MicroVal Study (2015LR49): Qualitative Method

Renewal Validation of the Assurance® GDS for *E. coli* O157:H7 Tq (MicroVal 2015LR49) following ISO 16140-2:2016 and ISO 16140-6:2019 Extension for the Detection of *E. coli* O157:H7 in Select Foods and Environmental Samples

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The report is prepared in accordance with ISO 16140-2:2016 and MicroVal Technical Committee interpretation of ISO 16140-2, version 1.0 and the Guidance on the transition from ISO 16140 (2003) to ISO 16140-2 (2016).

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Method/Kit name: Assurance® GDS for *E*. *coli* O157:H7 Tq

Validation standards:

1. ISO 16140-2:2016 Microbiology of food chain – Method Validation – Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method
2. ISO 16140-6:2019 Microbiology of food chain – Method Validation – Part 6: Protocol for the validation of alternative (proprietary) methods for microbiological confirmation and typing procedures

Reference methods: ISO 16654:2001 Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Escherichia coli* O157

Scope of validation:

Original validation claims: Raw beef meats (25 g), Fruits and vegetables (25 g), Raw beef meats (375 g), Environmental samples (25 g or surface sampling), Dairy products (25 g)

Additional claims obtained during renewal: Alternative confirmation method for *E*. *coli* O157:H7

Certification organization: Lloyd's Register

List of abbreviations

A(lt), Alternative method
AL, Acceptability Limit
Art. Cont., Artificial contamination
CFU, Colony Forming Units
EL, Expert Laboratory
FP, False Positive
FPR, False Positive Ratio
g, Gram
h, Hour

LOD,	Level of Detection
MCS,	Method Comparison Study
min,	minute
ml,	millilitre
MR,	(MicroVal) Method Reviewer
MVTC,	MicroVal Technical Committee
NA,	Negative Agreement
na,	not applicable
ND,	Negative Deviation
neg (-),	negative/no growth/no reaction/target not detected
PA,	Positive Agreement
PD,	Positive Deviation
pos (+),	positive/growth/target detected
PPNA,	Presumptive Positive Negative Argreement (False Positive result)
PPND,	Presumptive Positive Negative Deviation (False Positive result)
R(ef),	Reference method
RLOD,	Relative Level of Detection
RT,	Relative Trueness
SE,	Relative Sensitivity
SP,	Relative Specificity
TP,	True Positive
mEHEC,	mEHEC® Broth

Contents

1 Introduction

This project, a MicroVal renewal study based on ISO 16140-2 :2016 ~~and the transition guidance document from ISO 16140 (2003) to ISO 16140-2:2016~~ was condducted. All data was reanalyzed ~~data generated~~ in the original validation according to the statistical guidelines outlined in the ISO 16140-2:2016 to dermine if the acceptance criteria was met. An additional alternative confirmation method for *E*. *coli* O157:H7 was also added to the scope. Necessary supplemental testing was conducted following a sensitivity outline for the categories that are already claimed following ISO 16140-6: 2019.

Below is a summary of the different enrichment protocols used for analysis by the alternative method.

1.1. Twenty-five (25) gram samples were enriched with 225 mL of mEHEC® broth (1:10 sample/media ratio), 375 g samples were enriched with 1,500 mL of mEHEC® broth (1:5 sample/media ratio), environmental sponges were enriched in 100 mL of mEHEC® broth, and environmental swabs were enriched with 10 mL of mEHEC® broth. The mEHEC® broth was prewarmed to 41.5 ± 1°C before use. Test portions were incubated at 41.5 ± 1°C for 8 - 14 h.

1.1.1. All test portions were evaluated after both the minimum enrichment time and the maximum enrichment time points.

a. Following enrichment (10 and 14 hour time points), an alternative confirmation protocol, a direct streak from the primary enrichment, was conducted onto 3 different agars: CHROMagar O157 (CHROMagar), CT-SMAC (Remel), and EC O157:H7 ChromoSelect Agar (Sigma). The 3 plates were incubated according to their package insert(s) and typical colonies were examined.

1.1.2. Typical *E*. *coli* O157:H7 colonies were confirmed as needed using Abraxis *E*. *coli* O157:H7 or OXOID *E*. *coli* O157:H7 latex agglutination kits. Typical *E*. *coli* O157:H7 colonies for the 3 different agars are listed below.

a. CHROMagar O157 (CHROMagar) produces characteristic mauve color colonies after incubation.
b. CT-SMAC (Remel) produces characteristic colorless colonies after incubation.
c. EC O157:H7 ChromoSelect Agar (Sigma) produces characteristic dark purple to magenta colonies.

Reference method: The reference method used in the original validation was: ISO 16654:2001. For the current validation, all work will be conducted using ISO 16654:2001.

Scope of the original validation study is: Select foods and environmental samples.

Samples were prepared in accordance with ISO 6887 parts 1-5.

Categories included:

(Original Categories) validated according to ISO 16140:2 (2003)

- Raw beef meats (25 g and 375 g)
- Fruits and vegetables (25 g)
- Dairy products (25 g)
- Environmental samples (25 g and surface sampling)

Criteria evaluated during the study:

- Method Comparison Study (MCS)
- *Reanalyzed according to revised standard,* ISO 16140-2:2016
    - Sensitivity study: ISO 16140-2:2016 (alternative confirmation supplmentary testing conducted following a sensitivity outline)
    - Relative level of detection (RLOD) study: Inclusivity and exclusivity study (alternative confirmation according to ISO 16140:6:2019)

- Interlaboratory Study (ILS)
- *Reanalyzed according to revised standard,* ISO 16140-2:2016
    - Specificity
    - Sensitivity
    - Relative trueness
    - False positive ratio

2 Method protocols

The Method Comparison Study for the original validation (MicroVal 2015LR49) was carried out using 25 gram test portions of sample material for all food matrices for raw beef meats, dairy products, and fruits and vegetables. In addition, 375 gram test portions were also carried out for the raw beef meats. For environmental samples, testing was conducted using environmental sponges/swabs or 25 g test portions. Data from these studies was reanalyzed statistically to ensure acceptance criteria for the ~~updated~~ ISO 16140-2:2016 were met.

An alternative protocol for the confirmation of the positive Assurance® GDS for *E*. *coli* O157:H7 Tq (GDS EHEC) samples was also evaluated in order to meet the new requirements for an alternative confirmation method as per ISO 16140-Part 6 (2019). An additional 70 inoculated representative food items (alternative enrichment only, no PCR analysis) were evaluated following ISO 16140-2:2016. All test portions were evaluated after 10 and 14 hours of incubation by a direct streak from the primary enrichment onto the 3 different agars: CHROMagar O157 (CHROMagar), CT-SMAC (Remel), and EC O157:H7 ChromoSelect Agar (Sigma). The three plate types were incubated according to their package inserts and typical *E*. *coli* O157:H7 colonies

were observed. Abraxis *E*. *coli* O157:H7 and OXOID *E*. *coli* O157:H7 latex agglutination kits were used to confirm the typical *E*. *coli* O157 colonies observed.

2.1 Reference method

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

Sample preparations used in the reference method was done according to ISO 16654:2001 for the food types. Confirmations were performed for all samples according to ISO 16654:2001.

2.2 Alternative method

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

The GDS EHEC is an automated nucleic acid amplification system for the detection of EHEC in foods and environmental samples. Sample preparations used in the alternative method were done according to the kit insert. Confirmations were performed for all samples according to ISO 16654:2001.

In a supplemental study the alternative confirmation method (a direct streak) will be conducted from the primary enrichment onto the 3 different chromogenic agars: CHROMagar O157 (CHROMagar), CT-SMAC (Remel), and EC O157:H7 ChromoSelect Agar (Sigma). The 3 plates were incubated according to their package insert(s) and typical colonies will be examined.Typical *E*. *coli* O157:H7 colonies were confirmed as needed using Abraxis *E*. *coli* O157:H7 or OXOID *E*. *coli* O157:H7 latex agglutination kits

2.3 Study design

For all test portions, there was no shared initial (pre)-enrichment step for the reference and the alternative method. Different test portions coming from the same batch of product (Item) were used for the two methods. All resulting data was treated as **unpaired** data (EN-ISO 16140-2:2016).

3 Method comparison study

3.1 Sensitivity Study

The sensitivity study (SE) is the ability of the method selected to detect the analyte by either the reference or the alternative method.

3.1.1 Categories and sample types

The study design of the original validation (MicroVal 2015LR49) for the three categories plus environmentals were analyzed to meet the updated requirements of ISO 16140-2:2016. Data from the original valdiation was reanalyzed following the new statistical parameters.
The categories, the types, item examples, and the number of samples analyzed from the original validation (performed by ADRIA Développement, Expert Lab) are presented in **Table 1**.

Table 1. List of Categories, Types, and Examples of Items Tested within the Original Validation Study *(obtained from original report by ADRIA Développement, Expert Lab)*[1]

Category	Type	Items (Examples)	# of Samples Analyzed
Raw beef meats (25 g)	Fresh beef meats	Fresh ground beef, fresh beef tips, fresh beef cuts	23
	Frozen then thawed beef	Frozen thawed beef trim and ground beef	20
	Meats with seasonings	Carpaccios, tartars, seasoned ground beef	20
Raw beef meats (375 g)	Fresh raw beef	Fresh raw beef trim and ground beef	32
	Frozen then thawed beef	Frozen thawed beef trim and ground beef	31
Dairy products (25 g)	Raw milk products	Raw milks and raw fermented milks	21
	Pasteurized products	Pasterurized cheese	20
	Raw milk cheeses	Raw cheese	26
Fruits and vegetables (25 g)	Fresh and frozen produces	Fresh or frozen vegetables	23
	Fresh and frozen sprouts or baby leafs	Spinach fresh or frozen	21
	Fresh raw, frozen fruit	Fresh or frozen fruits	20
Environmental samples (25 g or surface)	Surfaces	Swabs, sponges	35
	Process water	Washing water, process water	20
	Dusts	Dusts, sweepings	20

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25 g and 375 g sampling), fruits & vegetables (with 25 g sampling), dairy products (with 25 g sampling), and environmental samples (with 25 g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DÉVELOPPEMENT.

A total of 332 samples were analyzed in the original study (performed by ADRIA Développement, Expert Lab). The reanalysis of the distribution of positive and negative samples per tested category and type is given respectively in **Table 2**.

Table 2. Distribution Per Tested Category and Type: Reanalysis of the Original Sensitivity Data

Category	Type	Positive Samples	Negative Samples	Total
Raw Beef meats (25 g)	Fresh meats	11	12	23
	Frozen and thawed meats	11	9	20
	Meats with seasonings (Carpaccios, tartars, seasoned ground beef, etc.)	10	9	19
	Total	32	30	62
Raw beef meats (375 g)	Fresh beef trim and ground beef	16	16	32
	Frozen and thawed beef trim and ground beef	17	14	31
	Total	33	30	63
Dairy Products	Raw Milks and raw fermented milks	11	10	21
	Pasteurized cheeses	7	8	15
	Raw milk cheeses	14	12	26
	Total	32	30	62
Fruits and Vegetables	Fresh and frozen produces, deli salads	5	12	17
	Fresh and frozen sprouts, baby leaves	9	7	16
	Fresh and frozen fruits	10	6	16
	Read to eat food (non pasteurized ciders and fruit juices, deli-salads, etc.)	6	5	11
	Total	30	30	60
Environmental Samples	Swabs, sponges	15	20	35
	Process water	9	7	16
	Dusts, siphons	8	4	12
	Total	32	31	63
Total All Categories		**159**	**151**	**310**

3.1.2 Test sample preparation

For the retained data from the original study (performed by ADRIA Développement, Expert Lab), 1.3% (2 total samples) of the samples were naturally contaminated and 98.7% for the samples were artificially contaminated. In total 189 samples were artificially contaminated, using 56 different strains. A total of 156 samples gave a positive result. Strains used to inoculate items were used on a maximum of 6 different items. A total of 134 samples were inoculated at a level equal or below 5 CFU/sample. A total of 22 samples were inoculated at a level between 5.2 and 7.4 CFU/sample.

Artificial contaminations were done by seeding or spiking protocols.

For the strains used to inoculate samples, the level of injury was evaluated by plating on a non-selective agar (TSAYE) and a selective agar (CT-SMAC). As proposed, a ≥ 0.5 log of injured cells was obtained. Raw data and results for seeding and spiking obtained for the sensitivity portion of testing can be found in **Annex D** with data obtained from the original validation report (written by ADRIA Développement, Expert Lab).

Regardless of presumptive result, all test portions analyzed by the alternative method were confirmed following ISO 16654:2001 reference method after a total enrichment time of 24 hours, beginning with an IMS step on 1 mL aliquots of sample. See Annex A for confirmation steps of the ISO 16654:2001 reference method.

In order to improve the practicability of the method to user labs, enrichment broths for the alternative method were stored for 72 h at 2-8 ºC. All presumptive positive and discrepant results were reanalyzed with the Assurance GDS EHEC method after the 72 h hold time. All samples were reconfirmed at 72 h following the ISO 16654:2001 reference method, and the alternative confirmation method. Results obtained for the 72 h hold for the original study (performed by ADRIA Développement, Expert Lab) can be found in **Annex E.**

3.1.3 Confirmation protocols

ISO 16654:2001 / Traditional Confirmation

During the original study (performed by ADRIA Développement, Expert Lab) all 25 g samples were enriched with 225 mL of mTSB + novobiocin, all 375 g samples were enriched with 3,375 mL of mTSB + novobiocin, and the environmental sponges were enriched with 100 mL of mTSB + novobiocin. Enrichments were incubated at 41.5 ± 1 °C for 6 and 24 hours.

Following incubation, 1 mL of enrichment was transferred into an Eppendorf tube and IMS was performed. After performing IMS a 50 µL aliqout was plated onto CT-SMAC and Chromagar O157 (CHROMagar). Both CT-SMAC and Chromagar O157 plates were incubated for 24 hours at 37 ± 1°C. Following incubation plates were examined for typical colonies and characteristic colonies were subcultured to PCA and incubated for 24 hours at 37 ± 1°C. Final confirmation for *E*. *coli* O157:H7 was obtained through peforming indole test and latex agglutination tests.

3.1.4 *Sensitivity study results*

The three categories and environmental samples of the original validation (MicroVal 2015LR50) meet the requirements of ISO 16140-2:2016 when reanalyzed. Summary of results are presented in the tables below. Raw data and results obtained for the sensitivity portion of testing can be found in **Annex E** with data obtained from the original validation report (written by ADRIA Développement, Expert Lab).

Table 3 shows the summary of reanalyzed results of the reference method and the alternative methods for all categories of the original study (performed by ADRIA Développement, Expert Lab).

Table 4 shows the Interpretation of reanalyzed sample results between the reference and alternative method (based on the confirmed alternative method) of the original study (performed by ADRIA Développement, Expert Lab).

Table 3. Summary of Reanalyzed Sensitivity Study Results – All Categories of the Original Study

Result	Reference method positive (R+)	Reference method negative (R-)
Alternative method positive (A+)	Positive agreement (A+/ R+) **PA = 71**	Positive deviation (R-/A+) **PD = 77**
Alternative method negative (A-)	Negative deviation (A-/ R+). **ND = 11**	Negative agreement (A-/ R-) **NA = 151**

Table 4. Interpretation of Reanalyzed Sample Results Between the Reference and Alternative Method *(Based on the Confirmed Alternative Method)* of the Original Study

Category	Type	PA	NA	PD	ND	PPND	PPNA
Raw Beef meats (25 g)	Fresh meats	5	12	5	1	0	0
	Frozen and thawed meats	6	9	5	0	0	0
	Meats with seasonings (carpaccios, tartars, seasoned ground beef, etc.)	7	10	3	0	0	0
	Total	18	31	13	1	0	0
Raw beef meats (375 g)	Fresh beef trim and ground beef	3	16	12	1	0	0
	Frozen and thawed beef trim and ground beef	8	14	6	3	0	0
	Total	11	30	18	4	0	0
Dairy Products	Raw milks and raw fermented milks	8	10	3	0	0	0
	Pasteurized cheeses	3	13	4	0	0	0
	Raw milk cheeses	10	12	3	1	0	0
	Total	21	35	10	1	0	0
Fruits and Vegetables	Fresh and frozen produces, deli salads	5	12	6	0	0	0
	Fresh and frozen sprouts, baby leaves	4	12	4	1	0	0
	Fresh, raw, frozen fruits, fresh fruit juices	3	10	6	1	0	0
	Total	12	34	16	2	0	0
Environmental Samples	Swabs, sponges	2	20	11	2	0	0
	Process water	4	11	5	0	0	0
	Dusts, siphons	2	13	4	1	0	0
	Total	8	44	20	3	0	0
All Categories		**70**	**174**	**77**	**11**	**0**	**0**

3.1.5 Sensitivity study calculations

The sensitivity study parameters were calculated for all Categories and Types as specified in **Table 5**, and the overview is given in **Tables 6** for the reanalysis of the categories for the original study (performed by ADRIA Développement, Expert Lab).

Table 5. Formulas to Calculate the Sensitivity Parameters

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

Table 6. Overview for the Reanalyzed Calculated Sensitivity Parameters Per Category and Type for the Categories for the Original Study and Renewal Study

Category	Type	PA	NA	PD	ND	PPND	PPNA	SE alt %	SE ref %	RT %	FPR %	ND-PD	Acceptance Limit Allowed
Raw Beef meats (25 g)	Fresh Meats	5	12	5	1	0	0	90.9	54.5	73.9	0.0		
	Frozen and thawed meats	6	9	5	0	0	0	100.0	54.5	75.0	0.0		
	Meats with seasonings (Carpaccios, tartars, seasoned ground beef, etc.)	7	10	3	0	0	0	100.0	70.0	85.0	0.0		
	Total	18	31	13	1	0	0	96.9	59.4	77.8	0.0	-12	**3**
Raw beef meats (375 g)	Fresh beef trim and ground beef	3	16	12	1	0	0	93.8	25.0	59.4	0.0		
	Frozen and thawed beef trim and ground beef	8	14	6	3	0	0	82.4	64.7	71.0	0.0		
	Total	11	30	18	4	0	0	87.9	45.5	65.1	0.0	-14	**3**
Dairy Products	Raw Milks and raw fermented milks	8	10	3	0	0	0	100.0	72.7	85.7	0.0		
	Pasteurized cheeses	3	13	4	0	0	0	100.0	42.9	80.0	0.0		
	Raw milk cheeses	10	12	3	1	0	0	92.9	78.6	84.6	0.0		
	Total	21	35	10	1	0	0	96.9	68.8	83.6	0.0	-9	**3**
Fruits and Vegetables	Fresh and frozen produces, deli salads	5	12	6	0	0	0	100.0	45.5	73.9	0.0		
	Fresh and frozen sprouts, baby leaves	4	12	4	1	0	0	88.9	55.6	76.2	0.0		
	Fresh, raw, frozen fruits, fresh fruit juices	3	10	6	1	0	0	90.0	40.0	65.0	0.0		
	Total	12	34	16	2	0	0	93.3	46.7	71.9	0.0	-14	**3**
Environmental Samples	Swabs, sponges	2	20	11	2	0	0	86.7	26.7	62.9	0.0		
	Process water	4	11	5	0	0	0	100.0	44.4	75.0	0.0		
	Dusts, siphons	2	13	4	1	0	0	85.7	42.9	75.0	0.0		
	Total	8	44	20	3	0	0	90.3	35.5	69.3	0.0	-17	**3**
All Categories		**70**	**174**	**77**	**11**	**0**	**0**	**93.0**	**51.3**	**73.5**	**0.0**	-66	5

3.1.6 Discordant results

The deviations that were observed during the sensitivity evaluation are listed below in **Table 7 and Table 8** for the categories of the original study (performed by ADRIA Développement, Expert Lab).

