	0	0	0	5	5	5	8	8	8
K	0	6	8	2	0	0	7	6	6	8	8	8
L	0	5	8	3	0	0	6	6	6	8	8	8
M	0	5	8	0	0	0	6	6	6	8	8	8
N	0	5	8	2	0	0	4	4	4	8	8	8
O	0	6	8	0	0	0	6	6	6	8	8	8
Total	P_0 3	P_1 75	P_2 120	P_0 10	2	CP_0 0	P_1 78	76	CP_1 76	P_2 120	120	CP_2 120

With the reference method, two labs found positive results with unspiked samples:

- Lab D: D22 – D23
- Lab G: G15

With the alternative method, five labs found positive results with unspiked samples:

- Lab D: D8 – D23
- Lab E: E19
- Lab K: K15 – K23
- Lab L: L15 – L19 – L23
- Lab N: N2 – N8

None of these ten samples were confirmed as positive with cultural procedures. Note that lab L repeated the PCR tests and got negative results.

According to the AFNOR technical rules, data from labs with more than one contamination at Level 0 were removed for interpretation, i.e. Lab D, Lab K, Lab L and Lab N.

Microbact™ galleries were provided to run the characteristic colony confirmation. Some labs encountered difficulties in the gallery's interpretation. Despite the identifications not fitting with the expected results, their results were taken into account based on the recovery of characteristic

colonies. Note that the characteristic colonies were identified to *Cronobacter* spp. by the labs familiar with the use of the Microbact™ gallery.

In particular event of discordant results with the biochemical identification kit (difficulty for reading), the labs should refer to the technical instructions.

Finally, the results from 11 labs were kept: A, B, C, E, F, G, H, I, J, M and O.

4.3.3. Collaborators results retained for the interpretation

The results obtained with the 11 labs kept for interpretation are presented in Table 33.

Table 33: Positive results of reference and alternative methods kept for interpretation (P_x : number of positive results for the reference method and number of presumed positive results for the alternative method, CP_x : number of confirmed positive results for the alternative method)

Lab	Contamination level											
	Reference method results			Alternative method results								
	L_0	L_1	L_2	L_0			L_1			L_2		
				PCR	Conf.	Final	PCR	Conf.	Final	PCR	Conf.	Final
A	0	7	8	0	0	0	7	7	7	8	8	8
B	0	5	8	0	0	0	5	5	5	8	8	8
C	0	4	8	0	0	0	4	4	4	8	8	8
E	0	5	8	1	0	0	5	5	5	8	8	8
F	0	5	8	0	0	0	5	5	5	8	8	8
G	1	4	8	0	0	0	5	5	5	8	8	8
H	0	4	8	0	0	0	4	4	4	8	8	8
I	0	3	8	0	0	0	3	3	3	8	8	8
J	0	5	8	0	0	0	5	5	5	8	8	8
M	0	5	8	0	0	0	6	6	6	8	8	8
O	0	6	8	0	0	0	6	6	6	8	8	8
Total	P_0 1	P_1 53	P_2 88	P_0 1	0	CP_0 0	P_1 55	55	CP_1 55	P_2 88	88	CP_2 88

4.4. Calculation and interpretation of the results

4.4.1. Calculation of the specificity percentage (SP)

The percentage specificities (SP) of the reference method and of the alternative method, using the data after confirmation, based on the results of level L0 are the following (See Table 34).

Table 34: Specificity percentages (N : number of all L_0 tests, P_0 = total number of false-positive results obtained with the blank samples before confirmation, CP_0 = total number of false-positive results obtained with the blank samples)

Specificity for the reference method	$SP_{ref} = \left(1 - \left(\frac{P_0}{N_-}\right)\right) \times 100 \% =$	98.9%
Specificity for the alternative method	$SP_{alt} = \left(1 - \left(\frac{CP_0}{N_-}\right)\right) \times 100 \% =$	100%

4.4.2. Calculation of the sensitivity (SE_{alt}), the sensitivity for the reference method (SE_{ref}), the relative trueness (RT) and the false positive ratio for the alternative method (FPR)

Fractional positive results were obtained for the low inoculation level (L_1). The interpretation was thus done for this inoculation level.

A summary of the results of the collaborators retained for interpretation and obtained with the reference and the alternative methods for Level 1 is provided in Table 35.

Table 35: Summary of the obtained results with the reference method and the alternative method for Level 1

Response	Reference method positive (R+)	Reference method negative (R-)
Alternative method positive (A+)	Positive agreement (A+/R+) PA = 54	Positive deviation (R-/A+) PD = 1
Alternative method negative (A-)	Negative deviation (A-/R+) ND = 0	Negative agreement (A-/R-) NA = 33

Based on the data summarized in Table 33, the values of sensitivity of the alternative and reference methods, as well as the relative trueness and false positive ratio for the alternative method taking account the confirmations, are the following (See Table 36).

Table 36: Sensitivity, relative trueness and false positive ratio percentages

Sensitivity for the alternative method:	$SE_{alt} = \frac{(PA+PD)}{(PA+PD+ND)} \times 100\% =$	100.0%
Sensitivity for the reference method:	$SE_{ref} = \frac{(PA+ND)}{(PA+PD+ND)} \times 100\% =$	98.2%
Relative trueness	$RT = \frac{(PA+NA)}{N} \times 100\% =$	98.9%
False positive ratio for the alternative method	$FPR = \frac{FP}{NA} \times 100\% =$	0.0%

4.4.3. Interpretation of the data

For a paired study design, the difference between (ND – PD) and the addition (ND + PD) are calculated for the level(s) where fractional recovery is obtained (so L_1 and possibly L_2). The observed value found for (ND – PD) and (ND + PD) shall not be higher than the AL.

For 11 Labs, the calculated values and the acceptability limits are the following (See Table 37).

Table 37: acceptability limits

Values	Calculated values	AL	Conclusion
ND - PD	-1	4	ND - PD ≤ AL
ND + PD	1	4	ND + PD ≤ AL

The EN ISO 16140-2:2016 requirements are fulfilled as (ND - PD) and (ND + PD) meet the AL (calculated values ≤ AL).

4.4.4. Evaluation of the RLOD between laboratories

The RLOD was calculated using the EN ISO 16140-2:2016 Excel spreadsheet available at http://standards.iso.org/iso/16140/-2/ed-1/en/RLOD_inter-lab-study_16140-2_AnnexF_ver1_28-06-2017.xls. The results are used only for information (see Table 38).

Table 38: acceptability limits

Method	LOD50%	LOD95%	RLOD
Reference	0.73 [0.54 ; 0.97]	3.15 [2.35 ; 4.21]	0.97 [0.69-1.36]
Alternative	0.70 [0.53 ; 0.94]	3.04 [2.28 ; 4.07]	

5. Conclusion

The comparative study of the methods was performed according to the EN ISO 16140-2:2016 standard.

Tests were performed with 3 thermal cyclers (depending on the categories tested): PikoReal, 7500 Fast and Quant Studio 5 PCR instruments.

- **Sensitivity study**

The performance of the SureTect Cronobacter method was compared to that of the ISO 22964 reference method by analyzing 276 samples.

The observed values (ND – PD) were below the acceptability limits for each category and for all categories after the initial test and after three days of conservation at $5\pm 3^{\circ}\text{C}$.

Statistically, the alternative method produces results comparable to that of the reference method.

- **Relative level of detection study**

The relative detection level of the SureTect Cronobacter method and reference method was evaluated by artificially contaminating matrices of the application scope.

The SureTect Cronobacter method and the reference method showed similar LODs values for the detection of *Cronobacter* spp in the categories tested.

- **Inclusivity and exclusivity study**

The specificity of the method is satisfactory, as all target strains were detected (inclusivity) and no cross-reactions were observed among non-targeted tested strains (exclusivity).

- **Interlaboratory study**

The data and interpretations comply with the ISO 16140-2:2016 requirements.

The Thermo Scientific™ SureTect™ Cronobacter species PCR Assay is considered equivalent to the ISO 22964:2017 method.

SureTect™ Cronobacter species PCR Assay is a valuable method for the testing of infant formula with and without probiotics, infant cereals, ingredients linked to the preparation of infant formula and the testing of environmental samples.

Le Lion d'Angers, June 21, 2022

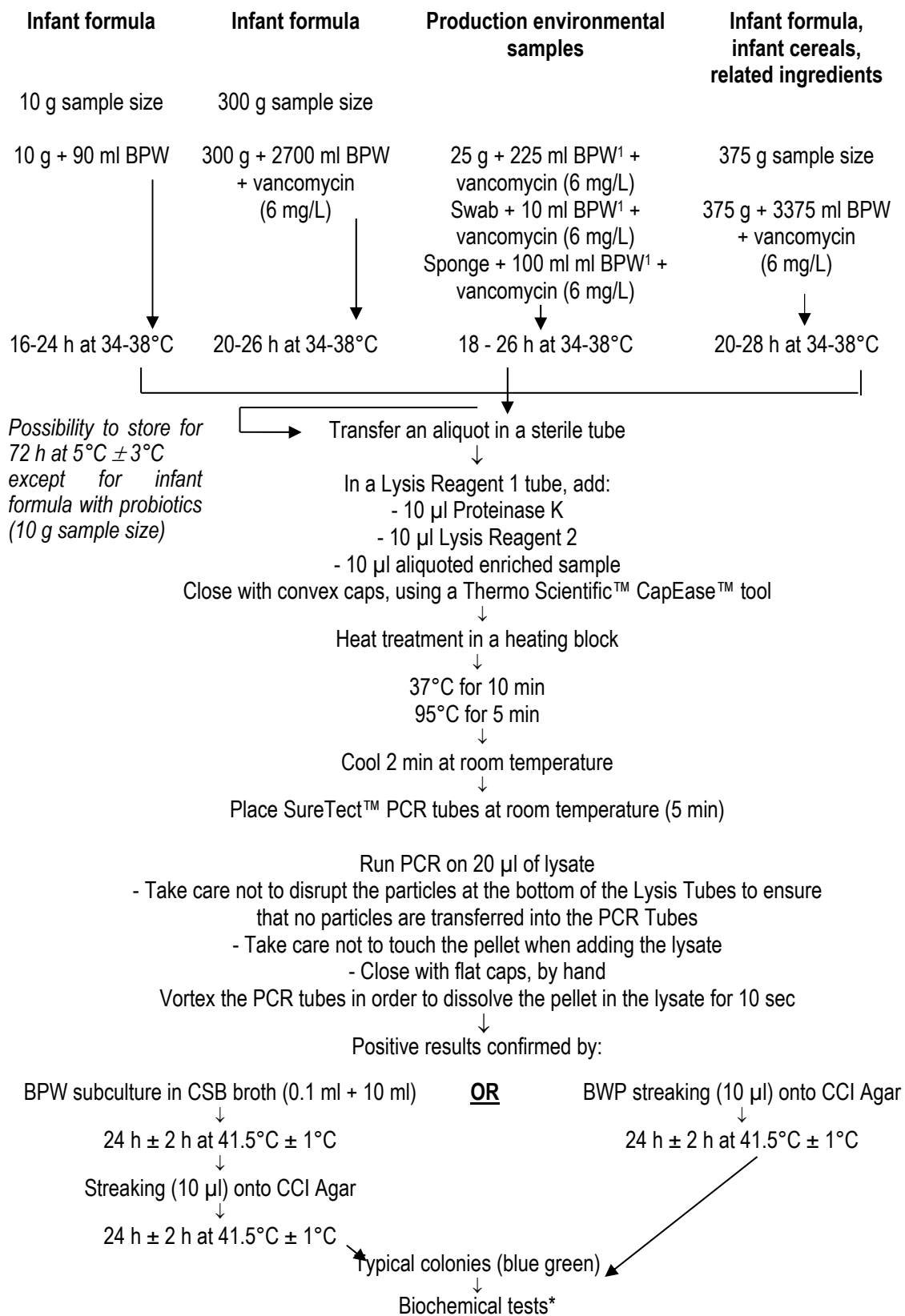
François Le Nestour

Head of the Microbiology Department



APPENDICES

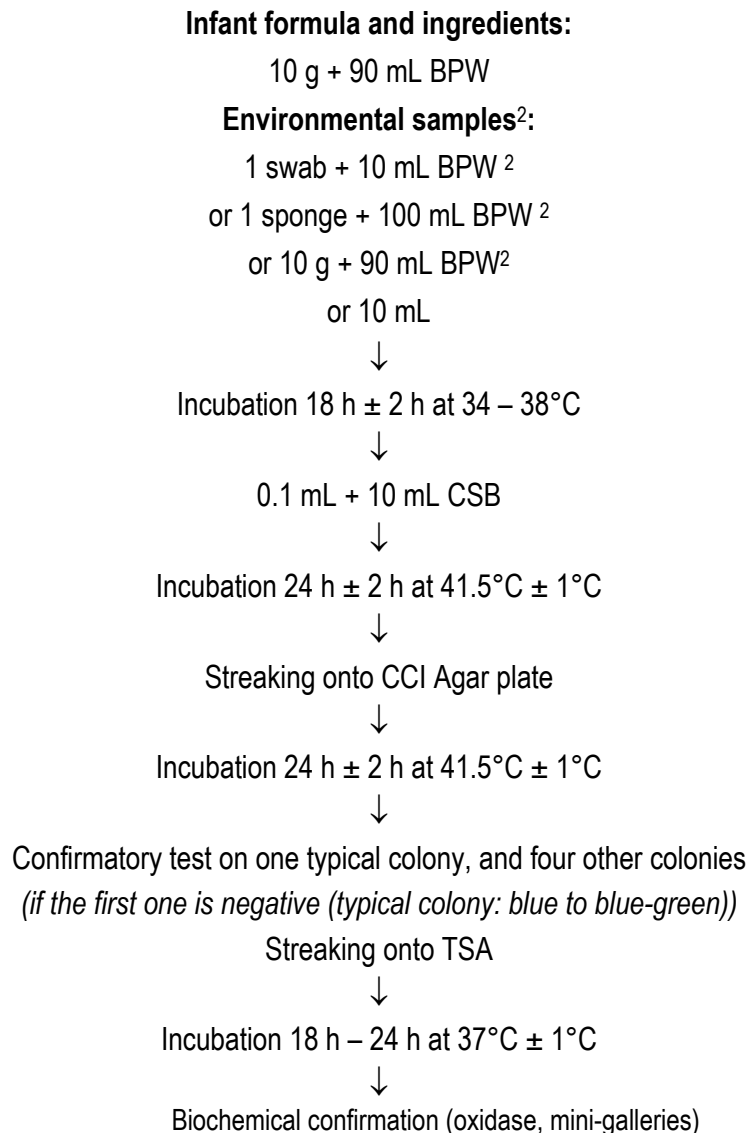
Appendix A – Flow diagram of the alternative method: Thermo Scientific™ SureTect™ *Cronobacter* species PCR Assay for the detection of *Cronobacter spp*



*According to ISO rules, it as well possible to use ISO 16140-6:2019 validated confirmation method.

- ¹ For sampling after cleaning process premoisten
- 1 swab + 1 ml broth universal neutralizing (+ 9 ml BPW)
 - 1 sponge + 10 ml broth universal neutralizing (+ 90 ml BPW)
 - 1 wipe + BPW + 10 % neutralizing agent (+ 225 ml BPW)

**Appendix B – Flow diagram of the reference method:
ISO 22964 (April 2017) - Microbiology of the food chain -
Horizontal method for the detection of *Cronobacter* spp.**



² For sampling after cleaning process premoisten

- 1 swab + 1 ml broth universal neutralizing (+ 9 ml BPW)
- 1 sponge + 10 ml broth universal neutralizing (+ 90 ml BPW)
- 1 wipe + BPW + 10 % neutralizing agent (+ 225 ml BPW)

Appendix C - Artificial contamination of the samples – Initial validation study

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
2310	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (3,6.10 ⁹ /g)	<i>Cronobacter sakazakii</i> Ad 1446	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	3,8	-	1	a
4885	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 704	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,3	-	1	a
4886	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 704	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,3	-	1	a
4887	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 831	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	1,1	-	1	a
4888	Poudre de lait infantile 0-36 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 831	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	1,1	-	1	a
4889	Poudre de lait infantile croissance	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 916	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,3	+	1	a
4890	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 916	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,3	-	1	a
4891	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1418	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	1	+	1	a
4892	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1446	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,4	+	1	a
4893	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1446	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,4	+	1	a
4894	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1446	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,4	+	1	a
4895	Poudre de lait infantile croissance	Infant formula milk powder	<i>Cronobacter malonaticus</i> E752	Baby food	Spiking-HT 56°C 8 min	>0,90	0-0-0-0-1 (0,2)	-	1	a
4896	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter malonaticus</i> E752	Baby food	Spiking-HT 56°C 8 min	>0,90	0-0-0-0-1 (0,2)	-	1	a

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
4897	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter malonaticus</i> E752	Baby food	Spiking-HT 56°C 8 min	>0,90	0-0-0-0-1 (0,2)	-	1	a
4898	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter dublinensis</i> subsp <i>lactaridi</i> E791	/	Spiking-HT 56°C 8 min	>0,90	0-1-0-3-0 (0,8)	-	1	a
4899	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter dublinensis</i> subsp <i>lactaridi</i> E791	/	Spiking-HT 56°C 8 min	>0,90	0-1-0-3-0 (0,8)	-	1	a
4900	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ⁴ /g)	<i>Cronobacter dublinensis</i> subsp <i>lactaridi</i> E791	/	Spiking-HT 56°C 8 min	>0,90	0-1-0-3-0 (0,8)	-	1	a
4901	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,8.10 ⁴ /g)	<i>Cronobacter dublinensis</i> subsp <i>lactaridi</i> E791	/	Spiking-HT 56°C 8 min	>0,90	0-1-0-3-0 (0,8)	-	1	a
4902	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<200/g)	<i>Cronobacter malonaticus</i> E752	Baby food	Spiking-HT 56°C 8 min	>0,90	0-0-0-0-1 (0,2)	-	1	a
4903	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ⁶ /g)	<i>Cronobacter malonaticus</i> E752	Baby food	Spiking-HT 56°C 8 min	>0,90	0-0-0-0-1 (0,2)	-	1	a
5070	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1437	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	2,5	+	1	a
5071	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1437	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	2,5	+	1	a
5072	Poudre de lait infantile 1-3 ans	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1437	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	2,5	+	1	a
5073	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1437	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	2,5	+	1	a
5074	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 1437	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	2,5	+	1	a
5075	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 940	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	1,7	-	1	a
5076	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 940	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	1,7	+	1	a
5077	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 940	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	1,7	-	1	a

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
5078	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 893	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	0,6	+	1	a
5079	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 893	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	0,6	+	1	a
5080	Poudre de lait infantile 0-6 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 893	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	0,6	+	1	a
5081	Poudre de lait infantile 6-12 mois	Infant formula milk powder	<i>Cronobacter sakazakii</i> Ad 893	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	0,6	+	1	a
5082	Poudre de lait infantile avec probiotiques-croissance	Infant formula milk powder with probiotics (<200/g)	<i>Cronobacter sakazakii</i> Ad 940	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	1,7	-	1	a
5206	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,4.10 ³ cfu/g)	<i>Cronobacter malonaticus</i> E752	Baby food	Spiking-HT 56°C 8 min	0,55	0-0-0-2-3 (1,0)	-	1	a
5207	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (2,0.10 ² cfu /g)	<i>Cronobacter malonaticus</i> E752	Baby food	Spiking-HT 56°C 8 min	0,55	0-0-0-2-3 (1,0)	-	1	a
5208	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ² cfu /g)	<i>Cronobacter malonaticus</i> E752	Baby food	Spiking-HT 56°C 8 min	0,55	0-0-0-2-3 (1,0)	-	1	a
5240	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (7,9.10 ⁶ cfu /g)	<i>Cronobacter sakazakii</i> Ad 1707	Environment dairy industry	Seeding-Lyophilized strain, 1 week at 20°C	/	3,0	+	1	a
5241	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ⁴ cfu /g)	<i>Cronobacter sakazakii</i> Ad 1437	Milk powder	Seeding-Lyophilized strain, 1 week at 20°C	/	1,5	+	1	a
5242	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (2,0.10 ⁴ cfu /g)	<i>Cronobacter sakazakii</i> Ad 940	Dairy product	Seeding-Lyophilized strain, 1 week at 20°C	/	1,7	+	1	a
1455	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (2,0.10 ⁴ /g)	<i>Cronobacter sakazakii</i> Ad 704	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,2	+	1	b

