MicroVal Study (2023LR117): Confirmation

Validation of the Autof ms1000 (2023LR117) for Confirmation of *Cronobacter* species

Version 3
October 7, 2025

Method/Kit: Autof ms method

Instrument(s) and Software: Autof ms1000, Version 2.0.196

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This report is prepared in accordance with ISO 16140-6:2019 and MicroVal Technical Committee interpretation of ISO 16140-6 (TC 2022-069, V2.5).

Company: Autobio Diagonistics Co., Ltd.

Expert Laboratory: Q Laboratories

Method/Kit Name: Autof ms1000

Validation Standards:

- ISO 16140-6:2019 Microbiology of the food chain – Method Validation – Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures.

Reference Methods:

1. ISO 22964:2017 Microbiology of food chain – Horizontal method for the detection of *Cronobacter* spp.

Scope of validation: The confirmation of presumptive *Cronobacter* spp. colonies isolated from selective and non-selective agars and under specified conditions for a genus level claim.

Certification Organization: LRQA

List of abbreviations

-	No typical colonies but presence of background microflora
AL	Acceptability Limit
Alt	Alternative method
DT	Direct transfer procedure
EDT	Extended direct transfer procedure
EXT	Extraction procedure
EL	Expert Laboratory
GN	Gram-negative
h	Hour
ILS	Interlaboratory Study
MALDI-TOF	Matrix Assisted Laser Desorption/Ionization Time-Of-Flight (MALDI-TOF)
MS	Mass Spectrometry
MCS	Method Comparison Study
min	Minute
ml	Millilitre
MSP	Main Spectrum or Main Spectra
MVTC	MicroVal Technical Committee
ED	Exclusivity deviation
ID	Inclusivity deviation
EA	Exclusivity agreement
IA	Inclusivity agreement
NA	Negative agreement
ND	Negative deviation
NOIP	No organism identification possible
PA	Positive agreement
PD	Positive deviation
pos (+)	positive/growth/target detected
CCI	Cronobacter Chromohenic Isolation Agar
DFI	Brilliance Cronobacter Sakazakii Agar
HCCS	HardyCHROM Sakazakii Agar
TSA	Tryptic Soy Agar

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1 Introduction

The Autof ms1000 method is a mass spectrometer system using Matrix Assisted Laser Desorption/Ionization Time-of-Flight (MALDI-TOF) for the confirmation of isolated colonies of bacteria, yeasts, and molds from a variety of agar media. The technological principle of the Autof ms1000 is based on unique ribosomal protein patterns of microorganisms obtained via mass spectrometry. This type of mass spectrometry involves the use of a liquid matrix, commonly α-Cyano-4-hydroxycinnamic acid (CHCA). This technique is considered soft ionization because the matrix mediates the energy absorption to ionize the large analyte biomolecules with relatively no fragmentation or decomposition. The charged ions are accelerated by an electrostatic field that transmits a constant kinetic energy in the time-of-flight analyzer. The ions arrive at the detector based on their m/z (mass-to-charge ratio) and a spectrum is created.

The test organism's spectrum (measured mass peaks) is compared with a reference spectra library. The spectra library is a database of compiled m/z measurements based on one or more reference organisms. The Autof ms1000 system software determines a probability ranking of the organism identification based on the test spectrum results compared to the library results.

The MicroVal validation was based on ISO 16140-6:2019, and the MicroVal Technical Committee interpretation of ISO 16140-6 (TC 2022-069, V2.5). The evaluated the Autof ms1000 (software version 2.2.157) for the confirmation of *Cronobacter* spp. at the genus level. The following agars were evaluation during the valiation:

Selective Agars:

1.) Cronobacter Chromogenic Isolation Agar (CCI) — Thermo Scientific (Waltham, MA) Cat. No. CM1122B
2.) Brilliance Cronobacter Sakazakii Agar (DFI formulation) — Thermo Scientific (Waltham, MA) Cat. No. CM1055B
3.) HardyCHROM Sakazakii (HCCS) — Hardy Diagnostics (Santa Maria, CA) Cat. No. G315

Non-selective (Reference) Agar:

1.) Tryptic Soy Agar (TSA) – Hardy Diagnostics (Santa Maria, CA) Cat. No. G60

The evaluation was performed by Q Laboratories as the MicroVal Expert Laboratory and consisted of:

- Method Comparison Study (MCS)
- Interlaboratory Study (ILS)

1.1. Reference method:

All work was conducted using the confirmation steps as outlined in the following reference methods:

1.) ISO 22964:2017 Microbiology of food chain – Horizontal method for the detection of *Cronobacter* spp.

1.2. Alternative method:

A summary of the different agars and conditions that were evaluated for the confirmation of presumptive *Cronobacter* spp. colonies is listed below.

Agar	Incubation
Selective	
Cronobacter Chromogenic Isolation Agar (CCI) — Thermo Scientific (Waltham, MA) Cat. No. CM1122B	41.5 ± 1°C for 24 ± 2 h
Brilliance Cronobacter Sakazakii Agar (DFI formulation) — Thermo Scientific (Waltham, MA) Cat. No. CM1055B	35 – 37 °C for 24 h
HardyCHROM Sakazakii (HCCS) — Hardy Diagnostics (Santa Maria, CA) Cat. No. G315	35 ± 2°C for 24 ± 2 h
Non-selective (Reference)	**Incubation**
Tryptic Soy Agar (TSA) – Hardy Diagnostics (Santa Maria, CA) Cat. No. G60	35 ± 2°C for 24 ± 2 h

Microorganisms were identified from cultures isolated on an agar plate using the Autof ms1000 with three sample preparation procedures, which are presented in **Annex C** and include the following:

1.) Direct transfer procedure (DT method)
2.) Extended direct transfer procedure (eDT method)
3.) Extraction procedure (Ext method)

The DT method (sample preparation 1) was utilized for most bacteria isolates. If a ranking score below 9.000 was obtained from sample preparation 1 then the subsequent procedures, eDT method (sample preparation option 2) followed by Ext method (sample preparation option 3), were conducted until a score of 9.000 or above was obtained.

2 Method protocols

2.1 Reference method

See the flow diagram in **Annex A**.

2.2 Alternative method

See the flow diagram of the alternative method in **Annex B**.

2.2.1 Instrumentation and Workflow

The Autof ms1000 method is a mass spectrometer system using MALDI-TOF for the confirmation of isolated colonies of bacteria, yeasts, and molds from a variety of agar media. The technological principle is based on unique ribosomal protein patterns of microorganisms obtained via mass spectrometry. The test organism's spectrum (measured mass peaks) is compared with a reference spectra library. The spectra library is a database of compiled m/z measurements based on one or more reference organisms. The Autof ms1000 system software determines a probability ranking of the organism identification based on the test spectrum results compared to the library results. The probability ranking is represented as an identification score between 0.000 and 10.000 as summarized in **Table 1** below.

Table 1. Result probability ranking

Ranking	Interpretation
9.500 – 10.000	Reliable species and subspecies identification result
9.000 – 9.499	Reliable species identification result
6.000 – 8.999	Reliable genus identification result
0.000 – 5.999	Unreliable identification result

Sample preparations used in the alternative method were done according to the Autof ms100 kit insert as referenced in **Annex C** and include the following:

1.) DT method
2.) eDT method
3.) Ext method

The DT method (sample preparation 1) was utilized for most bacteria isolates. If a ranking score below 9.000 was obtained from sample preparation 1 then the subsequent procedures, eDT method (preparation option 2) followed by Ext method (preparation option 3), were conducted until a score of 9.000 or above was obtained.

2.2.2 Instrument Features and Software Library

The **Autof ms100** and **Autof Acquire** are dedicated instrument and software packages for microorganism identification based on MALDI-TOF MS profile spectra. The Autof Acquire software controls mass spectrometry data acquisition and matches acquired spectra against the database for final identification results. The software generates a report using score values.

The database contains 5,041 species, a total of 17,662 strains, in the product database covering most common food and environmental bacteria, fungi, and other microorganisms.

2.2.3 Calculation of Ranking Score and Interpretation

The Autof Acquirer software compares the spectrometry data acquired from an unknown sample and matches it against the database for final results. The result uses a score system from 0.000 to 10.000 for final interpretation as outlined in **Table 1** above.

2.2.4 Targets and Consumables

The samples can be spotted:

- Reusable 96 cell polished steel target slide

The following consumables are required:

- Matrix for the sample preparation.
- Calibrator, i.e. mass spectrometry calibration standard containing ribonuclease and protein extracted from *Escherichia coli*, which shows typical peptide and protein peaks in MALDI-TOF MS. **It is mandatory to get a valid calibrator control per run.**

Additionally, the reagent, Lysate 1 (60% formic acid) was used for the eDT method. Distilled water, ethyl alcohol, Lysate 1 (60% formic acid), and Lysate 2 (100% acetonitrile) was used for the Ext method.

2.3 Study design

Following the requirements of the ISO 16140-6:2019, and Annex A of ISO 16140-6:2019 a total of at least 150 different target strains were analyzed for inclusivity, and at least 100 different non-target strains were analyzed for exclusivity.

A complete list of the inclusivity and exclusivity strains evaluated are provided in **Annex D**.

3 Method comparison study

In the method comparison study (MCS), the alternative confirmation method results are compared to the results obtained through confirmation procedures outlined in the reference method for the specific group of microorganisms. The method comparison study consists of an inclusivity and exclusivity study of the alternative method.

3.1 Inclusivity and Exclusivity Study

3.1.1 Selection of Strains

A wide range of strains were used adhering to the requirements of ISO 16140-6:2019; and Annex A of ISO 16140-6:2019, to satisfy the claims for confirmation of ***Cronobacter* spp. at the genus level**. This included the following:

Inclusivity: at least 150 target strains representing a diversity of the genus

- *C. condimenti*
- *C. dublinensis* subsp. *dublinensis*
- *C. dublinensis* subsp. *lactaridi*
- *C. dublinensis* subsp. *lausannensis*
- *C. malonaticus*
- *C. muytjensii*
- *C. sakazakii*
- *C. turicensis*
- *C. universalis*
-

Exclusivity: at least 100 non-*Cronobacter* strains.

- A variety of closely related Gram-negative (GN) species including: *Franconibacter*, *Siccibacter*, and *Pluralibacter*, as these genera are closely related to *Cronobacter* and were recently separated taxonomically.
- Organisms likely to grow on the target agars.
- Organisms that may form suspect or interfering colonies on any of the media types.

A complete list of the inclusivity and exclusivity strains evaluated are provided in **Annex D**.

3.1.2 Strains Tested

All inclusivity and exclusivity strains were selected by considering the measurement principle of the alternative method. All inclusivity and exclusivity strains were isolated mostly from foods, feed, the food-processing environment, or from primary production in consideration of the scope of the validation. Clinical, environmental and culture collection strains were also used. The original source of the isolates were traceable and held in a local (e.g., expert laboratory), national or international culture collection enabling them to be used in future testing if required.

Highly characterized pure strains were used for confirmation procedures following the requirements as specified in ISO 22964:2017. Required previously generated data was already available for the reference confirmation procedure, therefore, it was not necessary to repeat the reference confirmation procedure with the alternative confirmation method for the MCS. The validation study was carried out using strains cultured from stock on a nonselective medium or stored on microbeads at -80°C.

3.1.3 Testing of Inclusivity Strains

A total of 150 *Cronobacter* spp. strains were tested at the genus level. Each strain was first recovered on a nonselective agar incubated at 35±1°C for 18-24 h (TSA, standard formulation), as well as on the following three selective agars:

- CCI - (Thermo Scientific (Waltham, MA) Cat. No. CM1122B) at 41.5±1°C for 24±2 h
- DFI - (Thermo Scientific (Waltham, MA) Cat. No. CM1055B) at 35-37°C for 24 h
- HCCS - (Hardy Diagnostics (Santa Maria, CA) Cat. No. G315) at 35±2°C for 24±2 h

From each selective agar and nonselective agar strains were analyzed by sample preparations used in the alternative method according to the Autof ms1000 kit insert as referenced in **Annex C** and included the following:

1.) DT method
2.) eDT method
3.) Ext method

The DT method (sample preparation 1) was utilized for most bacteria isolates. If the ranking score below 9.000 was obtained from sample preparation 1 then the subsequent procedures, eDT method (sample preparation option 2) followed by Ext method (sample preparation option 3), were conducted until a score of 9.000 or above was obtained. All three proposed methods were used to analyze five inclusivity isolates on one claimed agar (CCI) as per the decision of the MVTC.

3.1.4 Testing of Exclusivity Strains

A total of 100 non-target strains were tested at the genus level. Each strain was first recovered on a nonselective agar (TSA, standard formulation) at conditions optimal for growth. Organisms were also recovered on the three selective agars listed above (subsection 3.1.3 *Testing of Inclusivity Strains*).

Some of the strains from the exclusivity lists did not grow or showed characteristic colonies on the tested selective agars. The strains used in exclusivity testing that exhibited growth were tested as outlined above (subsection 3.1.3 *Testing of Inclusivity Strains*) to ensure there was no cross-reactivity with the chosen selective agar. The characteristics of the colonies are shown in the raw data in **Annex E**.