Table 7. Discordant Results (Negative Deviations) for the Categories of the Original Study *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Category	Sample n°	PCR Results	Confirmatory tests		Inoculation (CFU/sample)
			After 8 Hr Incubation Time	*After 24 Hr Incubation Time*	
Beef meats (25 g)	1703	-	-	-	*Escherichia coli* O157:H7 Ad 1248 (1.8)
Beef Meats (375 g)	2748	-	-	-	*Escherichia coli* O157:H7 Ad 487(1.0)
	2752	-	-	-	*Escherichia coli* O157:H7 Ad 925 (1.0)
	2757	-	-	-	*Escherichia coli* O157:H7 Ad 487 (1.0)
	3004	-	-	-	*Escherichia coli* O157:H7 Ad 489 (0.8)
Dairy Products	1847	-	-	-	*Escherichia coli* O157:H7 Ad 571 (1.0)
Fruits and vegetables	2454	-	-	-	*Escherichia coli* O157:H7 Ad 580 (0.6)
	2460	-	-	-	*Escherichia coli* O157:H7 Ad 557 (0.6)
Environmental samples	350	-	-	-	*Escherichia coli* O157:H7 Ad 686 (2.4)
	486	-	-	-	*Escherichia coli* O157:H7 Ad 686 (0.8)
	496	-	-	-	*Escherichia coli* O157:H7 Ad 554 (1.4)

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 8. Discordant Results (Positive Deviations) for the Categories of the Original Study *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Category	Sample n°	PCR result	Confirmation	(inoculation level CFU/sample)
Raw beef meats (25 g)	1545	+	+	Naturally contaminated
	1699	+	+	*E. coli* O157:H7 Ad1248 (1.8)
	1700	+	+	*E. coli* O157:H7 Ad684 (1)
	1702	+	+	*E. coli* O157:H7 Ad976 (1.8)
	1706	+	+	*E. coli* O157:H7 Ad976 (1.8)
	1708	+	+	*E. coli* O157:H7 Ad687 (2.4)
	1709	+	+	*E. coli* O157:H7 Ad976 (1.8)
	1710	+	+	*E. coli* O157:H7 Ad1248 (1.8)
	2843	+	+	*E. coli* O157:H7 Ad922 (0.6)
	2845	+	+	*E. coli* O157:H7 Ad486 (1.8)
	2846	+	+	*E. coli* O157:H7 Ad486 (1.8)
	2847	+	+	*E. coli* O157:H7 Ad486 (1.8)
	2848	+	+(after IMS captivate and regrowth BHI)	*E. coli* O157:H7 Ad559 (1.2)
Raw beef meats (375 g)	**2288**	+	+	*E. coli* O157:H7 Ad1501 (1.4)
	2289	+	+	*E. coli* O157:H7 Ad975 (0.6)
	2293	+	+	*E. coli* O157:H7 Ad933 (2)
	2294	+	+	*E. coli* O157:H7 Ad1501 (1.4)
	2296	+	+	*E. coli* O157:H7 Ad933 (2)
	2297	+	+	*E. coli* O157:H7 Ad1501 (1.4)
	2298	+	+	*E. coli* O157:H7 Ad975 (0.6)
	2300	+	+	*E. coli* O157:H7 Ad1501 (1.4)
	2302	+	+	*E. coli* O157:H7 Ad933 (2)
	2749	+	+	*E. coli* O157:H7 Ad925 (1)
	2753	+	+	*E. coli* O157:H7 Ad924 (1.6)
	2755	+	+	*E. coli* O157:H7 Ad925 (1)
	2758	+	+	*E. coli* O157:H7 Ad925 (1)
	3002	+	+	*E. coli* O157:H7 Ad488 (1.4)
	3003	+	+ (after regrowth in BHI overnight)	*E. coli* O157:H7 Ad489 (0.8)
	3005	+	+	*E. coli* O157:H7 Ad489 (0.8)
	3007	+	+	*E. coli* O157:H7 Ad1071 (2.6)
	3009	+	+	*E. coli* O157:H7 Ad591 (3.4)
Dairy Products	**1586**	+	+	*E. coli* O157:H7 Ad576 (6.8)
	1843	+	+	*E. coli* O157:H7 Ad571 (1)
	1845	+	+ after an IMS with captivate/regrowth in BHIplating on CT-SMAC	*E. coli* O157:H7 Ad579 (2)
	1848	+	+	*E. coli* O157:H7 Ad571 (1)
	1850	+	+	*E. coli* O157:H7 Ad579 (2)
	1851	+	+	*E. coli* O157:H7 Ad574 (0.6)
	1853	+	+	*E. coli* O157:H7 Ad574 (0.6)
	1856	+	+	*E. coli* O157:H7 Ad579 (2)
	1857	+	+	*E. coli* O157:H7 Ad582 (0.6)
	2660	+	+	*E. coli* O157:H7 Ad486 (1.4)

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 8: Continued. Discordant Results (Positive Deviations) for the Categories of the Original Study *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Category	Sample n°	PCR result	Confirmation	(inoculation level CFU/sample)
Fruits and Vegetables	**2448**	+	+	E. coli O157:H7 Ad557
	2449	+	+	E. coli O157:H7 Ad577
	2450	+	+	E. coli O157:H7 Ad580
	2452	+	+	E. coli O157:H7 Ad557
	2453	+	+	E. coli O157:H7 Ad577
	2457	+	+	E. coli O157:H7 Ad577
	2459	+	+	E. coli O157:H7 Ad556
	2461	+	+	E. coli O157:H7 Ad577
	2796	+	+	E. coli O157:H7 Ad558
	2797	+	+	E. coli O157:H7 Ad572
	2799	+	+	E. coli O157:H7 Ad558
	3405	+	+	E. coli O157:H7 Ad578
	3407	+	+	E. coli O157:H7 Ad582
	3408	+	+	E. coli O157:H7 Ad578
	3412	+	+	E. coli O157:H7 Ad573
	3419	+	+	E. coli O157:H7 Ad572
Environmental Samples	**352**	+	+	E. coli O157:H7 Ad688
	353	+	+	E. coli O157:H7 Ad1745
	360	+	+	E. coli O157:H7 Ad573
	365	+	pos after regrowth in BHI/plating on CT-SMAC	E. coli O157:H7 Ad572
	488	+	+	E. coli O157:H7 Ad688
	491	+	+	E. coli O157:H7 Ad552
	492	+	+	E. coli O157:H7 Ad552
	494	+	+	E. coli O157:H7 Ad553
	495	+	+	E. coli O157:H7 Ad553
	497	+	+	E. coli O157:H7 Ad554
	498	+	+	E. coli O157:H7 Ad554
	499	+	+	E. coli O157:H7 Ad555
	500	+	+	E. coli O157:H7 Ad555
	503	+	+	E. coli O157:H7 Ad567
	504	+	+	E. coli O157:H7 Ad567
	515	+	+	Naturally contaminated
	602	+	pos after an ims with captivate/plating on CT-SMAC	E. coli O157:H7 Ad552
	603	+	+	E. coli O157:H7 Ad553
	604	+	+	E. coli O157:H7 Ad685
	606	+	+	E. coli O157:H7 Ad553

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

In the original study, the three food and environmental categories of the original validation (MicroVal 2015LR50) meet the requirements of ISO 16140-2:2016 when reanalyzed for both individual and combined categories.

3.1.7 Conclusion sensitivity study

The three categories plus environmentals of the original validation (MicroVal 2015LR50) meet the requirements of ISO 16140-2:2016 when reanalyzed. The observed values for ND-PD for the individual categories and for all categories meet the acceptability limits (observed values ≤ AL) for the reanalysis of original study.

The reanalysis of the sensitivity study according to ISO 16140-2:2016 is given in **Table 9** for the categories from the original study.

Table 9. Interpretation of the Reanalysis of the Sensitivity Study Results for the Categories from the Original Study

Category	Type	PA	NA	PD	ND	PPND	PPNA	ND-PD	Acceptance Limit Allowed
Raw Beef meats (25 g)	Fresh meats	5	12	5	1	0	0		
	Frozen and thawed meats	6	9	5	0	0	0		
	Meats with seasonings (carpaccios, tartars, seasoned ground beef, etc.)	7	10	3	0	0	0		
	Total	18	31	13	1	0	0	-12	**3**
Raw beef meats (375 g)	Fresh beef trim and ground beef	3	16	12	1	0	0		
	Frozen and thawed beef trim and ground beef	8	14	6	3	0	0		
	Total	11	30	18	4	0	0	-14	**3**
Dairy Products	Raw milks and raw fermented milks	8	10	3	0	0	0		
	Pasteurized cheeses	3	13	4	0	0	0		
	Raw milk cheeses	10	12	3	1	0	0		
	Total	21	35	10	1	0	0	-9	**3**
Fruits and Vegetables	Fresh and frozen produces, deli salads	5	12	6	0	0	0		
	Fresh and frozen sprouts, baby leaves	4	12	4	1	0	0		
	Fresh, raw, frozen fruits, fresh fruit juices	3	10	6	1	0	0		
	Total	12	34	16	2	0	0	-14	**3**
Environmental Samples	Swabs, sponges	2	20	11	2	0	0		
	Process water	4	11	5	0	0	0		
	Dusts, siphons	2	13	4	1	0	0		
	Total	8	44	20	3	0	0	-17	**3**
All Categories		**70**	**174**	**77**	**11**	**0**	**0**	-66	**5**

3.1.8 Enrichment broth storage

Enrichment media, mEHEC® broth, storage was done at 2-8 °C for 72 h for the original study (performed by ADRIA Développement, Expert Lab). A total of three changes were observed as summarized in **Table 10**. These changes were due to the confirmatory test and not the PCR analysis. These three changes had no impact or change on the analysis of discordant results.

Table 10. Enrichment Storage Changes Observed in the Original Study (*obtained from original report by ADRIA Développement, Expert Lab)*[1]

Sample n°	Results before storage			Results after storage		
	PCR	*Confirmation*	*Agreement*	*PCR*	*Confirmation*	*Agreement*
2452	+	+	PD	+	-	NA
2453	+	+	PD	+	-	NA
365	+	+	PD	-	-	NA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Conclusion for the enrichment broth storage:

The changes were due to the confirmation tests for two of the samples. These changes have no impact on the analysis. Three of the positive samples could not be confirmed after storage of the enrichment, two of the PCR tests were positive and one was negative.

For results obtained from the original study (performed by ADRIA Développement, Expert Lab) The ND-PD for all individual and combined categories meets acceptability limits.

3.2 Relative level of detection study

The relative level of detection is the level of detection at P = 0.50 (LOD_{50}) of the alternative method divided by the level of detection at P = 0.50 (LOD_{50}) of the reference method.

3.2.1 Categories, sample types and strains

One sample type and one relevant target micro-organism for the sample type was chosen for each of the categories in the study. For the original study four matrix and strain pairs, and one environmental and strain pair were evaluated as described in **Table 11.**

Table 11. List of Selected Types and Strains, as Tested Within the Original Study

Food Types	Inoculated strain[1]	Origin	Storage Conditions Before Analysis
Raw ground beef	*E. coli* O157:H7 MK 41242	Ground Beef	Overnight Culture; Inoculated matrix held at 2 -8°C for 48 Hours
Raw beef trim	*E. coli* O157:H7 670T	Ground Beef	Overnight Culture; Inoculated matrix held at 2 -8°C for 72 Hours
Raw milk	*E. coli* O157:H7 R33-9	Feces	Overnight Culture; Inoculated matrix held at 2 -8°C for 48 Hours
Spinach	*E. coli* O157:H7 AA18-3	Feces	Overnight Culture; Inoculated matrix held at 2 -8°C for 72 Hours
Process Water	*E. coli* O157:H7 BV777	Slaughterhouse Surface	Overnight Culture; Inoculated matrix held at 2 -8°C for 48 Hours

3.2.2 Test sample preparations

Three levels of artificial contamination were prepared for each type:

- Negative control level: One uninoculated bulk in order to get 5 test portions,
- Low level: One inoculated bulk between 0.5 and 1.0 CFU/sample in order to get 25 test portions providing fractional recovery (5-15 positive results out of 20),
- High level: One inoculated bulk between 2.0 and 4.0 CFU/sample in order to get 5 test portions contaminated at a higher level.

A bulk lot of the food matrices were inoculated at each level homogenized and stored as described in **Table 11**.

3.2.3 RLOD study results

The four food types and environmental of the original validation (MicroVal 2015LR50) meet the requirements of ISO 16140-2:2016 when reanalyzed. The tabulated raw data of the RLOD study can be found in **Annex F** with data obtained from the original validation report (written by ADRIA Développement, Expert Lab).

The RLOD calculations were performed using the Excel spread sheet (version 06-07-2015) of the international standard as described in ISO 16140-2: 2016.

The RLOD per category combined is given in **Table 12** for the reanalysis of the original study (performed by ADRIA Développement, Expert Lab)

Table 12. Presentation of RLOD before and after confirmation for the Alternative Results for the Renewal Study

Name	RLOD	RLODL	RLODU	b=ln(RLOD)	sd(b)	z-Test statistic	p-value
Raw Ground Beef	1.847	0.763	4.475	0.614	0.442	1.387	0.165
Raw Beef Trim	0.717	0.280	1.835	-0.333	0.470	0.708	1.521
Raw Milk	0.896	0.402	2.002	-0.109	0.402	0.272	1.215
Spinach	0.843	0.297	2.397	-0.170	0.522	0.326	1.256
Process Water	0.043	0.005	0.342	-3.149	1.038	3.033	1.998
Combined	0.693	0.468	1.025	-0.367	0.196	1.876	1.939

1.RLOD of the alternative presumptive results and the alternative confirmed results were identical

3.2.4 Calculation of the LOD_{50}

The LOD_{50} calculations were conducted according to Wilrich and Wilrich POD-LOD calculation, Version 9 for each method. See **Table 13** and **Table 14** for the reference method and the alternative method LOD_{50} calulation for the original study (performed by ADRIA Développement, Expert Lab).

Table 13. Presentation of LOD_{50} for the Reference Method

Results of the POD-LOD calculations											
Matrix		Matrix effect	Log Matirx effect	SD of log matrix effect	$LOD_{50\%}$ = 50% limit of detection in cfu/g or cfu/ml			$LOD_{95\%}$ = 95% limit of detection in cfu/g or cfu/ml			Test statistic matrix effect
no.	Designation				Detection limit	Lower conf. limit	Upper conf limit	Detection limit	Lower conf. limit	Upper conf. limit	
i	$Matrix_i$	F_i	f_i	s_{fx}	$d_{0.5i}$	$d_{0.5iL}$	$d_{0.5iU}$	$d_{0.95i}$	$d_{0.95iL}$	$d_{0.95iU}$	$\|Z_i\|$
1	Ground Beef 5% fat	0.032	-3.435	0.271	0.860	0.500	1.479	3.718	2.162	6.394	0.001
2	Raw Beef Trim	0.016	-4.124	0.351	1.714	0.849	3.460	7.407	3.669	14.952	0.017
3	Raw Milk	0.030	-3.491	0.288	0.909	0.512	1.617	3.931	2.211	6.987	0.014
4	Fresh Spinach	0.036	-3.321	0.343	0.768	0.387	1.523	3.317	1.672	6.582	0.358
5	Process Water	0.001	-6.588	1.005	20.134	2.699	150.196	87.019	11.665	649.135	0.009
Combined results		0.019	-3.948	0.147	1.437	1.071	1.928	6.210	4.628	8.334	0.427
		based on the data of matrices 1, 2, 3, 4 and 5									

Table 14. Presentation of LOD_{50} for the Alternative Method

Results of the POD-LOD calculations											
Matrix		Matrix effect	Log Matirx effect	SD of log matrix effect	$LOD_{50\%}$ = 50% limit of detection in cfu/g or cfu/ml			$LOD_{95\%}$ = 95% limit of detection in cfu/g or cfu/ml			Test statistic matrix effect
no.	Designation				Detection limit	Lower conf. limit	Upper conf limit	Detection limit	Lower conf. limit	Upper conf. limit	
i	$Matrix_i$	F_i	f_i	s_{fx}	$d_{0.5i}$	$d_{0.5iL}$	$d_{0.5iU}$	$d_{0.95i}$	$d_{0.95iL}$	$d_{0.95iU}$	$\|Z_i\|$
1	Ground Beef 5% fat	0.019	-3.945	0.307	1.433	0.776	2.645	6.192	3.353	11.433	0.002
2	Raw Beef Trim	0.022	-3.805	0.315	1.246	0.664	2.338	5.384	2.869	10.103	0.015
3	Raw Milk	0.034	-3.381	0.280	0.815	0.465	1.428	3.524	2.012	6.173	0.014
4	Fresh Spinach	0.042	-3.173	0.335	0.662	0.339	1.293	2.860	1.464	5.589	0.342
5	Process Water	0.033	-3.398	0.275	0.829	0.479	1.436	3.584	2.069	6.208	0.004
Combined results		0.028	-3.569	0.133	0.983	0.754	1.283	4.250	3.257	5.546	0.386
		based on the data of matrices 1, 2, 3, 4 and 5									

3.2.5 Conclusion RLOD study

The RLOD values met the acceptability limit, 2.5 for unpaired test portions for all categories reanalyzed for the original study.

3.3 Inclusivity/exclusivity study

Inclusivity is the ability of the alternative method to detect the target analyte from a wide range of strains.

Exclusivity is the lack of interference from a relevant range of non-target strains of the alternative method.

Testing from the original validation met the requirements of the current ISO 16140-2 and no further analysis was conducted. Of the 50 *E*. *coli* O157:H7 strains tested all showed expected postive results. All 30 exclusivity strains tested gave the expected negative results except one which gave a positive PCR result and negative confirmatory test. The one exclusivity that gave a positive PCR result was *E. coli* O55:H7. The tabulated raw data of the Inclusivity and Exclusivity study can be found in **Annex G** with data obtained from the original validation report (written by ADRIA Développement, Expert Lab).

4 Conclusions - Method Comparison Study

Overall, the conclusions for the Method Comparison Study are:

The observed values for ND-PD for the individual categories and for all categories meet the acceptability limits (observed values ≤ AL) for the reanalysis of the original study.

The RLOD values meet the acceptability limit, which is 2.5 for unpaired studies, for all re-analysis of categories tested in the original study and for the new categories tested in the renewal study.

The alternative confirmation method utilizing 3 chromogenic agars: CHROMagar O157 (CHROMagar), CT-SMAC (Remel), and EC O157:H7 ChromoSelect Agar (Sigma) is selective and specific for both incubation times evaluated. No discrepant results were seen for both time points evaluated. All inclusivity strains were accurately detected and all exclusivity strains were accurately excluded.

5 Interlaboratory Study

Data from the Interlaboratory study (ILS) (supervised by ADRIA Développement, Expert Lab) performed during the original validation was reanalyzed according to the new statistical guidelines as presented in 16140-2:2016. The data still meets current acceptance criteria. For the original ILS, a total of 10 participants submitted data. The test matrix used was ground beef, inoculated with *E*. *coli* O157:H7 strain (ATCC 43888, isolated from human feces). **Table 15 and 16** provide the data generated for the alternative and reference method. **Table 17** provides a summary of the ILS results. The updated statistical analysis from the original ILS data is presented in **Table 18 - Table 20**.

Cross-contamination was observed for Level 0 (LO) of the reference method for 7 of the 10 retained labs. This level was dropped from review as decided with the reviewers of the MicroVal committee as per the original 2015LR49 report (performed by ADRIA Développement, Expert Lab).