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
1456	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (8,0.10 ⁴ /g)	<i>Cronobacter sakazakii</i> Ad 704	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,2	+	1	b
1457	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,6.10 ⁶ /g)	<i>Cronobacter sakazakii</i> Ad 704	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,2	-	1	b
1458	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,0.10 ⁵ /g)	<i>Cronobacter sakazakii</i> Ad 831	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,4	+	1	b
1459	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (5,8.10 ⁷ /g)	<i>Cronobacter sakazakii</i> Ad 831	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,4	-	1	b
1460	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	<i>Cronobacter sakazakii</i> Ad 831	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,4	+	1	b
1461	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	<i>Cronobacter sakazakii</i> Ad 916	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,2	+	1	b
1462	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	<i>Cronobacter sakazakii</i> Ad 916	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,2	-	1	b
1463	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	<i>Cronobacter sakazakii</i> Ad 916	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,2	-	1	b
1464	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	<i>Cronobacter sakazakii</i> Ad 1418	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	5,3	-	1	b
1465	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (2,2.10 ⁶ /g)	<i>Cronobacter sakazakii</i> Ad 1418	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	5,3	+	1	b
1466	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,3.10 ⁷ /g)	<i>Cronobacter sakazakii</i> Ad 1418	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	5,3	+	1	b

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
1467	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,5.10 ⁶ /g)	<i>Cronobacter sakazakii</i> Ad 1446	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	5,7	-	1	b
1468	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ⁴ /g)	<i>Cronobacter sakazakii</i> Ad 1446	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	5,7	-	1	b
1469	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,2.10 ⁷ /g)	<i>Cronobacter sakazakii</i> Ad 1446	Milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	5,7	-	1	b
2303	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,7.10 ⁶ /g)	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,9	-	1	b
2304	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (5,4.10 ⁶ /g)	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,9	+	1	b
2305	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (6,0.10 ⁶ /g)	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,9	-	1	b
2306	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (7,0.10 ⁵ /g)	<i>Cronobacter sakazakii</i> Ad 1418	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	4,1	+	1	b
2307	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (8,0.10 ⁵ /g)	<i>Cronobacter sakazakii</i> Ad 1418	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	4,1	+	1	b
2308	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (3,2.10 ⁵ /g)	<i>Cronobacter sakazakii</i> Ad 1418	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	4,1	+	1	b
2309	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (8,8.10 ⁵ /g)	<i>Cronobacter sakazakii</i> Ad 1446	Infant formula milk powder	Seeding-Lyophilized strain, 2 weeks at 20°C	/	3,8	+	1	b
2049	Eau de rinçage	Rinsing water	<i>Cronobacter sakazakii</i> Ad 893	Dairy product	Seeding-48 h 4°C	/	1-3-3-7-5 (3,8)	+	2	a
2050	Eau de rinçage	Rinsing water	<i>Cronobacter sakazakii</i> Ad 947	Dairy product	Seeding-48 h 4°C	/	6-2-3-3-0 (2,8)	+	2	a

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
2051	Eau de rinçage	Rinsing water	<i>Cronobacter sakazakii</i> Ad 1428	Dairy product	Seeding-48 h 4°C	/	4-3-1-1-1 (2,0)	+	2	a
2052	Eau de rinçage	Rinsing water	<i>Cronobacter sakazakii</i> Ad 1435	Dairy product	Seeding-48 h 4°C	/	3-0-1-5-2 (2,2)	+	2	a
2053	Eau de rinçage	Rinsing water	<i>Cronobacter sakazakii</i> Ad 947	Dairy product	Seeding-48 h 4°C	/	6-2-3-3-0 (2,8)	+	2	a
2446	Eau de process	Process water	<i>Cronobacter sakazakii</i> Ad 1708	Environment dairy industry	Spiking-HT 8 min 56°C	1,93	0-0-0-0-0 (0,0)	-	2	a
2447	Eau de nettoyage	Cleaning water	<i>Cronobacter sakazakii</i> Ad 1708	Environment dairy industry	Spiking-HT 8 min 56°C	1,93	0-0-0-0-0 (0,0)	-	2	a
4085	Eau de rinçage	Rinsing water	<i>Cronobacter sakazakii</i> Ad 1437	Dairy product	Spiking-pH4 and HT 8 min 56°C	0,60	0-0-1-0-2 (0,6)	-	2	a
2448	Eau de syphon	Siphon water	<i>Cronobacter sakazakii</i> Ad 1428	Dairy product	Spiking-pH4 during 7days	0,57	3-0-1-1-0 (1,0)	+	2	b
2677	Poussières laiterie	Dusts	<i>Cronobacter sakazakii</i> Ad 704	Dairy product	Spiking-Lyophilized strain	0,42	2-1-3-0-4 (2,0)	+	2	b
2678	Poussières aspirateur	Dusts	<i>Cronobacter sakazakii</i> Ad 704	Dairy product	Spiking-Lyophilized strain	0,42	2-1-3-0-4 (2,0)	+	2	b
2679	Déchets poudre de lait	Dusts	<i>Cronobacter sakazakii</i> Ad 916	Dairy product	Spiking-Lyophilized strain	0,48	2-3-1-4-4 (2,8)	+	2	b
2680	Poussières laiterie	Dusts	<i>Cronobacter sakazakii</i> Ad 916	Dairy product	Spiking-Lyophilized strain	0,48	2-3-1-4-4 (2,8)	+	2	b
2681	Poussières aspirateur	Dusts	<i>Cronobacter sakazakii</i> Ad 831	Dairy product	Spiking-Lyophilized strain	0,48	0-0-2-3-2 (1,4)	+	2	b
2682	Déchets poudre de lait	Dusts	<i>Cronobacter sakazakii</i> Ad 831	Dairy product	Spiking-Lyophilized strain	0,48	0-0-2-3-2 (1,4)	+	2	b
3479	Eponge poussières (industrie PDL)	Dusts sponge	<i>Cronobacter sakazakii</i> Ad 1437	Milk powder	Spiking-pH4 during 7days	0,52	1-0-0-2-0 (0,6)	-	2	b
3480	Eponge poussières (industrie PDL)	Dusts sponge	<i>Cronobacter sakazakii</i> Ad 893	Milk powder	Spiking-pH4 during 7days	0,41	0-1-0-0-0 (0,2)	-	2	b
3481	Eponge poussières (industrie PDL)	Dusts sponge	<i>Cronobacter sakazakii</i> Ad 940	Milk powder	Spiking-pH4 during 7days	0,56	4-3-3-4-8 (4,4)	+	2	b

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
2055	Lingette étagère salle de stockage poudre de lait	Wipe	<i>Cronobacter sakazakii</i> Ad 947	Dairy product	Seeding-48 h 4°C	/	6-2-3-3-0 (2,8)	+	2	c
2056	Lingette étagère salle de stockage poudre de lait	Wipe	<i>Cronobacter sakazakii</i> Ad 1428	Dairy product	Seeding-48 h 4°C	/	4-3-1-1-1 (2,0)	+	2	c
2057	Lingette plan de travail salle de stockage poudre de lait	Wipe	<i>Cronobacter sakazakii</i> Ad 1435	Dairy product	Seeding-48 h 4°C	/	3-0-1-5-2 (2,2)	+	2	c
2058	Lingette plan de travail salle de stockage poudre de lait	Wipe	<i>Cronobacter sakazakii</i> Ad 2290	Dairy product	Seeding-48 h 4°C	/	0-1-1-1-2 (1,0)	+	2	c
2440	Lingette transport pneumatique avant nettoyage	Wipe	<i>Cronobacter sakazakii</i> Ad 1708	Environment dairy industry	Spiking-HT 8 min 56°C	1,93	0-0-0-0-0 (0,0)	+	2	c
2441	Lingette sol	Wipe	<i>Cronobacter sakazakii</i> Ad 1708	Environment dairy industry	Spiking-HT 8 min 56°C	1,93	0-0-0-0-0 (0,0)	+	2	c
2443	Lingette transport pneumatique après nettoyage	Wipe	<i>Cronobacter sakazakii</i> Ad 1428	Dairy product	Spiking-pH4 during 7days	0,57	3-0-1-1-0 (1,0)	+	2	c
2444	Lingette sol après nettoyage	Wipe	<i>Cronobacter sakazakii</i> Ad 1428	Dairy product	Spiking-pH4 during 7days	0,57	3-0-1-1-0 (1,0)	+	2	c
2445	Lingette porte tour séchage après nettoyage	Wipe	<i>Cronobacter sakazakii</i> Ad 1428	Dairy product	Spiking-pH4 during 7days	0,57	3-0-1-1-0 (1,0)	+	2	c
3339	Ecouvillon douchette réserve	Swab	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Spiking-Lyophilized strain	0,40	0-0-2-2-1 (1,0)	+	2	c
3340	Ecouvillon dilumate	Swab	<i>Cronobacter sakazakii</i> Ad 1446	Infant formula	Spiking-Lyophilized strain	0,56	2-1-1-3-1 (1,6)	+	2	c
3341	Ecouvillon E5	Swab	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Spiking-Lyophilized strain	0,40	0-0-2-2-1 (1,0)	-	2	c
3342	Ecouvillon 35	Swab	<i>Cronobacter sakazakii</i> Ad 1446	Infant formula	Spiking-Lyophilized strain	0,56	2-1-1-3-1 (1,6)	+	2	c
3477	Eponge surface (industrie PDL)	Surface sponge	<i>Cronobacter sakazakii</i> Ad 893	Milk powder	Spiking-pH4 during 7days	0,41	0-1-0-0-0 (0,2)	+	2	c

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			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
3478	Eponge surface (industrie PDL)	Surface sponge	<i>Cronobacter sakazakii</i> Ad 940	Milk powder	Spiking-pH4 during 7days	0,56	4-3-3-4-8 (4,4)	+	2	c
3265	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 831	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,6	+	3	a
3266	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 831	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,6	+	3	a
3267	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 1446	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	<1,0	-	3	a
3268	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 1446	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	<1,0	+	3	a
3269	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 940	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	3,0	+	3	a
3270	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 940	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	3,0	+	3	a
3271	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 940	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	3,0	+	3	a
3272	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 1420	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	<1,0	+	3	a
3273	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 1420	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	<1,0	+	3	a
3483	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter dublinensis</i> DSM18705	Milk powder	Spiking-HT 8 min 56°C	1,1	5-2-1-0-0 (1,6)	+	3	a
3484	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter dublinensis</i> DSM18705	Milk powder	Spiking-HT 8 min 56°C	1,1	5-2-1-0-0 (1,6)	-	3	a
3485	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter dublinensis</i> DSM18705	Milk powder	Spiking-HT 8 min 56°C	1,1	5-2-1-0-0 (1,6)	-	3	a
3486	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter turicensis</i> Ad 1445	Infant formula	Spiking-HT 8 min 56°C	0,7	1-0-2-2-2 (1,4)	-	3	a
3487	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter dublinensis</i> DSM18705	Milk powder	Spiking-HT 8 min 56°C	1,1	5-2-1-0-0 (1,6)	-	3	a
3488	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter turicensis</i> Ad 1445	Infant formula	Spiking-HT 8 min 56°C	0,7	1-0-2-2-2 (1,4)	-	3	a

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
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3489	Poudre de lait infantile 1er âge avec probiotiques (<10cfu/g)	Infant formula with probiotics (<10cfu/g)	<i>Cronobacter turicensis</i> Ad 1445	Infant formula	Spiking-HT 8 min 56°C	0,7	1-0-2-2-2 (1,4)	-	3	a
3490	Poudre de lait infantile 2e âge avec probiotiques (1,1 10 ⁶ cfu/g)	Infant formula with probiotics (1,1 10 ⁶ cfu/g)	<i>Cronobacter turicensis</i> Ad 1445	Infant formula	Spiking-HT 8 min 56°C	0,7	1-0-2-2-2 (1,4)	-	3	a
3753	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter dublinensis</i> DSM18705	Milk powder	Spiking-HT 8 min 56°C	0,5	0-0-0-3-1 (0,8)	-	3	a
3754	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter dublinensis</i> DSM18705	Milk powder	Spiking-HT 8 min 56°C	0,5	0-0-0-3-1 (0,8)	+	3	a
3755	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter dublinensis</i> DSM18705	Milk powder	Spiking-HT 8 min 56°C	0,5	0-0-0-3-1 (0,8)	-	3	a
3756	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter turicensis</i> Ad 1445	Infant formula	Spiking-HT 8 min 56°C	0,7	0-4-3-2-1 (2,0)	-	3	a
3757	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter turicensis</i> Ad 1445	Infant formula	Spiking-HT 8 min 56°C	0,7	0-4-3-2-1 (2,0)	-	3	a
3758	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter turicensis</i> Ad 1445	Infant formula	Spiking-HT 8 min 56°C	0,7	0-4-3-2-1 (2,0)	+	3	a
3759	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter malonaticus</i> DSM18702	Milk powder	Spiking-HT 8 min 56°C	0,5	1-6-3-4-3 (3,4)	+	3	a
4086	Eau de rinçage	Rinsing water	<i>Cronobacter sakazakii</i> Ad 1437	Dairy product	Spiking-pH4 and HT 8 min 56°C	0,60	0-0-1-0-2 (0,6)	-	3	a
4087	Eau de rinçage	Rinsing water	<i>Cronobacter sakazakii</i> Ad 1437	Dairy product	Spiking-pH4 and HT 8 min 56°C	0,60	0-0-1-0-2 (0,6)	-	3	a
4398	Eau de rinçage production PDL	Rinsing water	<i>Cronobacter turicensis</i> Ad 1445	Dairy product	Seeding-48 h 4°C	/	2-1-0-3-5 (2,2)	+	3	a
4399	Eau de rinçage FOARMOR	Rinsing water	<i>Cronobacter turicensis</i> Ad 1445	Dairy product	Seeding-48 h 4°C	/	2-1-0-3-5 (2,2)	+	3	a
1750	Poudre de lait infantile 1er âge avec probiotiques (<10cfu/g)	Infant formula with probiotics (<10cfu/g)	<i>Cronobacter sakazakii</i> Ad 704	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,2	+	3	b
1751	Poudre de lait infantile 1er âge avec probiotiques (<10cfu/g)	Infant formula with probiotics (<10cfu/g)	<i>Cronobacter sakazakii</i> Ad 704	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,2	+	3	b

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
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1752	Poudre de lait infantile 1er âge avec probiotiques (<10cfu/g)	Infant formula with probiotics (<10cfu/g)	<i>Cronobacter sakazakii</i> Ad 704	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	0,2	+	3	b
1753	Poudre de lait infantile 1er âge avec probiotiques (1,5 10 ⁵ cfu/g)	Infant formula with probiotics (1,5 10 ⁵ cfu/g)	<i>Cronobacter sakazakii</i> Ad 916	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,8	+	3	b
1754	Poudre de lait infantile 1er âge avec probiotiques (9,7 10 ⁵ cfu/g)	Infant formula with probiotics (9,7 10 ⁵ cfu/g)	<i>Cronobacter sakazakii</i> Ad 916	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	2,8	+	3	b
1755	Poudre de lait infantile 3e âge avec probiotiques (8,4 10 ⁴ cfu/g)	Infant formula with probiotics (8,4 10 ⁴ cfu/g)	<i>Cronobacter sakazakii</i> Ad 916	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	3,0	+	3	b
1756	Poudre de lait infantile 1er âge avec probiotiques (1,0 10 ⁶ cfu/g)	Infant formula with probiotics (1,0 10 ⁶ cfu/g)	<i>Cronobacter sakazakii</i> Ad 916	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	3,0	+	3	b
1757	Poudre de lait infantile 1er âge avec probiotiques (2,2 10 ⁵ cfu/g)	Infant formula with probiotics (2,2 10 ⁵ cfu/g)	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	<1,0	+	3	b
1758	Poudre de lait infantile 2e âge avec probiotiques (1,1 10 ⁶ cfu/g)	Infant formula with probiotics (1,1 10 ⁶ cfu/g)	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	<1,0	+	3	b
1759	Poudre de lait infantile 1er âge avec probiotiques (1,0 10 ⁶ cfu/g)	Infant formula with probiotics (1,0 10 ⁶ cfu/g)	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	<1,0	+	3	b
1760	Poudre de lait infantile 2e âge avec probiotiques (20 cfu/g)	Infant formula with probiotics (20 cfu/g)	<i>Cronobacter sakazakii</i> Ad 1437	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	1,2	-	3	b
1761	Poudre de lait infantile 1er âge avec probiotiques (8,0 10 ⁵ cfu/g)	Infant formula with probiotics (8,0 10 ⁵ cfu/g)	<i>Cronobacter sakazakii</i> Ad 1437	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	1,2	+	3	b
1762	Poudre de lait infantile 1er âge avec probiotiques (<10cfu/g)	Infant formula with probiotics (<10cfu/g)	<i>Cronobacter sakazakii</i> Ad 1437	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	1,2	+	3	b

Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Artificial contamination					Global result	Category	Type
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level CFU/sample			
1763	Poudre de lait infantile 1er âge avec probiotiques (6,0 10 ⁵ cfu/g)	Infant formula with probiotics (6,0 10 ⁵ cfu/g)	<i>Cronobacter sakazakii</i> Ad 1420	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	<1,0	+	3	b
1764	Poudre de lait infantile 1er âge avec probiotiques (3,0 10 ⁵ cfu/g)	Infant formula with probiotics (3,0 10 ⁵ cfu/g)	<i>Cronobacter sakazakii</i> Ad 1420	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	<1,0	+	3	b
3264	Poudre de lait infantile 1er âge avec probiotiques (3,9 10 ⁵ cfu/g)	Infant formula with probiotics (3,9 10 ⁵ cfu/g)	<i>Cronobacter sakazakii</i> Ad 831	Dairy product	Seeding-Lyophilized strain, 2 weeks at 20°C	/	5,6	+	3	b
3760	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter malonaticus</i> DSM18702	Milk powder	Spiking-HT 8 min 56°C	0,5	1-6-3-4-3 (3,4)	-	3	b
3761	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter malonaticus</i> DSM18702	Milk powder	Spiking-HT 8 min 56°C	0,5	1-6-3-4-3 (3,4)	+	3	b
3940	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	+	3	b
3941	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 953	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	+	3	b
3942	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 1437	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	+	3	b
3943	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 1437	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	+	3	b
3944	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 893	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	+	3	b
3945	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 893	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	+	3	b
3946	Poudre de lait infantile 1er âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 893	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	+	3	b
3947	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 1446	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	-	3	b
3948	Poudre de lait infantile 2e âge	Infant formula without probiotics	<i>Cronobacter sakazakii</i> Ad 1446	Dairy product	Seeding, lyophilized strain, 2 weeks at 20°C	/	5,0	+	3	b