3.1.5 Data Discrepancy

In the case of discrepancies between the alternative and reference method, the strains were additionally confirmed by 16S rDNA sequencing. This was the case for some exclusivity strains, with one exclusivity deviation observed for confirmation of the target pathogen.

3.1.6 Summary of the Inclusivity and Exclusivity Testing

A summary of the tests conducted is provided in **Table 2** below. Only strains where colonies were present were tested.

Table 2. Summary of Tests Conducted

Target	Media Tested	Inclusivity	Exclusivity	Total
		Number of Tests	Number of Tests	
Cronobacter spp.	CCI	150	100	250
	DFI	150	100	250
	HCCS	150	100	250
	TSA	150	100	250
Total		600	400	1000

3.1.7 Expression and Interpretation of Results

All raw data for inclusivity and exclusivity testing is provided in **Annex E**. All inclusivity strains were confirmed as *Cronobacter* spp.

For the inclusivity strains, 150 strains were able to grow on the non-selective agar (TSA) and on all selective agars evaluated. For exclusivity strains, all strains were able to grow on the non-selective agar (TSA) out of 100 strains. However, no growth was observed for 9 out of 100 strains on CCI, 12 out of 100 strains on DFI, and 13 out of 100 strains on HCCS. This data is provided in **Annex E** as summarized in **Table 3** and **Table 4** below.

Table 3. Summary of Strains with No Growth

Media	Sample Number	Strain with Observed No Growth
CCI	401	*Acidovorax temperans* Q Labs QL21274-1
	402	*Acinetobacter calcoaceticus* ATCC 23055
	409	*Brevundimonas mediterranea* Q Labs QL 0692733.2
	410	*Brevundimonas vesicularis* Q Labs QL 0695864.9
	437	*Flavobacterium hydatis* NRRL B-14732
	438	*Flavobacterium johnsoniae* NRRL B-14733
	439	*Flavobacterium aquatile* NRRL B-14842
	440	*Flavobacterium saccharophilum/piscis* Q Labs QL 0694946.3a
	493	*Shewanella baltica* NRRL B-41146
DFI	401	*Acidovorax temperans* Q Labs QL21274-1
	402	*Acinetobacter calcoaceticus* ATCC 23055
	409	*Brevundimonas mediterranea* Q Labs QL 0692733.2
	410	*Brevundimonas vesicularis* Q Labs QL 0695864.9
	427	*Edwardsiella tarda* Q Labs QL 021111D
	428	*Edwardsiella tarda* Q Labs QL 11007-11
	436	*Escherichia fergusonii* ATCC 35469
	437	*Flavobacterium hydatis* NRRL B-14732
	438	*Flavobacterium johnsoniae* NRRL B-14733
	439	*Flavobacterium aquatile* NRRL B-14842
	440	*Flavobacterium saccharophilum/piscis* Q Labs QL 0694946.3a
	493	*Shewanella baltica* NRRL B-41146

Table 3. Summary of Strains with No Growth Continued

Media	Sample Number	Strain with Observed No Growth
HCCS	401	*Acidovorax temperans* Q Labs QL21274-1
	402	*Acinetobacter calcoaceticus* ATCC 23055
	404	*Acinetobacter junii* Q Labs QL 0696826.1
	409	*Brevundimonas mediterranea* Q Labs QL 0692733.2
	410	*Brevundimonas vesicularis* Q Labs QL 0695864.9
	424	*Dickeya chrysanthemi* CCUG 47021
	437	*Flavobacterium hydatis* NRRL B-14732
	438	*Flavobacterium johnsoniae* NRRL B-14733
	439	*Flavobacterium aquatile* NRRL B-14842
	440	*Flavobacterium saccharophilum/piscis* Q Labs QL 0694946.3a
	482	*Roseomonas mucosa* Q Labs QL 0695267.6c
	493	*Shewanella baltica* NRRL B-41146
	494	*Shewanella putrefaciens* NRRL B-951

For exclusivity strains where growth was observed, a total of one exclusivity strain was confirmed as *Cronobacter* spp. These results are provided in **Annex E** and summarized in **Table 6** below**.**

A summary of growth for inclusivity and exclusivity testing is provided in **Table 4**.

Table 4. Summary of Observed Culture Growth

Study	Media	Number of Strains with ***Characteristic*** Growth	Number of Strains with ***Non-Characteristic*** Growth	Number of Strains with ***No*** Growth
Inclusivity	CCI	150/150	0/150	0/150
	DFI	150/150	0/150	0/150
	HCCS	150/150	0/150	0/150
	TSA	150/150	0/150	0/150
Exclusivity	CCI	11/100	80/100	9/100
	DFI	10/100	78/100	12/100
	HCCS	12/100	75/100	13/100
	TSA	100/100	0 /100	0/100

For inclusivity strains, the DT method confirmed 597 strains, the eDT confirmed 3 strains, and the Ext method confirmed zero strains at the genus level. All three proposed methods were used to analyze five inclusivity isolates on one claimed agar (CCI) as per the decision of the MVTC. For the exclusivity strains, the DT method confirmed 348 strains, the eDT confirmed 11 strains, and the Ext method confirmed 7 strains. A summary of results obtained by each method is provided in **Table 5** below.

Table 5. Summary of the Method Used for Identification for Inclusivity and Exclusivity

Study	Media	Number of Strains with No Growth	Number of Strains with Growth		
			DT Method	***eDT Method***	***Ext Method***
Inclusivity	CCI	0	150[a]	0 (5)[a]	0 (5)[a]
	DFI	0	148	2	0
	HCCS	0	149	1	0
	TSA	0	150	0	0
	Total	0	597	3 (5)[a]	0 (5)[a]
			Overall Total 600 (610)[a]		
	Percentage		**99.5%[a]**	**1.3%[a]**	**0.8%[a]**
Exclusivity	CCI	9	88	1	2
	DFI	12	85	3	0
	HCCS	13	84	0	3
	TSA	0	91	7	2
	Total	34	348	11	7
			Overall Total 366		
	Percentage		**95.1%**	**3.0%**	**1.9%**

[a] *A total of 5 isolates were identified using all preparation methods based on the MVTC decision*

3.1.8 Discrepancies

No discrepancies were observed for inclusivity strains, and all strains were confirmed at the genus level as *Cronobacter* spp. for all agars evaluated.

A total of 26 exclusivity disagreements were observed as outlined in **Table 6** below. A total of 25 out of the 26 strains did not confirm as the target strain at the genus or species level, and therefore only one exclusivity deviation (ED) was observed for *Franconibacter pulveris*. These strains were characterized by 16S rDNA sequencing to verify the original identity of the strain. The majority of the disagreements were correctly confirmed to the genus level. The lack of species level confirmation was mainly due to lack of spectra in the software library. It is often a challenge to adequately differentiate between *Cronobacter, Franconibacter*, and *Siccibacter* isolates at the species level and reliance on these methods may result in misidentifications without the use of WGS as a determination.

Following the completion of the MCS and ILS evaluations, an update to the database was released as version V.1.1.23, with the addition of 26 spectra including 12 *Franconibacter* strains to improve the specificity of the alternative method to allow for better rank scores and improve the selectivity of the method. As a result, the *Franconibacter pulveris* strain that previously confirmed as Cronobacter was correctly excluded on all three agars.

Table 6. Observed Exclusivity Disagreements

Original Strain Identification	Identification with the Autof ms1000	Identification with 16S rDNA Sequencing	Conclusion	Database Version
Acinetobacter calcoaceticus ATCC 23055	*Acinetobacter baumannii* complex	*Acinetobacter calcoaceticus*	*Acinetobacter baumannii* complex includes *A. baumannii*, *A. pittii*, *A. nosocomialis*, and *A. calcoaceticus*. The Autof ms1000 gives the correct identification in most cases to the genus level.	V2.0.196 and V1.1.23
Acinetobacter baumannii CCUG 70743		*Acinetobacter baumannii*		
Aeromonas caviae CCUG 57693	*Aeromonas caviae/hydrophila*	*Aeromonas caviae*	Correct identification obtained in some cases. Confirmation of *Aeromonas* to the species level usually requires additional biochemical confirmation or whole genome sequencing.	
Brevundimonas mediterranea QL 0692733.2	*Brevundimonas* spp.	*Brevundimonas mediterranea*	Correct to the genus level, with lack of species level confirmation due to limited spectra in the software library. Unable to form precise conclusion.	
Buttiauxella agrestis CCUG 21133	*Buttiauxella* spp.	*Buttiauxella agrestis*	Correct to the genus level, with lack of species level confirmation due to lack of strain specific spectra in the software library.	
Citrobacter youngae ATCC 11102	*Citrobacter freundii* complex	*Citrobacter youngae*	*Citrobacter freundii* complex includes *C. braakii, C. freundii, C. gillenii, C. murliniae, C. portucalensis, C. sedlakii*, and *C. youngae*. The Autof ms1000 gives the correct identification in most cases to the genus level. Confirmation of *Citrobacter* to the species level usually requires additional biochemical confirmation or whole genome sequencing.	
Citrobacter koseri ATCC 27156		*Citrobacter koseri*		
Citrobacter braakii ATCC 43162		*Citrobacter braakii*		
Citrobacter farmeri ATCC 51633		*Citrobacter farmeri*		
Citrobacter freundii QL 11007-10		*Citrobacter freundii*		
Edwardsiella tarda QL 021111D	*Edwardsiella* spp., and correct in some cases	*Edwardsiella tarda*	Correct to the genus level, with lack of species level confirmation due to limited spectra in the software library. Unable to form precise conclusion.	
Edwardsiella tarda QL 11007-11		*Edwardsiella tarda*		
Enterobacter hormaechei CCUG 63314	*Enterobacter cloacae* complex	*Enterobacter hormaechei*	The *Enterobacter cloacae* complex includes *E. asburiae*, *E. cancerogenus*, *E. cloacae*, *E. cowanii*, *E. hormaechei*, *E. kobei*, *E. ludwigii*, *E. mori*, *E. nimipressuralis*, and *E. coli* The Autof ms1000 gives the correct identification in most cases to the genus level. Confirmation of *Enterobacter* to the species level usually requires additional biochemical confirmation or whole genome sequencing.	
Enterobacter cancerogenus QL 11010-1		*Enterobacter cancerogenus*		
Enterobacter cloacae ATCC 23355		*Enterobacter cloacae*		
Enterobacter amnigenus QL 112413-2	*Lelliottia amnigena*	*Enterobacter amnigenus*	Unable to form precise conclusion. Recent literature has identified *Lelliottia amnigena* as a distinct species formerly classified as *Enterobacter*.	
Escherichia fergusonii ATCC 35469	*Escherichia* spp.	*Escherichia fergusonii*	Correct to the genus level, with lack of species level confirmation due to limited spectra in the software library.	
Flavobacterium aquatile NRRL B-14842	*Flavobacterium* spp.	*Flavobacterium aquatile*	Correct to the genus level, with lack of species level confirmation due to limited spectra in the software library.	
Flavobacterium saccharophilum QL 0694946.3a		*Flavobacterium saccharophilum*		
Klebsiella variicola CCUG 73431	*Klebsiella* spp.	*Klebsiella variicola*	Correct to the genus level, with lack of species level confirmation due to limited spectra in the software library.	
Pseudomonas fluorescens QL 17041-3	*Pseudomonas fluorescens* group	*Pseudomonas fluorescens*	The *Pseudomonas fluorescens* group consists of over 20 different *Pseudomonas* spp. Autof ms1000 gives the correct identification in most cases to the genus level. Confirmation of *Pseudomonas* to the species level usually requires additional biochemical confirmation or whole genome sequencing.	
Pseudomonas gessardii QL 17041-12		*Pseudomonas gessardii*		

Table 6. Observed Exclusivity Disagreements Continued

Original Identification of the strain(s)	Identification with the Autof ms1000	Identification with 16S rDNA Sequencing	Conclusion	Database Version
Shewanella putrefaciens NRRL B-951	*Shewanella* spp.	*Shewanella putrefaciens*	Correct to the genus level, with lack of species level confirmation due to limited spectra in the software library.	V2.0.196 and V1.1.23
Franconibacter helveticus QL 17031.10	*Franconibacter pulveris*	*Franconibacter helveticus*	Correct to the genus level, with lack of species level confirmation due to limited spectra in the software library.	
Franconibacter helveticus QL 17031.9	*Franconibacter pulveris*	*Franconibacter helveticus*	Correct to the genus level, with lack of species level confirmation due to limited spectra in the software library.	
Franconibacter pulveris[a] QL 17031.11	*Cronobacter* spp.	*Franconibacter pulveris*	Limited representative strains in the software library. It has been recognized that the sequencing of housekeeping genes such as *rpo*, or even in that case whole genome sequencing, is required to differentiate the closely related strains of *Siccibacter* spp., *Franconibacter* spp., *Cronobacter* spp., and *Enterobacter* spp.	V2.0.196 (result resolved with V1.1.23)

[a]All exclusivity disagreements for the strain *Franconibacter pulveris* QL 17031.11 were resolved following the database update which included 12 additional Franconibacter strains. The updated database confirmed this isolate as *Franconibacter daqui*.