Table 15. Positive Results (before and after confirmation) by the alternative method (data *obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborators	Contamination level					
	L0		L1		L2	
	before confirmation	*after confirmation*	*before confirmation*	*after confirmation*	*before confirmation*	*after confirmation*
A1	0	0	8	8	8	8
A2	2	0	8	7	8	8
B	1	0	6	6	8	8
C1	0	0	8	8	8	8
C2	0	0	7	7	8	8
D	0	0	7	7	8	8
E1	0	0	7	7	8	8
E2	1	0	7	7	8	8
F1	5	5	6	6	5	5
G	0	0	8	7	8	8
H	0	0	4	4	8	8
I	0	0	7	7	8	7
J1	1	0	7	7	8	8
J2	0	0	8	8	8	8
Total	**P_0 = 10**	**CP_0 = 5**	**P_1 = 98**	**CP_1 = 96**	**P_2 = 109**	**CP_2 = 108**

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 16. Positive Results by the reference method (data *obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborators	Contamination level		
	L0	L1	L2
A1	1	8	8
A2	0	6	8
B	2	8	8
C1	1	8	8
C2	7	8	8
D[1]	1	8	8
E1	0	8	8
E2	2	7	8
F1	2	7	8
G	6	7	8
H	0	5	8
I	1	6	8
J1	2	7	8
J2	7	6	8
Total	**P_0 = 32**	**P_1 = 99**	**P_2 = 112**

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Unexpected positives were observed in control samples. After investigation, Collaborators D, F1, J1 and J2 were removed from the study for not following the protocol.

Table 17. Summary of Obtained ILS Results (data *obtained from original report by ADRIA Développement, Expert Lab)*[1]

	Response	Reference method positive (R+)	Reference method negative (R-)
Level 1	**Alternative method positive (A+)**	Positive agreement (A+/R+) **PA = 62**	Positive deviation (R-/A+) **PD = 6**
	Alternative method negative (A-)	Negative deviation (A-/R+) **ND = 9**	Negative agreement (A-/R-) **NA = 3**
Level 2	**Alternative method positive (A+)**	Positive agreement (A+/R+) **PA = 79**	Positive deviation (R-/A+) **PD = 0**
	Alternative method negative (A-)	Negative deviation (A-/R+) **ND = 1**	Negative agreement (A-/R-) **NA = 0**

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

[1] Samples for the reference and alternative methods analyzed at different dates

Table 18. Reanalysis of the Original ILS Data

Results of the PODLOD calculations									
Method	Method effect	Log method effect	SD of log method effect	$LOD_{50\%}$ = 50% limit of detection in cfu/g or cfu/ml			$LOD_{95\%}$ = 95% limit of detection in cfu/g or cfu/ml		
				Detection limit	Lower conf. limit	Upper conf limit	Detection limit	Lower conf. limit	Upper conf. limit
	F_i	f_i	s_{fx}	$d_{0.5i}$	$d_{0.5iL}$	$d_{0.5iU}$	$d_{0.95i}$	$d_{0.95iL}$	$d_{0.95iU}$
Reference	0.659	-0.417	0.247	1.05	0.64	1.72	4.55	2.78	7.45
Alternative	0.255	-1.365	0.194	2.71	1.84	4.00	11.73	7.96	17.29
Conclusions	The methods are significantly different at the 5% significance level (change in deviance of the model with method effects to the null model D_{method} = 9.47 with 1 degree of freedom, p-value 0).								
	The relative limit of detection (RLOD) of the alternative method, as compared to the reference method, is 2.58 with a 90% confidence interval of 1.54 - 4.32.								

Results by laboratories					
no.	Laboratory Designation Laboratory$_i$	Method effect	Log method effect	SD of log method effect	
		F_i	f_i	s_{fx}	
1	B1-1				
2	C1-1	0.701	-0.355	0.305	
3	D1-1				
4	D2-1				
5	F-1				
6	G-1	1.155	0.144	0.349	
7	H-1				
8	I-1				
9	A1-2	0.177	-1.734	0.227	
10	B-2				
Combined Results		0.347	-1.057	0.149	based on the data of laboratories 2,6, and 9
Conclusion	The probabilities of detection (POD) of the laboratories are significantly different at the 5% significance level (change in deviance of the model with laboratory effects to the null model Dlab = 28 with 2 degrees of freedom, p-value 0).				

Table 19. Summary of Statistical Analysis of the ILS Study (*data obtained from original report by ADRIA Développement, Expert Lab)*[1]

	Level 1	Level 2
Sensitivity for the Alternative Method	88.3%	98.8%
Sensitivity for the Reference Method	92.2%	100.0%
Relative Trueness	81.3%	98.8%
False Positive Ratio for the Alternative Method	66.7	/

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 20. ILS Calculations Obtained (*data obtained from original report by ADRIA Développement, Expert Lab)*[1]

	Level 1	Level 2
NX	80	80
(p+)ref	0.9	1.0
(p+)alt	0.9	1.0
AL = (ND - PD) max	7.41	1.73
ND - PD	3	1
Conclusion	(ND - PD) < AL	(ND - PD) < AL

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

With the 10 valid sets of data, L0 was dropped from the calculation as there was gross cross contamination observed in the control samples. Level 0 was dropped based on reviewer and MicroVal committee members feedback. In the 10 valid data sets, fractional positive recovery was observed at L1 and L2. The tabulated raw data of the ILS can be found in **Annex H** with data obtained from the original validation report (written by ADRIA Développement, Expert Lab).

6 Extension: Alternative Confirmation

6.1 Sensitivity

For validation of the alternative confirmation method, an additional 70 inoculated representative food items (alternative enrichment only, no PCR analysis) were evaluated following a sensitivity outline according to ISO 16140-2:2016.

6.1.1 *Sample Type and Preparation*

The categories, the types, item examples, and the number of samples analyzed are presented in **Table 21.**

Table 21 - List of Categories, Types, and Examples of Items Tested within the Validation of the Alternative Confirmation

Category	Type	Items (Examples)	# of Samples Analyzed
Raw beef meats (25 g)	Fresh beef meats	Fresh ground beef, fresh beef tips, fresh beef cuts	5
	Frozen then thawed beef	Frozen thawed beef trim and ground beef	5
	Meats with seasonings	Carpaccio's, tartars, seasoned ground beef	5
Raw beef meats (375 g)	Fresh raw beef	Fresh raw beef trim and ground beef	5
	Frozen then thawed beef	Frozen thawed beef trim and ground beef	5
Dairy products (25 g)	Raw milk products	Raw milks and raw fermented milks	5
	Pasteurized products	Pasterurized cheese	5
	Raw milk cheeses	Raw cheese	5
Fruits and vegetables (25 g)	Fresh and frozen produces	Fresh or frozen vegetables	5
	Fresh and frozen sprouts or baby leafs	Spinach fresh or frozen	5
	Fresh raw, frozen fruit	Fresh or frozen fruits	5
Environmental samples (25 g or surface)	Surfaces	Swabs, sponges	5
	Process water	Washing water, process water	5
	Dusts	Dusts, sweepings	5

The ISO 16140-6 criteria were utilized to validate an alternative confirmation procedure. After both 10 and 14 h of enrichment, the enriched samples were struck to 3 different chromogenic agars: CHROMagar O157 (CHROMagar), CT-SMAC (Remel), and EC O157:H7 ChromoSelect Agar (Sigma). The three plates types were incubated according to their package inserts and typical *E*. *coli* O157 colonies were observed. Abraxis *E*. *coli* O157:H7 and OXOID *E*. *coli* O157:H7 latex agglutination kits were used to confirm the typical *E*. *coli* O157 colonies observed. All positive enrichments and discrepancies were reanalyzed after a 48-72 hour hold at 4 °C.

6.1.2 *Sensitivity Results*

All samples showed the expected positive result at all time points analyzed. Zero (0) samples showed a negative result. All samples showed the expected positive results after reanalysis after a 48-72 hour hold at 4 °C at all time points analyzed. Zero discrepant results were observed for the initial testing and enrichment broth storage. All raw data for the alternative confirmation validation is presented in **Annex I**.

The three categories and environmental samples of the alternative confirmation validation (MicroVal 2015LR50) meet the requirements of ISO 16140-2:2016 when analyzed. Summary of results are presented in the **Table 22** below.

Table 22. Overview for the Reanalyzed Calculated Sensitivity Parameters Per Category and Type for the Categories for the Alternative Confirmation Validation

Sensitivity Calculations												
Category	**Type**	**PA**	**NA**	**PD**	**ND**	**PPND**	**PPNA**	**SE alt %**	**SE ref %**	**RT %**	**ND-PD**	**Acceptance Limit Allowed**
Raw beef meats (25 g)	Fresh beef meats	5	0	0	0	0	0	100.0	100.0	100.0		
	Frozen then thawed beef	5	0	0	0	0	0	100.0	100.0	100.0		
	Meats with seasonings	5	0	0	0	0	0	100.0	100.0	100.0		
	Total	15	0	0	0	0	0	100.0	100.0	100.0	0	**3**
Raw beef meats (375 g)	Fresh raw beef	5	0	0	0	0	0	100.0	100.0	100.0		
	Frozen then thawed beef	5	0	0	0	0	0	100.0	100.0	100.0		
	Total	10	0	0	0	0	0	100.0	100.0	100.0	0	**3**
Dairy products (25 g)	Raw milk products	5	0	0	0	0	0	100.0	100.0	100.0		
	Pasteurized products	5	0	0	0	0	0	100.0	100.0	100.0		
	Raw milk cheeses	5	0	0	0	0	0	100.0	100.0	100.0		
	Total	15	0	0	0	0	0	100.0	100.0	100.0	0	**3**
Fruits and vegetables (25 g)	Fresh and frozen produces	5	0	0	0	0	0	100.0	100.0	100.0		
	Fresh and frozen sprouts or baby leafs	5	0	0	0	0	0	100.0	100.0	100.0		
	Fresh raw, frozen fruit	5	0	0	0	0	0	100.0	100.0	100.0		
	Total	15	0	0	0	0	0	100.0	100.0	100.0	0	**3**
Environmental samples (25 g or surface)	Surfaces	5	0	0	0	0		100.0	100.0	100.0		
	Process water	5	0	0	0	0	0	100.0	100.0	100.0		
	Dusts	5	0	0	0	0	0	100.0	100.0	100.0		
	Total	15	0	0	0	0	0	100.0	100.0	100.0	0	**3**
All Categories		**70**	**0**	**0**	**0**	**0**	**0**	**100.0**	**100.0**	**100.0**	0	**4**

For the data from the alternative confirmation validation, 100% of the samples were artificially contaminated. In total 70 samples were artificially contaminated, using 18 different strains. A total of 70 samples gave a positive result. Strains used to inoculate items were used on a maximum of 5 different items. A total of ~~71~~ 66 samples were inoculated at a level equal or below 5 CFU/sample. A total of ~~6~~ 4 samples were inoculated at a level between 5 and 10 CFU/sample.

Artificial contaminations were done by seeding or spiking protocols. For the strains used to inoculate samples, the level of injury was evaluated by plating on a non-selective agar (TSAYE) and a selective agar (CT-SMAC). As proposed, a ≥ 0.5 log of injured cells was obtained. Raw data and results for seeding and spiking obtained for the sensitivity portion of testing can be found in **Annex D.**

6.2 Alternative Confirmation- Inclusivity and Exclusivity Evaluation

The ISO 16140-6 criteria were utilized to validate an alternative confirmation procedure. After both 10 and 14 h of enrichment, the enriched samples were struck to 3 different chromogenic agars: CHROMagar O157 (CHROMagar), CT-SMAC (Remel), and EC O157:H7 ChromoSelect Agar (Sigma). For inclusivity and exclusivity, 100 *E*. *coli* O157:H7 cultures and 100 non-*E*. *coli* O157:H7 organisms were struck to the 3 agars and incubated according the manufacturer's instructions. All plates were observed for typical colony growth. An isolated typical colony (per plate type) was agglutinated with Abraxis *E*. *coli* O157:H7(CAT# 541070) and OXOID *E*. *coli* O157:H7 latex agglutination (CAT# DR0620) kits.

6.2.1 *Protocols (alternative confirmation)*

Inclusivity: One hundred (100) *E. coli* O157:H7 strains were freshly cultured in BHI medium at 37 ± 1°C. Dilutions were made in order to inoculate 10 -100 CFU/ 225 mL enrichment broth (mEHEC). Samples were struck to the 3 different chromogenic agars after an enrichment time of 10 and 14 h at 41.5 ± 1 ºC. An isolated typical colony (per plate type) was agglutinated with Abraxis *E*. *coli* O157:H7 (CAT# 541070) and OXOID *E*. *coli* O157:H7 latex agglutination (CAT# DR0620) kits. Typical isolates were compared against known confirmation results.

Exclusivity: One hundred (100) non-*E*. *coli* O157:H7 strains were freshly cultured in BHI medium at 37 ± 1°C for 16 h. Samples were struck to the 3 different chromogenic agars after an enrichment time of 10 and 14 h at 41.5 ± 1 ºC. Typical isolates were compared against known confirmation results.

6.2.2 *Results inclusivity and exclusivity study: alternative confirmation*

All raw data on inclusivity and exclusivity for the alternative confirmation are given in **Annex J.**

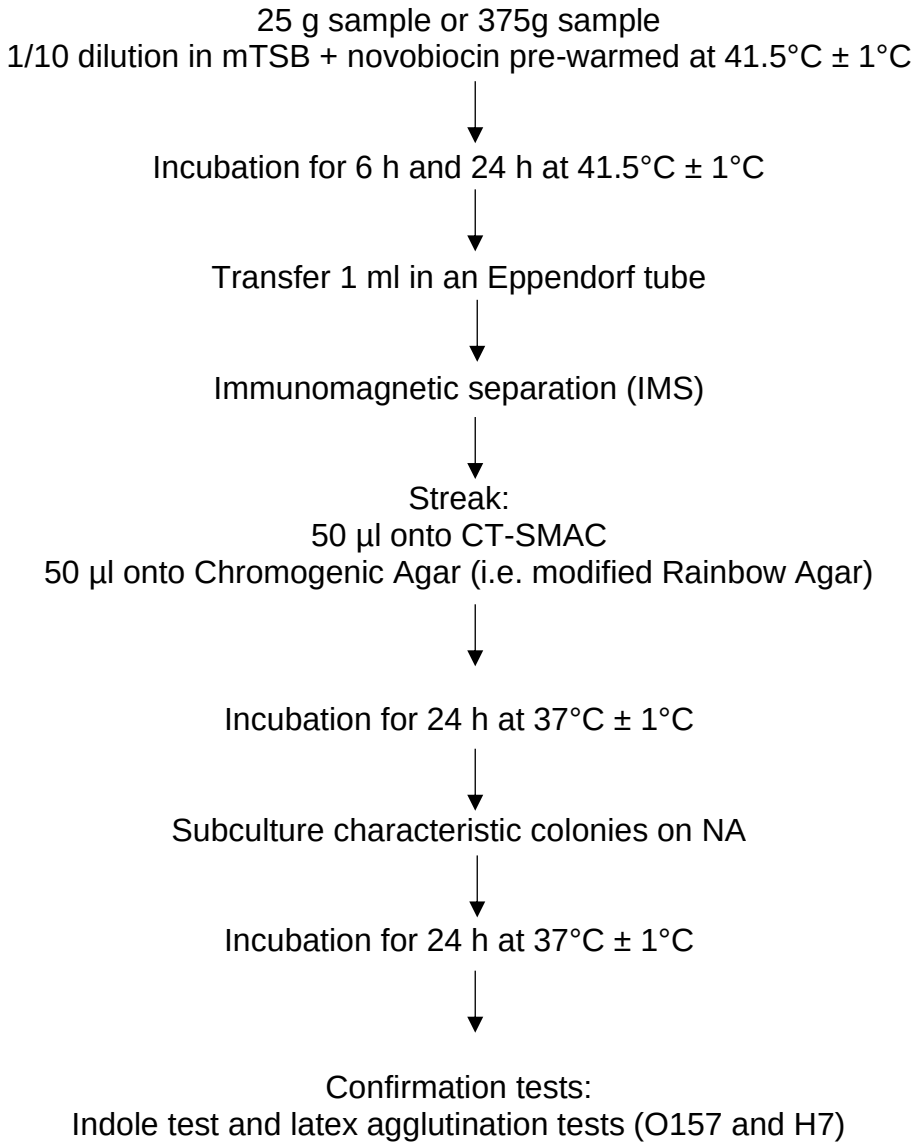
A total of 100 strains were tested for **inclusivity**. All 100 of these strains showed the expected positive result. Zero (0) strains showed a negative result.

A total of 100 strains were tested for **exclusivity**. All 100 of these strains showed the expected negative result. Zero (0) strains showed a positive result.

6.2.3 *Conclusion of Alternative Confirmation Inclusivity and Exclusivity Evaluation*

The alternative confirmation detection method is both selective and specific for the detection of *E*. *coli* O157:H7 species.

ANNEX A: Flow Diagram of the Reference Method



ANNEX B: Flow Diagram of the Assurance® GDS for *E. coli* O157:H7 Tq

Food Types[1]:
25 g + 225 mL mEHEC
375 g + 1,500 mL mEHEC (raw beef only)
Environmental samples:
1 swab + 10 mL mEHEC
or 1 sponge + 100 mL mEHEC
or 25 g or 25 mL + 225 mL mEHEC

↓

Incubation 41.5°C ± 1°C

for 8 – 14 h

↓

IMS and GDS (PCR)

↓ **OR** ↓

Confirm ISO 16654: 2001 (ANNEX A)

(Optional alternative confirmation)

Streak primary enrichment

↓

Streak 10 µL Primary enrichment to one of the following:

CHROMagar O157 (CHROMagar Cat# EE222)

CT-SMAC (Remel Cat# R110241), or equivalent

EC O157:H7 ChromoSelect Agar (Sigma Cat# 92587)

↓

Incubation of plates at manufacturer specified incubation temperature and time

↓

Observe plates for typical colonies and conduct latex agglutination on typical colonies