APPENDIX C - Artificial contamination - Extension study

Sample N°	Product (probiotics enumeration CFU/g)	Type	Result	Strain	Strain code	Seeding protocol		Contamination level (CFU/test portion)
2034825	Infant formula milk powder with probiotics (<i>Lactobacillus reuteri</i> 5,5.10 ⁵ CFU/g)	a	Neg.	<i>Cronobacter dublinensis</i>	GVV828	Lyophilized	2 weeks at ambient temperature	2,6
2034826	Infant formula milk powder with probiotics (<i>Bifidobacterium infantis</i> 3,1.10 ⁶ CFU/g)	a	Neg.	<i>Cronobacter malonaticus</i>	HSE835	Air-dried	2 weeks at ambient temperature	1,8
2034829	Infant formula milk powder with probiotics (<i>Lactobacillus fermentum hereditum</i> 1,0.10 ⁶ CFU/g)	a	Neg.	<i>Cronobacter turicensis</i>	HZN090	Lyophilized	2 weeks at ambient temperature	2,6
2034842	Infant formula milk powder with probiotics (<i>Lactobacillus fermentum hereditum</i> 1,0.10 ⁶ CFU/g)	a	Neg.	<i>Cronobacter muytjensii</i>	GVW884	Air-dried	2 weeks at ambient temperature	1,6
2034843	Infant cereals with probiotics (biscuit) (<i>B. lactis</i> 7,0.10 ⁵ CFU/g)	a	Neg.	<i>Cronobacter turicensis</i>	HZN090	Lyophilized	2 weeks at ambient temperature	2,6
2034844	Infant cereals with probiotics (honey) (<i>B. lactis</i> 3,4.10 ⁶ CFU/g)	a	Neg.	<i>Cronobacter sakazakii</i>	JGG241	Lyophilized	2 weeks at ambient temperature	2,2
2034841	Infant cereals with probiotics (<i>B. lactis</i> 6,8.10 ⁶ CFU/g)	a	Neg.	<i>Cronobacter sakazakii</i>	AWX553	Air-dried	2 weeks at ambient temperature	2,2
1978475	Infant formula milk powder with probiotics (<i>Lactobacillus reuteri</i> 4,0.10 ⁵ CFU/g)	a	Neg.	<i>Cronobacter malonaticus</i>	HSE835	Air-dried	2 weeks at ambient temperature	1,8
2034846	Infant cereals with probiotics (5 cereals) (<i>B. lactis</i> 5,0.10 ⁵ CFU/g)	a	Neg.	<i>Cronobacter turicensis</i>	HZN090	Air-dried	2 weeks at ambient temperature	2,0
2034847	Infant cereals with probiotics (chocolate & biscuit) (<i>B. lactis</i> 7,0.10 ⁵ CFU/g)	a	Neg.	<i>Cronobacter muytjensii</i>	GVW884	Air-dried	2 weeks at ambient temperature	2,4
2034824	Infant formula milk powder with probiotics (<i>Lactobacillus reuteri</i> 5,5.10 ⁵ CFU/g)	a	Pos.	<i>Cronobacter dublinensis</i>	GVV828	Lyophilized	2 weeks at ambient temperature	2,6
2034827	Infant formula milk powder with probiotics (<i>Bifidobacterium lactis</i> 4,5.10 ⁶ CFU/g)	a	Pos.	<i>Cronobacter sakazakii</i>	JCT201	Lyophilized	2 weeks at ambient temperature	2,8
2034828	Infant formula milk powder with probiotics (<i>Bifidobacterium lactis</i> 2,1.10 ⁷ CFU/g)	a	Pos.	<i>Cronobacter sakazakii</i>	JCT201	Lyophilized	2 weeks at ambient temperature	2,8
2034845	Infant cereals with probiotics (cocoa) Batch 2 (<i>B. lactis</i> 5,6.10 ⁶ CFU/g)	a	Pos.	<i>Cronobacter sakazakii</i>	AWX553	Air-dried	2 weeks at ambient temperature	2,2
2034884	Infant formula milk powder with probiotics (<i>Lactobacillus reuteri</i> 6,1.10 ⁶ CFU/g)	a	Pos.	<i>Cronobacter sakazakii</i>	JGG241	Lyophilized	2 weeks at ambient temperature	2,4
2034885	Infant formula milk powder with probiotics (<i>Bifidobacterium infantis</i> 3,1.10 ⁵ CFU/g)	a	Pos.	<i>Cronobacter sakazakii</i>	JGG241	Lyophilized	2 weeks at ambient temperature	2,4
2034886	Infant cereals with probiotics (honey) (<i>B. lactis</i> 3,4.10 ⁶ CFU/g)	a	Pos.	<i>Cronobacter malonaticus</i>	HSE835	Air-dried	2 weeks at ambient temperature	1,2
2034892	Infant cereals with probiotics (<i>B. lactis</i> 6,8.10 ⁶ CFU/g)	a	Pos.	<i>Cronobacter sakazakii</i>	AWX553	Air-dried	2 weeks at ambient temperature	1,0
2066812	Infant cereals with probiotics (chocolate & biscuit) (<i>B. lactis</i> 7,0.10 ⁵ CFU/g)	a	Pos.	<i>Cronobacter turicensis</i>	HZN090	Air-dried	2 weeks at ambient temperature	2,8
2034830	Infant formula milk powder 6 - 12 months	b	Neg.	<i>Cronobacter dublinensis</i>	GVV828	Lyophilized	2 weeks at ambient temperature	2,6
2034831	Infant formula milk powder 0 - 6 months	b	Neg.	<i>Cronobacter dublinensis</i>	GVV828	Lyophilized	2 weeks at ambient temperature	2,6
2034832	Infant formula milk powder 12 - 36 months batch 1	b	Neg.	<i>Cronobacter malonaticus</i>	HSE835	Air-dried	2 weeks at ambient temperature	1,8
2034833	Infant formula milk powder 12 - 36 months batch 2	b	Neg.	<i>Cronobacter muytjensii</i>	GVW884	Air-dried	2 weeks at ambient temperature	1,6
2034834	Infant cereals w/o probiotics	b	Neg.	<i>Cronobacter muytjensii</i>	GVW884	Air-dried	2 weeks at ambient temperature	1,6
2034835	Infant formula milk powder 0 - 6 months	b	Neg.	<i>Cronobacter turicensis</i>	HZN090	Lyophilized	2 weeks at ambient temperature	2,6
2034848	Infant formula milk powder 12 - 36 months batch 2	b	Neg.	<i>Cronobacter turicensis</i>	HZN090	Lyophilized	2 weeks at ambient temperature	2,6
2034849	Infant cereals w/o probiotics (biscuit)	b	Neg.	<i>Cronobacter sakazakii</i>	JGG241	Lyophilized	2 weeks at ambient temperature	2,2
2034850	Infant cereals w/o probiotics (wheat & vanilla)	b	Neg.	<i>Cronobacter sakazakii</i>	JGG241	Lyophilized	2 weeks at ambient temperature	2,2
2034852	Infant cereals w/o probiotics (wheat & cocoa)	b	Pos.	<i>Cronobacter muytjensii</i>	GVW884	Air-dried	2 weeks at ambient temperature	2,4
2066815	Infant formula milk powder 0 - 6 months	b	Pos.	<i>Cronobacter sakazakii</i>	HYD216	Lyophilized	2 weeks at ambient temperature	2,0
1978477	Infant cereals w/o probiotics	b	Pos.	<i>Cronobacter sakazakii</i>	AWX553	Air-dried	2 weeks at ambient temperature	2,2
2034851	Infant cereals w/o probiotics (vanilla)	b	Pos.	<i>Cronobacter turicensis</i>	HZN090	Air-dried	2 weeks at ambient temperature	2,0
2034888	Infant formula milk powder 6 - 12 months batch 1	b	Pos.	<i>Cronobacter malonaticus</i>	HSE835	Air-dried	2 weeks at ambient temperature	1,2
2034889	Infant formula milk powder 0 - 6 months	b	Pos.	<i>Cronobacter sakazakii</i>	HXN562	Lyophilized	2 weeks at ambient temperature	3,0
2034890	Infant formula milk powder 12 - 36 months batch 1	b	Pos.	<i>Cronobacter sakazakii</i>	HXN562	Lyophilized	2 weeks at ambient temperature	3,0
2034891	Infant formula milk powder 12 - 36 months batch 2	b	Pos.	<i>Cronobacter sakazakii</i>	JCT201	Lyophilized	2 weeks at ambient temperature	<1
2066813	Infant cereals w/o probiotics (wheat & cocoa)	b	Pos.	<i>Cronobacter dublinensis</i>	GVV828	Lyophilized	2 weeks at ambient temperature	3,0
2066814	Infant cereals w/o probiotics (biscuit)	b	Pos.	<i>Cronobacter muytjensii</i>	GVW884	Air-dried	2 weeks at ambient temperature	3,2
2034836	Caseinate powder	c	Neg.	<i>Cronobacter sakazakii</i>	HXN562	Lyophilized	2 weeks at ambient temperature	1,2
2034837	Lactosérum powder	c	Neg.	<i>Cronobacter turicensis</i>	HZN090	Lyophilized	2 weeks at ambient temperature	2,6

APPENDIX C - Artificial contamination - Extension study

Sample N°	Product (probiotics enumeration CFU/g)	Type	Result	Strain	Strain code	Seeding protocol		Contamination level (CFU/test portion)
2034839	Lecithine soja powder	c	Neg.	<i>Cronobacter sakazakii</i>	AWX553	Air-dried	2 weeks at ambient temperature	2,2
2034840	Lactose powder	c	Neg.	<i>Cronobacter dublinensis</i>	GVV828	Lyophilized	2 weeks at ambient temperature	2,6
1978476	Lactoserum permeat batch 2	c	Neg.	<i>Cronobacter muytjensii</i>	GVW884	Air-dried	2 weeks at ambient temperature	2,4
1978478	Lactoserum permeat batch 1	c	Neg.	<i>Cronobacter sakazakii</i>	JGG241	Lyophilized	2 weeks at ambient temperature	2,2
2034838	Maltodextrine batch 1	c	Pos.	<i>Cronobacter malonaticus</i>	HSE835	Air-dried	2 weeks at ambient temperature	1,8
1978479	Rice flour batch 1	c	Pos.	<i>Cronobacter sakazakii</i>	AWX553	Air-dried	2 weeks at ambient temperature	2,2
1978480	Powdered whole milk	c	Pos.	<i>Cronobacter dublinensis</i>	GVV828	Lyophilized	2 weeks at ambient temperature	2,6
2034887	Lactoserum powder	c	Pos.	<i>Cronobacter sakazakii</i>	HXN562	Lyophilized	2 weeks at ambient temperature	3,0
2034893	Lactose	c	Pos.	<i>Cronobacter sakazakii</i>	HXN562	Lyophilized	2 weeks at ambient temperature	3,0
2034894	Lecithine soja powder	c	Pos.	<i>Cronobacter sakazakii</i>	HXN562	Lyophilized	2 weeks at ambient temperature	3,0
2034895	Powdered whole milk	c	Pos.	<i>Cronobacter sakazakii</i>	JCT201	Lyophilized	2 weeks at ambient temperature	<1
2066816	Lactoserum permeat	c	Pos.	<i>Cronobacter muytjensii</i>	GVW884	Air-dried	2 weeks at ambient temperature	3,2
2066817	Wheat flour	c	Pos.	<i>Cronobacter sakazakii</i>	HYD216	Lyophilized	2 weeks at ambient temperature	2,0

Appendix D - Sensitivity: Initial validation study

Bold typing : artificially inoculated samples

***Cronobacter* detection results:**

m:	minoritary level of target analyte
M :	majoritary level of target analyte
P:	pure culture level of target analyte
1/2 :	50% level of target analyte
(x):	number of colonies in the plate
-:	no typical colonies but presence of background microflora
st:	plate without any colony
i:	PCR inhibition
PA:	positive agreement
NA:	negative agreement
ND:	negative deviation
PD:	positive deviation
PPNA:	positive presumptive negative agreement
PPND :	positive presumptive negative deviation
d:	doubtful result
NC:	non characteristic colony
ox:	oxidase test
*	1/5 dilution of the lysate
**	lysate stored at - 80°C tested again for this extension study

Discordant result between 7500 Fast (initial validation result) and QS5, lysates tested again with 7500 Fast in 2018 (**)

Lysate no more available

INFANT FORMULA MILK POWDER (10 g sample size)																												
Year of analysis	Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Reference method: ISO 22964			Thermo Scientific SureTect Cronobacter species																					Type
				CCI	Confirmatory tests		Final result	BPW 16-20 h at 37°C ± 1°C									Storage 72 h for 5°C ± 3°C											
					OX	Gallery		PCR result (Cq)			All confirmatory tests	Final result			Agreement			PCR result (Cq)			All confirmatory tests	Final result			Agreement			
								Piko Real	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5	
2016	4885	Poudre de lait infantile 6-12 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4886	Poudre de lait infantile 0-6 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4887	Poudre de lait infantile 0-6 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4888	Poudre de lait infantile 0-36 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4889	Poudre de lait infantile croissance	Infant formula milk powder	+p	-	+	+	+(22,97)	+(23,61)	+(26,06)	+	+	+	+	PA	PA	PA	+(25,41)	+(21,28)	+(25,81)	+	+	+	+	PA	PA	PA	a
2016	4890	Poudre de lait infantile 6-12 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4891	Poudre de lait infantile 0-6 mois	Infant formula milk powder	+p	-	+	+	+(25,65)	+(23,98)	+(28,14)	+	+	+	+	PA	PA	PA	+(23,08)	+(22,64)	+(24,72)	+	+	+	+	PA	PA	PA	a
2016	4892	Poudre de lait infantile 6-12 mois	Infant formula milk powder	+p	-	+	+	+(21,34)	+(19,71)	+(23,55)	+	+	+	+	PA	PA	PA	+(20,57)	+(18,90)	+(22,88)	+	+	+	+	PA	PA	PA	a
2016	4893	Poudre de lait infantile 0-6 mois	Infant formula milk powder	+p	-	+	+	+(23,73)	+(23,78)	+(25,54)	+	+	+	+	PA	PA	PA	+(22,64)	+(22,47)	+(25,27)	+	+	+	+	PA	PA	PA	a
2016	4894	Poudre de lait infantile 0-6 mois	Infant formula milk powder	+p	-	+	+	+(27,04)	+(26,28)	+(34,09)	+	+	+	+	PA	PA	PA	+(26,13)	+(23,95)	+(28,90)	+	+	+	+	PA	PA	PA	a
2016	4895	Poudre de lait infantile croissance	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4896	Poudre de lait infantile 0-6 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4897	Poudre de lait infantile 6-12 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4898	Poudre de lait infantile 0-6 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	4899	Poudre de lait infantile 6-12 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	5070	Poudre de lait infantile 0-6 mois	Infant formula milk powder	+p	-	+	+	+(25,75)	+(26,13)	+(28,96)	+	+	+	+	PA	PA	PA	+(26,02)	+(25,01)	+(26,11)	+	+	+	+	PA	PA	PA	a
2016	5071	Poudre de lait infantile 6-12 mois	Infant formula milk powder	+p	-	+	+	+(22,82)	+(22,46)	+(26,42)	+	+	+	+	PA	PA	PA	+(23,26)	+(21,25)	+(26,31)	+	+	+	+	PA	PA	PA	a
2016	5072	Poudre de lait infantile 1-3 ans	Infant formula milk powder	+p	-	+	+	+(21,47)	+(20,40)	+(22,10)	+	+	+	+	PA	PA	PA	+(19,39)	+(18,35)	+(21,65)	+	+	+	+	PA	PA	PA	a
2016	5073	Poudre de lait infantile 6-12 mois	Infant formula milk powder	+p	-	+	+	+(21,46)	+(20,14)	+(21,73)	+	+	+	+	PA	PA	PA	+(21,16)	+(20,01)	+(21,87)	+	+	+	+	PA	PA	PA	a
2016	5074	Poudre de lait infantile 0-6 mois	Infant formula milk powder	+p	-	+	+	+(22,78)	+(21,37)	+(21,95)	+	+	+	+	PA	PA	PA	+(22,84)	+(20,93)	+(23,67)	+	+	+	+	PA	PA	PA	a
2016	5075	Poudre de lait infantile 6-12 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a
2016	5076	Poudre de lait infantile 0-6 mois	Infant formula milk powder	+p	-	+	+	+(24,05)	+(23,40)	+(24,50)	+	+	+	+	PA	PA	PA	+(24,82)	+(23,72)	+(25,68)	+	+	+	+	PA	PA	PA	a
2016	5077	Poudre de lait infantile 0-6 mois	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a
2016	5078	Poudre de lait infantile 6-12 mois	Infant formula milk powder	+p	-	+	+	+(23,97)	+(22,99)	+(24,07)	+	+	+	+	PA	PA	PA	+(24,03)	+(23,19)	+(25,23)	+	+	+	+	PA	PA	PA	a
2016	5079	Poudre de lait infantile 0-6 mois	Infant formula milk powder	+p	-	+	+	+(26,83)	+(27,22)	+(27,68)	+	+	+	+	PA	PA	PA	+(26,37)	+(25,56)	+(26,76)	+	+	+	+	PA	PA	PA	a
2016	5080	Poudre de lait infantile 0-6 mois	Infant formula milk powder	+p	-	+	+	+(25,86)	+(24,18)	+(26,64)	+	+	+	+	PA	PA	PA	+(24,84)	+(22,84)	+(26,22)	+	+	+	+	PA	PA	PA	a
2016	5081	Poudre de lait infantile 6-12 mois	Infant formula milk powder	+p	-	+	+	+(23,37)	+(21,80)	+(25,00)	+	+	+	+	PA	PA	PA	+(22,40)	+(20,92)	+(22,80)	+	+	+	+	PA	PA	PA	a
2016	5203	Poudre de lait infantile-Bio	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA												a

INFANT FORMULA MILK POWDER (10 g sample size)																													
Year of analysis	Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Reference method: ISO 22964			Thermo Scientific SureTect Cronobacter species																					Type	
				CCI	Confirmatory tests		Final result	BPW 16-20 h at 37°C ± 1°C									Storage 72 h for 5°C ± 3°C												
					OX	Gallery		PCR result (Cq)			All confirmatory tests	Final result			Agreement			PCR result (Cq)			All confirmatory tests	Final result			Agreement				
								Piko Real	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5		
2016	5204	Poudre de lait infantile-Croissance	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA													a
2016	5205	Poudre de lait infantile-Croissance	Infant formula milk powder	st			-	-	-	-	-	-	-	NA	NA	NA													a
2016	1455	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (2,0.10 ⁴ /g)	+	-	+	+	+(25,95)	+(27,75)	+(27,35)	+	+	+	+	PA	PA	PA												b
2016	1456	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (8,0.10 ⁴ /g)	+	-	+	+	+(24,89)	+(22,21)	+(24,74)	+	+	+	+	PA	PA	PA												b
2016	1457	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,6.10 ⁶ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b
2016	1458	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,0.10 ⁵ /g)	+	-	+	+	+(36,80)	+(38,42)	+(37,80)	+	+	+	+	PA	PA	PA												b
2016	1459	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (5,8.10 ⁷ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b
2016	1460	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	+	-	+	+	+(32,84)	+(33,80)	+(32,93)	+	+	+	+	PA	PA	PA												b
2016	1461	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	+	-	+	+	+(32,30)	+(34,44)	+(33,57)	+	+	+	+	PA	PA	PA												b
2016	1462	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b
2016	1463	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b
2016	1464	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<2,0.10 ⁴ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b
2016	1465	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (2,2.10 ⁶ /g)	+	-	+	+	+(32,89)	+(32,56)	+(32,66)	+	+	+	+	PA	PA	PA												b
2016	1466	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,3.10 ⁷ /g)	+	-	+	+	+(26,03)	+(22,22)	+(26,92)	+	+	+	+	PA	PA	PA												b
2016	1467	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,5.10 ⁶ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b
2016	1468	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ⁴ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b
2016	1469	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,2.10 ⁷ /g)	st			-	-	i/-	-	-	-	-	NA	NA	NA													b
2016	2303	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,7.10 ⁶ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b
2016	2304	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (5,4.10 ⁶ /g)	+	-	+	+	+(30,57)	+(27,53)	i/+(28,41)*	+	+	+	+	PA	PA	PA												b
2016	2305	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (6,0.10 ⁶ /g)	st			-	-	-	-	-	-	-	NA	NA	NA													b