Agreement between methods	Correct in some cases	Disagreement between methods	Not possible to conclude

3.1.9 Final Evaluation

For each agar evaluated, the results were tabulated and included in the final interpretation as outlined in ISO 16140-6:2019. Any discrepancies were investigated, and an explanation is provided in the tabulated results. The results for both inclusivity and exclusivity for the study were summarized based on the final interpretations. The Autof ms only confirms *Cronobacter* to the genus level. Summarized results are presented in **Table 5** and **Table 6** above as well as the raw data in **Annex E**.

The summarized results were be used in accordance with the acceptability limit (AL) requirement given in ISO 16140-6:2019 as outlined below:

Inclusivity: ID ≤ AL, where ID is an inclusivity deviation

Exclusivity: ED ≤ AL, where ED is an exclusivity deviation

3.1.10 Expression of Results

The summary and analysis of the inclusivity and exclusivity Method Comparison Study according to ISO 16140-6:2016 is given in **Table 7.1** below for the original results. Table **7.2** summarizes the results following the database update.

Table 7 Summary of Analysis of Results with Database Version V2.0.196

Media	Testing Strains	Number of Strains	IA	ID	EA[1]	ED	AL[2]
CCI	Inclusivity	150	150	0	Not Applicable	Not Applicable	1
	Exclusivity	100	Not Applicable	Not Applicable	87	1	2
DFI	Inclusivity	150	150	0	Not Applicable	Not Applicable	1
	Exclusivity	100	Not Applicable	Not Applicable	84	1	2
HCCS	Inclusivity	150	150	0	Not Applicable	Not Applicable	1
	Exclusivity	100	Not Applicable	Not Applicable	82	1	2
TSA	Inclusivity	150	150	0	Not Applicable	Not Applicable	1
	Exclusivity	100	Not Applicable	Not Applicable	95	1	2

[1] Studies with N<100 are due to no growth. [2] AL for genus level identification.

Table 7.2 Summary of Analysis of Results with Database Version V1.1.23

Media	Testing Strains	Number of Strains	IA	ID	EA[1]	ED	AL[2]
CCI	Inclusivity	150	150	0	Not Applicable	Not Applicable	1
	Exclusivity	100	Not Applicable	Not Applicable	88	0	2
DFI	Inclusivity	150	150	0	Not Applicable	Not Applicable	1
	Exclusivity	100	Not Applicable	Not Applicable	85	0	2
HCCS	Inclusivity	150	150	0	Not Applicable	Not Applicable	1
	Exclusivity	100	Not Applicable	Not Applicable	83	0	2
TSA	Inclusivity	150	150	0	Not Applicable	Not Applicable	1
	Exclusivity	100	Not Applicable	Not Applicable	96	0	2

[1] Studies with N<100 are due to no growth. [2] AL for genus level identification.

For the Inclusivity ID was ≤ AL. For the exclusivity ED was ≤ AL for all agars evaluated.

4 Interlaboratory Study

4.1 Protocol and Materials

A total of 16 participants participated in the Interlaboratory Study. Two participants did not receive their samples due to customs issues and were excluded from the evaluation. Each participant received 16 target strains and 8 non-target strains. For the inclusivity and exclusivity studies, pure cultures of all strains were tested with the reference confirmation procedure and with the alternative confirmation method. The list of target and non-target strains tested is provided in **Annex F**.

The strains were propagated onto Tryptic Soy Agar (TSA) with 5 % sheep blood (SBA) from Q Laboratories' frozen stock cultures stored at -80°C. Each organism was incubated for 24 - 48 hours at temperatures and atmospheric conditions most appropriate for organism growth. Isolated colonies were streaked to TSA plates and incubated under proper conditions for optimal growth prior to being shipped to each site. All samples were labelled with a randomized, blind-coded 3-digit number affixed to the TSA plate.

4.2 Transport

Isolates were shipped on Friday 17 January 2025 via overnight delivery according to the Category B Dangerous Good Shipment regulations by the International Air Transport Association (IATA). The UN3373 package used for shipment included a primary receptacle that included the isolate and a secondary package that encapsulated the primary receptacle. Upon receipt, samples were held by the collaborator at refrigerated temperature (2 - 8°C) until the following Tuesday when analysis was initiated. All packages were delivered in good condition according to **Tables 8 and 9** below.

Table 8 - Package Receipt and Analysis Date

Participant	Receipt date	Analysis date
A	1-20-25	1-30-25
B	1-20-25	1-30-25
C	1-20-25	1-20-25
D	1-20-25	1-20-25
E	1-21-25	1-22-25
F	1-21-25	1-23-25
G	1-21-25	1-23-25
H	1-21-25	1-22-25
I	1-31-25	2-3-25
J[1]	N/A	N/A
K	1-20-25	1-29-25
L[1]	N/A	N/A
M	1-27-25	1-27-25
N	1-23-25	1-28-25
O	1-20-25	1-22-25
P	1-21-25	1-22-25

[1]Participant shipment did not clear customs and were not able to complete testing.

Table 9. Temperature Data by Laboratory

Participant	Temperature Data (°C)
A	0.3
B	0.4
C	2.5
D	2.0
E	2.6
F	3.0
G	3.3
H	0.3
I	5.6
J[1]	N/A
K	3.5
L[1]	N/A
M	6.1
N	2.2
O	0.5
P	2.5

[1]Participant shipment did not clear customs and were not able to complete testing.

4.3 Analysis

The participants and the Expert Laboratory tested the blind coded strains as described in **Annex G**. Each collaborator streaked the blind coded target and non-target strains onto a non-selective (TSA) and selective agar plates before applying the alternative MALDI-TOF Confirmation Procedure (CCI, HardyCHROM Sakazakii). All the strains were also tested using the ISO standard procedures from the non-selective agar plate (TSA).

4.4 Expression of Results

All agars were kept for all 14 participants in the study. A summary of the results and discrepant results are given in **Tables 10-17**.

A summary of the results used for the interpretation are given **Table 10** for TSA, **Table 11** for CCI and **Table 12** for HardyCHROM Sakazakii.

Table 10. **Summary of the Results Obtained for TSA**

	TSA			
	Number of Inclusivity Strains Correctly Confirmed		**Number of Exclusivity Strains Correctly Non-confirmed**	
Participants	Reference Confirmation Procedure	Alternative Confirmation Procedure	Reference Confirmation Procedure	Alternative confirmation method
A	16/16	16/16	8/8	8/8
B	16/16	16/16	8/8	8/8
C	16/16	16/16	8/8	8/8
D	16/16	16/16	8/8	7/8
E	16/16	16/16	8/8	8/8
F	15/16	16/16	8/8	8/8
G	15/16	16/16	8/8	8/8
H	15/16	16/16	8/8	8/8
I	16/16	16/16	8/8	8/8
K	16/16	16/16	7/8	8/8
M	16/16	16/16	8/8	8/8
N	16/16	16/16	8/8	8/8
O	16/16	16/16	8/8	8/8
P	16/16	16/16	8/8	8/8
TOTAL	**221/224**	**224/224**	**111/112**	**111/112**
14 labs	**221/224**	**224/224**	**111/112**	**111/112**

Table 11. Summary of the Results Obtained for CCI

Collaborators	CCI	
	Number of Inclusivity Strains Correctly Confirmed (PA)	**Number of Exclusivity Strains Correctly Non-confirmed (NA)**
	Alternative confirmation method	Alternative confirmation method
A	16/16	8/8
B	16/16	8/8
C	16/16	8/8
D	16/16	7/8
E	16/16	8/8
F	16/16	8/8
G	16/16	8/8 (including 4 NA no growth)
H	16/16	8/8
I	16/16	8/8
K	16/16	8/8
M	16/16	8/8
N	16/16	8/8
O	16/16	8/8
P	16/16	8/8
TOTAL	**224/224**	**111/112**
14 labs	**224/224**	**111/112**

Table 12. Summary of the results obtained for HardyCHROM Sakazakii

Collaborators	HardyCHROM Sakazakii	
	Number of Inclusivity Strains Correctly Confirmed (PA)	**Number of Exclusivity Strains Correctly Non-confirmed (NA)**
	Alternative confirmation method	Alternative confirmation method
A	15/16 1 NO GROWTH	8/8
B	16/16	8/8
C	16/16	8/8
D	16/16	8/8
E	16/16	8/8
F	16/16	8/8
G	15/16 1 NO GROWTH	8/8
H	16/16	8/8
I	16/16	7/8[a]
K	16/16	8/8
M	16/16	8/8
N	16/16	8/8
O	16/16	8/8
P	16/16	8/8
TOTAL	**222/224**	**111/112**
14 labs	**222/224**	**111/112**

[a] Following a database update, the result has been updated to 8/8 and the total number of exclusivity strains correctly non-confirmed is 112/112.

Table 13. Discrepant Results for the Participants with Database version V2.0.196

Participant	Agar	Result	Comments
A	HardyCHROM Sakazakii	No Growth	Samples were repicked from the original sample plate twice and both times observed no growth
D	TSA	*Cronobacter spp.*	The alternative method identified the exclusivity organism *Franconibacter helveticus* as *Cronobacter* spp.
D	CCI	*Cronobacter spp.*	The alternative method identified the exclusivity organism *Franconibacter helveticus* as *Cronobacter* spp.
F	TSA	*Citrobacter koseri*	The reference method identified the inclusivity organism *Cronobacter* spp./*Citrobacter koseri.*
G	TSA	*Serratia odorifera*	The reference method identified the inclusivity organism *Cronobacter* spp./*Serratia odorifera.*
G	HardyCHROM Sakazakii	No Growth	Samples were repicked from the original sample plate and both times observed no growth
H	TSA	*Enterobacter aerogenes*	The reference method identified the inclusivity organism *Cronobacte*r spp. as *Enterobacter aerogenes.*
I	HardyCHROM Sakazakii	*Cronobacter spp.*	The alternative method identified the exclusivity organism *Franconibacter helveticus* as *Cronobacter* spp.
K	TSA	*Cronobacter sakazakii*	The reference method identified the exclusivity organism *Franconibacter helveticus* as *Cronobacter* spp.

Table 13.2 Discrepant Results for the Participants with database version V1.1.23

Participant	Agar	Result	Comments
A	HardyCHROM Sakazakii	No Growth	Samples were repicked from the original sample plate twice and both times observed no growth
D	TSA	*Cronobacter spp.*	The alternative method identified the exclusivity organism *Franconibacter helveticus* as *Cronobacter* spp.

D	CCI	*Cronobacter spp.*	The alternative method identified the exclusivity organism *Franconibacter helveticus* as *Cronobacter* spp.
F	TSA	*Citrobacter koseri*	The reference method identified the inclusivity organism *Cronobacter* spp./*Citrobacter koseri.*
G	TSA	*Serratia odorifera*	The reference method identified the inclusivity organism *Cronobacter* spp./*Serratia odorifera.*
G	HardyCHROM Sakazakii	No Growth	Samples were repicked from the original sample plate and both times observed no growth
H	TSA	*Enterobacter aerogenes*	The reference method identified the inclusivity organism *Cronobacte*r spp. as *Enterobacter aerogenes.*
K	TSA	*Cronobacter sakazakii*	The reference method identified the exclusivity organism *Franconibacter helveticus* as *Cronobacter* spp.

4.5 Interpretation and Evaluation

The results of the interlaboratory study are summarized in **Tables 14 and 16** and the results evaluated according to the acceptability limits (AL) are given in **Tables 15 and 17**.

Upon initial review of the participant data, 11 labs had difficulty obtaining a result for the exclusivity strain, *Franconibacter helveticus.* The spectra files were requested to initiate a root cause investigation. Further discussions with the participants indicated that they did not have the proper database setting turned on within the software that contain the additional spectra for this organism that is commonly confirmed inaccurately as *Cronobacter* spp. Reanalysis of the spectra using the appropriate settings resolved all of these discrepant results except for isolates from three agars.

During both the MCS and ILS studies, a limited number of *Franconibacte*r isolates were available for inclusion in the MALDI-ToF library for the alternative method which likely led to the misidentifications and, consequently, false positive confirmations for *Cronobacter* spp. Additional confirmatory biochemical testing may be required for confirmation in these cases. Following the completion of the ILS study, an update to the database was released (V1.1.23) and additional spectra were added to improve the specificity of the alternative method following the validation study. A reanalysis of the spectra from each participating laboratory resulted in resolution of all exclusivity deviations, except for one laboratory, Lab D. Based on the interpretation of the spectra provided by this participant, the Method Developer concluded that the pattern is highly indicative of a preparation-related issue—most likely insufficient extraction, poor colony quality, or suboptimal matrix crystallization. These factors reduce the complexity and clarity of the spectrum, making reliable identification impossible. As a result, the system attempts to match the degraded spectrum to the closest available profile, which in this case is often *Cronobacter*, due to overlapping mass regions. Table 13.2 above summarizes the discrepancies following the reanalyzed spectra in the updated database.