1. For dairy product samples, a secondary transfer to BHI for 2-4 hours at 37°C ± 1°C is conducted.

ANNEX C: Artificial Contaminations

Table 1-Artificail Contamination- Original Study *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

n° sample	Product (French name)	Product	Artificial contamination					Global Result
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level	
1533	Steak haché à l'oignon surgelé	Frozen seasoned ground beef	E. coli O157:H7 Ad485	Ground beef	Seeding -20°C / 72h	/	5-7-6-3-2 (4.6)	+
1537	Steak haché à la tomate surgelé	Frozen seasoned ground beef	E. coli O157:H7 Ad485	Ground beef	Seeding -20°C / 72h	/	5-7-6-3-2 (4.6)	+
1538	Steak haché surgelé 15% MG	Frozen ground beef 15% fat	E. coli O157:H7 Ad485	Ground beef	Seeding -20°C / 72h	/	5-7-6-3-2 (4.6)	+
2845	Effeuillé de charolais surgelé	Frozen beef trim	E. coli O157:H7 Ad486	Ground beef	Spiking -20°C / 33 days	1.72	0-2-3-2-2 (1.8)	+
2846	Bifteck de charolais surgelé	Frozen beef trim	E. coli O157:H7 Ad486	Ground beef	Spiking -20°C / 33 days	1.72	0-2-3-2-2 (1.8)	+
2847	Steak haché surgelé	Frozen ground beef	E. coli O157:H7 Ad486	Ground beef	Spiking -20°C / 33 days	1.72	0-2-3-2-2 (1.8)	+
2654	Bethmale (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad486	Environmental sample	Spiking 4°C / 10 days	0.42	1-2-1-1-1 (1.4)	+
2657	Cantal (lait de vache pasteurisé)	Pasteurized cow milk cheese	E. coli O157:H7 Ad486	Environmental sample	Spiking 4°C / 10 days	0.42	1-2-1-1-1 (1.4)	+
2660	Saint Nectaire (lait de vache pasteurisé)	Raw cow milk cheese	E. coli O157:H7 Ad486	Environmental sample	Spiking 4°C / 10 days	0.42	1-2-1-1-1 (1.4)	+
2663	Lait cru de vache	Raw cow milk	E. coli O157:H7 Ad486	Environmental sample	Spiking 4°C / 10 days	0.42	1-2-1-1-1 (1.4)	+
2748	Egréné de bœuf surgelé	Frozen ground beef	E. coli O157:H7 Ad487	Ground beef	Seeding -20°C / 21 days	/	1-2-0-2-0 (1.0)	+
2751	Viande bourguignon surgelée	Frozen beef trim	E. coli O157:H7 Ad487	Ground beef	Seeding -20°C / 21 days	/	1-2-0-2-0 (1.0)	-
2754	Boulettes surgelées	Frozen beef balls	E. coli O157:H7 Ad487	Ground beef	Seeding -20°C / 21 days	/	1-2-0-2-0 (1.0)	+
2757	Entrecôtes surgelées	Frozen beef trim	E. coli O157:H7 Ad487	Ground beef	Seeding -20°C / 21 days	/	1-2-0-2-0 (1.0)	+
2760	Bavettes d'Aloyau surgelées	Frozen beef trim	E. coli O157:H7 Ad487	Ground beef	Seeding -20°C / 21 days	/	1-2-0-2-0 (1.0)	-
3001	Steack haché 15% MG	Ground beef 15% fat	E. coli O157:H7 Ad488	Ground beef	Spiking 4°C / 4 days	0.69	3-2-2-0-0 (1.4)	-
3002	Entrecôtes	Beef trim	E. coli O157:H7 Ad488	Ground beef	Spiking 4°C / 4 days	0.69	3-2-2-0-0 (1.4)	+
3003	Faux filets	Beef trim	E. coli O157:H7 Ad489	Ground beef	Spiking 4°C / 4 days	0.69	0-1-1-1-1 (0.8)	+
3004	Rond de gîte de bœuf	Beef trim	E. coli O157:H7 Ad489	Ground beef	Spiking 4°C / 4 days	0.69	0-1-1-1-1 (0.8)	+
3005	Rumsteack	Beef trim	E. coli O157:H7 Ad489	Ground beef	Spiking 4°C / 4 days	0.69	0-1-1-1-1 (0.8)	+
490	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad552	Environmental sample	Seeding 4°C / 48h	/	2-2-1-1-1 (1.4)	-
491	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad552	Environmental sample	Seeding 4°C / 48h	/	2-2-1-1-1 (1.4)	+
492	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad552	Environmental sample	Seeding 4°C / 48h	/	2-2-1-1-1 (1.4)	+
602	Eau de process (végétaux)	Process water (vegetables industry)	E. coli O157:H7 Ad552	Environmental sample	Seeding 4°C / 48h	/	1-6-2-1-0 (2.0)	+
605	Eau bac échaudage	Process water (meat industry)	E. coli O157:H7 Ad552	Environmental sample	Seeding 4°C / 48h	/	1-6-2-1-0 (2.0)	+
493	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad553	Environmental sample	Seeding 4°C / 48h	/	2-1-0-1-3 (1.4)	-
494	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad553	Environmental sample	Seeding 4°C / 48h	/	2-1-0-1-3 (1.4)	+
495	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad553	Environmental sample	Seeding 4°C / 48h	/	2-1-0-1-3 (1.4)	+

Table 1-Artificail Contamination- Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

n° sample	Product (French name)	Product	Artificial contamination					Global Result
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level	
603	Eau de process (végétaux)	Process water (vegetables industry)	E. coli O157:H7 Ad553	Environmental sample	Seeding 4°C / 48h	/	0-1-3-2-0 (1.0)	+
606	Déchets pousses de soja	Waste(soya)	E. coli O157:H7 Ad553	Environmental sample	Seeding 4°C / 48h	/	0-1-3-2-0 (1.0)	+
496	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad554	Environmental sample	Seeding 4°C / 48h	/	1-0-4-0-2 (1.4)	+
497	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad554	Environmental sample	Seeding 4°C / 48h	/	1-0-4-0-2 (1.4)	+
498	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad554	Environmental sample	Seeding 4°C / 48h	/	1-0-4-0-2 (1.4)	+
499	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad555	Environmental sample	Seeding 4°C / 48h	/	2-2-1-3-1 (1.8)	+
500	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad555	Environmental sample	Seeding 4°C / 48h	/	2-2-1-3-1 (1.8)	+
501	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad555	Environmental sample	Seeding 4°C / 48h	/	2-2-1-3-1 (1.8)	+
2447	Mâche	Mash	E. coli O157:H7 Ad556	Environmental sample	Seeding 4°C / 72h	/	0-1-1-0-0 (0.4)	-
2451	Salade duo de saumon	Deli salad	E. coli O157:H7 Ad556	Environmental sample	Seeding 4°C / 72h	/	0-1-1-0-0 (0.4)	+
2455	Pousses de roquettes aflalfa	Sprouts	E. coli O157:H7 Ad556	Environmental sample	Seeding 4°C / 72h	/	0-1-1-0-0 (0.4)	-
2459	Jus d'ananas	Pineapple juice	E. coli O157:H7 Ad556	Environmental sample	Seeding 4°C / 72h	/	0-1-1-0-0 (0.4)	+
372	Déchets végétaux préparation	Wastes (sprout industry)	E. coli O157:H7 Ad556	Environmental sample	Seeding 4°C / 48h	/	0-4-2-1-3 (1.8)	-
2448	Mesclun	Mesclun	E. coli O157:H7 Ad557	Environmental sample	Seeding 4°C / 72h	/	0-1-0-1-1 (0.6)	+
2452	Salade campagnarde	Deli salad	E. coli O157:H7 Ad557	Environmental sample	Seeding 4°C / 72h	/	0-1-0-1-1 (0.6)	+
2456	Kup ananas	Pineapple	E. coli O157:H7 Ad557	Environmental sample	Seeding 4°C / 72h	/	0-1-0-1-1 (0.6)	-
2460	Jus multi nature	Multifruit juice	E. coli O157:H7 Ad557	Environmental sample	Seeding 4°C / 72h	/	0-1-0-1-1 (0.6)	+
2796	Smoothie fraise/banane	Strawberry/banana smoothie	E. coli O157:H7 Ad558	Environmental sample	Spiking 4°C / 25 days	1.13	6-6-7-6-8 (6.6)	+
2799	Mesclun (jeunes pousses)	Mesclun (baby leaves)	E. coli O157:H7 Ad558	Environmental sample	Spiking 4°C / 25 days	1.13	6-6-7-6-8 (6.6)	+
2800	Roquette (jeunes pousses)	Roquette (baby leaves)	E. coli O157:H7 Ad558	Environmental sample	Spiking 4°C / 25 days	1.13	6-6-7-6-8 (6.6)	+
2802	Mâche	Mash	E. coli O157:H7 Ad558	Environmental sample	Spiking 4°C / 25 days	1.13	6-6-7-6-8 (6.6)	+
373	Eau de process pousses de soja	Process water (sprout industry)	E. coli O157:H7 Ad558	Environmental sample	Seeding 4°C / 48h	/	1-2-2-2-3 (2.0)	-
374	Déchets végétaux conditionnement	Wastes (sprout industry)	E. coli O157:H7 Ad558	Environmental sample	Seeding 4°C / 48h	/	1-2-2-2-3 (2.0)	-
2848	Steak haché surgelé 15% MG	Frozen ground beef 15% fat	E. coli O157:H7 Ad559	Ground beef	Spiking -20°C / 33 days	2.01	1-2-1-2-0 (1.2)	+
2849	Egréné de bœuf surgelé 15% MG	Frozen ground beef 15% fat	E. coli O157:H7 Ad559	Ground beef	Spiking -20°C / 33 days	2.01	1-2-1-2-0 (1.2)	+
2850	Egréné de bœuf surgelé 5% MG	Frozen ground beef 5% fat	E. coli O157:H7 Ad559	Ground beef	Spiking -20°C / 33 days	2.01	1-2-1-2-0 (1.2)	+
502	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad567	Environmental sample	Seeding 4°C / 48h	/	0-0-1-3-3 (1.0)	-
503	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad567	Environmental sample	Seeding 4°C / 48h	/	0-0-1-3-3 (1.0)	+
504	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad567	Environmental sample	Seeding 4°C / 48h	/	0-0-1-3-3 (1.0)	+
1843	Reblochon (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad571	Environmental sample	Seeding 4°C / 48h	/	2-1-1-0-1 (1.0)	+

Table 1-Artificail Contamination- Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

n° sample	Product (French name)	Product	Artificial contamination					Global Result
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level	
1847	Fromage de chèvre (lait cru de chèvre)	Raw goat milk cheese	E. coli O157:H7 Ad571	Environmental sample	Seeding 4°C / 48h	/	2-1-1-0-1 (1.0)	+
1848	Maroilles (lait de vache pasteurisé)	Pasteurized cow milk cheese	E. coli O157:H7 Ad571	Environmental sample	Seeding 56°C / 8min	/	2-1-1-0-1 (1.0)	+
1849	Munster (lait de vache pasteurisé)	Pasteurized cow milk cheese	E. coli O157:H7 Ad571	Environmental sample	Seeding 56°C / 8min	/	2-1-1-0-1 (1.0)	-
357	Eau de forage	Process water (sprout industry)	E. coli O157:H7 Ad571	Feces	Seeding 4°C / 48h	/	3-4-0-4-0 (2.2)	+
358	Eau de lavage	Process water (sprout industry)	E. coli O157:H7 Ad571	Feces	Seeding 4°C / 48h	/	3-4-0-4-0 (2.2)	+
2797	Smoothie pomme/banane/kiwi	Apple/banana/kiwi smoothie	E. coli O157:H7 Ad572	Feces	Spiking 4°C / 25 days	1.66	1-4-2-1-3 (2.2)	+
3410	Mélange de jeunes pousses	Baby leaves	E. coli O157:H7 Ad572	Feces	Spiking 4°C / 14 days	0.67	2-0-2-1-1 (1.2)	+
3414	Pousses d'épinards	Spinach baby leaves	E. coli O157:H7 Ad572	Feces	Spiking 4°C / 14 days	0.67	2-0-2-1-1 (1.2)	-
3419	Taboulé	Tabouleh	E. coli O157:H7 Ad572	Feces	Spiking 4°C / 14 days	0.67	2-0-2-1-1 (1.2)	+
359	Eau de rinçage	Process water (sprout industry)	E. coli O157:H7 Ad572	Feces	Seeding 4°C / 48h	/	1-1-1-0-2 (1.0)	-
365	Déchets ligne soja	Wastes (sprout industry)	E. coli O157:H7 Ad572	Feces	Seeding 4°C / 48h	/	1-1-1-0-2 (1.0)	+
3406	Duo de haricots plats surgelés	Frozen flat beans	E. coli O157:H7 Ad573	Feces	Spiking 4°C / 14 days	0.85	2-1-1-2-0 (1.2)	+
3409	Ananas en morceaux surgelés	frozen pieces of pine apple	E. coli O157:H7 Ad573	Feces	Spiking 4°C / 14 days	0.85	2-1-1-2-0 (1.2)	+
3412	Pousses de betteraves	Beets baby leaves	E. coli O157:H7 Ad573	Feces	Spiking 4°C / 14 days	0.85	2-1-1-2-0 (1.2)	+
3417	Salade de concombres	Cucumber deli salad	E. coli O157:H7 Ad573	Feces	Spiking 4°C / 14 days	0.85	2-1-1-2-0 (1.2)	+
360	Eau d'irrigation	Process water (sprout industry)	E. coli O157:H7 Ad573	Feces	Seeding 4°C / 48h	/	3-4-1-1-2 (2.2)	+
361	Lingette table blanche	Wipe (sprout industry)	E. coli O157:H7 Ad573	Feces	Seeding 4°C / 48h	/	3-4-1-1-2 (2.2)	+
1844	Brie (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad574	Environmental sample	Seeding 4°C / 48h	/	2-0-1-0-0 (0.6)	-
1851	Fromage bleu (lait pasteurisé)	Pasteurized milk cheese	E. coli O157:H7 Ad574	Environmental sample	Seeding 56°C / 8min	/	2-0-1-0-0 (0.6)	+
1852	Fromage de chèvre (lait de chèvre pasteurisé)	Pasteurized goat milk cheese	E. coli O157:H7 Ad574	Environmental sample	Seeding 56°C / 8min	/	2-0-1-0-0 (0.6)	-
1853	Lait cru	Raw milk	E. coli O157:H7 Ad574	Environmental sample	Seeding 4°C / 48h	/	2-0-1-0-0 (0.6)	+
362	Lingette tapis transfert ligne soja	Wipe (sprout industry)	E. coli O157:H7 Ad574	Feces	Seeding 4°C / 48h	/	0-1-0-1-2 (0.6)	-
363	Eau d'irrigation	Process water (sprout industry)	E. coli O157:H7 Ad574	Feces	Seeding 4°C / 48h	/	0-1-0-1-2 (0.6)	-
1577	Lait cru	Raw milk	E. coli O157:H7 Ad575	Feces	Seeding 4°C / 48h	/	4-4-4-8-10 (6.0)	+
1581	Lait fermenté	Fermented milk	E. coli O157:H7 Ad575	Feces	Seeding 4°C / 48h	/	4-4-4-8-10 (6.0)	+
1585	Crottin de chavignol (lait cru de chèvre)	Raw goat milk cheese	E. coli O157:H7 Ad575	Feces	Seeding 4°C / 48h	/	4-4-4-8-10 (6.0)	+
1578	Lait cru	Raw milk	E. coli O157:H7 Ad576	Feces	Seeding 4°C / 48h	/	4-6-6-9-9 (6.8)	+
1582	Emmental (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad576	Feces	Seeding 4°C / 48h	/	4-6-6-9-9 (6.8)	+
1586	Reblochon (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad576	Feces	Seeding 4°C / 48h	/	4-6-6-9-9 (6.8)	+
1589	Morbier (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad576	Feces	Seeding 4°C / 48h	/	4-6-6-9-9 (6.8)	+

Table 1-Artificail Contamination- Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

n° sample	Product (French name)	Product	Artificial contamination					Global Result
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level	
354	Poussière	Dusts (sprout industry)	E. coli O157:H7 Ad576	Bovine feces	Seeding 4°C / 48h	/	3-0-0-1-1 (1.0)	+
2449	Jeunes pousses corsées	Baby leaves	E. coli O157:H7 Ad577	Feces	Seeding 4°C / 72h	/	2-1-1-1-1 (1.2)	+
2453	Pousses de soja	Sprouts	E. coli O157:H7 Ad577	Feces	Seeding 4°C / 72h	/	2-1-1-1-1 (1.2)	+
2457	Pêche en salade	Peach salad	E. coli O157:H7 Ad577	Feces	Seeding 4°C / 72h	/	2-1-1-1-1 (1.2)	+
2461	Jus pomme mangue	Apple/Mango juice	E. coli O157:H7 Ad577	Feces	Seeding 4°C / 72h	/	2-1-1-1-1 (1.2)	+
355	Poussière	Dusts (sprout industry)	E. coli O157:H7 Ad577	Bovine feces	Seeding 4°C / 48h	/	1-3-0-0-2 (1.2)	-
3405	Choux de Bruxelles surgelés	Frozen Brussels cabbages	E. coli O157:H7 Ad578	Feces	Spiking 4°C / 14 days	0.97	1-2-1-1-1 (1.2)	+
3408	Framboises entières surgelées	Frozen raspberries	E. coli O157:H7 Ad578	Feces	Spiking 4°C / 14 days	0.97	1-2-1-1-1 (1.2)	+
3411	Mélange de jeunes pousses	Baby leaves	E. coli O157:H7 Ad578	Feces	Spiking 4°C / 14 days	0.97	1-2-1-1-1 (1.2)	+
3415	Gaspacho	Gaspacho	E. coli O157:H7 Ad578	Feces	Spiking 4°C / 14 days	0.97	1-2-1-1-1 (1.2)	-
356	Poussière	Dusts (sprout industry)	E. coli O157:H7 Ad578	Bovine feces	Seeding 4°C / 48h	/	1-0-4-0-1 (1.2)	-
1845	Camembert (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad579	Environmental sample	Seeding 4°C / 48h	/	1-1-3-3-2 (2.0)	+
1850	Brique brebis (lait de brebis pasteurisé)	Pasteurized sheep milk cheese	E. coli O157:H7 Ad579	Environmental sample	Seeding 56°C / 8min	/	1-1-3-3-2 (2.0)	+
1854	Lait fermenté	Fermented milk	E. coli O157:H7 Ad579	Environmental sample	Seeding 4°C / 48h	/	1-1-3-3-2 (2.0)	-
1856	Lait fermenté	Fermented milk	E. coli O157:H7 Ad579	Environmental sample	Seeding 4°C / 48h	/	1-1-3-3-2 (2.0)	+
364	Eau de forage	Process water (sprout industry)	E. coli O157:H7 Ad579	Feces	Seeding 4°C / 48h	/	0-0-1-7-1 (1.8)	+
2450	Salade italienne au jambon cru	Deli salad	E. coli O157:H7 Ad580	Feces	Seeding 4°C / 72h	/	0-1-0-1-1 (0.6)	+
2454	Pousses alfalfa	Sprouts	E. coli O157:H7 Ad580	Feces	Seeding 4°C / 72h	/	0-1-0-1-1 (0.6)	+
2458	Salade de fruits	Fruit mix salad	E. coli O157:H7 Ad580	Feces	Seeding 4°C / 72h	/	0-1-0-1-1 (0.6)	+
2655	Saint Nectaire (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad581	Feces	Spiking 4°C / 10 days	0.84	7-6-3-5-5 (5.2)	+
2658	Chaumes (lait de vache pasteurisé)	Raw cow milk cheese	E. coli O157:H7 Ad581	Feces	Spiking 4°C / 10 days	0.84	7-6-3-5-5 (5.2)	+
2661	Féta (lait pasteurisé)	Raw sheep milk cheese	E. coli O157:H7 Ad581	Feces	Spiking 4°C / 10 days	0.84	7-6-3-5-5 (5.2)	+
2664	Lait cru de vache	Raw cow milk	E. coli O157:H7 Ad581	Feces	Spiking 4°C / 10 days	0.84	7-6-3-5-5 (5.2)	+
1846	Coulomier (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad582	Environmental sample	Seeding 4°C / 48h	/	0-0-0-2-1 (0.6)	-
1855	Lait cru	Raw milk	E. coli O157:H7 Ad582	Environmental sample	Seeding 4°C / 48h	/	0-0-0-2-1 (0.6)	+
1857	Lait fermenté	Fermented milk	E. coli O157:H7 Ad582	Environmental sample	Seeding 4°C / 48h	/	0-0-0-2-1 (0.6)	+
3407	Carottes rondelles surgelées	Frozen sliced carrots	E. coli O157:H7 Ad582	Feces	Spiking 4°C / 14 days	0.36	2-2-1-2-3 (2.0)	+
3413	Mélange de pousses	Baby leaves	E. coli O157:H7 Ad582	Feces	Spiking 4°C / 14 days	0.36	2-2-1-2-3 (2.0)	+
3416	Jus de pomme	Apple juice	E. coli O157:H7 Ad582	Feces	Spiking 4°C / 14 days	0.36	2-2-1-2-3 (2.0)	+
3418	Carottes râpées	Seasoned sliced carrots	E. coli O157:H7 Ad582	Feces	Spiking 4°C / 14 days	0.36	2-2-1-2-3 (2.0)	+
3009	Steak haché 20% MG surgelé	Frozen ground beef 20% fat	E. coli O157:H7 Ad591	Ground beef	Seeding 4°C / 72h	/	3-4-2-2-6 (3.4)	+
3010	Carpaccio surgelé	Frozen beef trim	E. coli O157:H7 Ad591	Ground beef	Seeding 4°C / 72h	/	3-4-2-2-6 (3.4)	+