INFANT FORMULA MILK POWDER (10 g sample size)																																
Year of analysis	Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Reference method: ISO 22964			Thermo Scientific SureTect <i>Cronobacter</i> species																					Type				
				CCI	Confirmatory tests		Final result	BPW 16-20 h at 37°C ± 1°C						Storage 72 h for 5°C ± 3°C																		
					OX	Gallery		PCR result (Cq)			All confirmatory tests	Final result			Agreement			PCR result (Cq)			All confirmatory tests	Final result			Agreement							
								Piko Real	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5					
2016	2306	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (7,0.10 ⁵ /g)	st			-	+(30,12)	+(28,61)	+(29,97)	+	+	+	+	PD	PD	PD												b			
2016	2307	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (8,0.10 ⁵ /g)	+	-	+	+	+(24,11)	+(20,75)	+(23,33)	+	+	+	+	PA	PA	PA													b		
2016	2308	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (3,2.10 ⁵ /g)	+	-	+	+	+(24,22)	+(21,62)	+(23,86)	+	+	+	+	PA	PA	PA													b		
2016	2309	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (8,8.10 ⁵ /g)	+	-	+	+	+(25,04)	+(22,75)	+(24,80)	+	+	+	+	PA	PA	PA													b		
2016	2310	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (3,6.10 ⁶ /g)	st			-	i/-	-	-	-	-	-	-	NA	NA	NA													b		
2016	4900	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ⁴ /g)	st			-	-	-	-	-	-	-	-	NA	NA	NA	/							/						b	
2016	4901	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,8.10 ⁴ /g)	st			-	-	-	-	-	-	-	-	NA	NA	NA	/							/						b	
2016	4902	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (<200/g)	st			-	-	-	-	-	-	-	-	NA	NA	NA	/							/						b	
2016	4903	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ⁶ /g)	st			-	-	-	-	-	-	-	-	NA	NA	NA	/							/						b	
2016	5082	Poudre de lait infantile avec probiotiques-croissance	Infant formula milk powder with probiotics (<200/g)	st			-	-	-	-	-	-	-	-	NA	NA	NA	/							/						b	
2016	5206	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (1,4.10 ³ /g)	st			-	-	+(38,64)	+(40,10)	-	-	-	-	NA	PPNA	PPNA	/							/						b	
2016	5207	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (2,0.10 ² /g)	st			-	+(42,00)	-	-	-	-	-	-	PPNA	NA	NA	/							/						b	
2016	5208	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ² /g)	st			-	+(41,52)	+(39,00)	+(39,34)	-	-	-	-	PPNA	PPNA	PPNA	/							/						b	
2016	5240	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (7,9.10 ⁶ /g)	+p	-	+	+	+(24,85)	+(22,94)	+(24,45)	+	+	+	+	PA	PA	PA	/							/						b	
2016	5241	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (4,0.10 ⁴ /g)	+p	-	+	+	+(22,47)	+(20,54)	+(22,02)	+	+	+	+	PA	PA	PA	/							/							b
2016	5242	Poudre de lait infantile avec probiotiques	Infant formula milk powder with probiotics (2,0.10 ⁴ /g)	+	-	+	+	+(25,17)	+(22,68)	+(25,78)	+	+	+	+	PA	PA	PA	/							/							b

PRODUCTION ENVIRONMENTAL SAMPLES																																	
Year of analysis	Sample N°	Product (French name)	Product	Reference method : ISO 22964			Thermo Scientific SureTect Cronobacter species																										
				CCI	Confirmatory tests		Final result	BPW + 6 mg/L vancomycin 18-22 h at 37°C ± 1°C									Storage for 72 h at 5°C ± 3°C									Type							
					OX	Gallery		PCR result (Cq)			All confirmatory tests	Final result			Agreement			PCR result (Cq)			All confirmatory tests	Final result			Agreement								
								PikoReal	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real		7500 Fast	QS5					
2016	2049	Eau de rinçage	Rinsing water	+	-	+	+	+(21,40)	+(19,08)	+(24,99)	+	+	+	+	PA	PA	PA	+(21,15)	+(18,95)	+(22,33)	+	+	+	+	PA	PA	PA	a					
2016	2050	Eau de rinçage	Rinsing water	+	-	+	+	+(21,67)	+(20,01)	+(22,76)	+	+	+	+	PA	PA	PA	+(21,73)	+(19,16)	+(22,53)	+	+	+	+	PA	PA	PA	a					
2016	2051	Eau de rinçage	Rinsing water	+	-	+	+	+(20,59)	+(18,58)	+(24,58)	+	+	+	+	PA	PA	PA	+(21,25)	+(19,83)	+(20,75)	+	+	+	+	PA	PA	PA	a					
2016	2052	Eau de rinçage	Rinsing water	+	-	+	+	+(21,15)	+(20,16)	il+(24,97)*	+	+	+	+	PA	PA	PA	+(22,64)	+(21,25)	+(24,17)	+	+	+	+	PA	PA	PA	a					
2016	2053	Eau de rinçage	Rinsing water	st			-	+(21,12)	+(19,58)	+(21,85)	+	+	+	+	PD	PD	PD	+(20,54)	+(19,58)	+(22,18)	+	+	+	+	PD	PD	PD	a					
2016	2446	Eau de process	Process water	-			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	2447	Eau de nettoyage	Cleaning water	-			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4075	Eau de rinçage	Rinsing water	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4076	Eau de rinçage	Rinsing water	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4077	Eau de rinçage	Rinsing water	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4078	Eau de rinçage	Rinsing water	st			-	-	-	il-*	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4079	Eau de rinçage	Rinsing water	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4085	Eau de rinçage	Rinsing water	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4086	Eau de rinçage	Rinsing water	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4087	Eau de rinçage	Rinsing water	st			-	+(42,36)	-	-	-	-	-	PPNA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4398	Eau de rinçage production PDL	Rinsing water	+	-	+	+	+(20,86)	+(19,56)		+	+	+		PA	PA		+(22,95)	+(22,06)		+	+	+		PA	PA		a					
2016	4399	Eau de rinçage FOARMOR	Rinsing water	+	-	+	+	+(30,64)	+(28,83)		+	+	+		PA	PA		+(33,71)	+(29,88)		+(1)	+	+		PA	PA		a					
2016	4024	Eau de process pâtisserie	Process water (pastry)	-			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4027	Eau de rinçage	Rinsing water	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	a					
2016	4028	Eau de process	Process water	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	5					
2016	2448	Eau de syphon	Siphon water	+	-	+	+	+(26,13)	+(23,27)	+(26,15)	+	+	+	+	PA	PA	PA	+(25,81)	+(22,66)	+(26,52)	+	+	+	+	PA	PA	PA	b					
2016	2677	Poussières laiterie	Dusts	+	-	+	+	-	-	-	-	-	-	ND	ND	ND	-	-	-	-	-	-	-	-	ND	ND	ND	b					
2016	2678	Poussières aspirateur	Dusts	+	-	+	+	+(25,69)	+(23,23)	+(24,47)	+	+	+	+	PA	PA	PA	+(24,19)	+(23,15)	+(25,93)	+	+	+	+	PA	PA	PA	b					
2016	2679	Déchets poudre de lait	Dusts	+	-	+	+	+(29,60)	+(27,21)	+(27,80)	+	+	+	+	PA	PA	PA	+(28,43)	+(26,56)	+(28,54)	+	+	+	+	PA	PA	PA	b					
2016	2680	Poussières laiterie	Dusts	+	-	+	+	+(26,85)	+(24,60)	+(25,80)	+	+	+	+	PA	PA	PA	+(25,14)	+(23,54)	+(24,63)	+	+	+	+	PA	PA	PA	b					
2016	2681	Poussières aspirateur	Dusts	+	-	+	+	+(25,57)	+(22,81)	+(23,87)	+	+	+	+	PA	PA	PA	+(24,85)	+(22,29)	+(23,12)	+	+	+	+	PA	PA	PA	b					
2016	2682	Déchets poudre de lait	Dusts	-			-	+(31,71)	+(29,48)	+(30,85)	+	+	+	+	PD	PD	PD	+(32,2)	+(29,08)	+(30,67)	+	+	+	+	PD	PD	PD	b					
2016	3479	Eponge poussières (industrie PDL)	Dusts sponge	-			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	b					
2016	3480	Eponge poussières (industrie PDL)	Dusts sponge	-			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	b					
2016	3481	Eponge poussières (industrie PDL)	Dusts sponge	+	-	+	+	+(31,60)	+(30,99)	+(32,94)	+	+	+	+	PA	PA	PA	+(32,10)	+(28,11)	+(30,92)	+	+	+	+	PA	PA	PA	b					
2016	3488	Eponge poussières (industrie PDL)	Dusts sponge	-			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	b					
2016	3489	Eponge poussières (industrie PDL)	Dusts sponge	-			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	b					
2016	3490	Eponge poussières (industrie PDL)	Dusts sponge	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	b					
2016	3491	Eponge poussières (industrie PDL)	Dusts sponge	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	b					
2016	3492	Eponge poussières (industrie PDL)	Dusts sponge	st			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	b					
2016	3493	Eponge poussières (industrie PDL)	Dusts sponge	-			-	-	-	-	-	-	-	NA	NA	NA	-	-	-	-	-	-	-	-	NA	NA	NA	b					

INFANT FORMULA (300 g sample size)

Year of analysis	Sample N°	Product (French name)	Product (probiotics enumeration CFU/g)	Reference method : ISO 22964			Thermo Scientific SureTect <i>Cronobacter</i> species																				Type	
				CCI	Confirmatory tests		Final result	BPW + 6 mg/L vancomycin 18-22 h at 37°C ± 1°C									Storage for 72 h at 5°C ± 3°C											
					OX	Gallery		PCR result (Cq)			All confirmatory tests	Final result			Agreement			PCR result (Cq)			All confirmatory tests	Final result			Agreement			
								PikoReal	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5	Piko Real	7500 Fast	QS5		Piko Real	7500 Fast	QS5	Piko Real	7500 Fast		QS5
2016	3265	Poudre de lait infantile 2e âge	Infant formula without probiotics	+p	-	+	+	+(19,18)	+(19,42)	+(20,50)	+	+	+	+	PA	PA	PA	+(18,29)	+(19,35)	+(20,86)	+	+	+	+	PA	PA	PA	a
2016	3266	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	+(21,16)	+(21,29)	+(22,14)	+	+	+	+	PA	PA	PA	+(19,49)	+(19,43)	+(22,76)	+	+	+	+	PA	PA	PA	a
2016	3267	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	+(41,05)/-/(42,43)	-/(39,68**)	+(46,58)	-	-	-	-	PPNA	NA	PPNA	-	-	-	-	-	-	-	NA	NA	NA	a
2016	3268	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	-	-	+(44,15)	-	-	-	-	ND	ND	PPND	-	-	-	-	-	-	-	ND	ND	ND	a
2016	3269	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	+(28,06)	+(27,26)	+(30,05)	+	+	+	+	PD	PD	PD	+(24,81)	+(25,22)	+(27,34)	+	+	+	+	PD	PD	PD	a
2016	3270	Poudre de lait infantile 2e âge	Infant formula without probiotics	+p	-	+	+	+(30,18)	+(29,53)	+(34,84)	+	+	+	+	PA	PA	PA	+(29,11)	+(29,24)	+(30,16)	+	+	+	+	PA	PA	PA	a
2016	3271	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	-	-	-	-	-	-	-	ND	ND	ND	-	-	-	-	-	-	-	ND	ND	ND	a
2016	3272	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	+(32,93)	+(33,00)	+(36,12)	+	+	+	+	PD	PD	PD	+(27,82)	+(28,29)	+(29,95)	+	+	+	+	PD	PD	PD	a
2016	3273	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	+(30,72)	+(30,90)	+(33,02)	+	+	+	+	PD	PD	PD	+(25,24)	+(26,11)	+(34,86)	+	+	+	+	PD	PD	PD	a
2016	3363	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3365	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3367	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3368	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3369	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3370	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3371	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3372	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3374	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3375	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3376	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3377	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3483	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	+(26,70)	+(26,64)	+(25,77)	+	+	+	+	PD	PD	PD	+(21,69)	+(22,67)	+(25,20)	+	+	+	+	PD	PD	PD	a
2016	3484	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3485	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3486	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-/-	-/-	-	+	-	-	-	NA	NA	NA	+(36,49)	+(35,74)	+(39,66)	+	+	+	+	PD	PD	PD	a
2016	3487	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-/-	-/-	-	+	-	-	-	NA	NA	NA	+(34,84)	+(36,61)	+(22,00)	+	+	+	+	PD	PD	PD	a
2016	3488	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3753	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3754	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	+(30,38)	+(31,20)	+(37,52)	+	+	+	+	PD	PD	PD	+(29,01)	+(29,30)	+(33,95)	+	+	+	+	PD	PD	PD	a
2016	3755	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3756	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3757	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3758	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	+(35,07)	+(34,23)	+(36,73)	+	+	+	+	PD	PD	PD	+(32,00)	+(32,33)	+(33,32)	+	+	+	+	PD	PD	PD	a
2016	3759	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	-	-	-	-	-	-	-	ND	ND	ND	-	-	-	-	-	-	-	ND	ND	ND	a
2016	3760	Poudre de lait infantile 1er âge	Infant formula without probiotics	st			-	-	-	-	-	-	-	-	NA	NA	NA											a
2016	3761	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	-	-	-	-	-	-	-	ND	ND	ND	-	-	-	-	-	-	-	ND	ND	ND	a
2016	3940	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	+(20,32)	+(19,87)	+(21,28)	+	+	+	+	PA	PA	PA	+(18,35)	+(18,35)	+(19,35)	+	+	+	+	PA	PA	PA	a
2016	3941	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	+(20,15)	+(19,47)	+(21,31)	+	+	+	+	PA	PA	PA	+(18,31)	+(17,42)	+(19,99)	+	+	+	+	PA	PA	PA	a
2016	3942	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	+(19,43)	+(19,21)	+(22,28)	+	+	+	+	PA	PA	PA	+(19,15)	+(19,38)	+(20,45)	+	+	+	+	PA	PA	PA	a
2016	3943	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	+(21,2)	+(21,92)	+(25,35)	+	+	+	+	PA	PA	PA	+(19,24)	+(19,38)	+(20,99)	+	+	+	+	PA	PA	PA	a
2016	3944	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	+(20,28)	+(19,25)	+(23,62)	+	+	+	+	PA	PA	PA	+(21,48)	+(20,65)	+(21,11)	+	+	+	+	PA	PA	PA	a
2016	3945	Poudre de lait infantile 2e âge	Infant formula without probiotics	+p	-	+	+	+(20,12)	+(19,39)	+(23,22)	+	+	+	+	PA	PA	PA	+(20,69)	+(19,71)	+(21,04)	+	+	+	+	PA	PA	PA	a
2016	3946	Poudre de lait infantile 1er âge	Infant formula without probiotics	+p	-	+	+	+(20,51)	+(19,20)	+(24,13)	+	+	+	+	PA	PA	PA	+(19,00)	+(18,95)	+(21,91)	+	+	+	+	PA	PA	PA	a
2016	3947	Poudre de lait infantile 2e âge	Infant formula without probiotics	st			-	-	-	-	+	-	-	-	NA	NA	NA	i/-	-/(37,02**)	+(38,35)	+	-	-	+	NA	NA	PD	a
2016	3948	Poudre de lait infantile 2e âge	Infant formula without probiotics	+p	-	+	+	+(20,6)	+(20,02)	+(23,18)	+	+	+	+	PA	PA	PA	+(18,20)	+(17,64)	+(20,21)	+	+	+	+	PA	PA	PA	a
2016	1750	Poudre de lait infantile 1er âge avec probiotiques (<10cfu/g)	Infant formula with probiotics (<10cfu/g)	+p	-	+	+	+(19,97)	+(19,03)	+(20,24)	+	+	+	+	PA	PA	PA	+(18,85)	+(17,75)	+(19,11)	+	+	+	+	PA	PA	PA	b
2016	1751	Poudre de lait infantile 1er âge avec probiotiques (<10ufc/g)	Infant formula with probiotics (<10ufc/g)	+p	-	+	+	+(21,37)	+(20,99)	+(19,90)	+	+	+	+	PA	PA	PA	+(19,33)	+(18,05)	+(19,67)	+	+	+	+	PA	PA	PA	b
2016	1752	Poudre de lait infantile 1er âge avec probiotiques (<10ufc/g)	Infant formula with probiotics (<10ufc/g)	+p	-	+	+	+(21,65)	+(20,69)	+(21,68)	+	+	+	+	PA	PA	PA	+(19,78)	+(18,35)	+(20,21)	+	+	+	+	PA	PA	PA	b