Additionally, the ISO reference method produced a total of 4 discrepant results during the ILS study where two inclusivity strains produced a slash line result (*Cronobacter* spp and another genus), one inclusivity strain was a different genus and species and one exclusivity strain was confirmed as *Cronobacter* spp. It was observed that the use of biochemical galleries, including API 20E or VITEK 2 GN did not provide reliable results as the confidence percentages were at 0%, requiring additional tests, or below the acceptable identification confidence limit of 80%, as specified in the IFU for both methods. These results further support the challenges associated with proper confirmation and differentiation of *Franconibacter* and *Cronobacter* and additional confirmatory tests may be done to obtain a final confirmed result. A summary and interpretation of the reference method results in are provided in Table 16 and 17 below.

See Table **14-17** below for additional details. See Tables **14.2** and **15.2** for the summary of results from the updated database.

Table 14. Summary of the Autof ms1000 Results in the Interlaboratory Study with Database Version V2.0.196

Media Tested	Number of Collaborators	Study	N	IA	ID	EA	ED
Non-selective Agar	14	Inclusivity	224	224	1	Not Applicable	Not Applicable
	14	Exclusivity	112	Not Applicable	Not Applicable	111	1
CCI	14	Inclusivity	224	224	0	Not Applicable	Not Applicable
	14	Exclusivity	112	Not Applicable	Not Applicable	111	1
HardyCHROM Sakazakii	14	Inclusivity	224	222	2	Not Applicable	Not Applicable
	14	Exclusivity	112	Not Applicable	Not Applicable	111	1

Table 14.2 Summary of the Autof ms1000 Results in the Interlaboratory Study with Database Version V1.1.23

Media Tested	Number of Collaborators	Study	N	IA	ID	EA	ED
Non-selective Agar	14	Inclusivity	224	224	0	Not Applicable	Not Applicable
	14	Exclusivity	112	Not Applicable	Not Applicable	111	1
CCI	14	Inclusivity	224	224	0	Not Applicable	Not Applicable
	14	Exclusivity	112	Not Applicable	Not Applicable	111	1
HardyCHROM Sakazakii	14	Inclusivity	224	222	2	Not Applicable	Not Applicable
	14	Exclusivity	112	Not Applicable	Not Applicable	112	0

Table 15. Interpretation of the Autof ms1000 Interlaboratory Study Results with Database Version V2.0.196

Media Tested	Number of Collaborators	Study	N	AL	ID	ID≤AL	ED	ED≤AL	Evaluation
Non-selective Agar	14	Inclusivity	224	3	1	0≤3	Not Applicable	Not Applicable	Accepted
	14	Exclusivity	112	3	Not Applicable	Not Applicable	1	1≤3	Accepted
CCI	14	Inclusivity	224	3	0	0≤3	Not Applicable	Not Applicable	Accepted
	14	Exclusivity	112	3	Not Applicable	Not Applicable	1	1≤3	Accepted
HardyCHROM Sakazakii	14	Inclusivity	224	3	2	2≤3	Not Applicable	Not Applicable	Accepted
	14	Exclusivity	112	3	Not Applicable	Not Applicable	1	0≤3	Accepted

Table 15.2 Interpretation of the Autof ms1000 Interlaboratory Study Results with Database Version V1.1.23

Media Tested	Number of Collaborators	Study	N	AL	ID	ID≤AL	ED	ED≤AL	Evaluation
Non-selective Agar	14	Inclusivity	224	3	0	0≤3	Not Applicable	Not Applicable	Accepted
	14	Exclusivity	112	3	Not Applicable	Not Applicable	1	1≤3	Accepted
CCI	14	Inclusivity	224	3	0	0≤3	Not Applicable	Not Applicable	Accepted
	14	Exclusivity	112	3	Not Applicable	Not Applicable	1	1≤3	Accepted
HardyCHROM Sakazakii	14	Inclusivity	224	3	2	2≤3	Not Applicable	Not Applicable	Accepted
	14	Exclusivity	112	3	Not Applicable	Not Applicable	0	1≤3	Accepted

For the Inclusivity ID was ≤ AL and for exclusivity ED ≤ AL for all agars evaluated.

Table 16. Summary of the Reference Method results in the Interlaboratory Study

Media Tested	Number of Collaborators	Study	N	IA	ID	EA	ED
Non-selective Agar	14	Inclusivity	224	221	3	Not Applicable	Not Applicable
	14	Exclusivity	112	Not Applicable	Not Applicable	111	1

Table 17. Interpretation of the Reference Method Interlaboratory Study Results

Media Tested	Number of Collaborators	Study	N	AL	ID	ID≤AL	ED	ED≤AL	Evaluation
Non-selective Agar	14	Inclusivity	224	3	3	3≤3	Not Applicable	Not Applicable	Accepted
	14	Exclusivity	112	3	Not Applicable	Not Applicable	1	1≤3	Accepted

For the Inclusivity ID was ≤ AL and for exclusivity ED ≤ AL for all agars evaluated

5 Conclusions

Method Comparison Study:

For the Inclusivity ID was ≤ AL of 1 for all target strains analyzed. For the exclusivity ED was ≤ AL of 2 for all agars.

The alternative confirmation method utilizing 3 selective agars: Cronobacter Chromogenic Isolation Agar (CCI), Brilliance Cronobacter Sakazakii Agar (DFI formulation), and HardyCHROM Sakazakii (HCCS) is selective and specific for the incubation times evaluated.

All inclusivity strains were accurately detected, and a total of 99/100 strains were accurately excluded. One exclusivity deviation was observed for *Franconibacter pulveris*, a closely related genus to *Cronobacter*. With this the 1 observed ED, the AL of 2 met for the exclusivity acceptance criteria.

After the database update, the one exclusivity deviation was resolved.

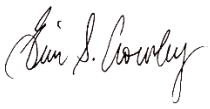
Interlaboratory Study:

The AL was met for the three tested media during the interlaboratory study (TSA, CCI, HardyCHROM Sakazakii), as the value for ID for the inclusivity study were lower than the AL, as well as the value for ED for the exclusivity study.

The data and interpretation confirm the reliability and robustness of the Autof ms as a confirmation method for *Cronobacter* spp from isolated colonies.

On the 7 October 2025

I attest to the validation of the verification and the conformity of the report, both the opinion and interpretation. I attest to the validation of the results of the analysis carried out were under A2LA accreditation.

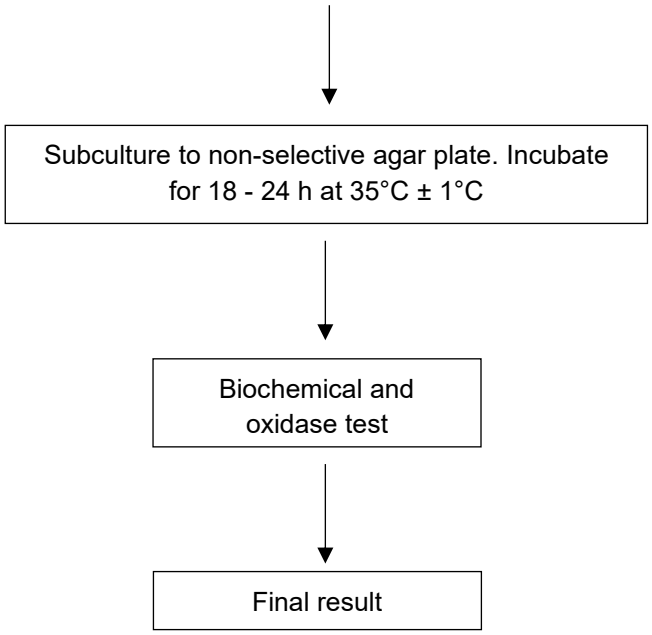


Erin S. Crowley; Chief Scientific Officer, Q Laboratories

ANNEX A: Flow Diagram of the Reference Method

Propagation of known isolate culture to agars according to:

Agar	Incubation
Selective	
Cronobacter Chromogenic Isolation Agar (CCI) — Thermo Scientific (Waltham, MA) Cat. No. CM1122B	41.5 ± 1°C for 24 ± 2 h
Brilliance Cronobacter Sakazakii Agar (DFI formulation) — Thermo Scientific (Waltham, MA) Cat. No. CM1055B	35 – 37 °C for 24 h
HardyCHROM Sakazakii (HCCS) — Hardy Diagnostics (Santa Maria, CA) Cat. No. G315	35 ± 2°C for 24 ± 2 h
Non – Selective (Reference)	**Incubation**
Tryptic Soy Agar (TSA) – Hardy Diagnostics (Santa Maria, CA) Cat. No. G60	35 ± 2°C for 24 ± 2 h



ANNEX B: Flow Diagram of the Alternative Method

Propagation of known isolate culture to agars according to:

Agar	Incubation
Selective	
Cronobacter Chromogenic Isolation Agar (CCI) — Thermo Scientific (Waltham, MA) Cat. No. CM1122B	41.5 ± 1°C for 24 ± 2 h
Brilliance Cronobacter Sakazakii Agar (DFI formulation) — Thermo Scientific (Waltham, MA) Cat. No. CM1055B	35 – 37 °C for 24 h
HardyCHROM Sakazakii (HCCS) — Hardy Diagnostics (Santa Maria, CA) Cat. No. G315	35 ± 2°C for 24 ± 2 h
Non-selective (Reference)	**Incubation**
Tryptic Soy Agar (TSA) – Hardy Diagnostics (Santa Maria, CA) Cat. No. G60	35 ± 2°C for 24 ± 2 h

1) Conduct the Direct Transfer (**DT**) Method[1]:

Smear one well-isolated characteristic colony directly to the sample spot on the target plate.

2.) Conduct the Extended Direct Transfer (**eDT**) method[1]:

Smear one well isolated characteristic colony directly to the sample spot on the target plate.

Overlay the sample spot with 1 µL of Lysate 1. Allow to dry.

3.) Conduct the Extraction (**Ext**) method[1]:

Add 1 µL loopful of organism growth into 300 µL of sterile distilled water and vortex.

Add 900 µL ethyl alcohol absolute to the tube and vortex. Centrifuge at 13,000 rpm (12,500 × g) for 2-4 minutes.

Remove as much supernatant as possible without disturbing the pellet. Dry pellet at 37-40°C for 2-5 minutes. Add 10 µL of Lysate 1 to the tube and vortex. Then add 10 µL of Lysate 2 to the tube and vortex. Centrifuge at 13,000 rpm (12,500 × g) for 2-4 minutes.

Pipette 1 µL of supernatant onto the sample spot on the target plate. Allow to dry.

Overlay the sample spot with 1 µL of Matrix. Allow to dry.

Analyze using Autof ms1000, Version 2.2.157

[1] The DT method (sample preparation 1) was utilized for most bacteria isolates. If a ranking score below 9.000 was obtained from sample preparation 1 then each of the subsequent procedures, eDT method (preparation option 2) followed by Ext method (preparation option 3), was conducted until a score of 9.000 or above is obtained. All three proposed preparation methods were used to analyze five inclusivity isolates from one of the claimed agars.

ANNEX C: Alternative Method Technical Product Information

See separate attachment for Complete Instructions for Use

4.3 Sample Target Plate Preparation

4.3.1 Sample Requirement

The organism intended for identification by Autof ms1000 must be taken from a colony-forming unit (CFU) from solid agar medium, ideally the organism is isolated in a pure culture. Non-selective and selective media may be utilized.

Prepare bacterial isolates by the Direct Transfer (DT) method. If results are unreliable (Identification Score <6.0), repeat the analysis using the Extended Direct Transfer (eDT) method. If results are still unreliable (Identification Score <6.0), repeat the analysis using the Gram Positive Bacilli (GPB) method for Gram-positive bacilli or the Extraction (Ext) method.

Prepare yeast isolates by the eDT method. If the results are unreliable (Identification Score <6.0), repeat the analysis using the Ext method.

Prepare filamentous fungi (mold) isolates by the filamentous fungi method. If the results are unreliable (Identification Score <6.0), repeat the analysis using the Ext method. *Note*: Once sample preparation is started, testing should be completed within 2 hours.

Medium selection: It is recommended to use a common non-selective medium for microbiology laboratory use.

Non-selective and selective media specific to the microorganisms from validations or certifications may be utilized.

NOTE:

Pretreatment reagents should be mass spectrometry grade.

4.3.2 Sample Preparation System

4.3.2.1 Treatment Method of Common Bacteria

1) **Direct Transfer Method**
   a. Touch one isolated colony with a needle.
      - Note: If too much of the colony growth is applied, the matrix will not mix well with the organism.
   b. Smear microorganism onto a sample spot on the target plate.
      - Note: Ensure there is a visible smear of the colony on the target plate spot.
   c. Overlay the sample spot with 1 µL of matrix solution and dry at room temperature.
      - Note: Once dried, the sample may exhibit a metallic sheen.
   d. Test the sample with the Autof ms1000.

2) **Extended Direct Transfer Method**
   a. Touch one isolated colony with a needle.
      - Note: If too much of the colony growth is applied, the matrix will not mix well with the organism.
   b. Smear microorganism onto a sample spot on the target plate.
      - Note: Ensure there is a visible smear of the colony on the target plate spot.
   c. Overlay the sample spot with 1 µL Lysate 1 (60% formic acid) and dry at room temperature.
   d. Overlay the sample spot with 1 µL of matrix solution and dry at room temperature.
      - Note: Once dried, the sample may exhibit a metallic sheen.
   e. Test the sample with the Autof ms1000.