Table 1-Artificail Contamination- Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

n° sample	Product (French name)	Product	Artificial contamination					Global Result
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level	
1541	Egréné de bœuf surgelé 20% MG	Frozen ground beef 20% fat	E. coli O157:H7 Ad683	Ground beef	Seeding -20°C / 72h	/	4-5-4-2-4 (3.8)	+
1542	Boulettes de bœuf surgelé	Frozen beef balls	E. coli O157:H7 Ad683	Ground beef	Seeding -20°C / 72h	/	4-5-4-2-4 (3.8)	+
1543	Boulettes de bœuf tomate/parmesan surgelées	Frozen seasoned beef balls	E. coli O157:H7 Ad683	Ground beef	Seeding -20°C / 72h	/	4-5-4-2-4 (3.8)	+
1696	Carpaccio nature	Carpaccio	E. coli O157:H7 Ad684	Carpaccio	Spiking 4°C / 6 days	0.33	1-0-1-2-1 (1.0)	+
1700	Carpaccio au pistou	Seasoned Carpaccio	E. coli O157:H7 Ad684	Carpaccio	Spiking 4°C / 6 days	0.33	1-0-1-2-1 (1.0)	+
1704	Steak haché 15% MG	Ground beef 15% fat	E. coli O157:H7 Ad684	Carpaccio	Spiking 4°C / 6 days	0.33	1-0-1-2-1 (1.0)	+
604	Eau de process (végétaux)	Process water (vegetables industry)	E. coli O157:H7 Ad685	Environmental sample	Seeding 4°C / 48h	/	0-1-3-1-0 (1.0)	+
607	Déchets pousses de soja	Waste(soya)	E. coli O157:H7 Ad685	Environmental sample	Seeding 4°C / 48h	/	0-1-3-1-0 (1.0)	+
350	Déchet poudre de lait	Dusts (dairy industry)	E. coli O157:H7 Ad686	Environmental sample	Spiking 4°C / 8 days	0.74	3-2-3-2-2 (2.4)	+
351	Poussière	Dusts (dairy industry)	E. coli O157:H7 Ad686	Environmental sample	Spiking 4°C / 8 days	0.74	3-2-3-2-2 (2.4)	+
485	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad686	Environmental sample	Seeding 4°C / 48h	/	0-0-0-3-1-0 (0.8)	-
486	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad686	Environmental sample	Seeding 4°C / 48h	/	0-0-0-3-1-0 (0.8)	+
487	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad686	Environmental sample	Seeding 4°C / 48h	/	0-0-0-3-1-0 (0.8)	-
1697	Carpaccio nature	Carpaccio	E. coli O157:H7 Ad687	Beef trim	Spiking 4°C / 6 days	0.34	2-4-1-4-1 (2.4)	+
1701	Carpaccio huile d'olive/basilic	Seasoned Carpaccio	E. coli O157:H7 Ad687	Beef trim	Spiking 4°C / 6 days	0.34	2-4-1-4-1 (2.4)	+
1705	Steak haché 5% MG	Ground beef 5% fat	E. coli O157:H7 Ad687	Beef trim	Spiking 4°C / 6 days	0.34	2-4-1-4-1 (2.4)	+
1708	Rumsteak	Beef trim	E. coli O157:H7 Ad687	Beef trim	Spiking 4°C / 6 days	0.34	2-4-1-4-1 (2.4)	+
1580	Lait ribot	Fermented milk	E. coli O157:H7 Ad688	Environmental sample	Seeding 4°C / 48h	/	8-6-9-9-5 (7.4)	+
1584	Camembert (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad688	Environmental sample	Seeding 4°C / 48h	/	8-6-9-9-5 (7.4)	-
1588	Comté (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad688	Environmental sample	Seeding 4°C / 48h	/	8-6-9-9-5 (7.4)	+
1591	Chabichou (lait cru de chèvre)	Raw goat milk cheese	E. coli O157:H7 Ad688	Environmental sample	Seeding 4°C / 48h	/	8-6-9-9-5 (7.4)	+
352	Poussière	Dusts (dairy industry)	E. coli O157:H7 Ad688	Environmental sample	Spiking 4°C / 8 days	0.76	5-2-2-7-3 (3.8)	+
488	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad688	Environmental sample	Seeding 4°C / 48h	/	1-0-0-2-0 (0.6)	+
489	Lingette atelier boucherie	Wipe (meat industry)	E. coli O157:H7 Ad688	Environmental sample	Seeding 4°C / 48h	/	1-0-0-2-0 (0.6)	-
2843	Viande hachée bolognaise	Seasoned ground beef	E. coli O157:H7 Ad922	Seasoned ground beef	Seeding 4°C / 48h	/	1-1-1-0-0 (0.6)	+
2844	Carpaccio basilic	Seasoned Carpaccio	E. coli O157:H7 Ad922	Seasoned ground beef	Seeding 4°C / 48h	/	1-1-1-0-0 (0.6)	+
2747	Egréné de bœuf surgelé	Frozen ground beef	E. coli O157:H7 Ad924	Ground beef	Seeding -20°C / 21 days	/	2-1-1-1-3 (1.6)	-
2750	Steak haché 15% MG surgelé	Frozen ground beef 15% fat	E. coli O157:H7 Ad924	Ground beef	Seeding -20°C / 21 days	/	2-1-1-1-3 (1.6)	+
2753	Boulettes surgelées 15% MG	Frozen beef balls 15% fat	E. coli O157:H7 Ad924	Ground beef	Seeding -20°C / 21 days	/	2-1-1-1-3 (1.6)	+
2756	Carpaccio surgelé	Frozen Carpaccio	E. coli O157:H7 Ad924	Ground beef	Seeding -20°C / 21 days	/	2-1-1-1-3 (1.6)	+
2759	Pavés de bœuf surgelé	Frozen beef trim	E. coli O157:H7 Ad924	Ground beef	Seeding -20°C / 21 days	/	2-1-1-1-3 (1.6)	+
2746	Egréné de bœuf surgelé	Frozen ground beef	E. coli O157:H7 Ad925	Ground beef	Seeding -20°C / 21 days	/	0-0-3-0-2 (1.0)	+

Table 1-Artificail Contamination- Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

n° sample	Product (French name)	Product	Artificial contamination					Global Result
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level	
2749	Egréné de bœuf surgelé	Frozen ground beef	E. coli O157:H7 Ad925	Ground beef	Seeding -20°C / 21 days	/	0-0-3-0-2 (1.0)	+
2752	Viande bourguignon surgelée	Frozen beef trim	E. coli O157:H7 Ad925	Ground beef	Seeding -20°C / 21 days	/	0-0-3-0-2 (1.0)	+
2755	Carpaccio surgelé	Frozen Carpaccio	E. coli O157:H7 Ad925	Ground beef	Seeding -20°C / 21 days	/	0-0-3-0-2 (1.0)	+
2758	Faux filets surgelées	Frozen beef trim	E. coli O157:H7 Ad925	Ground beef	Seeding -20°C / 21 days	/	0-0-3-0-2 (1.0)	+
2290	Steak haché 15% MG	Ground beef 15% fat	E. coli O157:H7 Ad933	Ground beef	Spiking 4°C / 8 days	0.9	0-2-2-3-3 (2.0)	+
2293	Entrecôtes	Beef trim	E. coli O157:H7 Ad933	Ground beef	Spiking 4°C / 8 days	0.9	0-2-2-3-3 (2.0)	+
2296	Capa désossé	Beef trim	E. coli O157:H7 Ad933	Ground beef	Spiking 4°C / 8 days	0.9	0-2-2-3-3 (2.0)	+
2299	Bavettes d'Aloyau	Beef trim	E. coli O157:H7 Ad933	Ground beef	Spiking 4°C / 8 days	0.9	0-2-2-3-3 (2.0)	+
2302	Steak haché 15% MG	Ground beef 15% fat	E. coli O157:H7 Ad933	Ground beef	Spiking 4°C / 8 days	0.9	0-2-2-3-3 (2.0)	+
2289	Haché tradition 15% MG	Ground beef 15% fat	E. coli O157:H7 Ad975	Beef trim	Spiking 4°C / 8 days	0.56	1-1-0-1-0 (0.6)	+
2292	Faux filets	Beef trim	E. coli O157:H7 Ad975	Beef trim	Spiking 4°C / 8 days	0.56	1-1-0-1-0 (0.6)	-
2295	Roti de bœuf	Beef trim	E. coli O157:H7 Ad975	Beef trim	Spiking 4°C / 8 days	0.56	1-1-0-1-0 (0.6)	-
2298	Gite de bœuf	Beef trim	E. coli O157:H7 Ad975	Beef trim	Spiking 4°C / 8 days	0.56	1-1-0-1-0 (0.6)	+
2301	Steak haché façon bouchère	Ground beef	E. coli O157:H7 Ad975	Beef trim	Spiking 4°C / 8 days	0.56	1-1-0-1-0 (0.6)	-
1698	Carpaccio nature	Carpaccio	E. coli O157:H7 Ad976	Beef meat	Spiking 4°C / 6 days	0.89	1-4-0-4-0 (1.8)	-
1702	Carpaccio parmesan	Seasoned Carpaccio	E. coli O157:H7 Ad976	Beef meat	Spiking 4°C / 6 days	0.89	1-4-0-4-0 (1.8)	+
1706	Steak haché 5% MG	Ground beef 5% fat	E. coli O157:H7 Ad976	Beef meat	Spiking 4°C / 6 days	0.89	1-4-0-4-0 (1.8)	+
1709	Steak	Beef trim	E. coli O157:H7 Ad976	Beef meat	Spiking 4°C / 6 days	0.89	1-4-0-4-0 (1.8)	+
3006	Viande hachée surgelée	Frozen ground beef	E. coli O157:H7 Ad1071	Ground beef	Seeding 4°C / 72h	/	1-1-8-6-0 (2.6)	+
3007	Bavettes d'Aloyau surgelées	Frozen beef trim	E. coli O157:H7 Ad1071	Ground beef	Seeding 4°C / 72h	/	1-1-8-6-0 (2.6)	+
3008	Faux filets surgelées	Frozen beef trim	E. coli O157:H7 Ad1071	Ground beef	Seeding 4°C / 72h	/	1-1-8-6-0 (2.6)	+
1536	Steak haché à l'oignon surgelé	Frozen seasoned ground beef	E. coli O157:H7 Ad1174	Ground beef	Seeding -20°C / 72h	/	4-5-4-2-4 (3.8)	+
1540	Steak haché surgelé 5% MG	Frozen ground beef 5% fat	E. coli O157:H7 Ad1174	Ground beef	Seeding -20°C / 72h	/	4-5-4-2-4 (3.8)	+
1544	Steak haché à l'oignon surgelé	Frozen seasoned ground beef	E. coli O157:H7 Ad1174	Ground beef	Seeding -20°C / 72h	/	4-5-4-2-4 (3.8)	+
1699	Carpaccio nature	Carpaccio	E. coli O157:H7 Ad1248	Beef trim	Spiking 4°C / 6 days	0.34	0-2-1-3-3 (1.8)	+
1703	Steak haché 15% MG	Ground beef 15% fat	E. coli O157:H7 Ad1248	Beef trim	Spiking 4°C / 6 days	0.34	0-2-1-3-3 (1.8)	+
1707	Faux-filet	Beef trim	E. coli O157:H7 Ad1248	Beef trim	Spiking 4°C / 6 days	0.34	0-2-1-3-3 (1.8)	+
1710	Bavette	Beef trim	E. coli O157:H7 Ad1248	Beef trim	Spiking 4°C / 6 days	0.34	0-2-1-3-3 (1.8)	+
2288	Steak haché façon bouchère 15% MG	Ground beef 15% fat	E. coli O157:H7 Ad1501	Ground beef	Spiking 4°C / 8 days	0.46	0-2-1-3-1 (1.4)	+
2291	Steak haché 5% MG	Ground beef 5% fat	E. coli O157:H7 Ad1501	Ground beef	Spiking 4°C / 8 days	0.46	0-2-1-3-1 (1.4)	+
2294	Cœur de rumsteak	Beef trim	E. coli O157:H7 Ad1501	Ground beef	Spiking 4°C / 8 days	0.46	0-2-1-3-1 (1.4)	+
2297	Palette	Beef trim	E. coli O157:H7 Ad1501	Ground beef	Spiking 4°C / 8 days	0.46	0-2-1-3-1 (1.4)	+
2300	Bourguignon	Beef trim	E. coli O157:H7 Ad1501	Ground beef	Spiking 4°C / 8 days	0.46	0-2-1-3-1 (1.4)	+

Table 1-Artificail Contamination- Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

n° sample	Product (French name)	Product	Artificial contamination					Global Result
			Strain	Origin	Injury protocol	Injury measurement	Inoculation level	
1579	Lait ribot	Fermented milk	E. coli O157:H7 Ad1745	Raw milk cheese	Seeding 4°C / 48h	/	6-12-8-6-4 (7.2)	+
1583	Abondance (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad1745	Raw milk cheese	Seeding 4°C / 48h	/	6-12-8-6-4 (7.2)	+
1587	Beaumont de Savoie (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad1745	Raw milk cheese	Seeding 4°C / 48h	/	6-12-8-6-4 (7.2)	+
1590	Tome de Savoie (lait cru de vache)	Raw cow milk cheese	E. coli O157:H7 Ad1745	Raw milk cheese	Seeding 4°C / 48h	/	6-12-8-6-4 (7.2)	+
353	Poussière	Dusts (dairy industry)	E. coli O157:H7 Ad1745	Cheese	Spiking 4°C / 8 days	0.72	2-2-1-4-4 (2.6)	+

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 2. Artificial Contamination- Extension Study

Category	Type	Item	Sample No	Species & supspecies	Serovar	Source and Strain [1,2,3]	Orgin	Injury Protocol	Injury Evaluation (Log10)	Inoculation (CFU/ Sample)	CHROMagar O157	CT-SMAC	EC 0157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
Raw Beef (25g)	Fresh beef meats	Raw Ground Beef (85% Lean)	087.1	*Escherichia coli*	O157:H7	ATCC 43895	Raw hamburger meat implicated in hemorrhagic collitis out break	48 h at 5 ± 3°C	/	4.2	+	+	+	+	+	PA
		Raw Ground Beef (96% Lean)	087.2	*Escherichia coli*	O157:H7	ATCC 43895	Raw hamburger meat implicated in hemorrhagic collitis out break	48 h at 5 ± 3°C	/	4.2	+	+	+	+	+	PA
		Raw Beef Tips	087.3	*Escherichia coli*	O157:H7	QL# 164673	Beef Trim	48 h at 5 ± 3°C	/	2.2	+	+	+	+	+	PA
		Raw Shaved Beef	087.4	*Escherichia coli*	O157:H7	QL# 164673	Beef Trim	48 h at 5 ± 3°C	/	2.2	+	+	+	+	+	PA
		Raw Beef Serloin	087.5	*Escherichia coli*	O157:H7	QL# 164673	Beef Trim	48 h at 5 ± 3°C	/	2.2	+	+	+	+	+	PA
	Frozen then thawed beef	Frozen Thawed Quarter Pound Beef Patties	087.6	*Escherichia coli*	O157:H7	ATCC 43895	Raw hamburger meat implicated in hemorrhagic collitis out break	72 h at -20 °C	/	4.2	+	+	+	+	+	PA
		Frozen Thawed Angus Beef Check Brisket Blend Burgers	087.7	*Escherichia coli*	O157:H7	MSU TW02302	Hamburger	72 h at -20 °C	/	1.8	+	+	+	+	+	PA
		Frozen Thawed 80% Lean Ground Beef Burgers	087.8	*Escherichia coli*	O157:H7	ATCC 43895	Raw hamburger meat implicated in hemorrhagic collitis out break	72 h at -20 °C	/	4.2	+	+	+	+	+	PA
		Frozen Thawed 100% Angus Beef Patties	087.9	*Escherichia coli*	O157:H7	MSU TW02302	Hamburger	72 h at -20 °C	/	1.8	+	+	+	+	+	PA
		Frozen Thawed Bacon Cheddar Beef Patties	087.10	*Escherichia coli*	O157:H7	MSU TW02302	Hamburger	72 h at -20 °C	/	1.8	+	+	+	+	+	PA
	Meats with seasonings	Raw seasoned beef patties	087.11	*Escherichia coli*	O157:H7	ATCC 43895	Raw hamburger meat implicated in hemorrhagic collitis out break	48 h at 5 ± 3°C	/	4.2	+	+	+	+	+	PA
		Raw Angus Beef Steakhous Tri Tip	087.12	*Escherichia coli*	O157:H7	QL# 164673	Beef Trim	48 h at 5 ± 3°C	/	2.2	+	+	+	+	+	PA
		Raw Black Peppercorn Ribeye	087.13	*Escherichia coli*	O157:H7	QL 2-701	Beef	48 h at 5 ± 3°C	/	5.6	+	+	+	+	+	PA
		Raw Angus Sweet and Smokey Angus Beef tip	087.14	*Escherichia coli*	O157:H7	QL 2-701	Beef	48 h at 5 ± 3°C	/	5.6	+	+	+	+	+	PA
		Bacon and Black Peppercorn Wrapped Beef Tender	087.15	*Escherichia coli*	O157:H7	QL 2-701	Beef	48 h at 5 ± 3°C	/	5.6	+	+	+	+	+	PA
Raw Beef (375 g)	Fresh beef meats	Raw Ground Beef (85% Lean)	087.16	*Escherichia coli*	O157:H7	MSU TW02302	Hamburger	48 h at 5 ± 3°C	/	1.8	+	+	+	+	+	PA
		Raw Ground Beef (96% Lean)	087.17	*Escherichia coli*	O157:H7	QL 14077.5	Ground Beef	48 h at 5 ± 3°C	/	3.2	+	+	+	+	+	PA
		Raw Beef Tips	087.18	*Escherichia coli*	O157:H7	QL 14077.8	Gound Beef	48 h at 5 ± 3°C	/	1.6	+	+	+	+	+	PA
		Raw Shaved Beef	087.19	*Escherichia coli*	O157:H7	QL 2-701	Beef	48 h at 5 ± 3°C	/	5.6	+	+	+	+	+	PA
		Raw Beef Serloin	087.20	*Escherichia coli*	O157:H7	QL 14077.8	Gound Beef	48 h at 5 ± 3°C	/	1.6	+	+	+	+	+	PA
	Frozen then thawed beef	Frozen Thawed Quarter Pound Beef Patties	087.21	*Escherichia coli*	O157:H7	QL 14077.5	Ground Beef	72 h at -20 °C	/	3.2	+	+	+	+	+	PA
		Frozen Thawed Angus Beef Check Brisket Blend Burgers	087.22	*Escherichia coli*	O157:H7	QL 14077.5	Ground Beef	72 h at -20 °C	/	3.2	+	+	+	+	+	PA
		Frozen Thawed 80% Lean Ground Beef Burgers	087.23	*Escherichia coli*	O157:H7	QL 14077.5	Ground Beef	72 h at -20 °C	/	3.2	+	+	+	+	+	PA
		Frozen Thawed 100% Angus Beef Patties	087.24	*Escherichia coli*	O157:H7	QL 14077.8	Gound Beef	72 h at -20 °C	/	1.6	+	+	+	+	+	PA
		Frozen Thawed Bacon Cheddar Beef Patties	087.25	*Escherichia coli*	O157:H7	QL 14077.8	Gound Beef	72 h at -20 °C	/	1.6	+	+	+	+	+	PA
Dairy Products	Raw milk products	Raw Bovine Milk	087.26	*Escherichia coli*	O157:H7	MSU DEC3A	Human	48 h at 5 ± 3°C	/	2.6	+	+	+	+	+	PA
		Raw Goat Milk	087.27	*Escherichia coli*	O157:H7	MSU DEC3A	Human	48 h at 5 ± 3°C	/	2.6	+	+	+	+	+	PA
		Raw Sheep Milk	087.28	*Escherichia coli*	O157:H7	MSU DEC3A	Human	48 h at 5 ± 3°C	/	2.6	+	+	+	+	+	PA
		Raw Bovine Milk 2	087.29	*Escherichia coli*	O157:H7	MSU DEC4B	Human	48 h at 5 ± 3°C	/	3.2	+	+	+	+	+	PA
		Raw Sheep Milk 2	087.30	*Escherichia coli*	O157:H7	MSU DEC4B	Human	48 h at 5 ± 3°C	/	3.2	+	+	+	+	+	PA
	Pasteurized products	Shreaded Sharp Cheddar	087.31	*Escherichia coli*	O157:H7	MSU DEC4B	Human	Heat treatment (50 - 55°C for 10-15 min.)	0.62	2.4	+	+	+	+	+	PA
		Shreaded Low Fat Mozzarella	087.32	*Escherichia coli*	O157:H7	MSU DEC3A	Human	Heat treatment (50 - 55°C for 10-15 min.)	0.7	2.6	+	+	+	+	+	PA
		Swiss Cheese	087.33	*Escherichia coli*	O157:H7	MSU DEC4B	Human	Heat treatment (50 - 55°C for 10-15 min.)	0.62	3.2	+	+	+	+	+	PA
		Gouda Cheese	087.34	*Escherichia coli*	O157:H7	QL 14077.3	Salami	Heat treatment (50 - 55°C for 10-15 min.)	0.76	1.2	+	+	+	+	+	PA
		Provolone Cheese	087.35	*Escherichia coli*	O157:H7	QL 14077.3	Salami	Heat treatment (50 - 55°C for 10-15 min.)	0.76	1.2	+	+	+	+	+	PA
	Raw milk cheeses	Brie	087.36	*Escherichia coli*	O157:H7	MSU TW00116	Human	48 h at 5 ± 3°C	/	3.8	+	+	+	+	+	PA
		Feta	087.37	*Escherichia coli*	O157:H7	MSU TW00116	Human	48 h at 5 ± 3°C	/	3.8	+	+	+	+	+	PA
		Queso Blanco	087.38	*Escherichia coli*	O157:H7	QL 14077.3	Salami	48 h at 5 ± 3°C	/	1.2	+	+	+	+	+	PA
		Goat Cheese	087.39	*Escherichia coli*	O157:H7	QL 14077.3	Salami	48 h at 5 ± 3°C	/	1.2	+	+	+	+	+	PA
		Raw Cheddar Cheese	087.40	*Escherichia coli*	O157:H7	MSU TW00116	Human	48 h at 5 ± 3°C	/	3.8	+	+	+	+	+	PA