APPENDIX D

Sensitivity raw results - Extension study

Bacterial burden

∅: no culture

L = low

M = moderate

H = high

/: not realized

Distribution of flora

A = pure culture of suspect colonies

B = mixture with a majority of suspect colonies

C = mixture with a minority of suspect colonies

D = mixture with rare suspect colonies

E = absence of suspect colonies

(x): x colonies characteristic of Salmonella if $x \leq 5$

PA: positive agreement

NA: negative agreement

ND: negative deviation

PD: positive deviation

PPNA: positive presumptive negative agreement

PPND : positive presumptive negative deviation

/: not realized

Type	Sample N°	Product (probiotics enumeration CFU/g)	Thermo Scientific SureTect Cronobacter species																									
			Reference method (■)			BPW 6 mg/L vancomycine																BPW 6 mg/L vancomycine					Agreement	
			ISO 22964			20 h at 26 h at 34-38°C																After storage 72h at 4°C					Agreement	
			CCI after CSB	Confirmation tests		Final result	PCR result (Cq)		Confirmation tests: CCI+bioch			Confirmation tests: CSB+CCI+bioch			Final result		Agreement		PCR result (Cq)		Confirmation tests: CCI+bioch			Final result		Agreement		
OX	Gallery	7500 Fast		Q55	CCI		OX	Gallery	CCI After CSB	OX	Gallery	7500 Fast	Q55	7500 Fast	Q55	7500 Fast	Q55	7500 Fast	Q55	CCI	OX	Gallery	7500 Fast	Q55	7500 Fast	Q55		
a-	2055439	Infant cereals with probiotics (milk chocolate) <i>B.lactis</i> 6,8.10 ⁵ CFU/g	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
a-	2034825	Infant formula milk powder with probiotics <i>Lactobacillus reuteri</i> 5,5.10 ⁵ CFU/g	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
a-	2034826	Infant formula milk powder with probiotics <i>Bifidobacterium infantis</i> 3,1.10 ⁶ CFU/g	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
a-	2034829	Infant formula milk powder with probiotics <i>Lactobacillus fermentum hereditum</i> 1,0.10 ⁶ CFU/g	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
a-	2034842	Infant formula milk powder with probiotics <i>Lactobacillus fermentum hereditum</i> 1,0.10 ⁶ CFU/g	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
a-	2034843	Infant cereals with probiotics (biscuit) <i>B. lactis</i> 7,0.10 ⁵ CFU/g	Ø	/	/	A	-	-	EM	/	/	EM	/	/	A	A	NA	NA	-	-	EM	/	/	A	A	NA	NA	
a-	2034844	Infant cereals with probiotics (honey) <i>B. lactis</i> 3,4.10 ⁶ CFU/g	Ø	/	/	A	-	-	EL	/	/	EL	/	/	A	A	NA	NA	/	/	EL	/	/	A	A	NA	NA	
a-	2034841	Infant cereals with probiotics <i>B. lactis</i> 6,8.10 ⁶ CFU/g	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
a-	1978475	Infant formula milk powder with probiotics <i>Lactobacillus reuteri</i> 4,0.10 ⁵ CFU/g	Ø	/	/	A	-	+ (36,12) (-/-/-/-)	Ø	/	/	Ø	/	/	A	A (FP)	NA	NA (PP)	+ (37,14) -/-/-/-	+ (36,01) -/-/+ (35,58)	Ø	/	/	A (FP)	A (FP)	NA (PP)	NA (PP)	
a-	2034846	Infant cereals with probiotics (5 cereals) - <i>B. lactis</i> 5,0.10 ⁵ CFU/g	Ø	/	/	A	+ (36,17) (-/-/-/-)	-	DL (1 colony*) CCI bis: -	-	/	Ø	/	/	A (FP)	A	NA (PP)	NA	+ (36,88)/+ (36,48) (-/-/-/-)	-	Ø	/	/	A (FP)	A	NA (PP)	NA	
a-	2034847	Infant cereals with probiotics (chocolate & biscuit) - <i>B. lactis</i> 7,0.10 ⁵ CFU/g	Ø	/	/	A	-	-	DL (1 colony*) CCI bis: -	-	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
a-	2045398	Infant cereals with probiotics (5 cereals) - <i>B. lactis</i> 5,0.10 ⁵ CFU/g	Ø	/	/	A	-	-	EL	/	/	Ø	/	/	A	A	NA	NA	-	-	Ø	/	/	A	A	NA	NA	
a+	2034824	Infant formula milk powder with probiotics <i>Lactobacillus reuteri</i> 5,5.10 ⁶ CFU/g	AM	-	Cronobacter	P	-	-	Ø	/	/	Ø	/	/	A	A	ND	ND	-	-	EL	/	/	A	A	ND	ND	
a+	2034827	Infant formula milk powder with probiotics <i>Bifidobacterium lactis</i> 4,5.10 ⁶ CFU/g	AM	-	Cronobacter	P	-	-	Ø	/	/	Ø	/	/	A	A	ND	ND	-	-	Ø	/	/	A	A	ND	ND	
a+	2034828	Infant formula milk powder with probiotics <i>Bifidobacterium lactis</i> 2,1.10 ⁷ CFU/g	Ø	/	/	A	+ (19,68)	+ (19,12)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PD	PD	+ (19,32)	+ (17,80)	AM	-	Cronobacter	P	P	PD	PD	
a+	2034845	Infant cereals with probiotics (cocoa) Batch 2 - <i>B. lactis</i> 5,6.10 ⁶ CFU/g	Ø	/	/	A	+ (20,29)	+ (19,47)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PD	PD	+ (23,74)	+ (22,68)	AM	-	Cronobacter	P	P	PD	PD	
a+	2034884	Infant formula milk powder with probiotics <i>Lactobacillus reuteri</i> 6,1.10 ⁶ CFU/g	AM	-	Cronobacter	P	+ (23,48)	+ (21,96)	AM	-	Cronobacter	AL	-	Cronobacter	P	P	PA	PA	+ (23,12)	+ (20,82)	AM	-	Cronobacter	P	P	PA	PA	
a+	2034885	Infant formula milk powder with probiotics <i>Bifidobacterium infantis</i> 3,1.10 ⁶ CFU/g	AM	-	Cronobacter	P	+ (22,08)	+ (19,86)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PA	PA	+ (20,46)	+ (19,67)	AM	-	Cronobacter	P	P	PA	PA	
a+	2034886	Infant cereals with probiotics (honey) <i>B. lactis</i> 3,4.10 ⁶ CFU/g	AM	-	Cronobacter	P	+ (26,80)	+ (24,87)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PA	PA	+ (20,17)	+ (18,84)	AM	-	Cronobacter	P	P	PA	PA	
a+	2034892	Infant cereals with probiotics <i>B. lactis</i> 6,8.10 ⁶ CFU/g	AL	-	Cronobacter	P	-	-	EL	/	/	EL	/	/	A	A	ND	ND	-	-	EL	/	/	A	A	ND	ND	
a+	2045399	Infant cereals with probiotics (cocoa) Batch 1 - <i>B. lactis</i> 5,6.10 ⁶ CFU/g	AM	-	Cronobacter	P	+ (25,81)	+ (22,95)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PA	PA	+ (25,84)	+ (24,38)	AM	-	Cronobacter	P	P	PA	PA	
a+	2066812	Infant cereals with probiotics (chocolate & biscuit) - <i>B. lactis</i> 7,0.10 ⁵ CFU/g	AM	-	Cronobacter	P	-	-	EL	/	/	Ø	/	/	A	A	ND	ND	-	-	EL	/	/	A	A	ND	ND	
b-	2034830	Infant formula milk powder 6 - 12 months	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
b-	2034831	Infant formula milk powder 0 - 6 months	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
b-	2034832	Infant formula milk powder 12 - 36 months batch 1	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
b-	2034833	Infant formula milk powder 12 - 36 months batch 2	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
b-	2034834	Infant cereals w/o probiotics	Ø	/	/	A	-	-	CM blue & white colonies BIS: CCI -/-/-/-	-	ID32E: Ø Acinetobacter baumannii	EM white colonies	/	/	A	A	NA	NA	-	-	EM white colonies	/	/	A	A	NA	NA	
b-	2034835	Infant formula milk powder 0 - 6 months	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	
b-	2034848	Infant formula milk powder 12 - 36 months batch 2	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA	

Type	Sample N°	Product (probiotics enumeration CFU/g)	Thermo Scientific SureTect Cronobacter species																											
			Reference method (■)			BPW 6 mg/L vancomycine 20 h at 26 h at 34-38°C														Agreement		BPW 6 mg/L vancomycine After storage 72h at 4°C							Agreement	
			ISO 22964			PCR result (Cq)				Confirmation tests: CCI+bioch			Confirmation tests: CSB+CCI+bioch			Final result		Agreement		PCR result (Cq)		Confirmation tests: CCI+bioch			Final result		Agreement			
			CCI after CSB	Confirmation tests		Final result	7500 Fast	Q55	CCI	OX	Gallery	CCI After CSB	OX	Gallery	7500 Fast	Q55	7500 Fast	Q55	7500 Fast	Q55	CCI	OX	Gallery	7500 Fast	Q55	7500 Fast	Q55			
OX	Gallery	7500 Fast	Q55	CCI	OX																							Gallery	7500 Fast	Q55
b-	2034849	Infant cereals w/o probiotics (biscuit)	Ø	/	/	A	-	-	EL	/	/	Ø	/	/	A	A	NA	NA	/	/	EL	/	/	A	A	NA	NA			
b-	2034850	Infant cereals w/o probiotics (wheat & vanilla)	EL	/	/	A	-	-	EL	/	/	Ø	/	/	A	A	NA	NA	/	/	EL	/	/	A	A	NA	NA			
b-	2034852	Infant cereals w/o probiotics (wheat & cocoa)	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	+ (21,04)	+ (20,05)	AM	-	Cronobacter	P	P	PD	PD			
b-	2045400	Infant formula milk powder w/o probiotics 0-6 months	Ø	/	/	A	-	-	EM	/	/	EL	/	/	A	A	NA	NA	-	-	EL	/	/	A	A	NA	NA			
b-	2045401	Infant formula milk powder w/o probiotics 6-12 months	Ø	/	/	A	-	-	EM	/	/	Ø	/	/	A	A	NA	NA	-	-	Ø	/	/	A	A	NA	NA			
b-	2045403	Infant formula milk powder w/o probiotics 6-12 months	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	-	-	Ø	/	/	A	A	NA	NA			
b+	2066815	Infant formula milk powder 0 - 6 months	AM	-	Cronobacter	P	+ (23,45)	+ (22,18)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PA	PA	+ (22,57)	+ (24,71)	AM	-	Cronobacter	P	P	PA	PA			
b+	1978477	Infant cereals w/o probiotics	AM	-	Cronobacter	P	+ (25,21)	+ (24,68)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PA	PA	+ (25,14)	+ (23,97)	BM	-	Cronobacter	P	P	PA	PA			
b+	2034851	Infant cereals w/o probiotics (vanilla)	Ø	/	/	A	+ (20,40)	+ (18,84)	AM	-	Cronobacter	AL	-	Cronobacter	P	P	PD	PD	+ (20,07)	+ (18,63)	AM	-	Cronobacter	P	P	PD	PD			
b+	2034888	Infant formula milk powder 6 - 12 months batch 1	Ø	/	/	A	+ (33,15)	+ (31,39)	AL	-	Cronobacter	AL	-	Cronobacter	P	P	PD	PD	+ (31,19)	+ (29,05)	AL	-	Cronobacter	P	P	PD	PD			
b+	2034889	Infant formula milk powder 0 - 6 months	AM	-	Cronobacter	P	+ (20,29)	+ (19,62)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PA	PA	+ (20,74)	+ (18,82)	AM	-	Cronobacter	P	P	PA	PA			
b+	2034890	Infant formula milk powder 12 - 36 months batch 1	AM	-	Cronobacter	P	+ (20,12)	+ (19,47)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PA	PA	+ (20,63)	+ (18,79)	AM	-	Cronobacter	P	P	PA	PA			
b+	2034891	Infant formula milk powder 12 - 36 months batch 2	AL	-	Cronobacter	P	+ (19,64)	+ (19,61)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PA	PA	+ (19,77)	+ (17,54)	AL	-	Cronobacter	P	P	PA	PA			
b+	2034853	Infant formula milk powder 6 - 12 months batch 2	Ø	/	/	A	+ (22,87)	+ (20,33)	AM	-	Cronobacter	AL	-	Cronobacter	P	P	PD	PD	+ 38,76 (5x+ 20,85/21,06/21,25/ 21,13/20,84)	+ 36,48 (5x+ 21,04/20,63/20,58/ 20,64/20,21)	AL	-	Cronobacter	P	P	PD	PD			
b+	2066813	Infant cereals w/o probiotics (wheat & cocoa)	AL	-	Cronobacter	P	+ (19,64)	+ (19,54)	AM	-	Cronobacter	AL	-	Cronobacter	P	P	PA	PA	+ (19,20)	+ (19,66)	AM	-	Cronobacter	P	P	PA	PA			
b+	2066814	Infant cereals w/o probiotics (biscuit)	AL	-	Cronobacter	P	+ (18,92)	+ (18,60)	AL	-	Cronobacter	AL	-	Cronobacter	P	P	PA	PA	+ (18,80)	+ (18,18)	AM	-	Cronobacter	P	P	PA	PA			
c-	2034836	Caseinate powder	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA			
c-	2034837	Lactoserum powder	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA			
c-	2034839	Lecithin soja powder	Ø	/	/	A	-	-	EL	/	/	EL	/	/	A	A	NA	NA	/	/	Ø	/	/	A	A	NA	NA			
c-	2034840	Lactose powder	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	-	-	Ø	/	/	A	A	NA	NA			
c-	1978476	Lactoserum permeat batch 2	Ø	/	/	A	-	-	EM	/	/	EM white colonies	/	/	A	A	NA	NA	/	/	EM white colonies	/	/	A	A	NA	NA			
c-	1978478	Lactoserum permeat batch 1	Ø	/	/	A	-	-	Ø	/	/	EL white colonies	/	/	A	A	NA	NA	/	/	EL white colonies	/	/	A	A	NA	NA			
c-	2045402	Maltodextrin	Ø	/	/	A	-	-	EM	/	/	Ø	/	/	A	A	NA	NA	-	-	Ø	/	/	A	A	NA	NA			
c-	2055440	Honey powder	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	-	-	Ø	/	/	A	A	NA	NA			
c-	2055442	Powdered whole milk	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	-	-	Ø	/	/	A	A	NA	NA			
c-	2055443	Wheat flour	Ø	/	/	A	+ (34,99) (-/- /34,20 /36,75/ 32,88)	-	Ø	/	/	Ø	/	/	A (FP)	A	NA (PP)	NA	-	34,35 (+/+/-/-)	EL	/	/	A	A (FP)	NA	NA (PP)			
c-	2055444	Wheat starch	Ø	/	/	A	-	-	Ø	/	/	Ø	/	/	A	A	NA	NA	+ (38,34) (-/-/-/-)	-	Ø	/	/	A (FP)	A	NA (PP)	NA			
c+	2034838	Maltodextrin batch 1	Ø	/	/	A	+ (20,38)	+ (19,44)	AM	-	Cronobacter	AM	-	Cronobacter	P	P	PD	PD	+ (22,25)	+ (20,20)	AM	-	Cronobacter	P	P	PD	PD			
c+	1978479	Rice flour batch 1	AL	-	Cronobacter	P	+ (25,24)	+ (17,09)	AM	-	Cronobacter	BM	-	Cronobacter	P	P	PA	PA	+ (24,11)	+ (23,18)	BM	-	Cronobacter	P	P	PA	PA			
c+	1978480	Powdered whole milk	AM	-	Cronobacter	P	+ (27,29)	+ (25,44)	AH	-	Cronobacter	AH	-	Cronobacter	P	P	PA	PA	+ (21,54)	+ (20,58)	AH	-	Cronobacter	P	P	PA	PA			
c+	2034887	Lactoserum powder	AM	-	Cronobacter	P	+ (21,88)	+ (19,89)	AM	-	Cronobacter	AL	-	Cronobacter	P	P	PA	PA	+ (23,21)	+ (20,25)	AM	-	Cronobacter	P	P	PA	PA			

Type	Sample N°	Product (probiotics enumeration CFU/g)	Thermo Scientific SureTect <i>Cronobacter</i> species																												
			Reference method (■)			BPW 6 mg/L vancomycine 20 h at 26 h at 34-38°C														Agreement		BPW 6 mg/L vancomycine After storage 72h at 4°C								Agreement	
			ISO 22964			PCR result (Cq)				Confirmation tests: CCI+bioch				Confirmation tests: CSB+CCI+bioch				Final result		PCR result (Cq)				Confirmation tests: CCI+bioch				Final result			
			CCI after CSB	Confirmation tests		Final result	7500 Fast	Q55	CCI	OX	Gallery	CCI After CSB	OX	Gallery	7500 Fast	Q55	7500 Fast	Q55	7500 Fast	Q55	CCI	OX	Gallery	7500 Fast	Q55	7500 Fast	Q55	7500 Fast	Q55		
OX	Gallery	7500 Fast		Q55	CCI																									OX	Gallery
C+	2034893	Lactose	AM	-	<i>Cronobacter</i>	P	+ (31,77)	+ (30,39)	AL	-	<i>Cronobacter</i>	AL	-	<i>Cronobacter</i>	P	P	PA	PA	+ (24,04)	+ (22,68)	AL	-	<i>Cronobacter</i>	P	P	PA	PA				
C+	2034894	Lecithin soja powder	AM	-	<i>Cronobacter</i>	P	+ (27,80)	+ (26,59)	BH	-	<i>Cronobacter</i>	BM	-	<i>Cronobacter</i>	P	P	PA	PA	+ (26,34)	+ (25,50)	AM	-	<i>Cronobacter</i>	P	P	PA	PA				
C+	2034895	Powdered whole milk	AM	-	<i>Cronobacter</i>	P	+ (30,71)	+ (28,77)	AM	-	<i>Cronobacter</i>	AM	-	<i>Cronobacter</i>	P	P	PA	PA	+ (24,88)	+ (24,03)	AM	-	<i>Cronobacter</i>	P	P	PA	PA				
C+	2066816	Lactoserum permeat	AM	-	<i>Cronobacter</i>	P	+ (19,18)	+ (19,14)	AM	-	<i>Cronobacter</i>	AM	-	<i>Cronobacter</i>	P	P	PA	PA	+ (19,22)	+ (18,75)	AM	-	<i>Cronobacter</i>	P	P	PA	PA				
C+	2066817	Wheat flour	AM	-	<i>Cronobacter</i>	P	+ (20,17)	+ (19,51)	AM	-	<i>Cronobacter</i>	AM	-	<i>Cronobacter</i>	P	P	PA	PA	+ (19,82)	+ (19,52)	AM	-	<i>Cronobacter</i>	P	P	PA	PA				
C+	2055441	Rice flour batch 2	EM	/	/	A	+ (24,30)	+ (23,25)	BM	-	<i>Cronobacter</i>	BM	-	<i>Cronobacter</i>	P	P	PD	PD	+ (22,16)	+ (23,21)	BM	-	<i>Cronobacter</i>	P	P	PD	PD				

Appendix E – Relative detection levels: raw data – Initial validation study

Infant formula with probiotics (10 g sample size)

Strain: *Cronobacter sakazakii* Ad 1418

Sample N°	Product	Inoculation level/ sample	Reference method : ISO 22964				Alternative method : SureTect <i>Cronobacter</i> species							
			CCI	Confirmatory tests	Final result	Number positive samples/ Total	PCR result (Cq value)		Confirmatory tests		Final result Piko Real	Final result 7500 Fast	Number positive samples/ Total PikoReal	Number positive samples/ Total 7500 Fast
							Piko Real	7500 Fast	CCI (direct streaking)	CCI (streaking after subculture in CSB)				
3627	Infant formula with probiotics (Anaerobic lactic flora 5,5 10 ⁵ CFU/g)	0	st	/	-	0/5	-	-	st	st	-	-	0/5	0/5
3628			st	/	-		-	-	st	st	-	-		
3629			st	/	-		-	-	st	st	-	-		
3630			st	/	-		-	-	st	st	-	-		
3631			st	/	-		-	-	st	st	-	-		
3632		4,1	st	/	-	12/20	+(38,16)	+(38,21)	st	st	-	-	11/20	12/20
3633			+p	+	+		+(34,08)	+(30,86)	+p	+p	+	+		
3634			st	/	-		+(39,70)	+(34,85)	st	st	-	-		
3635			+p	+	+		+(41,64)	+(38,08)	+p	+p	+	+		
3636			+p	+	+		-	+(32,12)	+p	+p	-	+		
3637			+p	+	+		+(32,63)	+(29,87)	+p	+p	+	+		
3638			+p	+	+		+(42,39)	+(36,72)	+p	+p	+	+		
3639			+p	+	+		+(37,91)	+(34,07)	+p (2col)	+p	+	+		
3640			st	/	-		-	-	st	st	-	-		
3641			+p	+	+		+(38,53)	+(33,05)	+p	+p	+	+		
3642			+p	+	+		+(33,98)	+(29,29)	+p	+p	+	+		
3643			st	/	-		-	+(38,54)	st	st	-	-		
3644			st	/	-		-	-	st	st	-	-		
3645			+p	+	+		+(40,35)	+(34,32)	+p	+p	+	+		
3646			st	/	-		-	-	st	st	-	-		
3647			+p	+	+		+(36,53)	+(32,12)	+p	+p	+	+		
3648			st	/	-		-	-	st	st	-	-		
3649			+p	+	+		+(34,25)	+(31,16)	+p	+p	+	+		
3650			st	/	-		-	-	st	st	-	-		
3651			+p	+	+		+(39,11)	+(34,86)	+p	+p	+	+		
3652		8,2	+p	+	+	5/5	+(36,86)	+(37,77)	+p	+p	+	+	5/5	5/5
3653			+p	+	+		+(39,52)	+(36,98)	+p	+p	+	+		
3654			+p	+	+		+(40,10)	+(35,03)	+p	+p	+	+		
3655			+p	+	+		+(38,48)	+(35,22)	+p	+p	+	+		
3656			+p	+	+		+(36,85)	+(33,88)	+p	+p	+	+		

Infant formula without probiotics (10 g sample size)
Strain: Cronobacter sakazakii Ad 1418