3) **Extraction Method**

a. Add 300 µL sterile, distilled water to a centrifuge tube.
b. Inoculate a 1 µL loop-full of microorganism to the centrifuge tube.
c. Vortex the tube.
d. Add 900 µL absolute ethanol to the centrifuge tube and vortex.
e. Centrifuge the dissolved sample for 13,000 rpm for 2-4 minutes.
f. Remove as much supernatant as possible with a pipette. Be careful not to disturb the pellet.
g. If any supernatant remains, dry the pellet at 37-40°C for 2-5 minutes until the surface has no obvious liquid.
h. Add 10 µL Lysate 1 to the tube with the pellet.
i. Vortex.
j. Add 10 µL Lysate 2 to the tube.
k. Vortex.
l. Centrifuge the dissolved sample for 13,000 rpm for 2-4 minutes.
m. Inoculate 1 µL of the supernatant to the appropriate spot on the target plate.
n. Dry the sample spot at room temperature until there is no liquid visible.
o. Overlay the sample spot with 1 µL matrix solution.
p. Dry the sample spot at room temperature until there is no liquid visible.
q. Test the sample with the Autof ms1000.

4) Gram Positive Bacilli Method

a. Add 1 mL of 75% ethanol to a centrifuge tube.
b. Inoculate a 1 µL loopful of microorganism to the centrifuge tube.
c. Vortex the tube for 5-10 minutes.
d. Centrifuge the dissolved sample at 13,000 rpm for 2-4 minutes.
e. Remove as much supernatant as possible with a pipette. Be careful not to disturb the pellet.
f. Wash the pellet by adding 500 µL of sterile, distilled water, and vortex. Then centrifuge at 13,000 rpm for 2-4 minutes and discard the supernatant.
g. Add 15 µL of Lysate 2 to and vortex to re-suspend the pellet.
h. Add 0.1 mm glass beads (about half the volume as Lysate 2) and vortex for 1 minute.
i. Add 15 µL of Lysate 1 and vortex for 30 seconds. Let stand for 5 minutes.
j. Centrifuge the dissolved sample 13,000 rpm for 2-4 minutes.
k. Add 1 µL of supernatant to the target plate and dry at room temperature.
l. Cover the sample with 1 µL of matrix and dry at room temperature.

4.3.2.2 Treatment Method of Filamentous Fungi

a. Add 1 mL of 75% ethanol to a centrifuge tube.
b. In a biological safety cabinet, use a needle or sterile flocked swab to scrape the appropriate amount of mycelium or spores from the surface of the culture medium and inoculate into the centrifuge tube.
c. Vortex for 1 minute.
d. Centrifuge at 13,000 rpm for 2 minutes.
e. Remove as much supernatant as possible with a pipette. Be careful not to disturb the pellet.
f. Dry the pellet for 2-4 minutes at 37-40°C
g. Add 30 µL Lysate 1.
h. Let stand for 5-10 minutes, then vortex briefly.
i. Inoculate 1 µL of the supernatant to the appropriate spot on the target plate and dry at room temperature.

- Note: The mycelium must be completely lysed prior to inoculation to the target plate.

j. Overlay the sample spot with 1 µL matrix solution and dry at room temperature.
k. Test the sample with the Autof ms1000.

Important notice:

1) Pretreatment of filamentous fungi should take place in a biological safety cabinet (BSC).
2) The pellet should be dried thoroughly during each drying process.
3) Once started, the test should be completed within 2 hours.

ANNEX D: Inclusivity and Exclusivity Strains

Table 1. Inclusivity Strain List

Isolate Number	Genus	Species	Subspecies/Serovar	Source	Reference Number/Strain	Origin
251[a]	*Cronobacter*	*condimenti*		DSM	27966	Spiced Meat
252	*Cronobacter*	*condimenti*		Q Labs	QL 17031.1	Infant Formula
253[a]	*Cronobacter*	*dublinensis*	lausannensis	CCUG	58095	Water fountain
254	*Cronobacter*	*dublinensis*		Q Labs	QL 072623-1	Milk Powder
255	*Cronobacter*	*dublinensis*		Q Labs	QL 072623-2	Milk Powder
256	*Cronobacter*	*dublinensis*		Q Labs	QL 072623-3	Milk Powder
257	*Cronobacter*	*dublinensis*		Q Labs	QL 072623-4	Milk Powder
258	*Cronobacter*	*dublinensis*	dublinensis	Q Labs	QL 072623-5	Milk Powder
259	*Cronobacter*	*dublinensis*	lactaridi	Q Labs	QL 17031.2	Milk Powder
260	*Cronobacter*	*malonaticus*		CCUG	76247	Human urine, 75 year old man
261	*Cronobacter*	*malonaticus*		Cornell	FSL F6-030	Finished RTE product (dairy)
262	*Cronobacter*	*malonaticus*		Cornell	FSL F6-049	Human clinical
263	*Cronobacter*	*malonaticus*		Cornell	FSL F6-052	Human clinical
264	*Cronobacter*	*malonaticus*		Q Labs	QL 17031.3	Infant Formula
265	*Cronobacter*	*malonaticus*		Q Labs	QL123015-1	Environmental Isolate
266	*Cronobacter*	*malonaticus*		Q Labs	QL 061323-1	Infant Formula
267	*Cronobacter*	*malonaticus*		Q Labs	QL 061323-2	Infant Formula
268	*Cronobacter*	*malonaticus*		Q Labs	QL 061323-3	Environmental
269	*Cronobacter*	*malonaticus*		Q Labs	QL 061323-4	Environmental
270	*Cronobacter*	*malonaticus*		Q Labs	QL 062223-1	Environmental
271[a]	*Cronobacter*	*muytjensii*		Cornell	FSL F6-031	Not Available
272	*Cronobacter*	*muytjensii*		LMG	2787	Human clinical material
273	*Cronobacter*	*muytjensii*		Q Labs	QL 17031.6	Environmental Isolate
274	*Cronobacter*	*sakazakii*		ATCC	29004	Not Available
275[a]	*Cronobacter*	*sakazakii*		ATCC	BAA-894	Clinical specimen, Tennessee, US
276	*Cronobacter*	*sakazakii*		CCM	3460	Foot Wound
277	*Cronobacter*	*sakazakii*		CCM	3461	Abscess in spine
278	*Cronobacter*	*sakazakii*		CCM	3479	Bronchial secretion
279	*Cronobacter*	*sakazakii*		CCUG	21205	Not Available

Table 1. Inclusivity Strain List Continued

Isolate Number	Genus	Species	Subspecies/Serovar	Source	Reference Number/Strain	Origin
280	*Cronobacter*	*sakazakii*		CCUG	28857	Human cerebrospinal fluid
281	*Cronobacter*	*sakazakii*		CCUG	28858	Human cerebrospinal fluid
282	*Cronobacter*	*sakazakii*		CCUG	28859	Formula
283	*Cronobacter*	*sakazakii*		CCUG	28860	Formula
284	*Cronobacter*	*sakazakii*		CCUG	28861	Human cerebrospinal fluid
285	*Cronobacter*	*sakazakii*		CCUG	28864	Human cerebrospinal fluid, patient 8
286	*Cronobacter*	*sakazakii*		CCUG	28865	Human cerebrospinal fluid
287	*Cronobacter*	*sakazakii*		CCUG	28866	Human Vagina, newborn
288	*Cronobacter*	*sakazakii*		CCUG	28867	Formula
289	*Cronobacter*	*sakazakii*		CCUG	28868	Dish brush
290	*Cronobacter*	*sakazakii*		CCUG	28869	Dish brush
291	*Cronobacter*	*sakazakii*		CCUG	28870	Dish brush
292	*Cronobacter*	*sakazakii*		CCUG	28871	Human sputum, colonization
293	*Cronobacter*	*sakazakii*		CCUG	29129	Human cerebrospinal fluid, patient 6
294	*Cronobacter*	*sakazakii*		CCUG	64760	Environment, Industry
295	*Cronobacter*	*sakazakii*		CCUG	68998	Product
296	*Cronobacter*	*sakazakii*		CCUG	69041	Raw product, industry
297	*Cronobacter*	*sakazakii*		CCUG	75715	Human
298	*Cronobacter*	*sakazakii*		CCUG	76316	Human urine, 70 year old male
299	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-4	Powdered Milk
300	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-5	Powdered Milk
301	*Cronobacter*	*sakazakii*		Q Labs	QL 050323-1	Environmental
302	*Cronobacter*	*sakazakii*		Q Labs	QL 050323-2	Environmental
303	*Cronobacter*	*sakazakii*		Q Labs	QL 050323-3	Environmental
304	*Cronobacter*	*sakazakii*		Q Labs	QL 050323-4	Environmental
305	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-1	Infant Formula
306	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-2	Infant Formula
307	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-3	Infant Formula
308	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-4	Infant Formula
309	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-5	Infant Formula
310	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-6	Infant Formula

Table 1. Inclusivity Strain List Continued

Isolate Number	Genus	Species	Subspecies/Serovar	Source	Reference Number/Strain	Origin
311	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-7	Infant Formula
312	*Cronobacter*	*sakazakii*		Q Labs	QL 062823-1	Water
313	*Cronobacter*	*sakazakii*		Q Labs	QL 062823-2	Water
314	*Cronobacter*	*sakazakii*		Q Labs	QL 062823-3	Water
315	*Cronobacter*	*sakazakii*		Q Labs	QL 072023-1	Powdered Milk
316	*Cronobacter*	*sakazakii*		Q Labs	QL 072023-2	Powdered Milk
317	*Cronobacter*	*sakazakii*		Q Labs	QL 072023-3	Powdered Milk
318	*Cronobacter*	*sakazakii*		Q Labs	QL 072023-4	Powdered Milk
319	*Cronobacter*	*condimenti*		Q Labs	072623-11	Not Available
320	*Cronobacter*	*sakazakii*		Cornell	FSL F6-023	Human clinical
321	*Cronobacter*	*sakazakii*		Cornell	FSL F6-024	Finished RTE product (dairy)
322	*Cronobacter*	*sakazakii*		Cornell	FSL F6-025	Environment, food
323	*Cronobacter*	*sakazakii*		Cornell	FSL F6-027	Environment, food
324	*Cronobacter*	*sakazakii*		Cornell	FSL F6-028	Human clinical
325	*Cronobacter*	*sakazakii*		Cornell	FSL F6-029	Human clinical
326	*Cronobacter*	*sakazakii*		Cornell	FSL F6-032	Finished RTE product (dairy)
327	*Cronobacter*	*sakazakii*		Cornell	FSL F6-034	Human clinical
328	*Cronobacter*	*sakazakii*		Cornell	FSL F6-035	Human clinical
329	*Cronobacter*	*sakazakii*		Cornell	FSL F6-036	Environment, food
330	*Cronobacter*	*sakazakii*		Cornell	FSL F6-037	Environment, food
331	*Cronobacter*	*sakazakii*		Cornell	FSL F6-038	Environment, food
332	*Cronobacter*	*sakazakii*		Cornell	FSL F6-039	Environment, food
333	*Cronobacter*	*sakazakii*		Cornell	FSL F6-040	Environment, food
334	*Cronobacter*	*sakazakii*		Cornell	FSL F6-041	Environment, food
335	*Cronobacter*	*sakazakii*		Cornell	FSL F6-042	Finished RTE product (dairy)
336	*Cronobacter*	*sakazakii*		Cornell	FSL F6-043	Human clinical
337	*Cronobacter*	*sakazakii*		Cornell	FSL F6-044	Food
338	*Cronobacter*	*sakazakii*		Cornell	FSL F6-045i	Food
339	*Cronobacter*	*sakazakii*		Cornell	FSL F6-046	Finished RTE product (dairy)
340	*Cronobacter*	*sakazakii*		Cornell	FSL F6-047	Finished RTE product (dairy)
341	*Cronobacter*	*sakazakii*		Cornell	FSL F6-048	Finished RTE product (dairy)

Table 1. Inclusivity Strain List Continued

Isolate Number	Genus	Species	Subspecies/Serovar	Source	Reference Number/Strain	Origin
342	*Cronobacter*	*sakazakii*		Cornell	FSL F6-050	human clinical
343	*Cronobacter*	*sakazakii*		Cornell	FSL F6-051	human clinical
344	*Cronobacter*	*sakazakii*		Q Labs	QL 8368	Clinical
345	*Cronobacter*	*sakazakii*		Q Labs	QL 1946	Clinical
346	*Cronobacter*	*sakazakii*		Q Labs	QL 2323	Clinical
347	*Cronobacter*	*sakazakii*		Q Labs	QL 9110	Food, Spinach
348	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-1	Dust
349	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-2	Dust
350	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-3	Dust
351	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-4	Dust
352	*Cronobacter*	*sakazakii*		LMG	2758	Human ear
353	*Cronobacter*	*sakazakii*		LMG	2759	Human ear
354	*Cronobacter*	*sakazakii*		LMG	2762	Human blood culture
355	*Cronobacter*	*sakazakii*		LMG	2763	Human finger abscess
356	*Cronobacter*	*sakazakii*		LMG	2766	Human clinical material
357	*Cronobacter*	*sakazakii*		LMG	2768	Water
358	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-5	Dust
359	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-6	Dust
360	*Cronobacter*	*sakazakii*		Q Labs	QL 052323-1	Environmental
361	*Cronobacter*	*sakazakii*		Q Labs	QL 052323-2	Environmental
362	*Cronobacter*	*sakazakii*		Q Labs	QL 052323-3	Environmental
363	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-1	Powdered Milk
364	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-2	Powdered Milk
365	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-3	Powdered Milk
366	*Cronobacter*	*sakazakii*		NCCB (Westerdijk)	80008	Pond Water
367	*Cronobacter*	*sakazakii*		NCTC	9238	Not Available
368	*Cronobacter*	*sakazakii*		NCTC	5920	Not Available
369	*Cronobacter*	*sakazakii*		NCTC	8155	Not Available
370	*Cronobacter*	*sakazakii*		NCTC	9844	Not Available
371	*Cronobacter*	*sakazakii*		NCTC	9846	Not Available
372	*Cronobacter*	*sakazakii*		Q Labs	111717-1	Powdered Milk