Table 2. Artificial Contamination- Extension Study Continued

Category	Type	Item	Sample No	Species & supspecies	Serovar	Source and Strain [1,2,3]	Orgin	Injury Protocol	Injury Evaluation (Log10)	Inoculation (CFU/ Sample)	CHOMAgar O157	CT-SMAC	EC 0157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
Fruits and Vegetables (25 g)	Fresh and frozen produces	Chopped Chipotle Salad Kit	087.41	*Escherichia coli*	O157:H7	QL 062918.69	Spinach	48 h at 5 ± 3°C	/	1.2	+	+	+	+	+	PA
		Chopped Ceasar Salad Kit	087.42	*Escherichia coli*	O157:H7	MSU TW00116	Human	48 h at 5 ± 3°C	/	3.8	+	+	+	+	+	PA
		Garden Salad Kit	087.43	*Escherichia coli*	O157:H7	QL 062918.69	Spinach	48 h at 5 ± 3°C	/	1.2	+	+	+	+	+	PA
		Fresh Mixed Fruit Bowl	087.44	*Escherichia coli*	O157:H7	QL 062918.69	Spinach	48 h at 5 ± 3°C	/	1.2	+	+	+	+	+	PA
		Fresh Strawberry and Kiwi Bowl	087.45	*Escherichia coli*	O157:H7	QL 062918.69	Spinach	48 h at 5 ± 3°C	/	1.2	+	+	+	+	+	PA
	Fresh and frozen sprouts or baby leafs	Baby Spinach	087.46	*Escherichia coli*	O157:H7	QL 062918.74	Babby Spinach Leaf	48 h at 5 ± 3°C	/	3.0	+	+	+	+	+	PA
		Baby Arugula	087.47	*Escherichia coli*	O157:H7	QL 062918.74	Babby Spinach Leaf	48 h at 5 ± 3°C	/	3.0	+	+	+	+	+	PA
		Baby Kale	087.48	*Escherichia coli*	O157:H7	QL 062918.74	Babby Spinach Leaf	48 h at 5 ± 3°C	/	3.0	+	+	+	+	+	PA
		Baby bean Sprouts	087.49	*Escherichia coli*	O157:H7	QL 062918.74	Babby Spinach Leaf	48 h at 5 ± 3°C	/	3.0	+	+	+	+	+	PA
		Mung Sprouts	087.50	*Escherichia coli*	O157:H7	QL 071318.58	Spinach	48 h at 5 ± 3°C	/	1.6	+	+	+	+	+	PA
	Fresh raw, frozen fruit	Grapes	087.51	*Escherichia coli*	O157:H7	QL 14077.4	Apple Cider	48 h at 5 ± 3°C	/	2.8	+	+	+	+	+	PA
		Pineapple	087.52	*Escherichia coli*	O157:H7	QL 14077.4	Apple Cider	48 h at 5 ± 3°C	/	2.8	+	+	+	+	+	PA
		Apples	087.53	*Escherichia coli*	O157:H7	QL 14077.4	Apple Cider	48 h at 5 ± 3°C	/	2.8	+	+	+	+	+	PA
		Frozen Peaches	087.54	*Escherichia coli*	O157:H7	QL 14077.4	Apple Cider	72 h at -20 °C	/	2.8	+	+	+	+	+	PA
		Frozen Strawberries	087.55	*Escherichia coli*	O157:H7	QL 071318.58	Spinach	72 h at -20 °C	/	1.6	+	+	+	+	+	PA
Environmental Samples (25 g or surfaces)	Surfaces	Swab (food industry) Location 1	087.56	*Escherichia coli*	O157:H7	QL 14077.6	Environmental Sample	48 h at 5 ± 3°C	/	4.8	+	+	+	+	+	PA
		Sponge (food industry) Location 1	087.57	*Escherichia coli*	O157:H7	QL 14077.6	Environmental Sample	48 h at 5 ± 3°C	/	4.8	+	+	+	+	+	PA
		Swab (food industry) Location 2	087.58	*Escherichia coli*	O157:H7	QL 14077.6	Environmental Sample	48 h at 5 ± 3°C	/	4.8	+	+	+	+	+	PA
		Swab (food industry) Location 2	087.59	*Escherichia coli*	O157:H7	QL 14077.6	Environmental Sample	48 h at 5 ± 3°C	/	4.8	+	+	+	+	+	PA
		Sponge (food industry) Location 2	087.60	*Escherichia coli*	O157:H7	QL 062918.11	Environmental Sample	48 h at 5 ± 3°C	/	1.4	+	+	+	+	+	PA
	Process water	Processed Water (food industry) Location 1	087.61	*Escherichia coli*	O157:H7	QL 062918.60	Environmental Sample	Heat treatment (50 - 55°C for 10-15 min.)	0.58	2.0	+	+	+	+	+	PA
		Processed Water (food industry) Location 2	087.62	*Escherichia coli*	O157:H7	QL 062918.11	Environmental Sample	Heat treatment (50 - 55°C for 10-15 min.)	0.64	1.4	+	+	+	+	+	PA
		Processed Water (food industry) Location 3	087.63	*Escherichia coli*	O157:H7	QL 062918.11	Environmental Sample	Heat treatment (50 - 55°C for 10-15 min.)	0.64	1.4	+	+	+	+	+	PA
		Processed Water (food industry) Location 1	087.64	*Escherichia coli*	O157:H7	QL 062918.11	Environmental Sample	Heat treatment (50 - 55°C for 10-15 min.)	0.64	1.4	+	+	+	+	+	PA
		Processed Water (food industry) Location 3	087.65	*Escherichia coli*	O157:H7	QL 062918.60	Environmental Sample	Heat treatment (50 - 55°C for 10-15 min.)	0.58	2.0	+	+	+	+	+	PA
	Dusts	Dust (food industry) Location 1	087.66	*Escherichia coli*	O157:H7	QL 071318.62	Environmental Sample	48 h at 5 ± 3°C	/	2.2	+	+	+	+	+	PA
		Dust (food industry) Location 2	087.67	*Escherichia coli*	O157:H7	QL 062918.60	Environmental Sample	48 h at 5 ± 3°C	/	2.0	+	+	+	+	+	PA
		Dust (food industry) Location 3	087.68	*Escherichia coli*	O157:H7	QL 062918.60	Environmental Sample	48 h at 5 ± 3°C	/	2.0	+	+	+	+	+	PA
		Dust (food industry) Location 3	087.69	*Escherichia coli*	O157:H7	QL 071318.62	Environmental Sample	48 h at 5 ± 3°C	/	2.2	+	+	+	+	+	PA
		Dust (food industry) Location 1	087.70	*Escherichia coli*	O157:H7	QL 071318.62	Environmental Sample	48 h at 5 ± 3°C	/	2.2	+	+	+	+	+	PA

ANNEX D: Sensitivity Raw Data- Original Study

Table 3. Sensitivity Raw Data Original Study *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

RAW BEEF MEATS (25 g)																			
n° sample	Product (French name)	Product	Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq											
								Enrichment: 8h at 41.5°C		Enrichment: 24h at 41.5°C					Enrichment: 8h at 41.5°C + 72h at 2-8°C				
			ims 6h		ims 24h					IMS on negative samples									
			CT-SMAC	Chromagar	CT-SMAC	Chromagar	Final Result	PCR result	Confirmation	CT-SMAC	Chromagar	Final result	Final result 8h ims+wash	Agreement Alt/Ref	PCR result	Confirmation	Final result 8h ims+wash	Agreement Alt/Ref
1696	*Carpaccio nature*	Carpaccio	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1697	*Carpaccio nature*	Carpaccio	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1698	*Carpaccio nature*	Carpaccio	st	st	st	st	-	-	st	-	-	-	-	NA				
1699	*Carpaccio nature*	Carpaccio	st	st	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
1703	*Steak haché 15% MG*	Ground beef 15% fat	+	+	/	/	+	-	st	-	-	-	-	ND	-	-	-	ND
1704	*Steak haché 15% MG*	Ground beef 15% fat	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1705	*Steak haché 15% MG*	Ground beef 15% fat	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1706	*Steak haché 5% MG*	Ground beef 5% fat	st	st	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
1707	*Faux-filet*	Beef trim	+(1)	+(2)	-	-	+	+	+	/	/	/	+	PA	+	+	+	PA
1708	*Rumsteak*	Beef trim	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
1709	*Steak*	Beef trim	st	-	st	-	-	+	+	/	/	/	+	PD	+	+	+	PD
1710	*Bavette*	Beef trim	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2851	*Tartare 5% MG*	Tartar 85% fat	st	-	st	-	-	-	st	-	-	-	-	NA				
2852	*Viande hachée 5% MG*	Ground beef 5% fat	st	st	st	-	-	-	st	-	-	-	-	NA				
2853	*Viande hachée 15% MG*	Ground beef 15% fat	-	-	-	-	-	-	-	st	-	-	-	NA				
2854	*Carpaccio*	Carpaccio	st	st	st	-	-	-	st	st	-	-	-	NA				
2855	*Carpaccio*	Carpaccio	st	st	st	-	-	-	st	st	-	-	-	NA				
2856	*Carpaccio*	Carpaccio	st	st	st	-	-	-	st	-	-	-	-	NA				
2857	*Carpaccio*	Carpaccio	st	st	st	-	-	-	st	-	-	-	-	NA				
2858	*Bifteck*	Beef trim	st	st	st	-	-	-	st	-	-	-	-	NA				
2859	*Steak haché 15% MG*	Ground beef 15% fat	-	-	-	-	-	-	-	-	-	-	-	NA				
3083	*Tartare de bœuf*	Beef tartar	st	-	-	-	-	-	st	st	-	-	-	NA				
3084	*Tartare de bœuf*	Beef tartar	st	-	-	-	-	-	st	-	-	-	-	NA				
1538	*Steak haché surgelé 15% MG*	Frozen ground beef 15% fat	+	+	/	/	+	+	+	/	/	/	+	PA	+	+ (ims captivate)	+	PA
1540	*Steak haché surgelé 5% MG*	Frozen ground beef 5% fat	+	+	/	/	+	+	+	/	/	/	+	PA	+	+(ims GDS/ChromID)	+	PA
1541	*Egréné de bœuf surgelé 20% MG*	Frozen ground beef 20% fat	+	+	/	/	+	+	+	/	/	/	+	PA	+	+ (ims captivate)	+	PA
1542	*Boulettes de bœuf surgelé*	Frozen beef balls	+	+	/	/	+	+	+	/	/	/	+	PA	+	+ (ims captivate)	+	PA
1545	*Steak haché*	Ground beef	st	st	st	-	-	+	+	/	/	/	+	PD	+	+ (ims captivate)	+	PD
1546	*Steak haché*	Ground beef	st	st	st	st	-	-	st	st	-	-	-	NA				
1547	*Steak haché*	Ground beef	st	st	st	st	-	-	st	st	-	-	-	NA				
2845	*Effeuillé de charolais surgelé*	Frozen beef trim	st	st	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2846	*Bifteck de charolais surgelé*	Frozen beef trim	st	st	st	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2847	*Steak haché surgelé*	Frozen ground beef 15% fat	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2848	*Steak haché 15% MG surgelé*	Frozen ground beef 15% fat	st	-	-	-	-	+	+(after IMS captivate and regrowth BHI)	-	-	-	+	PD	+	+(after IMS captivate and regrowth BHI)	+	PD
2849	*Egréné de bœuf 15% MG surgelé*	Frozen ground beef 15% fat	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2850	*Egréné de bœuf 5% MG surgelé*	Frozen ground beef 5% fat	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2865	*Effeuillé de charolais surgelé*	Frozen beef trim	st	st	st	-	-	-	st	-	-	-	-	NA				
2866	*Bifteck de charolais surgelé*	Frozen beef trim	st	st	st	-	-	-	st	st	-	-	-	NA				

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

RAW BEEF MEATS (25 g)																		
n° sample	Product (French name)	Product	Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq										
								Enrichment: 8h at 41.5°C		Enrichment: 24h at 41.5°C			Final result 8h ims+wash	Agreement Alt/Ref	Enrichment: 8h at 41.5°C + 72h at 2-8°C		Final result 8h ims+wash	Agreement Alt/Ref
			ims 6h		ims 24h		Final Result	PCR result	Confirmation	IMS on negative samples					PCR result	Confirmation		
			CT-SMAC	Chromagar	CT-SMAC	Chromagar				CT-SMAC	Chromagar	Final result						
2867	Egréné de bœuf 5% MG surgelé	Frozen ground beef 5%fat	st	-	-	-	-	-	st	st	-	-	-	NA				
2868	Steak haché surgelé	Frozen ground beef	st	-	-	-	-	-	-	-	-	-	-	NA				
3089	Seak haché de boeuf bio surgelé	Frozen ground beef	st	st	st	-	-	-	-	st	-	-	-	NA				
3090	Steak haché de bœuf 5% MG surgelé	Frozen ground beef 5% fat	st	-	-	-	-	-	-	-	-	-	-	NA				
3091	Steak haché de bœuf surgelé	Frozen ground beef	st	-	-	-	-	-	st	st	-	-	-	NA				
1533	Steak haché à l'oignon surgelé	Frozen seasoned ground beef	+	+	/	/	+	+	+	/	/	/	+	PA	+	+ (ims captivate)	+	PA
1536	Steak haché à l'oignon surgelé	Frozen seasoned ground beef	+	+	/	/	+	+	+	/	/	/	+	PA	+	+ (ims captivate)	+	PA
1537	Steak haché à la tomate surgelé	Frozen seasoned ground beef	+	+	/	/	+	+	+	/	/	/	+	PA	+	+(ims GDS/ChromID)	+	PA
1543	Boulettes de bœuf tomate/parmesan surgelées	Frozen seasoned beef balls	+	+	/	/	+	+	+	/	/	/	+	PA	+	+(ims GDS/ChromID)	+	PA
1544	Steak haché à l'oignon surgelé	Frozen seasoned ground beef	+	+	/	/	+	+	+	/	/	/	+	PA	+	+ (ims captivate)	+	PA
1700	Carpaccio au pistou	Seasoned Carpaccio	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
1701	Carpaccio huile d'olive/basilic	Seasoned Carpaccio	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1702	Carpaccio parmesan	Seasoned Carpaccio	st	st	st	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2843	Viande hachée bolognaise	Seasoned ground beef	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2844	Carpaccio basilic	Seasoned Carpaccio	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2860	Haché bolognaise	Seasoned ground beef	st	-	-	-	-	-	-	-	-	-	-	NA				
2861	Carpaccio basilic	Seasoned Carpaccio	st	st	st	-	-	-	st	st	-	-	-	NA				
2862	Carpaccio agrumes	Seasoned Carpaccio	st	st	st	-	-	-	st	st	st	-	-	NA				
2863	Carpaccio parmesan	Seasoned Carpaccio	st	-	-	-	-	-	st	-	-	-	-	NA				
2864	Steak haché oignons surgelé	Seasoned frozen ground beef	st	st	-	-	-	-	-	-	-	-	-	NA				
3085	Pavé de rumsteak à l'échalote	Seasoned beef trim	st	-	-	-	-	-	-	-	-	-	-	NA				
3086	Pavé de rumsteak aux 3 poivres	Seasoned beef trim	st	-	-	-	-	-	-	-	-	-	-	NA				
3087	Haché bolognaise	Seasoned ground beef	st	-	-	-	-	-	-	-	-	-	-	NA				
3088	Boulettes de bœuf tomates parmesan surgelées	Frozen seasoned beef balls	st	st	st	st	-	-	st	st	st	-	-	NA				