Lysates discarded

Sample N°	Product	Inoculation level/sample	Reference method : ISO 22964				Alternative method : SureTect Cronobacter species BPW-16 h at 37°C ± 1°C							
			CCI	Confirmatory tests	Final result	Number positive samples/ Total	PCR result (Cq value)		Confirmatory tests		Final result Piko Real	Final result 7500 Fast	Number positive samples/ Total PikoReal	Number positive samples/ Total 7500 Fast
							Piko Real	7500 Fast	CCI (direct streaking)	CCI (streaking after subculture in CSB)				
4554	Infant formula (Aerobis mesophilic flora <10 CFU/g)	/	-	/	-	0/5	-	-	-	-	-	-	0/5	0/5
4555			-	/	-		-	-	-	-	-	-		
4556			-	/	-		-	-	-	-	-	-		
4557			-	/	-		-	-	-	-	-	-		
4558			-	/	-		-	-	-	-	-	-		
5050		3,5	+	+	+	15/20	+(24,77)	+(23,75)	+	+	+	+	15/20	15/20
5051			+	+	+		+(23,68)	+(23,22)	+	+	+	+		
5052			+	+	+		+(24,07)	+(23,34)	+	+	+	+		
5053			+	+	+		+(23,72)	+(23,27)	+	+	+	+		
5054			+	+	+		+(37,54)	+(35,39)	+	+	+	+		
5055			+	+	+		+(23,92)	+(22,60)	+	+	+	+		
5056			+	+	+		+(24,01)	+(23,04)	+	+	+	+		
5057			+	+	+		+(23,02)	+(22,03)	+	+	+	+		
5058			st	/	-		-	-	st	st	-	-		
5059			st	/	-		-	-	st	st	-	-		
5060			+	+	+		+(25,07)	+(24,73)	+	+	+	+		
5061			+	+	+		+(24,52)	+(22,49)	+	+	+	+		
5062			st	/	-		-	-	st	st	-	-		
5063			st	/	-		-	-	st	st	-	-		
5064			+	+	+		+(26,20)	+(24,90)	+	+	+	+		
5065			+	+	+		+(20,96)	+(19,93)	+	+	+	+		
5066			st	/	-		-	-	st	st	-	-		
5067			+	+	+		+(22,2)	+(21,88)	+	+	+	+		
5068		+	+	+	+(26,25)	+(25,21)	+	+	+	+				
5069		+	+	+	+(25,26)	+(25,13)	+	+	+	+				
4574		8,4	+	+	+	5/5	+(25,17)	+(24,49)	+	+	+	+	5/5	5/5
4575			+	+	+		+(23,31)	+(23,06)	+	+	+	+		
4576			+	+	+		+(28,53)	+(28,02)	+	+	+	+		
4577	+		+	+	+(23,8)		+(23,04)	+	+	+	+			
4578	+		+	+	+(23,63)		+(24,84)	+	+	+	+			

Process water
Strain: *Cronobacter turicensis* Ad 1445

Sample N°	Product	Inoculation level	Reference method : ISO 22964				Alternative method : SureTect <i>Cronobacter</i> species								
			CCI	Confirmatory tests	Final result	Number positive samples/ Total	PCR result (Cq value)		Confirmatory tests		Final result Piko Real	Final result 7500 Fast	Number positive samples/ Total PikoReal	Number positive samples/ Total 7500 Fast	
							Piko Real	7500 Fast	CCI (direct streaking)	CCI (streaking after subculture in CSB)					
4306	Process water(Rinse water during Milk powder production) Aerobic mesophilic flora: 6 CFU/ml	0 CFU/ml	st	/	-	0/5	-	-	st	st	-	-	0/5	0/5	
4307			st	/	-		-	-	st	st	-	-			
4308			st	/	-		-	-	st	st	-	-			
4309			st	/	-		-	-	st	st	-	-			
4310			st	/	-		-	-	st	st	-	-			
4311		0,7 CFU/ml	+	+	+	8/20	+(21,73)	+(21,35)	+	+	+	+	9/20	9/20	
4312			st	/	-		-	-	st	st	-	-			
4313			st	/	-		-	-	st	st	-	-			
4314			st	/	-		-	-	st	st	-	-			
4315			st	/	-		-	-	st	st	-	-			
4316			+	+	+		+	+	+	+	+	+			
4317			+	+	+		+	+	+	+	+	+			
4318			+	+	+		+	-	-	st	st	-			-
4319			+	+	+		+	+	+	+	+	+			
4320			+	+	+		+	-	-	st	st	-			-
4321			st	/	-		-	-	-	st	st	-			-
4322			st	/	-		-	+	+	+	+	+			+
4323			st	/	-		-	+	+	+	+	+			+
4324			st	/	-		-	-	-	st	st	-			-
4325			+	+	+		+	+	+	+	+	+			+
4326			st	/	-		-	-	-	st	st	-			-
4327			+	+	+		+	+	+	+	+	+			+
4328			st	/	-		-	+	+	+	+	+			+
4329			+	+	+		+	-	-	st	st	-			-
4330			st	/	-		-	-	-	st	st	-			-
4331		1,9 CfU/ml	+	+	+	4/5	+(20,68)	+(20,59)	+	+	+	+	3/5	3/5	
4332			st	/	-		+	+	+	+	+	+			
4333			+	+	+		-	-	st	st	-	-			
4334			+	+	+		-	-	st	st	-	-			
4335			+	+	+		+	+	+	+	+	+			

Infant formula with probiotics (300 g sample size)
Strain: *Cronobacter sakazakii* Ad1446

Sample N°	Product	Inoculation level/sample	Reference method : ISO 22964				Alternative method : SureTect <i>Cronobacter</i> species BPW + Vancomycin (6 mg/L)-20 h at 37°C ± 1°C										
			CCI	Confirmatory tests	Final result	Number positive samples/ Total	PCR result (Cq value)			Confirmatory tests		Final result Piko Real	Final result 7500 Fast	Final result QS5	Number positive samples/ Total PikoReal	Number positive samples/ Total 7500 Fast	Number positive samples/ Total QS5
							Piko Real	7500 Fast	QS5	CCI (direct streaking)	CCI (streaking after subculture in CSB)						
3583	Infant formula with probiotics (Anaerobic lactic flora 9,2 10 ⁵ CFU/g)	0	st		-	0/5	-	-	-	st	st	-	-	-	0/5	0/5	0/5
3584			st		-		-	-	-	st	st	-	-	-			
3585			st		-		!/-	-	-	st	st	-	-	-			
3586			st		-		-	-	-	st	st	-	-	-			
3587			st		-		-	-	-	st	st	-	-	-			
3950		1,5	st		-	13/20	-	-	-	+p	+p	-	-	-	12/20	12/20	12/20
3951			+p	+	+		+(31,88)	+(32,07)	+(33,26)	+p	+p	+	+	+			
3952			+p	+	+		+(36,18)	+(36,93)	+(38,04)	+p	+p	+	+	+			
3953			st		-		+(34,05)	+(35,87)	+(36,80)	+p	+p	+	+	+			
3954			st		-		+(35,53)	+(35,85)	+(36,18)	+p	+p	+	+	+			
4009			+p	+	+		-	-	-	-	+M	-	-	-			
4010			+p	+	+		+(37,17)	+(35,48)	+(37,69)	+p	+p	+	+	+			
4011			st		-		-	-/-	+(39,72)	st	+p	-	-	+			
4012			+p	+	+		-	-	-	st	+p	-	-	-			
4013			+p	+	+		-	-	-	st	+p	-	-	-			
4014			+p	+	+		-	+(37,64)	+(39,16)	+p	+p	-	+	+			
4015			st		-		+(34,79)	+(35,25)	+(36,50)	+p	+p	+	+	+			
4016			+p	+	+		+(35,70)	+(36,74)	+(37,76)	+p	+p	+	+	+			
4017			+p	+	+		-	-	-	st	st	-	-	-			
4018			+p	+	+		+(34,29)	+(34,88)	+(37,77)	+p	+p	+	+	+			
4019			+p	+	+		+(38,22)	+(38,82)/+(38,67)	-	+p	+p	+	+	-			
4020			+p	+	+		+(31,65)	+(32,05)	+(33,79)	+p	+p	+	+	+			
4021			st		-		+(30,79)	+(31,31)	+(33,30)	+p	+p	+	+	+			
4022			st		-		-	-	-	st	st	-	-	-			
4023			+p	+	+		+(38,24)	-	-	+p	+p	+	-	-			
3608		3,2	+p	+	+	+(35,04)	+(34,49)	+(33,50)	+p	+p	+	+	+	3/5	3/5	3/5	
3609			+p	+	+	-/-	+(39,43)/-/-	+(40,96)	+(6)	+p	-	+	+				
3610			+p	+	+	-	-	-	st	st	-	-	-				
3611			+p	+	+	+(36,25)	+(34,69)	+(38,49)	+1/2	+p	+	+	+				
3612			+p	+	+	-	-	-	st	st	-	-	-				

APPENDIX E - Relative level of detection - Extension study

Matrix: Infant cereals with probiotics

Enumeration of probiotics: 5,4.10⁶ UFC/g

Strain: *Cronobacter dublinensis* GVV828

Sample N°	Inoculation level / sample	ISO 22964 (■)				SureTect <i>Cronobacter</i> spp						
		CCI	Confirmation tests	Final result	Number positive samples / Total	BPW + Vancomycin (6mg/L)-20h at 34-38°C						
						7500 Fast	QS5	Confirmation tests	Final result 7500 Fast	Final result QS5	Number positive samples / Total 7500 FAST	Number positive samples / Total QS5
PCR result (Cq value)	PCR result (Cq value)											
2045429	0	∅	/	A	0/5	-	-	/	A	A	0/5	0/5
2045430		∅	/	A		-	-	/	A	A		
2045431		∅	/	A		-	-	/	A	A		
2045432		∅	/	A		-	-	/	A	A		
2045433		∅	/	A		-	-	/	A	A		
2045409	2,0	AM	+	P	13/20	+(21,46)	+(19,99)	+	P	P	12/20	12/20
2045410		∅	/	A		-	-	/	A	A		
2045411		AM	+	P		+(22,30)	+(20,44)	+	P	P		
2045412		AM	+	P		+(22,05)	+(20,00)	+	P	P		
2045413		AM	+	P		+(18,99)	+(17,38)	+	P	P		
2045414		AM	+	P		-	-	/	A	A		
2045415		AM	+	P		+(22,13)	+(20,74)	+	P	P		
2045416		∅	/	A		+(20,52)	+(18,41)	+	P	P		
2045417		AM	+	P		-	-	/	A	A		
2045418		AM	+	P		+(20,65)	+(19,89)	+	P	P		
2045419		∅	/	A		+(22,15)	+(20,81)	+	P	P		
2045420		∅	/	A		-	-	/	A	A		
2045421		AM	+	P		+(21,23)	+(18,98)	/	P	P		
2045422		AM	+	P		-	-	/	A	A		
2045423		∅	/	A		+(28,03)	+(26,62)	+	P	P		
2045424		AM	+	P		+(21,23)	+(19,93)	+	P	P		
2045425		∅	/	A		+(19,38)	+(18,11)	+	P	P		
2045426		AM	+	P		-	-	/	A	A		
2045427	AM	+	P	-	-	/	A	A				
2045428	∅	/	A	-	-	/	A	A				
2045434	6,0	AM	+	P	5/5	+(19,20)	+(18,33)	+	P	P	5/5	5/5
2045435		AM	+	P		+(20,37)	+(19,61)	+	P	P		
2045436		AM	+	P		+(21,03)	+(19,82)	+	P	P		
2045437		AM	+	P		+(20,24)	+(19,23)	+	P	P		
2045438		AM	+	P		+(20,82)	+(19,51)	+	P	P		

Appendix F - Inclusivity / Exclusivity: raw data

INCLUSIVITY								
n°	Genus	Species	N°	Origin	Inoculation level CFU/225ml	BPW + vancomycin (6 mg/L) for 18 h at 37°C		
						SureTect <i>Cronobacter</i> species PCR result (Cq)		CCI (direct streaking)
						PikoReal	7500 Fast	
1	<i>Cronobacter</i>	<i>dublinensis</i>	DSM18705	Dairy Product	34	+(20.82)	+(18.35)	+
2	<i>Cronobacter</i>	<i>malonaticus</i>	DSM18702	Dairy Product	11	+(21.28)	+(19.51)	+
3	<i>Cronobacter</i>	<i>malonaticus</i>	Ad1708	Dairy Product	53	+(21.41)	+(19.53)	+
4	<i>Cronobacter</i>	<i>muytjensii</i>	CIP103581	/	31	+(20.92)	+(18.24)	+
5	<i>Cronobacter</i>	<i>sakazakii</i>	Ad939	Infant formula	42	+(21.13)	+(19.12)	+
6	<i>Cronobacter</i>	<i>sakazakii</i>	Ad940	Infant formula	120	+(21.09)	+(19.76)	+
7	<i>Cronobacter</i>	<i>sakazakii</i>	Ad941	Infant formula	67	+(20.73)	+(19.24)	+
8	<i>Cronobacter</i>	<i>sakazakii</i>	Ad942	Infant formula	89	+(20.14)	+(19.09)	+
9	<i>Cronobacter</i>	<i>sakazakii</i>	Ad943	Infant formula	28	+(21.07)	+(19.58)	+
10	<i>Cronobacter</i>	<i>sakazakii</i>	Ad944	Infant formula	31	+(21.29)	+(19.05)	+
11	<i>Cronobacter</i>	<i>sakazakii</i>	Ad945	Infant formula	36	+(21.52)	+(19.18)	+
12	<i>Cronobacter</i>	<i>sakazakii</i>	Ad946	Infant formula	50	+21.52)	+(19.42)	+
13	<i>Cronobacter</i>	<i>sakazakii</i>	Ad947	Infant formula	46	+(21.77)	+(19.55)	+
14	<i>Cronobacter</i>	<i>sakazakii</i>	Ad948	Infant formula	47	+(20.59)	+(19.14)	+
15	<i>Cronobacter</i>	<i>sakazakii</i>	Ad949	Infant formula	71	+(21.66)	+(19.49)	+
16	<i>Cronobacter</i>	<i>sakazakii</i>	Ad950	Infant formula	49	+(21.25)	+(19.17)	+
17	<i>Cronobacter</i>	<i>sakazakii</i>	Ad951	Infant formula	41	+(21.74)	+(18.57)	+
18	<i>Cronobacter</i>	<i>sakazakii</i>	Ad952	Infant formula	37	+(21.30)	+(19.49)	+
19	<i>Cronobacter</i>	<i>sakazakii</i>	Ad953	Infant formula	29	+(21.63)	+(20.24)	+
20	<i>Cronobacter</i>	<i>sakazakii</i>	Ad963	Infant formula	18	+(21.85)	+(19.68)	+
21	<i>Cronobacter</i>	<i>sakazakii</i>	Ad704	Infant formula	26	+(21.28)	+(19.11)	+
22	<i>Cronobacter</i>	<i>sakazakii</i>	Ad831	Infant formula	12	+(21.40)	+(19.44)	+
23	<i>Cronobacter</i>	<i>sakazakii</i>	Ad829	Infant formula	23	+(21.59)	+(19.26)	+
24	<i>Cronobacter</i>	<i>sakazakii</i>	Ad916	Infant formula	17	+(20.73)	+(19.50)	+
25	<i>Cronobacter</i>	<i>sakazakii</i>	Ad893	Infant formula	26	+(20.35)	+(19.48)	+
26	<i>Cronobacter</i>	<i>sakazakii</i>	Ad894	Infant formula	14	+(21.20)	+(19.84)	+
27	<i>Cronobacter</i>	<i>sakazakii</i>	Ad895	Infant formula	28	+(20.73)	+(19.32)	+ (blue green)
28	<i>Cronobacter</i>	<i>sakazakii</i>	Ad896	Infant formula	28	+(20.74)	+(19.59)	+
29	<i>Cronobacter</i>	<i>sakazakii</i>	Ad897	Infant formula	2	+(20.88)	+(19.54)	+
30	<i>Cronobacter</i>	<i>sakazakii</i>	Ad898	Infant formula	17	+(21.11)	+(19.75)	+

INCLUSIVITY								
n°	Genus	Species	N°	Origin	Inoculation level CFU/225ml	BPW + vancomycin (6 mg/L) for 18 h at 37°C		CCI (direct streaking)
						SureTect <i>Cronobacter</i> species PCR result (Cq)		
						PikoReal	7500 Fast	
31	<i>Cronobacter</i>	<i>dublinensis lactaridi</i>	DSMZ18707 T	Dairy Product	20	+(21.0)	+(19.40)	+
32	<i>Cronobacter</i>	<i>dublinensis lausannensis</i>	DSMZ 18706 T	Dairy Product	16	+(20.65)	+(19.28)	+
33	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1418	Infant formula	18	+(20.65)	+(19.61)	+
34	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1419	Infant formula	21	+(20.64)	+(19.57)	+
35	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1420	Infant formula	27	+(20.96)	+(19.95)	+
36	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1421	Infant formula	10	+(20.98)	+(20.01)	+
37	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1424	Infant formula	12	+(21.16)	+(19.62)	+
38	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1425	Infant formula	13	+(20.33)	+(19.39)	+
39	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1426	Infant formula	28	+(22.31)	+(19.72)	+
40	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1427	Infant formula	32	+(20.66)	+(19.70)	+
41	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1428	Infant formula	24	+(19.67)	+(20.36)	+
42	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1429	Infant formula	27	+(22.66)	+(22.34)	+
43	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1430	Infant formula	24	+(20.10)	+(20.19)	+
44	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1431	Infant formula	31	+(19.88)	+(20.53)	+
45	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1432	Infant formula	24	+(20.10)	+(20.01)	+
46	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1433	Infant formula	31	+(20.12)	+(19.96)	+
47	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1434	Infant formula	30	+(20.79)	+(19.56)	+
48	<i>Cronobacter</i>	<i>sakazakii</i>	Ad1435	Infant formula	30	+(20.74)	+(20.29)	+
49	<i>Cronobacter</i>	<i>turicensis</i>	Ad 1445	Infant formula	17	+(20.35)	+(21.51)	+
50	<i>Cronobacter</i>	<i>turicensis</i>	DSMZ 18703	/	15	+(20.32)	+(21.02)	+
51	<i>Cronobacter</i>	<i>malonaticus</i>	E752	Baby food	17	+(21.31)	+(19.41)	+
52	<i>Cronobacter</i>	<i>turicensis</i>	E681	Food	15	+(27.46)	+(20.21)	+
53	<i>Cronobacter</i>	<i>muytjensii</i>	E769	Milk powder	9	+(26.95)	+(20.05)	+
54	<i>Cronobacter</i>	<i>dublinensis</i> subsp <i>dublinensis</i>	LMG 23823T	Environment	20	+(21.40)	+(20.43)	+
55	<i>Cronobacter</i>	<i>dublinensis</i> subsp <i>lausanensis</i>	E798	/	22	+(22.64)	+(25.01)	+
56	<i>Cronobacter</i>	<i>universalis</i>	NCTC 9529T	water	31	+(21.12)	+(20.31)	+
57	<i>Cronobacter</i>	<i>condimenti</i>	LMG 26250T	Spiced meat	15	+(21.34)	+(19.17)	+

EXCLUSIVITY

N°	Genus	Species	Reference	Origin	Inoculation level CFU/225ml	BPW for 24 h at 37°C	
						SureTect <i>Cronobacter</i> species PCR result (Cq)	
						PikoReal	7500 Fast
1	<i>Citrobacter</i>	<i>braakii</i>	Ad833	Beef	2.40E+05	-	-
2	<i>Citrobacter</i>	<i>diversus</i>	Ad173	Dairy product	2.00E+05	-	-
3	<i>Citrobacter</i>	<i>fameri</i>	Ad116	Environmental sample	3.00E+05	-	-
4	<i>Citrobacter</i>	<i>freundii</i>	39	Environmental sample	2.60E+05	-	-
5	<i>Citrobacter</i>	<i>koseri</i>	CIP105177	/	3.30E+05	-	-
6	<i>Enterobacter</i>	<i>aerogenes</i>	Ad889	Meat flour	2.30E+05	-	-
7	<i>Enterobacter</i>	<i>agglomerans</i>	11	Dairy product	2.20E+05	-	-
8	<i>Enterobacter</i>	<i>agglomerans</i>	136	Dairy product	1.70E+05	-	-
9	<i>Enterobacter</i>	<i>amnigenus</i>	52	Vegetables	7.20E+05	-	-
10	<i>Enterobacter</i>	<i>amnigenus</i>	129	Raw milk	1.70E+05	-	-
11	<i>Enterobacter</i>	<i>amnigenus</i>	A00C068	Poultry	3.40E+05	-	-
12	<i>Enterobacter</i>	<i>cloacae</i>	51	Vegetables	3.60E+05	-	-
13	<i>Enterobacter</i>	<i>cloacae</i>	10	Dairy product	1.60E+05	-	-
14	<i>Enterobacter</i>	<i>fergusonii</i>	2876	Environmental sample	3.10E+05	-	-
15	<i>Enterobacter</i>	<i>gergoviae</i>	CIP76.1	/	2.80E+05	-	-
16	<i>Enterobacter</i>	<i>helveticus</i>	DSM 18396 T	fruit powder	1.70E+05	-	-
17	<i>Enterobacter</i>	<i>hormaechei</i>	Ad990	Butter	2.60E+05	-	-
18	<i>Enterobacter</i>	<i>intermedius</i>	60	Vegetables	1.10E+05	-	-
19	<i>Enterobacter</i>	<i>kobei</i>	Ad706	Milk powder	4.00E+05	-	-
20	<i>Escherichia</i>	<i>coli</i>	16	Dairy product	4.10E+05	-	-
21	<i>Escherichia</i>	<i>hermanii</i>	Ad462	Dairy product	1.90E+05	-	-
22	<i>Hafnia</i>	<i>alvei</i>	Ad245	Dairy product	3.70E+05	-	-
23	<i>Klebsiella</i>	<i>pneumoniae</i>	122	Dairy product	2.00E+05	-	-
24	<i>Leclercia</i>	<i>adecarboxylata</i>	Ad707	Milk powder	6.60E+04	-	-
25	<i>Salmonella</i>	<i>arizonae</i> (51:z4,z23)	CIP 5523	/	3.00E+05	-	-
26	<i>Salmonella</i>	<i>diarizonae</i> SIIIb 65 :c :z	Ad 1298	Dairy environmental sample	3.60E+05	-	-
27	<i>Salmonella</i>	Typhimurium	Ad1333	Dairy product	5.30E+05	-	-
28	<i>Serratia</i>	<i>ficaria</i>	113	Vegetables	3.30E+05	-	-
29	<i>Serratia</i>	<i>marcescens</i>	Ad455	Raw milk	3.60E+05	-	-
30	<i>Yersinia</i>	<i>intermedia</i>	Ad133	Dairy product	3.20E+05	-	-
31	<i>Escherichia</i>	<i>coli</i> O103	Ad 1862	Dairy product	2.80E+05	-	-

Appendix G – Interlaboratory study raw results

Microbact galleries were provided to run the characteristic colonies confirmation. Some Labs encountered difficulties in the galleries interpretation. Despite the identifications not fitting with the expected results, their results were taken into account based on the recovery of characteristic colonies. Note that the characteristic colonies were identified correctly as *Cronobacter* spp. by the labs familiar with the Microbact gallery.