Table 1. Inclusivity Strain List Continued

Isolate Number	Genus	Species	Subspecies/Serovar	Source	Reference Number/Strain	Origin
373	*Cronobacter*	*sakazakii*		Q Labs	111717-2	Powdered Milk
374	*Cronobacter*	*sakazakii*		Q Labs	120117-1	Infant Formula
375	*Cronobacter*	*sakazakii*		Q Labs	120117-10	Infant Formula
376	*Cronobacter*	*sakazakii*		Q Labs	120117-11	Infant Formula
377	*Cronobacter*	*sakazakii*		Q Labs	120117-12	Infant Formula
378	*Cronobacter*	*sakazakii*		Q Labs	120117-2	Infant Formula
379	*Cronobacter*	*sakazakii*		Q Labs	120117-3	Infant Formula
380	*Cronobacter*	*sakazakii*		Q Labs	120117-4	Infant Formula
381	*Cronobacter*	*sakazakii*		Q Labs	120117-5	Infant Formula
382	*Cronobacter*	*sakazakii*		Q Labs	120117-6	Infant Formula
383	*Cronobacter*	*sakazakii*		Q Labs	120117-7	Infant Formula
384	*Cronobacter*	*sakazakii*		Q Labs	120117-8	Infant Formula
385	*Cronobacter*	*sakazakii*		Q Labs	120117-9	Infant Formula
386	*Cronobacter*	*sakazakii*		Q Labs	QL 17031.4	Infant Formula
387	*Cronobacter*	*sakazakii*		Q Labs	QL11007-9	Rice Flour
388	*Cronobacter*	*sakazakii*		Q Labs	QL123015-1A	Environmental Isolate
389	*Cronobacter*	*sakazakii*		Q Labs	QL 052323-4	Dust
390	*Cronobacter*	*sakazakii*		VTT	E-073044	Paper Mill
391	*Cronobacter*	*sakazakii*		VTT	E-991312	Broke of a paper mill
392	*Cronobacter*	*sakazakii*		VTT	E-991323	Chemi-mechanical refiner pulp of a paper mill
393	*Cronobacter*	*sakazakii*		Q Labs	QL 341552-11	Environmental Isolate
394	*Cronobacter*	*muytjensii*		Q Labs	QL 051423-6	Environmental
395	*Cronobacter*	*muytjensii*		Q Labs	QL 071123-1	Infant Cereal
396	*Cronobacter*	*muytjensii*		Q Labs	QL 071123-2	Milk Powder
397	*Cronobacter*	*turicensis*		Q Labs	QL 072623-6	Milk Powder
398[a]	*Cronobacter*	*turicensis*		Q Labs	QL 17031.5	Infant formula
399	*Cronobacter*	*universalis*		Q Labs	111323-1	Water
400	*Cronobacter*	*universalis*		Q Labs	111323-2	Water

[a] Isolates were evaluated by all sample preparations listed.

Table 2. Exclusivity Strain List

Isolate Number	Genus	Species	Source	Reference Number/Strain	Origin
401	*Acidovorax*	*temperans*	Q Labs	QL21274-1	Potable water
402	*Acinetobacter*	*calcoaceticus*	ATCC	23055	Not Available
403	*Acinetobacter*	*baumannii*	CCUG	70743	Human Wound
404	*Acinetobacter*	*junii*	Q Labs	QL 0696826.1	Environmental
405	*Aeromonas*	*caviae*	CCUG	57693	Human Feces
406	*Aeromonas*	*hydrophila*	Q Labs	QL 333046.21	Chicken Ceca
407	*Alcaligenes*	*faecalis*	ATCC	15554	Not Available
408	*Bordetella*	*bronchiseptica*	CCUG	56928	Human sputum, colonization
409	*Brevundimonas*	*mediterranea*	Q Labs	QL 0692733.2	Water
410	*Brevundimonas*	*vesicularis*	Q Labs	QL 0695864.9	Environmental
411	*Burkholderia*	*cepacia*	ATCC	25416	Onion
412	*Buttiauxella*	*gaviniae*	CCUG	35508T	Not Available
413	*Buttiauxella*	*izardii*	CCUG	35510T	Not Available
414	*Buttiauxella*	*noackiae*	CCUG	35511T	Not Available
415	*Buttiauxella*	*agrestis*	CCUG	21133	Soil
416	*Buttiauxella*	*ferragutiae*	CCUG	73587T	Soil
417	*Cedecea*	*davisae*	CCUG	23277	Water
418	*Cedecea*	*neteri*	CCUG	18763T	Human Foot
419	*Citrobacter*	*youngae*	ATCC	11102	Not Available
420	*Citrobacter*	*koseri*	ATCC	27156	Not Available
421	*Citrobacter*	*braakii*	ATCC	43162	Clinical isolate, California
422	*Citrobacter*	*farmeri*	ATCC	51633	Human feces, North Carolina
423	*Citrobacter*	*freundii*	Q Labs	QL 11007-10	Clinical Isolate
424	*Dickeya*	*chrysanthemi*	CCUG	47021	Human blood
425	*Edwardsiella*	*hoshinae*	CCUG	20938	Lizard
426	*Edwardsiella*	*anguillarum*	CCUG	64215T	Japanese eel
427	*Edwardsiella*	*tarda*	Q Labs	QL 021111D	Not Available
428	*Edwardsiella*	*tarda*	Q Labs	QL 11007-11	Clinical Isolate
429	*Enterobacter*	*hormaechei*	CCUG	63314	Human urine
430	*Enterobacter*	*cancerogenus*	Q Labs	QL 11010-1	Bottled water
431	*Enterobacter*	*amnigenus*	Q Labs	QL 112413-2	Milk
432	*Enterobacter*	*cloacae*	ATCC	23355	Not Available
433	*Escherichia*	*coli*	Q Labs	QL 030716-1A	Ground Beef
434	*Escherichia*	*coli*	Q Labs	QL 41411.1	Bottled water
435	*Escherichia*	*hermannii*	ATCC	33650	Mouse brain
436	*Escherichia*	*fergusonii*	ATCC	35469	Feces, human
437	*Flavobacterium*	*hydatis*	NRRL	B-14732	Gills of diseased salmon
438	*Flavobacterium*	*johnsoniae*	NRRL	B-14733	Moose dung
439	*Flavobacterium*	*aquatile*	NRRL	B-14842	Soil
440	*Flavobacterium*	*saccharophilum/piscis*	Q Labs	QL 0694946.3a	Environmental
441	*Franconibacter*	*helveticus*	Q Labs	QL 17031.10	Not Available
442	*Franconibacter*	*pulveris*	Q Labs	QL 17031.11	Milk Powder
443	*Franconibacter*	*helveticus*	Q Labs	QL 17031.9	Environmental Isolate
444	*Delftia*	*acidovorans*	Q Labs	QL 0692756.2B	Water
445	*Hafnia*	*alvei*	ATCC	51815	Milk, Minnesota
446	*Hafnia*	*alvei*	Q Labs	QL 102313	Milk
447	*Klebsiella*	*aerogenes*	ATCC	35029	Not Available
448	*Klebsiella*	*variicola*	CCUG	73431	Human Urine

Table 2. Exclusivity Strain List Continued

Isolate Number	Genus	Species	Source	Reference Number/Strain	Origin
449	*Klebsiella*	*pneumoniae*	Q Labs	QL 11007-7	Not Available
450	*Klebsiella*	*oxytoca*	ATCC	43165	Clinical isolate
451	*Kluyvera*	*georgiana*	CCUG	35513T	Not Available
452	*Kluyvera*	*ascorbata*	CCUG	29929	Human stool
453	*Kluyvera*	*cryocrescens*	CCUG	39258	Sewage
454	*Kluyvera*	*intermedia*	Q Labs	QL 081215-1	Water
455	*Leclercia*	*adecarboxylata*	Q Labs	0694739.4b	Environmental
456	*Lelliottia*	*amnigena*	CCUG	72458	Human pleura
457	*Leminorella*	*grimontii*	CCUG	20908	Source Unknown
458	*Leminorella*	*richardii*	CCUG	20911	Human Stool
459	*Mixta (Pantoea)*	*calida*	CCUG	63471	Human Wound
460	*Morganella*	*morganii*	Q Labs	QL 22214-11	Potable Water
461	*Morganella*	*morganii*	CCUG	44753	Human Feces
462	*Pandoraea*	*norimbergensis*	CCUG	39677	Milk Powder
463	*Pantoea*	*agglomerans*	CCUG	58262	Human sputum
464	*Pantoea*	*septica*	CCUG	67234	Human feces
465	*Pantoea*	*dispersa*	CCUG	25232T	Soil
466	*Pantoea*	*ananatis*	Q Labs	QL 103122-1	Not Available
467	*Pluralibacter (Enterobacter)*	*gergoviae*	CCUG	53235	Not Available
468	*Pluralibacter (Enterobacter)*	*pyrinus*	CCUG	48320T	Pear Leaves
469	*Proteus*	*penneri*	CCUG	25463	Human Urine
470	*Proteus*	*myxofaciens*	CCUG	18769T	Gypsy moth larvae
471	*Proteus*	*mirabilis*	Q Labs	QL 33046.2	Chicken Ceca
472	*Proteus*	*mirabilis*	ATCC	9240	Not Available
473	*Proteus*	*vulgaris*	CCUG	18984	Human Feces
474	*Pseudescherichia (Escherichia)*	*vulneris*	ATCC	29943	Human wound
475	*Pseudomonas*	*aeruginosa*	ATCC	15442	Water Bottle
476	*Pseudomonas*	*fluorescens*	Q Labs	QL 17041-3	Raw milk isolate
477	*Pseudomonas*	*gessardii*	Q Labs	QL 17041-12	Raw milk isolate
478	*Rahnella*	*aquatilis*	ATCC	55046	Soil, Wisconsin
479	*Raoultella*	*planticola*	CCUG	15719	Drinking water
480	*Raoultella*	*ornithinolytica*	CCUG	21208	Surface water
481	*Raoultella*	*terrigena*	CCUG	53452	Human sputum
482	*Roseomonas*	*mucosa*	Q Labs	QL 0695267.6c	Environmental
483	*Salmonella*	Bloemfontein	CCUG	12654	Not Available
484	*Salmonella*	Cerro	ATCC	10723	Not Available
485	*Salmonella*	Decatur	CCUG	12656	Not Available
486	*Salmonella*	Enteritidis	ATCC	4931	Case of gastroenteritis in Copenhagen
487	*Salmonella*	Abaetetuba	ATCC	35640	Creek water, Zaiman, Argentina
488	*Serratia*	*odorifera*	CCUG	10200	Human
489	*Serratia*	*liquefaciens*	CCUG	22907	Not Available
490	*Serratia*	*rubidaea*	CCUG	35289	Human sputum
491	*Serratia*	*fonticola*	CCUG	36604	Water
492	*Serratia*	*marcescens*	Q Labs	QL 11007-1	Bottled water
493	*Shewanella*	*baltica*	NRRL	B-41146	Ground beef
494	*Shewanella*	*putrefaciens*	NRRL	B-951	Not Available
495	*Shimwellia*	*blattae*	ATCC	29907	Insect (hindgut of cockroach)
496	*Siccibacter*	*turicensis*	CCUG	54945T	Not Available
497	*Siccibacter*	*colletis*	DSM	107916	Poppy Seeds
498	*Stenotrophomonas*	*maltophilia*	ATCC	13637	Oropharyngeal Region
499	*Stenotrophomonas*	*maltophilia*	Q Labs	QL 0695267.5a	Environmental
500	*Yersinia*	*enterocolitica*	ATCC	49397	Human clinical specimen

ANNEX E: Raw Data Inclusivity and Exclusivity

Observations of the culture plates		Data comparison between the alternative and the reference methods	
t	Only typical colonies present	PA	Positive Agreement
at	Only atypical colonies present	NA	Negative Agreement
ng	No growth present	PD	Positive Deviation
+	Indicates a positive reaction	ND	Negative Deviation
-	\Indicates a negative reaction	IA	Inclusivity Agreement
		ID	Inclusivity Deviation
		EA	Exclusivity Agreement
		ED	Exclusivity Deviation