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

RAW BEEF MEATS (375 g)																		
n° sample	Product (French name)	Product	Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq										
								Enrichment: 8h at 41.5°C		Enrichment: 24h at 41.5°C				Agreement Alt/Ref	Enrichment: 8h at 41.5°C + 72h at 2-8°C			
			ims 6h		ims 24h		Final Result			IMS on negative samples			Final result 8h ims+wash				Final result 8h ims+wash	Agreement Alt/Ref
			CT-SMAC	Chromagar	CT-SMAC	Chromagar		PCR result	Confirmation	CT-SMAC	Chromagar	Final result			PCR result	Confirmation		
2288	Steak haché façon bouchère 15% MG	Ground beef 15% fat	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2289	Haché tradition 15% MG	Ground beef 15% fat	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2290	Steak haché 15% MG	Ground beef 15% fat	st	+(3)	-	-	+	+	+	/	/	/	+	PA	+	+	+	PA
2291	Steak haché 5% MG	Ground beef 5% fat	+(13)	+(10)	+	+	+	+	+	/	/	/	+	PA	+	+	+	PA
2292	Faux filets	Beef trim	st	st	-	-	-	-	-	-	-	-	-	NA				
2293	Entrecôtes	Beef trim	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2294	Cœur de rumsteak	Beef trim	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2295	Rôti de bœuf	Beef trim	st	st	-	-	-	-	-	-	-	-	-	NA				
2296	Capa désossé	Beef trim	st	-	st	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2297	Palette	Beef trim	st	st	-	-	-	+	+	/	/	/	+	PD	+	+ (after regrowth in BHI/i ms with captivate/ plating on CT-SMAC and chromID)	+	PD
2298	Gite de bœuf	Beef trim	st	st	-	-	-	+	+	/	/	/	+	PD	+	+ (after regrowth in BHI/ ims with captivate/ plating on CT-SMAC and chromID)	+	PD
2299	Bavettes d'Aloyau	Beef trim	st	st	+	+	+	+	+	/	/	/	+	PA	+	+(1)	+	PA
2300	Bourguignon	Beef trim	st	-	st	-	-	+	+	/	/	/	+	PD	+	+(1)	+	PD
2301	Steak haché façon bouchère	Ground beef	st	st	-	-	-	-	-	-	-	-	-	NA				
2302	Steak haché 15% MG	Ground beef 15% fat	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
3001	Steack haché 15% MG	Ground beef 15% fat	st	st	-	-	-	-	-	-	-	-	-	NA				
3002	Entrecôtes	Beef trim	st	-	st	-	-	+	+	/	/	/	+	PD	+	+	+	PD
3003	Faux filets	Beef trim	st	st	-	-	-	+	+ (after regrowth in BHI overnight)	+p (Latex +/+)	+M	+	+	PD	+	+(2)	+	PD
3004	Rond de gîte de bœuf	Beef trim	st	st	+p	+m	+	-	-	st	st	-	-	ND	-	st	-	ND
3005	Rumsteack	Beef trim	st	-	st	-	-	+	+	/	/	/	+	PD	+	+	+	PD
87	Bavette	Beef trim	st	st	-	-	-	-		-	-	-	-	NA				
88	Dessus de palette	Beef trim	st	-	-	-	-	-		-	-	-	-	NA				
89	Bavette	Beef trim	st	st	st	-	-	-		st	-	-	-	NA				
90	Gite de bœuf	Beef trim	st	st	st	st	-	-		st	-	-	-	NA				
91	Faux filet	Beef trim	st	st	st	-	-	-		-	-	-	-	NA				
92	Entrecôtes	Beef trim	st	-	-	-	-	-		-	-	-	-	NA				
93	Pavé de rumsteak	Beef trim	st	st	-	-	-	-		-	-	-	-	NA				
94	Steak haché 15% MG	Ground beef 15% fat	st	st	-	-	-	-		-	-	-	-	NA				
95	Haché tradition 15% MG	Ground beef 15% fat	st	-	-	-	-	-		-	-	-	-	NA				
96	Steak haché 15% MG	Ground beef 15% fat	st	st	-	-	-	-		-	-	-	-	NA				
97	Steak haché façon boucgère	Ground beef	st	-	-	-	-	-		-	-	-	-	NA				
98	Steak haché façon boucgère	Ground beef	st	-	-	-	-	-		-	-	-	-	NA				
2746	Egréné de bœuf surgelé	Frozen ground beef	+	+	/	/	+	+	+	/	/	/	+	PA	+	+(1)	+	PA
2747	Egréné de bœuf surgelé	Frozen ground beef	st	st	st	-	-	-	-	-	-	-	-	NA				
2748	Egréné de bœuf surgelé	Frozen ground beef	+	+	/	/	+	-	-	-	-	-	-	ND	-	-	-	ND
2749	Egréné de bœuf surgelé	Frozen ground beef	st	st	st	-	-	+	+	/	/	/	+	PD	+	+(2)	+	PD
2750	Steak haché 15% MG surgelé	Frozen ground beef 15% fat	+	+	/	/	+	+	+	/	/	/	+	PA	+	+(3)	+	PA
2751	Viande bourguignon surgelée	Frozen beef trim	st	st	-	-	-	-	-	-	-	-	-	NA				
2752	Viande bourguignon surgelée	Frozen beef trim	+	+	/	/	+	-	-	-	-	-	-	ND	-	-	-	ND
2753	Boulettes surgelées	Frozen beef balls	st	st	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2754	Boulettes surgelées	Frozen beef balls	+	+	/	/	+	+	+	/	/	/	+	PA	+	+ (after regrowth in BHI /ims with captivate/ plating on CT-SMAC and chromID)	+	PA

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

RAW BEEF MEATS (375 g)																		
n° sample	Product (French name)	Product	Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq										
								Enrichment: 8h at 41.5°C		Enrichment: 24h at 41.5°C			Final result 8h ims+wash	Agreement Alt/Ref	Enrichment: 8h at 41.5°C + 72h at 2-8°C		Final result 8h ims+wash	Agreement Alt/Ref
			ims 6h		ims 24h		Final Result	PCR result	Confirmation	IMS on negative samples					PCR result	Confirmation		
			CT-SMAC	Chromagar	CT-SMAC	Chromagar				CT-SMAC	Chromagar	Final result						
2755	Carpaccio surgelé	Frozen Carpaccio	st	st	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2756	Carpaccio surgelé	Frozen Carpaccio	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2757	Entrecôtes surgelées	Frozen beef trim	+	+	/	/	+	-	-	-	-	-	-	ND	-	-	-	ND
2758	Faux filets surgelées	Frozen beef trim	st	st	-	-	-	+	+	/	/	/	+	PD	+	+ (after regrowth in BHI/ ims with captivete/ plating on CT-SMAC and chromID)	+	PD
2759	Pavés de bœuf surgelé	Frozen beef trim	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2760	Bavettes d'Aloyau surgelées	Frozen beef trim	st	st	-	-	-	-	-	-	-	-	-	NA				
3006	Viande hachée surgelée	Frozen ground beef	+p	+p	+M	+m	+	+	+	/	/	/	+	PA	+	+	+	PA
3007	Bavettes d'Aloyau surgelées	Frozen beef trim	st	st	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
3008	Faux filets surgelées	Frozen beef trim	+p	+p	+p	+M	+	+	+	/	/	/	+	PA	+	+	+	PA
3009	Steak haché 20% MG surgelé	Frozen ground beef 20% fat	st	-	st	-	-	+	+	/	/	/	+	PD	+	+	+	PD
3010	Carpaccio surgelé	Frozen beef trim	+(2)	+(5)	+p	+M	+	+	+	/	/	/	+	PA	+	+	+	PA
84	Haché tradition surgelé	Frozen ground beef	st	-	-	-	-	-		st	-	-	-	NA				
85	Viande hachée surgelée	Frozen ground beef	st	st	-	-	-	-		-	-	-	-	NA				
86	Egréné de bœuf surgelé	Frozen ground beef	st	st	st	-	-	-		st	-	-	-	NA				
99	Faux filet surgelé	Frozen beef trim	st	st	st	-	-	-		-	-	-	-	NA				
100	Entrecôtes surgelées	Frozen beef trim	st	-	-	-	-	-		-	-	-	-	NA				
101	Faux filet surgelé	Frozen beef trim	st	st	st	-	-	-		-	-	-	-	NA				
102	Entrecôtes surgelées	Frozen beef trim	st	st	-	-	-	-		-	-	-	-	NA				
103	Bavettes surgelées	Frozen beef trim	st	st	st	-	-	-		-	-	-	-	NA				
104	Bavettes surgelées	Frozen beef trim	st	st	-	-	-	-		st	st	-	-	NA				
105	Steak haché 20% MG surgelé	Frozen ground beef 20% fat	st	-	-	-	-	-		-	-	-	-	NA				
106	Egréné de bœuf surgelé	Frozen ground beef	st	st	-	-	-	-		-	-	-	-	NA				

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

DAIRY PRODUCTS																			
			Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq											
								Enrichment: 8h at 41.5°C + regrowth 2 h at 37°C		Enrichment: 24h at 41.5°C			Final result 8h ims+wash	Agreement Alt/Ref	Enrichment: 8h at 41.5°C + 72h at 2-8°C		Final result 8h ims+wash	Agreement Alt/Ref
			ims 6h		ims 24h					IMS on negative samples									
n° sample	Product (French name)	Product	CT-SMAC	Chromagar	CT-SMAC	Chromagar	Final Result	PCR result	Confirmation	CT-SMAC	Chromagar	Final result			PCR result	Confirmation			
1577	*Lait cru*	Raw milk	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
1578	*Lait cru*	Raw milk	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
1579	*Lait ribot*	Fermented milk	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
1580	*Lait ribot*	Fermented milk	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
1581	*Lait fermenté*	Fermented milk	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
1853	*Lait cru*	Raw milk	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD	
1854	*Lait fermenté*	Fermented milk	st	st	-	-	-	-	st	st	st	-	-	NA					
1855	*Lait cru*	Raw milk	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
1856	*Lait fermenté*	Fermented milk	st	st	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD	
1857	*Lait fermenté*	Fermented milk	st	st	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD	
2663	*Lait cru de vache*	Raw cow milk	+mol	+mol	+m	-	+	+	+	/	/	/	+	PA	+	+	+	PA	
2664	*Lait cru de vache*	Raw cow milk	+mol	+mol	+1/2	+m	+	+	+	/	/	/	+	PA	+	+	+	PA	
2942	*Gros lait*	Fermented milk	st	st	st	st	-	-	st	st	st	-	-	NA					
2943	*Lait fermenté*	Fermented milk	st	st	st	st	-	-	st	st	st	-	-	NA					
2944	*Lait ribot*	Fermented milk	st	st	st	st	-	-	st	st	st	-	-	NA					
2945	*Lait ribot maigre*	Fermented milk	st	st	st	st	-	-	st	st	st	-	-	NA					
2946	*Lait ribot entier*	Fermented milk	st	st	st	st	-	-	st	st	st	-	-	NA					
2947	*Lait cru*	Raw milk	-	-	-	-	-	-	st	-	-	-	-	NA					
2948	*Lait cru*	Raw milk	-	-	-	-	-	-	-	-	-	-	-	NA					
2949	*Lait cru*	Raw milk	-	-	-	-	-	-	-	-	-	-	-	NA					
2950	*Lait cru*	Raw milk	-	-	-	-	-	-	-	-	-	-	-	NA					
1848	*Maroilles (lait de vache pasteurisé)*	Pasteurized cow milk cheese	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD	
1849	*Munster (lait de vache pasteurisé)*	Pasteurized cow milk cheese	st	st	-	-	-	-	st	st	st	-	-	NA					
1850	*Brique brebis (lait de brebis pasteurisé)*	Pasteurized sheep milk cheese	st	st	st	st	-	+	+	/	/	/	+	PD	+	+	+	PD	
1851	*Fromage bleu (lait pasteurisé)*	Pasteurized milk cheese	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD	
1852	*Fromage de chèvre (lait de chèvre pasteurisé)*	Pasteurized goat milk cheese	st	st	st	-	-	-	st	st	st	-	-	NA					
2657	*Cantal (lait de vache pasteurisé)*	Pasteurized cow milk cheese	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
2658	*Chaumes (lait de vache pasteurisé)*	Raw cow milk cheese	+p	+mol	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
2660	*Saint Nectaire (lait de vache pasteurisé)*	Raw cow milk cheese	-	+mol (indol -)	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD	
2661	*Féta (lait pasteurisé)*	Raw sheep milk cheese	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	
2668	*Cantal (lait de vache pasteurisé)*	Pasteurized cow milk cheese	st	st	st	-	-	-	st	st	-	-	-	NA					
2669	*Chaumes (lait de vache pasteurisé)*	Pasteurized cow milk cheese	-	+ol (1: indol-)	-	-	-	-	st	st	-	-	-	NA					
2938	*Gouda au cumin (lait de vache pasteurisé)*	Pasteurized cow milk cheese	st	st	st	-	-	-	st	st	st	-	-	NA					
2939	*Tomme noire de brebis (lait de brebis pasteurisé)*	Pasteurized sheep milk cheese	st	st	st	-	-	-	st	st	-	-	-	NA					
2940	*Saint Nectaire (lait de vache pasteurisé)*	Pasteurized cow milk cheese	st	-	-	-	-	-	st	-	-	-	-	NA					
2941	*Tomme de brebis (lait de brebis pasteurisé)*	Pasteurized sheep milk cheese	st	st	-	-	-	-	st	st	st	-	-	NA					
1582	*Emmental (lait cru de vache)*	Raw cow milk cheese	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA	

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

DAIRY PRODUCTS																			
			Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq											
								Enrichment: 8h at 41.5°C + regrowth 2 h at 37°C		Enrichment: 24h at 41.5°C					Enrichment: 8h at 41.5°C + 72h at 2-8°C				
			ims 6h		ims 24h					IMS on negative samples									
n° sample	Product (French name)	Product	CT-SMAC	Chromagar	CT-SMAC	Chromagar	Final Result	PCR result	Confirmation	CT-SMAC	Chromagar	Final result	Final result 8h ims+wash	Agreement Alt/Ref	PCR result	Confirmation	Final result 8h ims+wash	Agreement Alt/Ref
1583	Abondance (lait cru de vache)	Raw cow milk cheese	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1584	Camembert (lait cru de vache)	Raw cow milk cheese	-	-	-	-	-	+	-	/	-	-	-	NA	+	-	-	PPNA
1585	Crottin de chavignol (lait cru de chèvre)	Raw goat milk cheese	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1586	Reblochon (lait cru de vache)	Raw cow milk cheese	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
1587	Beaumont de Savoie (lait cru de vache)	Raw cow milk cheese	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1588	Comté (lait cru de vache)	Raw cow milk cheese	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1589	Morbier (lait cru de vache)	Raw cow milk cheese	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1590	Tome de Savoie (lait cru de vache)	Raw cow milk cheese	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1591	Chabichou (lait cru de chèvre)	Raw goat milk cheese	+	+	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
1843	Reblochon (lait cru de vache)	Raw cow milk cheese	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
1844	Brie (lait cru de vache)	Raw cow milk cheese	st	-	st	-	-	-	st	st	-	-	-	NA				
1845	Camembert (lait cru de vache)	Raw cow milk cheese	-	-	-	-	-	+	+ after an ims with captivelel regrowth in BHI/ plating on CT-SMAC	/	/	/	+	PD	+	+ after an ims with captivelel regrowth in BHI/ plating on CT-SMAC	+	PD
1846	Coulommiers (lait cru de vache)	Raw cow milk cheese	-	-	-	-	-	-	-	-	-	-	-	NA				
1847	Fromage de chèvre (lait cru de chèvre)	Raw goat milk cheese	+	+	/	/	+	-	st	-	-	-	-	ND	-	st	-	ND
2653	Fromage de chèvre (lait cru)	Raw goat milk cheese	st	st	st	st	-	-	st	st	st	-	-	NA				
2654	Bethmale (lait cru de vache)	Raw cow milk cheese	+m	+mi	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2655	Saint Nectaire (lait cru de vache)	Raw cow milk cheese	+m	+mi	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2665	Bethmale (lait cru de vache)	Raw cow milk cheese	-	-	-	-	-	-	-	-	-	-	-	NA				
2666	Saint Nectaire (lait cru de vache)	Raw cow milk cheese	-	-	-	-	-	-	-	-	-	-	-	NA				
2667	Tomme (lait cru de vache)	Raw cow milk cheese	-	-	-	-	-	-	-	-	-	-	-	NA				
2933	Chèvre crémier (lait cru de chère)	Raw goat milk cheese	st	st	st	st	-	-	st	st	st	-	-	NA				
2934	Brie de Meaux (lait cru de vache)	Raw cow milk cheese	st	-	st	-	-	-	st	st	-	-	-	NA				
2935	Roquefort (lait cru de brebis)	Raw sheep milk cheese	st	st	-	-	-	-	st	-	-	-	-	NA				
2936	Beaumont de Savoie (lait cru de vache)	Raw cow milk cheese	st	st	st	st	-	-	st	st	st	-	-	NA				
2937	Emmental (lait cru de vache)	Raw cow milk cheese	st	st	-	-	-	-	st	-	-	-	-	NA				

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

FRUITS AND VEGETABLES																			
			Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq											
								Enrichment: 8h at 41.5°C		Enrichment: 24h at 41.5°C					Enrichment: 8h at 41.5°C + 72h at 2-8°C				
			ims 6h		ims 24h					IMS on negative samples									
n° sample	Product (French name)	Product	CT-SMAC	Chromagar	CT-SMAC	Chromagar	Final Result	PCR result	Confirmation	CT-SMAC	Chromagar	Final result	Final result 8h ims+wash	Agreement Alt/Ref	PCR result	Confirmation	Final result 8h ims+wash	Agreement Alt/Ref
2447	***Mâche***	Mash	st	st	st	st	-	-	st	st	st	-	-	NA				
2448	***Mesclun***	Mesclun	-	-	+mol (indol -)	+mol (indol -)	-	+	+	/	/	/	+	PD	+	+	+	PD
2802	***Mâche***	Mash	+M	+M	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
3069	*Mesclun*	Mesclun	-	-	-	-	-	-	-	-	-	-	-	NA				
3070	*Roquette*	Salad	-	-	-	-	-	-	st	-	-	-	-	NA				
3071	*Mâche*	Mash	+mol(indol -)	+mol (indol -)	-	-	-	-	st	-	-	-	-	NA				
3072	*Roquette*	Salad	-	-	st	-	-	-	st	-	-	-	-	NA				
3081	*Haricots plats surgelés*	Frozen flat beans	st	st	st	-	-	-	-	-	-	-	-	NA				
3082	*Choux de Bruxelles surgelés*	Frozen Brussels cabbage	st	st	-	-	-	-	-	st	st	-	-	NA				
3156	*Roquette*	Salad	-	-	-	-	-	-	-	-	-	-	-	NA				
3157	*Mâche*	Mash	+ol (NC)	-	-	-	-	-	-	-	-	-	-	NA				
3158	*Batavia*	Salad	-	-	-	-	-	-	-	-	-	-	-	NA				
3159	*Sucrine*	Salad	+ol (NC)	-	-	-	-	-	-	-	-	-	-	NA				
3405	***Choux de Bruxelles surgelés***	**Frozen Brussels cabbages**	st	st	st	st	-	+	+	/	/	/	+	PD	+	+	+	PD
3406	***Duo de haricots plats surgelés***	**Frozen flat beans**	+p	+M	/	/	+	+	+	/	/	/	+	PA	+	+(ims captivate+regrowth BHI)	+	PA
3407	***Carottes rondelles surgelées***	**Frozen sliced carrots**	st	st	s	st	-	+	+	/	/	/	+	PD	+	+	+	PD
454	*Epinard frais*	Spinach	st	st	st	st	-	-	st	-	-	-	-	NA				
2449	***Jeunes pousses corsées***	Baby leaves	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2453	***Pousses de soja***	Sprouts	-	-	-	-	-	+	+	-	-	-	+	PD	+	-(ims GDS+regrowth BHI)	-	PPNA
2454	***Pousses alfalfa***	Sprouts	+mol	+ol(2)	-	+ol(1)	+	-	-	-	-	-	-	ND	-	-	-	ND
2455	***Pousses de rogquettes alfalfa***	Sprouts	-	-	-	-	-	-	-	-	-	-	-	NA				
2799	***Mesclun (jeunes pousses)***	Mesclun (baby leaves)	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2800	***Roquette (jeunes pousses)***	Roquette (baby leaves)	+M	+m	+1/2	+m	+	+	+	/	/	/	+	PA	+	+	+	PA
3073	*Pousses de soja*	Soya sprouts	-	-	-	-	-	-	st	-	-	-	-	NA				
3074	*Jeunes pousses*	Baby leaves	-	-	-	-	-	-	-	-	-	-	-	NA				
3075	*Jeunes pousses*	Baby leaves	-	-	-	-	-	-	-	-	-	-	-	NA				
3160	*Mélange de jeunes pousses*	Baby leaves	st	-	-	-	-	-	-	st	-	-	-	NA				
3161	*Pousses de soja*	Soya sprouts	-	-	-	-	-	-	-	-	-	-	-	NA				
3410	***Mélange de jeunes pousses***	**Baby leaves**	+mol	+1/2	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
3411	***Mélange de jeunes pousses***	**Baby leaves**	+p	+M	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
3412	***Pousses de betteraves***	**Beets baby leaves**	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
3413	***Mélange de pousses***	**Baby leaves**	+1/2	-	+mol	+1/2	+	+	+	/	/	/	+	PA	+	+	+	PA
3414	***Pousses d'épinards***	**Spinach baby leaves**	-	-	-	-	-	-	/	-	-	-	-	NA	/	/	-	NA
2456	***Kup ananas***	Pineapple	st	st	st	st	-	-	st	st	st	-	-	NA				
2457	***Kup pêche***	Peach	st	st	s	st	-	+	+	/	/	/	+	PD	+	+	+	PD
2458	***Kup verger au jus***	Fruit mix	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2459	***Jus d'ananas***	Pinneapple juice	st	st	st	st	-	+	+	/	/	/	+	PD	+	+	+	PD
2460	***Jus multi nature***	Multifruit juice	+p	+p	/	/	+	-	st	st	st	-	-	ND	-	-	-	ND
2461	***Jus pomme mangue***	Apple/Mango juice	st	st	st	st	-	+	+	/	/	/	+	PD	+	-(+ims captivate)	+	PD
2796	***Smoothie fraise/banane***	Strawberry/banana smoothie	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