Laboratory

A

Lactic flora: 5.6 x10⁴/g

N° Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
						PCR			Confirmation			Final result	
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
A2	-	/	/	/	-	/	33.33	-	-	-	/	-	NA
A6	-	/	/	/	-	/	33.41	-	-	-	/	-	NA
A8	-	/	/	/	-	/	34.36	-	-	-	/	-	NA
A11	-	/	/	/	-	/	33.31	-	-	-	/	-	NA
A15	-	/	/	/	-	/	34.53	-	-	-	/	-	NA
A19	-	/	/	/	-	/	33.98	-	-	-	/	-	NA
A22	-	/	/	/	-	/	32.57	-	-	-	/	-	NA
A23	-	/	/	/	-	/	34.02	-	-	-	/	-	NA
A3	+	+	-	/	+	24.4	34.4	+	+	+	<i>Hafnia alvei</i>	+	PA
A7	+	+	-	/	+	23.6	33.84	+	+	+	<i>Serratia maltophilia</i>	+	PA
A9	+	+	-	/	+	22.77	35.39	+	+	+	<i>Hafnia alvei/Serratia maltophilia</i>	+	PA
A13	-	/	/	/	-	/	33.38	-	-	-	/	-	NA
A16	+	+	-	/	+	22.38	35.03	+	+	+	<i>Hafnia alvei/Serratia maltophilia</i>	+	PA
A18	+	+	-	/	+	22.89	33.8	+	+	+	<i>E.coli</i>	+	PA
A21	+	+	-	/	+	22.1	35.29	+	+	+	<i>Hafnia alvei</i>	+	PA
A24	+	+	-	/	+	22.32	37.24	+	+	+	<i>E.coli</i>	+	PA
A1	+	+	-	/	+	22.41	34.5	+	+	+	<i>Hafnia alvei</i>	+	PA
A4	+	+	-	/	+	23.48	34.67	+	+	+	<i>Hafnia alvei</i>	+	PA
A5	+	+	-	/	+	23.54	34.12	+	+	+	<i>Serratia maltophilia</i>	+	PA
A10	+	+	-	/	+	23.16	34.34	+	+	+	<i>Hafnia alvei/Serratia maltophilia</i>	+	PA
A12	+	+	-	/	+	23.59	34.03	+	+	+	<i>Hafnia alvei/Serratia maltophilia</i>	+	PA
A14	+	+	-	/	+	24.03	34.91	+	+	+	<i>Hafnia alvei</i>	+	PA
A17	+	+	-	/	+	23.22	35.31	+	+	+	<i>E.coli</i>	+	PA
A20	+	+	-	/	+	24.24	34.18	+	+	+	<i>Hafnia alvei</i>	+	PA

Laboratory

B

Lactic flora: 8.3 x10⁴/g

N° Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay						Agreement	
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation				Final result
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
B2	-	/	/	/	-	-	33.22	-	-	-	/	-	NA
B6	-	/	/	/	-	-	34.22	-	-	-	/	-	NA
B8	-	/	/	/	-	-	33.77	-	-	-	/	-	NA
B11	-	/	/	/	-	-	32.87	-	-	-	/	-	NA
B15	-	/	/	/	-	-	32.88	-	-	-	/	-	NA
B19	-	/	/	/	-	-	32.65	-	-	-	/	-	NA
B22	-	/	/	/	-	-	34,00	-	-	-	/	-	NA
B23	-	/	/	/	-	-	33.51	-	-	-	/	-	NA
B3	+	+	-	<i>Cronobacter sakazakii</i>	+	23.44	35.05	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B7	-	/	/	/	-	-	33.99	-	-	-	/	-	NA
B9	+	+	-	<i>Cronobacter sakazakii</i>	+	21.97	35.1	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B13	-	/	/	/	-	-	34.21	-	-	-	/	-	NA
B16	+	+	-	<i>Cronobacter sakazakii</i>	+	22.2	34.62	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B18	+	+	-	<i>Cronobacter sakazakii</i>	+	22.16	34.83	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B21	-	/	/	/	-	-	34.14	-	-	-	/	-	NA
B24	+	+	-	<i>Cronobacter sakazakii</i>	+	21.63	38.58	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B1	+	+	-	<i>Cronobacter sakazakii</i>	+	21.57	33.06	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B4	+	+	-	<i>Cronobacter sakazakii</i>	+	21.37	32.56	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B5	+	+	-	<i>Cronobacter sakazakii</i>	+	21.88	33.23	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B10	+	+	-	<i>Cronobacter sakazakii</i>	+	21.38	32.71	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B12	+	+	-	<i>Cronobacter sakazakii</i>	+	21.5	32.99	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B14	+	+	-	<i>Cronobacter sakazakii</i>	+	21.66	33.3	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B17	+	+	-	<i>Cronobacter sakazakii</i>	+	21.09	34.24	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
B20	+	+	-	<i>Cronobacter sakazakii</i>	+	20.53	34.07	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

C

Lactic flora: 8.4 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: Sure Tect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/CCI Agar	Biochemical galleries		
C2	-	/	/	/	-	/	34.62	-	-	-	/	-	NA
C6	-	/	/	/	-	/	33.5	-	-	-	/	-	NA
C8	-	/	/	/	-	/	34.66	-	-	-	/	-	NA
C11	-	/	/	/	-	/	34.46	-	-	-	/	-	NA
C15	-	/	/	/	-	/	34.65	-	-	-	/	-	NA
C19	-	/	/	/	-	/	33.26	-	-	-	/	-	NA
C22	-	/	/	/	-	/	34.19	-	-	-	/	-	NA
C23	-	/	/	/	-	/	34.2	-	-	-	/	-	NA
C3	-	/	/	/	-	/	33.87	-	-	-	/	-	NA
C7	-	/	/	/	-	/	34.18	-	-	-	/	-	NA
C9	-	/	/	/	-	/	34.32	-	-	-	/	-	NA
C13	-	/	/	/	-	/	32.99	-	-	-	/	-	NA
C16	+	+	-	<i>Hafnia alvei</i>	+	20.47	37.29	+	+	+	<i>Hafnia alvei</i>	+	PA
C18	+	+	-	<i>Hafnia alvei</i>	+	21.33	34.87	+	+	+	<i>Hafnia alvei</i>	+	PA
C21	+	+	-	<i>Hafnia alvei</i>	+	21.78	34.73	+	+	+	<i>Hafnia alvei</i>	+	PA
C24	+	+	-	<i>Hafnia alvei</i>	+	20.84	34.76	+	+	+	<i>Hafnia alvei</i>	+	PA
C1	+	+	-	<i>Hafnia alvei</i>	+	21.03	35.04	+	+	+	<i>Hafnia alvei</i>	+	PA
C4	+	+	-	<i>Hafnia alvei</i>	+	21.53	34.12	+	+	+	<i>Hafnia alvei</i>	+	PA
C5	+	+	-	<i>Hafnia alvei</i>	+	20.71	33.00	+	+	+	<i>Hafnia alvei</i>	+	PA
C10	+	+	-	<i>Hafnia alvei</i>	+	21.98	34.22	+	+	+	<i>Hafnia alvei</i>	+	PA
C12	+	+	-	<i>Hafnia alvei</i>	+	22.34	34.24	+	+	+	<i>Hafnia alvei</i>	+	PA
C14	+	+	-	<i>Hafnia alvei</i>	+	21.59	33.1	+	+	+	<i>Hafnia alvei</i>	+	PA
C17	+	+	-	<i>Hafnia alvei</i>	+	21.31	34.13	+	+	+	<i>Hafnia alvei</i>	+	PA
C20	+	+	-	<i>Hafnia alvei</i>	+	21.78	34.35	+	+	+	<i>Hafnia alvei</i>	+	PA

Laboratory

D

Lactic flora: 8.3 x10⁴ /g

N°Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
D2	-	/	/	/	-	/	35.16	-	-	-	/	-	NA
D6	-	/	/	/	-	/	34.48	-	-	-	/	-	NA
D8	-	/	/	/	-	35.33	/	+	-	-/*	/	-	PPNA
D11	-	/	/	/	-	/	35.17	-	+	+/*	<i>Cronobacter sakazakii</i>	-	NA
D15	-	/	/	/	-	/	34.31	-	+	+/*	<i>Cronobacter sakazakii</i>	-	NA
D19	-	/	/	/	-	/	34.32	-	-	-	/	-	NA
D22	+	+	-	<i>Cronobacter sakazakii</i>	+	/	33.51	-	-	-/*	/	-	ND
D23	+	+	-	<i>Cronobacter sakazakii</i>	+	39.36	/	+	-	-/*	/	-	PPND
D3	-	/	/	/	-	/	33.97	-	-	-	/	-	NA
D7	+	+	-	<i>Cronobacter sakazakii</i>	+	18.32	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D9	+	+	-	<i>E.coli</i>	+	19.87	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D13	+	+	-	<i>Klebsiella ozeanae</i>	+	22.57	/	+	+	+	<i>E.coli</i>	+	PA
D16	+	+	-	<i>Serratia liquefaciens</i>	+	20.36	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D18	-	/	/	/	-	/	34.64	-	-	-	/	-	NA
D21	+	+	-	<i>Cronobacter sakazakii</i>	+	20.39	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D24	+	+	-	<i>Cronobacter sakazakii</i>	+	35.09	/	+	-	-/*	/	-	PPND
D1	+	+	-	<i>Enterobacter aerogenes</i>	+	20.32	/	+	+	+	<i>E.coli</i>	+	PA
D4	+	+	-	<i>Cronobacter sakazakii</i>	+	20.37	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D5	+	+	-	<i>E.coli</i>	+	21.01	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D10	+	+	-	<i>Serratia liquefaciens</i>	+	20.21	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D12	+	+	-	<i>E.coli</i>	+	20.31	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D14	+	+	-	<i>Cronobacter sakazakii</i>	+	19.82	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D17	+	+	-	<i>Cronobacter sakazakii</i>	+	20.41	/	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
D20	+	+	-	<i>Cronobacter sakazakii</i>	+	20.4	/	+	+	+	<i>Klebsiella ozeanae</i>	+	PA

*: second streaking

Laboratory

E

Lactic flora: 5.3 x10⁴/g

N° Sample	Reference method: ISO/TS 22964					Alternative method: Sure Tect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
E2	-	/	/	/	-	/	34.7	-	-	-	/	-	NA
E6	-	/	/	/	-	/	33.71	-	-	-	/	-	NA
E8	-	/	/	/	-	/	34.8	-	-	-	/	-	NA
E11	-	/	/	/	-	/	34.5	-	-	-	/	-	NA
E15	-	/	/	/	-	/	34.06	-	-	-	/	-	NA
E19	-	/	/	/	-	38.32	34.11	+	-	-	/	-	PPNA
E22	-	/	/	/	-	/	30.93	-	-	-	/	-	NA
E23	-	/	/	/	-	/	31.91	-	-	-	/	-	NA
E3	+	+	-	<i>Cronobacter sakazakii</i>	+	22.3	33.44	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E7	+	+	-	<i>Cronobacter sakazakii</i>	+	22.23	33.86	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E9	+	+	-	<i>Cronobacter sakazakii</i>	+	21.53	34.26	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E13	-	/	/	/	-	/	33.39	-	-	-	/	-	NA
E16	+	+	-	<i>Cronobacter sakazakii</i>	+	21.36	34.76	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E18	-	/	/	/	-	/	32.6	-	-	-	/	-	NA
E21	-	/	/	/	-	/	34.02	-	-	-	/	-	NA
E24	+	+	-	<i>Cronobacter sakazakii</i>	+	21.63	33.68	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E1	+	+	-	<i>Cronobacter sakazakii</i>	+	19.83	34.22	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E4	+	+	-	<i>Cronobacter sakazakii</i>	+	20.1	34.46	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E5	+	+	-	<i>Cronobacter sakazakii</i>	+	20.17	34.38	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E10	+	+	-	<i>Cronobacter sakazakii</i>	+	20.89	31.24	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E12	+	+	-	<i>Cronobacter sakazakii</i>	+	22.97	33.53	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E14	+	+	-	<i>Cronobacter sakazakii</i>	+	20.83	34.23	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E17	+	+	-	<i>Cronobacter sakazakii</i>	+	20.34	35.3	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
E20	+	+	-	<i>Cronobacter sakazakii</i>	+	21.34	34.62	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

F

Lactic flora flora: 9.2 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay						Agreement	
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation				Final result
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
F2	-	/	/	/	-	/	33.25	-	-	-	/	-	NA
F6	-	/	/	/	-	/	33.11	-	-	-	/	-	NA
F8	-	/	/	/	-	/	34.02	-	-	-	/	-	NA
F11	-	/	/	/	-	/	33.36	-	-	-	/	-	NA
F15	-	/	/	/	-	/	33.33	-	-	-	/	-	NA
F19	-	/	/	/	-	/	33.48	-	-	-	/	-	NA
F22	-	/	/	/	-	/	33.06	-	-	-	/	-	NA
F23	-	/	/	/	-	/	33.23	-	-	-	/	-	NA
F3	+	+	-	<i>Cronobacter sakazakii</i>	+	24.16	35.35	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F7	-	/	/	/	-	/	33.95	-	-	-	/	-	NA
F9	+	+	-	<i>Cronobacter sakazakii</i>	+	22.17	35.32	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F13	+	+	-	<i>Cronobacter sakazakii</i>	+	24.16	34.11	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F16	-	/	/	/	-	/	33.58	-	-	-	/	-	NA
F18	+	+	-	<i>Cronobacter sakazakii</i>	+	25.35	33.84	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F21	-	/	/	/	-	/	32.98	-	-	-	/	-	NA
F24	+	+	-	<i>Cronobacter sakazakii</i>	+	24.14	34.94	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F1	+	+	-	<i>Cronobacter sakazakii</i>	+	20.51	34.9	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F4	+	+	-	<i>Cronobacter sakazakii</i>	+	20.63	33.63	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F5	+	+	-	<i>Cronobacter sakazakii</i>	+	21.58	34.44	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F10	+	+	-	<i>Cronobacter sakazakii</i>	+	21.52	34.73	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F12	+	+	-	<i>Cronobacter sakazakii</i>	+	22.48	34.04	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F14	+	+	-	<i>Cronobacter sakazakii</i>	+	21.04	34.15	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F17	+	+	-	<i>Cronobacter sakazakii</i>	+	22.86	36.79	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
F20	+	+	-	<i>Cronobacter sakazakii</i>	+	21.8	34.9	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

G

Lactic flora: 1.9 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: Sure Tect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
G2	-	/	/	/	-	/	33.7	-	-	-	/	-	NA
G6	-	/	/	/	-	/	34.41	-	-	-	/	-	NA
G8	-	/	/	/	-	/	33.51	-	-	-	/	-	NA
G11	-	/	/	/	-	/	33.29	-	-	-	/	-	NA
G15	+	+	-	<i>Cronobacter sakazakii</i>	+	/	33.33	-	-	-	/	-	ND
G19	-	/	/	/	-	/	33.54	-	-	-	/	-	NA
G22	-	/	/	/	-	/	34.11	-	-	-	/	-	NA
G23	-	/	/	/	-	/	34.49	-	-	-	/	-	NA
G3	-	/	/	/	-	/	35.08	-	-	-	/	-	NA
G7	+	+	-	<i>Cronobacter sakazakii</i>	+	21.73	34.38	+	+	-	+	+	PA
G9	+	+	-	<i>Cronobacter sakazakii</i>	+	21.68	35.01	+	+	-	+	+	PA
G13	-	/	/	/	-	/	32.85	-	-	-	/	-	NA
G16	-	/	/	/	-	19.6	34.28	+	+	+	<i>Cronobacter sakazakii</i>	+	PD
G18	+	+	-	<i>Cronobacter sakazakii</i>	+	20.02	33.87	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
G21	-	/	/	/	-	/	34.63	-	-	-	/	-	NA
G24	+	+	-	<i>Cronobacter sakazakii</i>	+	23.49	34.62	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
G1	+	+	-	+	+	21.09	34.56	+	+	-	+	+	PA
G4	+	+	-	<i>Cronobacter sakazakii</i>	+	21.00	34.29	+	+	-	+	+	PA
G5	+	+	-	<i>Cronobacter sakazakii</i>	+	20.56	35.01	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
G10	+	+	-	<i>Cronobacter sakazakii</i>	+	21.03	34.09	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
G12	+	+	-	<i>Cronobacter sakazakii</i>	+	19.09	33.98	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
G14	+	+	-	<i>Cronobacter sakazakii</i>	+	20.72	34.28	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
G17	+	+	-	<i>Cronobacter sakazakii</i>	+	20.67	35.18	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
G20	+	+	-	<i>Cronobacter sakazakii</i>	+	19.42	33.66	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