Table 1. Raw Data Inclusivity Results

Isolate No.	Genus	Species	Sub-species	Source	Reference Number/ Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
								Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
251[a]	*Cronobacter*	*condimenti*		DSM	27966	Spiced Meat	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
252	*Cronobacter*	*condimenti*		Q Labs	QL 17031.1	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
253[a]	*Cronobacter*	*dublinensis*	*lausannensis*	CCUG	58095	Water fountain	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
254	*Cronobacter*	*dublinensis*		Q Labs	QL 072623-1	Milk Powder	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
255	*Cronobacter*	*dublinensis*		Q Labs	QL 072623-2	Milk Powder	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
256	*Cronobacter*	*dublinensis*		Q Labs	QL 072623-3	Milk Powder	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
257	*Cronobacter*	*dublinensis*		Q Labs	QL 072623-4	Milk Powder	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
258	*Cronobacter*	*dublinensis*	*dublinensis*	Q Labs	QL 072623-5	Milk Powder	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
259	*Cronobacter*	*dublinensis*	*lactaridi*	Q Labs	QL 17031.2	Milk Powder	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
260	*Cronobacter*	*malonaticus*		CCUG	76247	Human urine, 75 year old man	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
261	*Cronobacter*	*malonaticus*		Cornell	FSL F6-030	Finished RTE product (dairy)	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
262	*Cronobacter*	*malonaticus*		Cornell	FSL F6-049	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
263	*Cronobacter*	*malonaticus*		Cornell	FSL F6-052	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
264	*Cronobacter*	*malonaticus*		Q Labs	QL 17031.3	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
265	*Cronobacter*	*malonaticus*		Q Labs	QL123015-1	Environmental Isolate	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
266	*Cronobacter*	*malonaticus*		Q Labs	QL 061323-1	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
267	*Cronobacter*	*malonaticus*		Q Labs	QL 061323-2	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
268	*Cronobacter*	*malonaticus*		Q Labs	QL 061323-3	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
269	*Cronobacter*	*malonaticus*		Q Labs	QL 061323-4	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
270	*Cronobacter*	*malonaticus*		Q Labs	QL 062223-1	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
27[a]	*Cronobacter*	*muytjensii*		Cornell	FSL F6-031	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA

[a] Identical results produced for all three sample preparations evaluated

Table 1. Raw Data Inclusivity Results Continued

Isolate No.	Genus	Species	Sub-species	Source	Reference Number/ Strain	Origin	Reference Method Result	CCI			DFI			HCC			TSA		
								Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
272	*Cronobacter*	*muytjensii*		LMG	2787	Human clinical material	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
273	*Cronobacter*	*muytjensii*		Q Labs	QL 17031.6	Environmental Isolate	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
274	*Cronobacter*	*sakazakii*		ATCC	29004	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
275[a]	*Cronobacter*	*sakazakii*		ATCC	BAA-894	Clinical specimen, Tennessee, US	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
276	*Cronobacter*	*sakazakii*		CCM	3460	Foot Wound	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
277	*Cronobacter*	*sakazakii*		CCM	3461	Abscess in spine	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
278	*Cronobacter*	*sakazakii*		CCM	3479	Bronchial secretion	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
279	*Cronobacter*	*sakazakii*		CCUG	21205	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
280	*Cronobacter*	*sakazakii*		CCUG	28857	Human cerebrospinal fluid	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
281	*Cronobacter*	*sakazakii*		CCUG	28858	Human cerebrospinal fluid	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
282	*Cronobacter*	*sakazakii*		CCUG	28859	Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
283	*Cronobacter*	*sakazakii*		CCUG	28860	Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
284	*Cronobacter*	*sakazakii*		CCUG	28861	Human cerebrospinal fluid	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
285	*Cronobacter*	*sakazakii*		CCUG	28864	Human cerebrospinal fluid, patient 8	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
286	*Cronobacter*	*sakazakii*		CCUG	28865	Human cerebrospinal fluid	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
287	*Cronobacter*	*sakazakii*		CCUG	28866	Human Vagina, newborn	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
288	*Cronobacter*	*sakazakii*		CCUG	28867	Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
289	*Cronobacter*	*sakazakii*		CCUG	28868	Dish brush	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
290	*Cronobacter*	*sakazakii*		CCUG	28869	Dish brush	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
291	*Cronobacter*	*sakazakii*		CCUG	28870	Dish brush	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
292	*Cronobacter*	*sakazakii*		CCUG	28871	Human sputum, colonization	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
293	*Cronobacter*	*sakazakii*		CCUG	29129	Human cerebrospinal fluid, patient 6	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
294	*Cronobacter*	*sakazakii*		CCUG	64760	Environment, Industry	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA

[a] Identical results produced for all three sample preparations evaluated

Table 1. Raw Data Inclusivity Results Continued

Isolate No.	Genus	Species	Sub-species	Source	Reference Number/ Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
								Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
295	*Cronobacter*	*sakazakii*		CCUG	68998	Product	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
296	*Cronobacter*	*sakazakii*		CCUG	69041	Raw product, industry	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
297	*Cronobacter*	*sakazakii*		CCUG	75715	Human	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
298	*Cronobacter*	*sakazakii*		CCUG	76316	Human urine, 70 year old male	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
299	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-4	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
300	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-5	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
301	*Cronobacter*	*sakazakii*		Q Labs	QL 050323-1	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
302	*Cronobacter*	*sakazakii*		Q Labs	QL 050323-2	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
303	*Cronobacter*	*sakazakii*		Q Labs	QL 050323-3	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
304	*Cronobacter*	*sakazakii*		Q Labs	QL 050323-4	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
305	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-1	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
306	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-2	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
307	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-3	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
308	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-4	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
309	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-5	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
310	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-6	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
311	*Cronobacter*	*sakazakii*		Q Labs	QL 051723-7	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
312	*Cronobacter*	*sakazakii*		Q Labs	QL 062823-1	Water	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
313	*Cronobacter*	*sakazakii*		Q Labs	QL 062823-2	Water	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
314	*Cronobacter*	*sakazakii*		Q Labs	QL 062823-3	Water	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
315	*Cronobacter*	*sakazakii*		Q Labs	QL 072023-1	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
316	*Cronobacter*	*sakazakii*		Q Labs	QL 072023-2	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
317	*Cronobacter*	*sakazakii*		Q Labs	QL 072023-3	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA

Table 1. Raw Data Inclusivity Results Continued

Isolate No.	Genus	Species	Sub-species	Source	Reference Number/ Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
								Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
318	*Cronobacter*	*sakazakii*		Q Labs	QL 072023-4	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
319	*Cronobacter*	*condimenti*		Q Labs	072623-11	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
320	*Cronobacter*	*sakazakii*		Cornell	FSL F6-023	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
321	*Cronobacter*	*sakazakii*		Cornell	FSL F6-024	Finished RTE product (dairy)	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
322	*Cronobacter*	*sakazakii*		Cornell	FSL F6-025	Environment, food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
323	*Cronobacter*	*sakazakii*		Cornell	FSL F6-027	Environment, food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
324	*Cronobacter*	*sakazakii*		Cornell	FSL F6-028	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
325	*Cronobacter*	*sakazakii*		Cornell	FSL F6-029	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
326	*Cronobacter*	*sakazakii*		Cornell	FSL F6-032	Finished RTE product (dairy)	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
327	*Cronobacter*	*sakazakii*		Cornell	FSL F6-034	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
328	*Cronobacter*	*sakazakii*		Cornell	FSL F6-035	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
329	*Cronobacter*	*sakazakii*		Cornell	FSL F6-036	Environment, food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
330	*Cronobacter*	*sakazakii*		Cornell	FSL F6-037	Environment, food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
331	*Cronobacter*	*sakazakii*		Cornell	FSL F6-038	Environment, food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
332	*Cronobacter*	*sakazakii*		Cornell	FSL F6-039	Environment, food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
333	*Cronobacter*	*sakazakii*		Cornell	FSL F6-040	Environment, food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
334	*Cronobacter*	*sakazakii*		Cornell	FSL F6-041	Environment, food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
335	*Cronobacter*	*sakazakii*		Cornell	FSL F6-042	Finished RTE product (dairy)	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
336	*Cronobacter*	*sakazakii*		Cornell	FSL F6-043	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
337	*Cronobacter*	*sakazakii*		Cornell	FSL F6-044	Food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
338	*Cronobacter*	*sakazakii*		Cornell	FSL F6-045i	Food	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
339	*Cronobacter*	*sakazakii*		Cornell	FSL F6-046	Finished RTE product (dairy)	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
340	*Cronobacter*	*sakazakii*		Cornell	FSL F6-047	Finished RTE product (dairy)	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
341	*Cronobacter*	*sakazakii*		Cornell	FSL F6-048	Finished RTE product (dairy)	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA

Table 1. Raw Data Inclusivity Results Continued

Isolate No.	Genus	Species	Sub-species	Source	Reference Number/ Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
								Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
342	*Cronobacter*	*sakazakii*		Cornell	FSL F6-050	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
343	*Cronobacter*	*sakazakii*		Cornell	FSL F6-051	Human clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
344	*Cronobacter*	*sakazakii*		Q Labs	QL 8368	Clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
345	*Cronobacter*	*sakazakii*		Q Labs	QL 1946	Clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
346	*Cronobacter*	*sakazakii*		Q Labs	QL 2323	Clinical	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
347	*Cronobacter*	*sakazakii*		Q Labs	QL 9110	Food, Spinach	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
348	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-1	Dust	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
349	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-2	Dust	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
350	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-3	Dust	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
351	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-4	Dust	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
352	*Cronobacter*	*sakazakii*		LMG	2758	Human ear	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
353	*Cronobacter*	*sakazakii*		LMG	2759	Human ear	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
354	*Cronobacter*	*sakazakii*		LMG	2762	Human blood culture	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
355	*Cronobacter*	*sakazakii*		LMG	2763	Human finger abscess	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
356	*Cronobacter*	*sakazakii*		LMG	2766	Human clinical material	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
357	*Cronobacter*	*sakazakii*		LMG	2768	Water	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
358	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-5	Dust	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
359	*Cronobacter*	*sakazakii*		Q Labs	QL 070723-6	Dust	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
360	*Cronobacter*	*sakazakii*		Q Labs	QL 052323-1	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
361	*Cronobacter*	*sakazakii*		Q Labs	QL 052323-2	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
362	*Cronobacter*	*sakazakii*		Q Labs	QL 052323-3	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
363	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-1	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
364	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-2	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
365	*Cronobacter*	*sakazakii*		Q Labs	QL 051423-3	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
366	*Cronobacter*	*sakazakii*		NCCB (Westerdijk)	80008	Pond Water	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
367	*Cronobacter*	*sakazakii*		NCTC	9238	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
368	*Cronobacter*	*sakazakii*		NCTC	5920	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
369	*Cronobacter*	*sakazakii*		NCTC	8155	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA

Table 1. Raw Data Inclusivity Results Continued

Isolate No.	Genus	Species	Sub-species	Source	Reference Number/ Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
								Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
370	*Cronobacter*	*sakazakii*		NCTC	9844	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
371	*Cronobacter*	*sakazakii*		NCTC	9846	Not Available	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
372	*Cronobacter*	*sakazakii*		Q Labs	111717-1	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
373	*Cronobacter*	*sakazakii*		Q Labs	111717-2	Powdered Milk	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
374	*Cronobacter*	*sakazakii*		Q Labs	120117-1	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
375	*Cronobacter*	*sakazakii*		Q Labs	120117-10	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
376	*Cronobacter*	*sakazakii*		Q Labs	120117-11	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
377	*Cronobacter*	*sakazakii*		Q Labs	120117-12	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
378	*Cronobacter*	*sakazakii*		Q Labs	120117-2	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
379	*Cronobacter*	*sakazakii*		Q Labs	120117-3	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
380	*Cronobacter*	*sakazakii*		Q Labs	120117-4	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
381	*Cronobacter*	*sakazakii*		Q Labs	120117-5	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
382	*Cronobacter*	*sakazakii*		Q Labs	120117-6	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
383	*Cronobacter*	*sakazakii*		Q Labs	120117-7	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
384	*Cronobacter*	*sakazakii*		Q Labs	120117-8	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
385	*Cronobacter*	*sakazakii*		Q Labs	120117-9	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
386	*Cronobacter*	*sakazakii*		Q Labs	QL 17031.4	Infant Formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
387	*Cronobacter*	*sakazakii*		Q Labs	QL11007-9	Rice Flour	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
388	*Cronobacter*	*sakazakii*		Q Labs	QL123015-1A	Environmental Isolate	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
389	*Cronobacter*	*sakazakii*		Q Labs	QL 052323-4	Dust	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
390	*Cronobacter*	*sakazakii*		VTT	E-073044	Paper Mill	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
391	*Cronobacter*	*sakazakii*		VTT	E-991312	Broke of a paper mill	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
392	*Cronobacter*	*sakazakii*		VTT	E-991323	Chemi-mechanical refiner pulp of a paper mill	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA

Table 1. Raw Data Inclusivity Results Continued

Isolate No.	Genus	Species	Sub-species	Source	Reference Number/ Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
								Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
393	*Cronobacter*	*sakazakii*		Q Labs	QL 341552-11	Environmental Isolate	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
394	*Cronobacter*	*muytjensii*		Q Labs	QL 051423-6	Environmental	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
395	*Cronobacter*	*muytjensii*		Q Labs	QL 071123-1	Infant Cereal	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
396	*Cronobacter*	*muytjensii*		Q Labs	QL 071123-2	Milk Powder	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
397	*Cronobacter*	*turicensis*		Q Labs	QL 072623-6	Milk Powder	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
398[a]	*Cronobacter*	*turicensis*		Q Labs	QL 17031.5	Infant formula	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
399	*Cronobacter*	*universalis*		Q Labs	111323-1	Water	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA
400	*Cronobacter*	*universalis*		Q Labs	111323-2	Water	+	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA	+(t)	PA	IA

[a] Identical results produced for all three sample preparations evaluated

Table 2. Raw Data Exclusivity Results

Isolate No.	Genus	Species	Source	Reference Number/Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
							Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
401	*Acidovorax*	*temperans*	Q Labs	QL21274-1	Potable water	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
402	*Acinetobacter*	*calcoaceticus*	ATCC	23055	Not Available	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
403	*Acinetobacter*	*baumannii*	CCUG	70743	Human Wound	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
404	*Acinetobacter*	*junii*	Q Labs	QL 0696826.1	Environmental	-	-(at)	NA	EA	-(at)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
405	*Aeromonas*	*caviae*	CCUG	57693	Human Feces	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
406	*Aeromonas*	*hydrophila*	Q Labs	QL 333046.21	Chicken Ceca	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
407	*Alcaligenes*	*faecalis*	ATCC	15554	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
408	*Bordetella*	*bronchiseptica*	CCUG	56928	Human sputum, colonization	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
409	*Brevundimonas*	*mediterranea*	Q Labs	QL 0692733.2	Water	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
410	*Brevundimonas*	*vesicularis*	Q Labs	QL 0695864.9	Environmental	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
411	*Burkholderia*	*cepacia*	ATCC	25416	Onion	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
412	*Buttiauxella*	*gaviniae*	CCUG	35508T	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
413	*Buttiauxella*	*izardii*	CCUG	35510T	Not Available	-	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(at)	NA	EA
414	*Buttiauxella*	*noackiae*	CCUG	35511T	Not Available	-	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(at)	NA	EA
415	*Buttiauxella*	*agrestis*	CCUG	21133	Soil	-	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(at)	NA	EA
416	*Buttiauxella*	*ferragutiae*	CCUG	73587T	Soil	-	-(at)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(at)	NA	EA
417	*Cedecea*	*davisae*	CCUG	23277	Water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
418	*Cedecea*	*neteri*	CCUG	18763T	Human Foot	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
419	*Citrobacter*	*youngae*	ATCC	11102	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
420	*Citrobacter*	*koseri*	ATCC	27156	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
421	*Citrobacter*	*braakii*	ATCC	43162	Clinical isolate, California	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
422	*Citrobacter*	*farmeri*	ATCC	51633	Human feces, North Carolina	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
423	*Citrobacter*	*freundii*	Q Labs	QL 11007-10	Clinical Isolate	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
424	*Dickeya*	*chrysanthemi*	CCUG	47021	Human blood	-	-(at)	NA	EA	-(at)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
425	*Edwardsiella*	*hoshinae*	CCUG	20938	Lizard	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
426	*Edwardsiella*	*anguillarum*	CCUG	64215T	Japanese eel	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
427	*Edwardsiella*	*tarda*	Q Labs	QL 021111D	Not Available	-	-(at)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA	-(at)	NA	EA

Table 2. Raw Data Exclusivity Results Continued

Isolate No.	Genus	Species	Source	Reference Number/Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
							Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
428	*Edwardsiella*	*tarda*	Q Labs	QL 11007-11	Clinical Isolate	-	-(at)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
429	*Enterobacter*	*hormaechei*	CCUG	63314	Human urine	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
430	*Enterobacter*	*cancerogenus*	Q Labs	QL 11010-1	Bottled water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
431	*Enterobacter*	*amnigenus*	Q Labs	QL 112413-2	Milk	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
432	*Enterobacter*	*cloacae*	ATCC	23355	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
433	*Escherichia*	*coli*	Q Labs	QL 030716-1A	Ground Beef	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
434	*Escherichia*	*coli*	Q Labs	QL 41411.1	Bottled water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
435	*Escherichia*	*hermannii*	ATCC	33650	Mouse brain	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
436	*Escherichia*	*fergusonii*	ATCC	35469	Feces, human	-	-(at)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
437	*Flavobacterium*	*hydatis*	NRRL	B-14732	Gills of diseased salmon	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
438	*Flavobacterium*	*johnsoniae*	NRRL	B-14733	Moose dung	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
439	*Flavobacterium*	*aquatile*	NRRL	B-14842	Soil	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(t)	NA	EA
440	*Flavobacterium*	*saccharophilum/piscis*	Q Labs	QL 0694946.3a	Environmental	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
441	*Franconibacter*	*helveticus*	Q Labs	QL 17031.10	Not Available	-	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA
442	*Franconibacter*	*pulveris*	Q Labs	QL 17031.11	Milk Powder	-	+(t)	ND	ED	+(t)	ND	ED	+(t)	ND	ED	+(t)	ND	ED
443	*Franconibacter*	*helveticus*	Q Labs	QL 17031.9	Environmental Isolate	-	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA
444	*Delftia*	*acidovorans*	Q Labs	QL 0692756.2B	Water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
445	*Hafnia*	*alvei*	ATCC	51815	Milk, Minnesota	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
446	*Hafnia*	*alvei*	Q Labs	QL 102313	Milk	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
447	*Klebsiella*	*aerogenes*	ATCC	35029	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
448	*Klebsiella*	*variicola*	CCUG	73431	Human Urine	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
449	*Klebsiella*	*pneumoniae*	Q Labs	QL 11007-7	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
450	*Klebsiella*	*oxytoca*	ATCC	43165	Clinical isolate	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
451	*Kluyvera*	*georgiana*	CCUG	35513T	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
452	*Kluyvera*	*ascorbata*	CCUG	29929	Human stool	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
453	*Kluyvera*	*cryocrescens*	CCUG	39258	Sewage	-	-(t)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
454	*Kluyvera*	*intermedia*	Q Labs	QL 081215-1	Water	-	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(at)	NA	EA

Table 2. Raw Data Exclusivity Results Continued

Isolate No.	Genus	Species	Source	Reference Number/Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
							Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
455	*Leclercia*	*adecarboxylata*	Q Labs	0694739.4b	Environmental	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
456	*Lelliottia*	*amnigena*	CCUG	72458	Human pleura	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
457	*Leminorella*	*grimontii*	CCUG	20908	Source Unkown	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
458	*Leminorella*	*richardii*	CCUG	20911	Human Stool	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
459	*Mixta (Pantoea)*	*calida*	CCUG	63471	Human Wound	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
460	*Morganella*	*morganii*	Q Labs	QL 22214-11	Potable Water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
461	*Morganella*	*morganii*	CCUG	44753	Human Feces	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
462	*Pandoraea*	*norimbergensis*	CCUG	39677	Milk Powder	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
463	*Pantoea*	*agglomerans*	CCUG	58262	Human sputum	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
464	*Pantoea*	*septica*	CCUG	67234	Human feces	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
465	*Pantoea*	*dispersa*	CCUG	25232T	Soil	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(t)	NA	EA
466	*Pantoea*	*ananatis*	Q Labs	QL 103122-1	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
467	*Pluralibacter (Enterobacter)*	*gergoviae*	CCUG	53235	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
468	*Pluralibacter (Enterobacter)*	*pyrinus*	CCUG	48320T	Pear Leaves	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
469	*Proteus*	*penneri*	CCUG	25463	Human Urine	-	-(at)	NA	EA	-(at)	NA	EA	-(t)	NA	EA	-(at)	NA	EA
470	*Proteus*	*myxofaciens*	CCUG	18769T	Gypsy moth larvae	-	-(at)	NA	EA	-(at)	NA	EA	-(t)	NA	EA	-(at)	NA	EA
471	*Proteus*	*mirabilis*	Q Labs	QL 33046.2	Chicken Ceca	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
472	*Proteus*	*mirabilis*	ATCC	9240	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
473	*Proteus*	*vulgaris*	CCUG	18984	Human Feces	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
474	*Pseudescherichia (Escherichia)*	*vulneris*	ATCC	29943	Human wound	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
475	*Pseudomonas*	*aeruginosa*	ATCC	15442	Water Bottle	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
476	*Pseudomonas*	*fluorescens*	Q Labs	QL 17041-3	Raw milk isolate	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
477	*Pseudomonas*	*gessardii*	Q Labs	QL 17041-12	Raw milk isolate	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
478	*Rahnella*	*aquatilis*	ATCC	55046	Soil, Wisconsin	-	-(t)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
479	*Raoultella*	*planticola*	CCUG	15719	Drinking water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
480	*Raoultella*	*ornithinolytica*	CCUG	21208	Surface water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
481	*Raoultella*	*terrigena*	CCUG	53452	Human sputum	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA

Table 2. Raw Data Exclusivity Results Continued

Isolate No.	Genus	Species	Source	Reference Number/Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
							Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
482	*Roseomonas*	*mucosa*	Q Labs	QL 0695267.6c	Environmental	-	-(at)	NA	EA	-(at)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
483	*Salmonella*	Bloemfontein	CCUG	12654	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
484	*Salmonella*	Cerro	ATCC	10723	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
485	*Salmonella*	Decatur	CCUG	12656	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
486	*Salmonella*	Enteritidis	ATCC	4931	Case of gastroenteritis in Copenhagen	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
487	*Salmonella*	Abaetetuba	ATCC	35640	Creek water, Zaiman, Argentina	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
488	*Serratia*	*odorifera*	CCUG	10200	Human	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
489	*Serratia*	*liquefaciens*	CCUG	22907	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
490	*Serratia*	*rubidaea*	CCUG	35289	Human sputum	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
491	*Serratia*	*fonticola*	CCUG	36604	Water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
492	*Serratia*	*marcescens*	Q Labs	QL 11007-1	Bottled water	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
493	*Shewanella*	*baltica*	NRRL	B-41146	Ground beef	-	-(ng)	NA	EA	-(ng)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
494	*Shewanella*	*putrefaciens*	NRRL	B-951	Not Available	-	-(at)	NA	EA	-(at)	NA	EA	-(ng)	NA	EA	-(at)	NA	EA
495	*Shimwellia*	*blattae*	ATCC	29907	Insect (hindgut of cockroach)	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
496	*Siccibacter*	*turicensis*	CCUG	54945T	Not Available	-	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA
497	*Siccibacter*	*colletis*	DSM	107916	Poppy Seeds	-	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA	-(t)	NA	EA
498	*Stenotrophomonas*	*maltophilia*	ATCC	13637	Oropharyngeal Region	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
499	*Stenotrophomonas*	*maltophilia*	Q Labs	QL 0695267.5a	Environmental	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA
500	*Yersinia*	*enterocolitica*	ATCC	49397	Human clinical specimen	-	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA	-(at)	NA	EA

Table 2.2 Raw Data Exclusivity Results with Updated Database Version V1.1.23

Isolate No.	Genus	Species	Source	Reference Number/Strain	Origin	Reference Method Result	CCI			DFI			HCCS			TSA		
							Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final	Final Result Alternative Result	Reference vs Alternative	Final
442	*Franconibacter*	*pulveris*	Q Labs	QL 17031.11	Milk Powder	-	+(t)	NA	EA	+(t)	NA	EA	+(t)	NA	EA	+(t)	NA	EA

ANNEX F- List of Strains:
List of Strains Tested in the Interlaboratory Study

	Cronobacter spp.
Target strains	*Cronobacter condiment* DSM 27966
	Cronobacter dublinensis subsp. *lausannensis* CCUG 58095
	Cronobacter dublinensis subsp. *dublinensis*
	Cronobacter dublinensis subsp. *lactaridii* QL 17091.2
	Cronobacter sakazakii Cornell FSL F6-042
	Cronobacter sakazakii QL 120117-1
	Cronobacter malonaticus CCUG 76247
	Cronobacter muytjensii Cornell FSL F6-031
	Cronobacter sakazakii ATCC BAA-894
	Cronobacter sakazakii CCUG 21205
	Cronobacter sakazakii CCUG 64760
	Cronobacter sakazakii CCUG 28871
	Cronobacter sakazakii Cornell FSL F6-036
	Cronobacter sakazakii QL 120117-6
	Cronobacter sakazakii Cornell FSL F6-046
	Cronobacter sakazakii QL 9110
Non-target strains	*Yersinia enterolitica* ATCC 49397
	Citrobacter freundii QL 11007-10
	Escherichia coli QL 030716-1A
	Klebsiella aerogenes ATCC 35029
	Hafnia alvei QL 102313
	Franconibacter helveticus QL17031.10
	Serratia marcescens QL 11007-1
	Pseudomonas aeruginosa ATCC 15442

ANNEX G - Raw data interlaboratory study

See Excel File: Autobio Autof *Cronobacter* ILS Data Annex G.xlsx