H

Lactic flora: 9.5 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
H2	-	/	/	/	-	/	33.8	-	-	-	/	-	NA
H6	-	/	/	/	-	/	33.8	-	-	-	/	-	NA
H8	-	/	/	/	-	/	33.6	-	-	-	/	-	NA
H11	-	/	/	/	-	/	34.05	-	-	-	/	-	NA
H15	-	/	/	/	-	/	33.49	-	-	-	/	-	NA
H19	-	/	/	/	-	/	34.27	-	-	-	/	-	NA
H22	-	/	/	/	-	/	34.13	-	-	-	/	-	NA
H23	-	/	/	/	-	/	34.06	-	-	-	/	-	NA
H3	+	+	-	<i>Cronobacter sakazakii</i>	+	21.11	31.96	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H7	+	+	-	<i>Cronobacter sakazakii</i>	+	21.48	33.12	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H9	+	+	-	<i>Cronobacter sakazakii</i>	+	21.76	33.83	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H13	-	/	/	/	-	/	33.47	-	-	-	/	-	NA
H16	-	/	/	/	-	/	33.98	-	-	-	/	-	NA
H18	+	+	-	<i>Cronobacter sakazakii</i>	+	20.8	33.9	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H21	-	/	/	/	-	/	34.33	-	-	-	/	-	NA
H24	-	/	/	/	-	/	33.18	-	-	-	/	-	NA
H1	+	+	-	<i>Cronobacter sakazakii</i>	+	19.94	34.35	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H4	+	+	-	<i>Cronobacter sakazakii</i>	+	20.49	31.96	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H5	+	+	-	<i>Cronobacter sakazakii</i>	+	21.51	33.09	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H10	+	+	-	<i>Cronobacter sakazakii</i>	+	20.79	33.5	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H12	+	+	-	<i>Cronobacter sakazakii</i>	+	20.45	32.62	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H14	+	+	-	<i>Cronobacter sakazakii</i>	+	20.6	33.46	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H17	+	+	-	<i>Cronobacter sakazakii</i>	+	20.23	34.8	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
H20	+	+	-	<i>Cronobacter sakazakii</i>	+	20.21	32.71	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

I

Lactic flora: 9.8 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
I2	-	/	/	/	-	/	35.9	-	-	-	/	-	NA
I6	-	/	/	/	-	/	36.14	-	-	-	/	-	NA
I8	-	/	/	/	-	/	33.38	-	-	-	/	-	NA
I11	-	/	/	/	-	/	34.32	-	-	-	/	-	NA
I15	-	/	/	/	-	/	35.31	-	-	-	/	-	NA
I19	-	/	/	/	-	/	34.96	-	-	-	/	-	NA
I22	-	/	/	/	-	/	35.12	-	-	-	/	-	NA
I23	-	/	/	/	-	/	35.09	-	-	-	/	-	NA
I3	-	/	/	/	-	/	36.87	-	-	-	/	-	NA
I7	-	/	/	/	-	/	35.1	-	-	-	/	-	NA
I9	-	/	/	/	-	/	33.71	-	-	-	/	-	NA
I13	-	/	/	/	-	/	35.75	-	-	-	/	-	NA
I16	+	+	-	<i>Klebsiella ozeanae</i>	+	21.08	34.18	+	+	+	<i>Serratia marcescens</i>	+	PA
I18	-	/	/	/	-	/	33.85	-	-	-	/	-	NA
I21	+	+	-	<i>Klebsiella ozeanae</i>	+	20.34	38.75	+	+	+	<i>C.lapagei</i>	+	PA
I24	+	+	-	<i>Serratia maltophilia</i>	+	20.56	39.29	+	+	+	<i>Serratia marcescens</i>	+	PA
I1	+	+	-	<i>Serratia maltophilia</i>	+	21.1	37.92	+	+	+	<i>Serratia maltophilia</i>	+	PA
I4	+	+	-	<i>Serratia maltophilia</i>	+	21.24	34.08	+	+	+	<i>Serratia maltophilia</i>	+	PA
I5	+	+	-	<i>Serratia maltophilia</i>	+	19.56	42.27	+	+	+	<i>Serratia maltophilia</i>	+	PA
I10	+	+	-	<i>Hafnia alvei</i>	+	20.00	39.08	+	+	+	<i>C.lapagei</i>	+	PA
I12	+	+	-	<i>Hafnia alvei</i>	+	22.72	48.05	+	+	+	<i>Hafnia alvei</i>	+	PA
I14	+	+	-	<i>C.lapagei</i>	+	22.05	33.22	+	+	+	<i>Serratia maltophilia</i>	+	PA
I17	+	+	-	<i>Serratia maltophilia</i>	+	22.16	33.88	+	+	+	<i>Serratia marcescens</i>	+	PA
I20	+	+	-	<i>Hafnia alvei</i>	+	20.52	39.01	+	+	+	<i>Cedecea spp</i>	+	PA

I13*: sample leaked

Laboratory

J

Lactic flora: 5.1 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
J2	-	/	/	/	-	/	34.33	-	-	-	/	-	NA
J6	-	/	/	/	-	/	33.84	-	-	-	/	-	NA
J8	-	/	/	/	-	/	34.13	-	-	-	/	-	NA
J11	-	/	/	/	-	/	34.24	-	-	-	/	-	NA
J15	-	/	/	/	-	/	33.36	-	-	-	/	-	NA
J19	-	/	/	/	-	/	35.13	-	-	-	/	-	NA
J22	-	/	/	/	-	/	33.46	-	-	-	/	-	NA
J23	-	/	/	/	-	/	34.37	-	-	-	/	-	NA
J3	+	+	-	<i>Cronobacter sakazakii</i>	+	23.45	35.97	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J7	-	/	/	/	-	/	34.73	-	-	-	/	-	NA
J9	-	/	/	/	-	/	33.81	-	-	-	/	-	NA
J13	+	+	-	<i>Cronobacter sakazakii</i>	+	23.11	33.59	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J16	+	+	-	<i>Cronobacter sakazakii</i>	+	24.53	33.61	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J18	+	+	-	<i>Cronobacter sakazakii</i>	+	22.77	34.95	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J21	-	/	/	/	-	/	34.77	-	-	-	/	-	NA
J24	+	+	-	<i>Cronobacter sakazakii</i>	+	22.58	34.11	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J1	+	+	-	<i>Cronobacter sakazakii</i>	+	20.57	33.35	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J4	+	+	-	<i>Cronobacter sakazakii</i>	+	21.76	33.43	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J5	+	+	-	<i>Cronobacter sakazakii</i>	+	22.12	34.44	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J10	+	+	-	<i>Cronobacter sakazakii</i>	+	19.79	33.91	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J12	+	+	-	<i>Cronobacter sakazakii</i>	+	21.58	34.39	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J14	+	+	-	<i>Cronobacter sakazakii</i>	+	22.59	35.56	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J17	+	+	-	<i>Cronobacter sakazakii</i>	+	22.41	34.74	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
J20	+	+	-	<i>Cronobacter sakazakii</i>	+	21.45	34.41	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

K

Lactic flora: 9.4 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: Sure Tect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
K2	-	/	/	/	-	/	32.87	-	-	-	/	-	NA
K6	-	/	/	/	-	/	32.15	-	-	-	/	-	NA
K8	-	/	/	/	-	/	34.32	-	-	-	/	-	NA
K11	-	/	/	/	-	/	34.89	-	-	-	/	-	NA
K15	-	/	/	/	-	37.07	33.41	+	-	-	/	-	PPNA
K19	-	/	/	/	-	/	33.52	-	-	-	/	-	NA
K22	-	/	/	/	-	/	33.79	-	-	-	/	-	NA
K23	-	/	/	/	-	42.12	32.63	+	-	-	/	-	PPNA
K3	+	+	-	<i>Cronobacter sakazakii</i>	+	22.33	33.03	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K7	+	+	-	<i>Cronobacter sakazakii</i>	+	20.61	33.84	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K9	-	/	/	/	-	/	34.12	-	-	-	/	-	NA
K13	+	+	-	<i>Cronobacter sakazakii</i>	+	21.51	32.95	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K16	+	+	-	<i>Cronobacter sakazakii</i>	+	20.49	33.32	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K18	+	+	-	<i>Cronobacter sakazakii</i>	+	20.55	33.2	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K21	-	/	/	/	-	39.96	34.1	-	-	-	/	-	PPNA
K24	+	+	-	<i>Cronobacter sakazakii</i>	+	21.08	33.61	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K1	+	+	-	<i>Cronobacter sakazakii</i>	+	19.8	34.82	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K4	+	+	-	<i>Cronobacter sakazakii</i>	+	20.44	31.19	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K5	+	+	-	<i>Cronobacter sakazakii</i>	+	20.84	33.19	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K10	+	+	-	<i>Cronobacter sakazakii</i>	+	20.01	35.36	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K12	+	+	-	<i>Cronobacter sakazakii</i>	+	21.23	33.05	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K14	+	+	-	<i>Cronobacter sakazakii</i>	+	20.83	33.94	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K17	+	+	-	<i>Cronobacter sakazakii</i>	+	20.32	33.42	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
K20	+	+	-	<i>Cronobacter sakazakii</i>	+	20.44	32.31	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

L

Lactic flora: 5.6 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/ CCI Agar	Biochemical galleries		
L2	-	/	/	/	-	/	33.98	-	-	-	/	-	NA
L6	-	/	/	/	-	/	34.02	-	-	-	/	-	NA
L8	-	/	/	/	-	/	34.53	-	-	-	/	-	NA
L11	-	/	/	/	-	/	34.1	-	-	-	/	-	NA
L15	-	/	/	/	-	39.16/-	34.92	+/-	-	-	/	-	PPNA
L19	-	/	/	/	-	40.78/-	33.46	+/-	-	-	/	-	PPNA
L22	-	/	/	/	-	/	33.61	-	-	-	/	-	NA
L23	-	/	/	/	-	40.75/-	34.19	+/-	-	-	/	-	PPNA
L3	+	+	-	<i>Cronobacter sakazakii</i>	+	21.29	33.69	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L7	+	+	-	<i>Cronobacter sakazakii</i>	+	23.52	34.29	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L9	+	+	-	<i>Cronobacter sakazakii</i>	+	21.06	34.29	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L13	+	+	-	<i>Cronobacter sakazakii</i>	+	19.91	33.39	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L16	+	+	-	<i>Cronobacter sakazakii</i>	+	19.87	33.03	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L18	+	+	-	<i>Cronobacter sakazakii</i>	+	21.9	33.46	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L21	-	/	/	/	-	/	33.53	-	-	-	/	-	NA
L24	-	/	/	/	-	/	35.04	-	-	-	/	-	NA
L1	+	+	-	<i>Cronobacter sakazakii</i>	+	22.1	35.28	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L4	+	+	-	<i>Cronobacter sakazakii</i>	+	22.17	34.39	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L5	+	+	-	<i>Cronobacter sakazakii</i>	+	21.19	32.53	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L10	+	+	-	<i>Cronobacter sakazakii</i>	+	21.3	34.52	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L12	+	+	-	<i>Cronobacter sakazakii</i>	+	20.75	33.78	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L14	+	+	-	<i>Cronobacter sakazakii</i>	+	21.89	34.8	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L17	+	+	-	<i>Cronobacter sakazakii</i>	+	21.63	35.59	+	+	/	<i>Cronobacter sakazakii</i>	+	PA
L20	+	+	-	<i>Cronobacter sakazakii</i>	+	21.46	33.95	+	+	/	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

M

Lactic flora: 1.5 x10⁵/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/CCI Agar	Biochemical galleries		
M2	-	/	/	/	-	/	34.08	-	-	-	/	-	NA
M6	-	/	/	/	-	/	35.29	-	-	-	/	-	NA
M8	-	/	/	/	-	/	34.16	-	-	-	/	-	NA
M11	-	/	/	/	-	/	36.04	-	-	-	/	-	NA
M15	-	/	/	/	-	/	34.01	-	-	-	/	-	NA
M19	-	/	/	/	-	/	33.95	-	-	-	/	-	NA
M22	-	/	/	/	-	/	33.7	-	-	-	/	-	NA
M23	-	/	/	/	-	/	36.14	-	-	-	/	-	NA
M3	+	+	-	<i>Cronobacter sakazakii</i>	+	21.83	34.09	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M7	-	/	/	/	-	/	35.77	-	-	-	/	-	NA
M9	+	+	-	<i>Cronobacter sakazakii</i>	+	21.27	34.6	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M13	+	+	-	<i>Cronobacter sakazakii</i>	+	20.03	33.72	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M16	-	/	/	/	-	/	34.94	-	-	-	/	-	NA
M18	+	+	-	<i>Cronobacter sakazakii</i>	+	23.33	35.12	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M21	+	+	-	<i>Cronobacter sakazakii</i>	+	21.88	33.83	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M24	+	+	-	<i>Cronobacter sakazakii</i>	+	22.88	35.52	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M1	+	+	-	<i>Cronobacter sakazakii</i>	+	20.08	33.12	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M4	+	+	-	<i>Cronobacter sakazakii</i>	+	21.1	32.07	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M5	+	+	-	<i>Cronobacter sakazakii</i>	+	20.09	32.74	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M10	+	+	-	<i>Cronobacter sakazakii</i>	+	20.01	33.57	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M12	+	+	-	<i>Cronobacter sakazakii</i>	+	21.17	33.7	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M14	+	+	-	<i>Cronobacter sakazakii</i>	+	21.92	34.81	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M17	+	+	-	<i>Cronobacter sakazakii</i>	+	20.24	35.13	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
M20	+	+	-	<i>Cronobacter sakazakii</i>	+	20.12	33.31	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

N

Lactic flora: 5.2 x10⁴/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: Sure Tect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/CCI Agar	Biochemical galleries		
N2	-	/	/	/	-	35.82	33.51	+	-	-	/	-	PPNA
N6	-	/	/	/	-	43.66	33.24	-	-	-	/	-	NA
N8	-	/	/	/	-	33.22	35.16	+	-	-	/	-	PPNA
N11	-	/	/	/	-	/	34.00	-	-	-	/	-	NA
N15	-	/	/	/	-	/	33.44	-	-	-	/	-	NA
N19	-	/	/	/	-	/	34.26	-	-	-	/	-	NA
N22	-	/	/	/	-	/	34.52	-	-	-	/	-	NA
N23	-	/	/	/	-	/	33.6	-	-	-	/	-	NA
N3	+	+	-	<i>Cronobacter sakazakii</i>	+	21.83	34.6	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N7	+	+	-	<i>Cronobacter sakazakii</i>	+	21.79	34.58	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N9	-	/	/	/	-	/	33.45	-	-	-	/	-	NA
N13	+	+	-	<i>Cronobacter sakazakii</i>	+	19.78	34.08	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N16	+	+	-	<i>Cronobacter sakazakii</i>	+	19.76	35.84	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N18	+	+	-	<i>Cronobacter sakazakii</i>	+	42.8	32.98	-	-	-	/	-	ND
N21	-	/	/	/	-	/	33.51	-	-	-	/	-	NA
N24	-	/	/	/	-	/	34.91	-	-	-	/	-	NA
N1	+	+	-	<i>Cronobacter sakazakii</i>	+	20.06	34.52	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N4	+	+	-	<i>Cronobacter sakazakii</i>	+	20.32	34.49	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N5	+	+	-	<i>Cronobacter sakazakii</i>	+	20.03	33.22	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N10	+	+	-	<i>Cronobacter sakazakii</i>	+	19.81	34.56	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N12	+	+	-	<i>Cronobacter sakazakii</i>	+	20.14	33.27	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N14	+	+	-	<i>Cronobacter sakazakii</i>	+	20.12	33.35	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N17	+	+	-	<i>Cronobacter sakazakii</i>	+	19.82	34.11	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
N20	+	+	-	<i>Cronobacter sakazakii</i>	+	20.35	35.16	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

0

Lactic flora: 1.2 x10⁵/g

N°Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/CCI Agar	Biochemical galleries		
O2	-	/	/	/	-	/	33.16	-	-	-	/	-	NA
O6	-	/	/	/	-	/	33.94	-	-	-	/	-	NA
O8	-	/	/	/	-	/	35.12	-	-	-	/	-	NA
O11	-	/	/	/	-	/	34.21	-	-	-	/	-	NA
O15	-	/	/	/	-	/	32.28	-	-	-	/	-	NA
O19	-	/	/	/	-	/	33.66	-	-	-	/	-	NA
O22	-	/	/	/	-	/	35.03	-	-	-	/	-	NA
O23	-	/	/	/	-	/	34.02	-	-	-	/	-	NA
O3	+	+	-	<i>Cronobacter sakazakii</i>	+	20.85	33.57	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O7	+	+	-	<i>Cronobacter sakazakii</i>	+	24.04	34.68	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O9	-	/	/	/	-	/	34.16	-	-	-	/	-	NA
O13	-	/	/	/	-	/	31.98	-	-	-	/	-	NA
O16	+	+	-	<i>Cronobacter sakazakii</i>	+	21.46	34.79	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O18	+	+	-	<i>Cronobacter sakazakii</i>	+	24.84	32.51	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O21	+	+	-	<i>Cronobacter sakazakii</i>	+	21.49	34.48	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O24	+	+	-	<i>Cronobacter sakazakii</i>	+	19.22	34.31	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O1	+	+	-	<i>Cronobacter sakazakii</i>	+	20.21	34.46	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O4	+	+	-	<i>Cronobacter sakazakii</i>	+	20.23	34.97	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O5	+	+	-	<i>Cronobacter sakazakii</i>	+	20.56	33.27	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O10	+	+	-	<i>Cronobacter sakazakii</i>	+	20.23	33.32	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O12	+	+	-	<i>Cronobacter sakazakii</i>	+	20.79	33.64	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O14	+	+	-	<i>Cronobacter sakazakii</i>	+	19.99	33.87	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O17	+	+	-	<i>Cronobacter sakazakii</i>	+	20.04	33.21	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
O20	+	+	-	<i>Cronobacter sakazakii</i>	+	20.77	34.58	+	+	+	<i>Cronobacter sakazakii</i>	+	PA

Laboratory

P (ADRIA)

Lactic flora: 8.5 x10⁴/g

N° Sample	Reference method: ISO/TS 22964					Alternative method: SureTect Cronobacter species PCR Assay							Agreement
	ESIA	TSA	Oxidase	Biochemical galleries	Final result	PCR			Confirmation			Final result	
						Cq target	Cq IAC	Test result	CCI Agar	CSB/CCI Agar	Biochemical galleries		
P2	-	/	/	/	-	/	33.66	-	-	-	/	-	NA
P6	-	/	/	/	-	/	33.69	-	-	-	/	-	NA
P8	-	/	/	/	-	/	35.11	-	-	-	/	-	NA
P11	-	/	/	/	-	/	33.89	-	-	-	/	-	NA
P15	-	/	/	/	-	/	34.04	-	-	-	/	-	NA
P19	-	/	/	/	-	/	34.35	-	-	-	/	-	NA
P22	-	/	/	/	-	/	33.37	-	-	-	/	-	NA
P23	-	/	/	/	-	/	34.34	-	-	-	/	-	NA
P3	-	/	/	/	-	/	34.97	-	-	-	/	-	NA
P7	-	/	/	/	-	/	33.44	-	-	-	/	-	NA
P9	+	+	+	<i>Cronobacter sakazakii</i>	+	20.36	35.39	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P13	-	/	/	/	-	/	33.91	-	-	-	/	-	NA
P16	-	/	/	/	-	/	34.28	-	-	-	/	-	NA
P18	-	/	/	/	-	/	34.05	-	-	-	/	-	NA
P21	+	+	+	<i>Cronobacter sakazakii</i>	+	22.05	33.9	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P24	-	/	/	/	-	/	34.38	-	-	-	/	-	NA
P1	+	+	+	<i>Cronobacter sakazakii</i>	+	19.85	34.64	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P4	+	+	+	<i>Cronobacter sakazakii</i>	+	20.39	34.51	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P5	+	+	+	<i>Cronobacter sakazakii</i>	+	20.23	32.2	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P10	+	+	+	<i>Cronobacter sakazakii</i>	+	21.31	34.34	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P12	+	+	+	<i>Cronobacter sakazakii</i>	+	20.72	34.44	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P14	+	+	+	<i>Cronobacter sakazakii</i>	+	20.79	33.85	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P17	+	+	+	<i>Cronobacter sakazakii</i>	+	20.27	34.15	+	+	+	<i>Cronobacter sakazakii</i>	+	PA
P20	+	+	+	<i>Cronobacter sakazakii</i>	+	20.51	32.9	+	+	+	<i>Cronobacter sakazakii</i>	+	PA