FRUITS AND VEGETABLES																		
n° sample	Product (French name)	Product	Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq										
								Enrichment: 8h at 41.5°C		Enrichment: 24h at 41.5°C			Final result 8h ims+wash	Agreement Alt/Ref	Enrichment: 8h at 41.5°C + 72h at 2-8°C		Final result 8h ims+wash	Agreement Alt/Ref
			ims 6h		ims 24h		Final Result	PCR result	Confirmation	IMS on negative samples					PCR result	Confirmation		
			CT-SMAC	Chromagar	CT-SMAC	Chromagar				CT-SMAC	Chromagar	Final result						
2797	*Smoothie pomme/banane/kiwi*	Apple/banana/kiwi smoothie	-	-	-	-	-	+	+	/	/	/	+	PD	+	-(+ims captivate)	+	PD
3076	*Framboises fraiches*	Fresh raspberries	st	st	st	st	-	-	-	st	-	-	-	NA				
3077	*Myrtilles*	Blueberries	st	st	st	st	-	-	-	st	st	-	-	NA				
3078	*Mélange de fruits rouges surgelés*	Frozen red fruits mix	st	st	st	st	-	-	-	st	st	-	-	NA				
3079	*Framboises surgelées*	Frozen raspberries	st	st	st	st	-	-	-	st	st	-	-	NA				
3080	*Mélange fruits exotiques surgelés*	Frozen exotic fruits mix	st	-	-	-	-	-	-	-	-	-	-	NA				
3408	*Framboises entières surgelées*	Frozen raspberries	st	st	s	st	-	+	+	/	/	/	+	PD	+	+	+	PD
3409	*Ananas en morceaux surgelés*	frozen pieces of pine apple	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
3416	*Jus de pomme*	Apple juice	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2450	*Salade italienne au jambon cru*	Deli salad	-	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
2451	*Salade duo de saumon*	Deli salad	+p	+M	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
2452	*Salade campagnarde*	Deli salad	-	-	-	+md (indol -)	-	+	+	/	/	/	+	PD	+	-(ims captivate+regrowth BHI)	-	PPNA
3162	*Carottes râpées*	Sliced carrots	st	st	st	st	-	-	-	st	-	-	-	NA				
3163	*Céleri rémoulade*	Ready to eat celery	st	-	-	-	-	-	-	-	-	-	-	NA				
3164	*Coleslaw*	Coleslaw	st	st	st	-	-	-	-	st	-	-	-	NA				
3165	*Betteraves*	Beets	st	st	st	-	-	-	-	st	st	-	-	NA				
3415	*Gaspacho*	Gazpacho	st	st	st	st	-	-	/	-	-	-	-	NA	/	/	-	NA
3417	*Salade de concombres*	Cucumber deli salad	+p(7)	+(1)	+Md	+Md	+	+	+	/	/	/	+	PA	+	+	+	PA
3418	*Carottes râpées*	Seasoned sliced carrots	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
3419	*Taboulé*	Tabouleh	st	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

ENVIRONMENTAL SAMPLES																		
n° sample	Product (French name)	Product	Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq										
								Enrichment: 8h at 41.5°C		Enrichment: 24h at 41.5°C			Final result 8h ims+wash	Agreement Alt/Ref	Enrichment: 8h at 41.5°C + 72h at 2-8°C		Final result 8h ims+wash	Agreement Alt/Ref
			ims 6h		ims 24h		Final Result			IMS on negative samples								
			CT-SMAC	Chromagar	CT-SMAC	Chromagar		PCR result	Confirmation	CT-SMAC	Chromagar	Final result			PCR result	Confirmation		
3011	Lingette	Wipe	st	st	st	-	-	-	-	st	st	-	-	NA				
3012	Lingette	Wipe	st	st	st	-	-	-	-	-	-	-	-	NA				
3013	Lingette	Wipe	st	st	-	-	-	-	-	st	st	-	-	NA				
3014	Lingette	Wipe	st	st	st	-	-	-	-	-	-	-	-	NA				
3015	Lingette	Wipe	st	st	st	-	-	-	-	-	-	-	-	NA				
361	Lingette table blanche	Wipe (sprout industry)	+ m	-	+ m	+ m	+	+	+	/	/	/	+	PA	+	+ after regrowth in BHI plating on CT-SMAC	+	PA
362	Lingette tapis transfert ligne soja	Wipe (sprout industry)	St	-	+ M	+ 1/2d	-	-	st	-	-	-	-	NA	-	st	-	NA
485	Lingette atelier boucherie	Wipe (meat industry)	St	St	+ pd	-	-	-	st	-	-	-	-	NA	-	-	-	NA
486	Lingette atelier boucherie	Wipe (meat industry)	+ p	+ p	/	/	+	-	st	-	-	-	-	ND	-	-	-	ND
487	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	-	st	st	st	-	-	NA	/	/		
488	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	-	-	+	+	/	/	/	+	PD	+	+	+	PD
489	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	-	-	-	st	st	st	-	-	NA	/	/		
490	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	-	st	st	st	-	-	NA	/	/		
491	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	+	+	/	/	/	+	PD	+	+	+	PD
492	Lingette atelier boucherie	Wipe (meat industry)	St	St	+ md	-	-	+	+	/	/	/	+	PD	+	+	+	PD
493	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	-	st	st	-	-	-	NA	/	/		
494	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	+	+	/	/	/	+	PD	+	+	+	PD
495	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	+	+	/	/	/	+	PD	+	+	+	PD
496	Lingette atelier boucherie	Wipe (meat industry)	+ p	+ p	/	/	+	-	st	st	st	-	-	ND	-	st	-	ND
497	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	+	+	/	/	/	+	PD	+	+	+	PD
498	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	+	+	/	/	/	+	PD	+	+	+	PD
499	Lingette atelier boucherie	Wipe (meat industry)	St	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
500	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	+	+	/	/	/	+	PD	+	+	+	PD
501	Lingette atelier boucherie	Wipe (meat industry)	St	+ p (2)	+ p	+ p	+	+	+	/	/	/	+	PA	+	+	+	PA
502	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	-	st	st	-	-	-	NA	/	/		
503	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	St	-	+	+	/	/	/	+	PD	+	+	+	PD
504	Lingette atelier boucherie	Wipe (meat industry)	St	St	St	-	-	+	+	/	/	/	+	PD	+	+	+	PD
505	Lingette atelier boucherie	Wipe (meat industry)	-	-	-	-	-	-	-	-	-	-	-	NA				
506	Lingette atelier boucherie (après désinfection)	Wipe (meat industry)	st	-	-	-	-	-	st	st	-	-	-	NA				
507	Lingette atelier boucherie	Wipe (meat industry)	st	st	-	-	-	-	-	-	-	-	-	NA				
508	Lingette atelier boucherie (après désinfection)	Wipe (meat industry)	st	st	-	-	-	-	-	-	-	-	-	NA				
509	Lingette atelier boucherie	Wipe (meat industry)	st	st	-	-	-	-	-	-	-	-	-	NA				
510	Lingette atelier boucherie	Wipe (meat industry)	st	st	st	st	-	-	st	st	st	-	-	NA				

Table 3. Sensitivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

ENVIRONMENTAL SAMPLES																			
			Reference method: ISO 16654 *					Alternative method: GDS E.coli O157:H7 Tq											
								Enrichment: 8h at 41.5°C		Enrichment: 24h at 41.5°C					Enrichment: 8h at 41.5°C + 72h at 2-8°C				
			ims 6h		ims 24h					IMS on negative samples									
n° sample	Product (French name)	Product	CT-SMAC	Chromagar	CT-SMAC	Chromagar	Final Result	PCR result	Confirmation	CT-SMAC	Chromagar	Final result	Final result 8h ims+wash	Agreement Alt/Ref	PCR result	Confirmation	Final result 8h ims+wash	Agreement Alt/Ref
511	Lingette atelier boucherie	Wipe (meat industry)	st	+mol	-	+mol	-	-	-	-	-	-	-	NA				
512	Lingette atelier boucherie	Wipe (meat industry)	st	st	st	st	-	-	st	st	st	-	-	NA				
357	Eau de forage	Process water (sprout industry)	+ p	+ p	/	/	+	+	+	/	/	/	+	PA	+	+ after regrowth in BHI/ plating on CT-SMAC	+	PA
358	Eau de lavage	Process water (sprout industry)	+ p	+ M	/	/	+	+	+	/	/	/	+	PA	+	1+	+	PA
359	Eau de rinçage	Process water (sprout industry)	St	St	-	-	-	-	st	-	-	-	-	NA	/	/		
360	Eau d'irrigation	Process water (sprout industry)	St	St	St	St	-	+	+	/	/	/	+	PD	+	+ after regrowth in BHI/ plating on CT-SMAC	+	PD
363	Eau d'irrigation	Process water (sprout industry)	St	St	St	St	-	-	st	-	-	-	-	NA	/	/		
364	Eau de forage	Process water (sprout industry)	+ p	+ p	/	/	+	+	+	/	/	/	+	PA	+1	1+	+	PA
373	Eau de process pousses de soja	Process water (sprout industry)	St	St	St	-	-	-	st	st	st	-	-	NA				
513	Eau bac échaudage	Process water (meat industry)	st	st	st	st	-	-	st	st	st	-	-	NA				
514	Eau bac échaudage	Process water (meat industry)	st	st	st	st	-	-	st	st	st	-	-	NA				
515	Eau bac tampon épileuse	Process water (meat industry)	+2d	+mol	-	+mol	-	+	+ after an ims with captivate/ plating on CT-SMAC	+	-	+	+	PD	+	+ after an ims with captivate/ plating on Chromagar	+	PD
516	Eau cuve de sang	Process water (meat industry)	st	-	st	-	-	-	-	-	-	-	-	NA				
517	Eau cuve de sang	Process water (meat industry)	st	-	-	+2d	-	-	st	-	-	-	-	NA				
602	Eau de process (végétaux)	Process water (vegetables industry)	st	st	st	-	-	+	+	/	/	/	+	PD	+	+ after regrowth captivate in BHI/ plating on Chromagar	+	PD
603	Eau de process (végétaux)	Process water (vegetables industry)	st	st	st	-	-	+	+	/	/	/	+	PD	+	+	+	PD
604	Eau de process (végétaux)	Process water (vegetables industry)	st	st	st	st	-	+	+	/	/	/	+	PD	+	+ after regrowth captivate in BHI/ plating on Chromagar	+	PD
605	Eau bac échaudage	Process water (meat industry)	+p	+p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
350	Déchet poudre de lait	Dusts (dairy industry)	St	St	+ p	+ p	+	-	+	+p	+p	+	-	ND	-	st	-	ND
351	Poussière	Dusts (dairy industry)	+ p	+ p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
352	Poussière	Dusts (dairy industry)	St	St	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
353	Poussière	Dusts (dairy industry)	St	St	+ m	-	-	+	+	/	/	/	+	PD	+	+	+	PD
354	Poussière	Dusts (sprout industry)	+ p	+ p	/	/	+	+	+	/	/	/	+	PA	+	+	+	PA
355	Poussière	Dusts (sprout industry)	St	St	St	St	-	-	st	st	st	-	-	NA	/	/		
356	Poussière	Dusts (sprout industry)	St	St	St	St	-	-	st	st	-	-	-	NA	/	/		
365	Déchets ligne soja	Wastes (sprout industry)	+ mol	-	-	-	-	+	+ after regrowth in BHI/ plating on CT-SMAC	+M	+M	+	+	PD	-	-	-	NA
372	Déchets végétaux préparation	Wastes (sprout industry)	-	-	-	-	-	-	-	-	-	-	-	NA				
374	Déchets végétaux conditionnement	Wastes (sprout industry)	-	-	-	-	-	-	-	-	-	-	-	NA				
606	Déchets pousses de soja	Waste (soya)	+1d	-	-	-	-	+	+	/	/	/	+	PD	+	+	+	PD
607	Déchets pousses de soja	Waste (soya)	+mol	+mol	+1/2	+1/2	+	+	+	/	/	/	+	PA	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

ANNEX E: Relative Detection Level (RLOD) Raw Data- Original Study

Table 4. RLOD Data Original Study *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Matrix : Ground beef 5% fat
Strain : Escherichia coli O157:H7 MK41242
Aerobic mesophilic flora: 600 CFU/g

N° sample	Level	Inoculation level (cfu/sample)	ISO 16654*						GDS E.coli O157:H7 Tq				
			ims 6h		ims 24h		Final Result	Number positive samples/Total	PCR result	Confirmation result- 8h 41,5°C	Confirmation result- 24h 41,5°C	Final result	Number positive samples/Total
			CT-SMAC	Chromagar O157	CT-SMAC	Chromagar O157							
2343	0	0	st	st	-	-	-	0/5	-	-	-	-	0/5
2344			st	st	-	-	-		-	-	-	-	
2345			st	st	st	-	-		-	-	-	-	
2346			st	st	-	-	-		-	-	-	-	
2347			st	st	-	-	-		-	-	-	-	
2394	Low	1.0	st	-	-	-	-	10/20	+	+	/	+	7/20
2395			st	st	-	-	-		-	+ (2 col on CT-SMAC)	+	-	
2396			st	-	-	-	-		+	+	/	+	
2397			+p	+p	/	/	+		-	-	-	-	
2398			st	-	-	-	-		+	+	/	+	
2399			+p	+p	/	/	+		+	+	/	+	
2400			st	-	-	-	-		-	-	-	-	
2401			-	-	-	-	-		-	-	-	-	
2402			st	-	-	-	-		+	+	/	+	
2403			st	-	-	-	-		-	-	-	-	
2404			st	-	-	-	-		+	+	/	+	
2405			+p	+p	/	/	+		+	+	/	+	
2406			+p	+M	/	/	+		-	-	-	-	
2407			st	-	-	-	-		-	-	-	-	
2408			+p	+p	/	/	+		-	-	-	-	
2409			+p	+p	/	/	+		-	-	-	-	
2410			+p	+p	/	/	+		-	-	-	-	
2411			+p	+M	/	/	+		-	-	-	-	
2412			+p	+M	/	/	+		-	-	-	-	
2413			+p	+M	/	/	+		-	-	-	-	
2414	High	2.5	+p	+M	/	/	+	5/5	-	-	-	-	4/5
2415			+p	+M	/	/	+		+	+	/	+	
2416			+p	+M	/	/	+		+	+	/	+	
2417			+p	+M	/	/	+		+	+	/	+	
2418			+p	+M	/	/	+		+	+	/	+	

Table 4. RLOD Data Original Study-Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Matrix : Beef trim
Strain : Escherichia coli O157:H7 670 T
Aerobic mesophilic flora : $2,3.10^4$ cfu/g

N° sample	Level	Inoculation level (cfu/375g)	ISO 16654*						GDS E.coli O157:H7 Tq				
			ims 6h		ims 24h		Final Result	Number positive samples/Total	PCR result	Confirmation result-8h 41,5°C	Confirmation result-24h 41,5°C	Final result	Number positive samples/Total
			CT-SMAC	Chromagar O157	CT-SMAC	Chromagar O157							
2869	0	0	st	-	-	-	-	0/5	-	st	-	-	0/5
2870			st	-	-	-	-		-	-	-	-	
2871			st	-	-	-	-		-	st	-	-	
2872			st	st	st	-	-		-	-	-	-	
2873			st	-	st	-	-		-	st	-	-	
2976	Low	0.8	st	-	-	-	-	4/20	+	+	/	+	9/20
2977			st	-	st	-	-		-	st	-	-	
2978			st	st	st	-	-		+	+	/	+	
2979			st	-	-	-	-		-	-	-	-	
2980			st	-	-	-	-		+	+	/	+	
2981			st	-	-	-	-		+	+	/	+	
2982			+p	+M	/	/	+		+	+	/	+	
2983			st	-	+M	+m	+		-	st	-	-	
2984			st	-	-	-	-		-	st	-	-	
2985			st	-	-	-	-		+	+	/	+	
2986			st	-	st	-	-		-	st	-	-	
2987			+p	+p	/	/	+		+	+	/	+	
2988			+p	-	/	/	+		+	+	/	+	
2989			st	-	st	-	-		-	st	-	-	
2990			st	-	st	-	-		-	st	-	-	
2991			st	-	-	-	-		-	st	-	-	
2992			st	-	st	-	-		+	+	/	+	
2993			st	-	st	-	-		-	st	-	-	
2994			st	-	st	-	-		-	st	-	-	
2995			st	-	-	-	-		-	st	-	-	
2996	High	2.0	st	-	+Md	+md	+	4/5	+	+	/	+	2/5
2997			st	-	-	-	-		-	st	-	-	
2998			st	-	+p	+M	+		-	st	-	-	
2999			st	-	+p	+M	+		-	-	-	-	
3000			st	st	+p	+M	+		+	+	/	+	

Table 4. RLOD Data Original Study-Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Matrix : Raw milk
Strain : Escherichia coli O157:H7 R33-9
Aerobic mesophilic flora :5,6.10^5 cfu/g

N° sample	Level	Inoculation level (cfu/25g)	ISO 16654*						GDS E.coli O157:H7 Tq				
			ims 6h		ims 24h		Final Result	Number positive samples/Total	PCR result	Confirmation result-8h 41,5°C	Confirmation result-24h 41,5°C	Final result	Number positive samples/Total
			CT-SMAC	Chromagar O157	CT-SMAC	Chromagar O157							
3908	0	0	-	-	-	-	-	0/5	-	-	-	-	0/5
3909			-	-	-	-	-		-	-	-	-	
3910			-	-	-	-	-		-	-	-	-	
3911			-	-	-	-	-		-	-	-	-	
3912			-	-	-	-	-		-	-	-	-	
3913	Low	0.8	+md	+md	-	-	-	9/20	-	-	-	-	10/20
3914			+1/2	+m	+m	+m	+		+	+	/	+	
3915			-	-	-	-	-		-	-	-	-	
3916			+1d	-	-	-	-		-	-	-	-	
3917			-	+md	-	-	-		+	+	/	+	
3918			-	-	-	-	-		+	+	/	+	
3919			+m	+m	/	/	+		-	-	-	-	
3920			+m	+m	-	-	-		-	-	-	-	
3921			+md	-	-	-	-		+	+	/	+	
3922			+m	+md	+m	+m	+		+	+	/	+	
3923			-	-	-	-	-		-	-	-	-	
3924			+m	+m	/	/	+		+	+	/	+	
3925			-	-	-	-	-		-	-	-	-	
3926			-	-	-	-	-		-	-	-	-	
3927			+m	+m	/	/	+		+	+	/	+	
3928			+m	+m	/	/	+		-	-	-	-	
3929			+m	+m	/	/	+		+	+	/	+	
3930			+m	+m	/	/	+		+	+	/	+	
3931			+m	+md	+m	+m	+		+	+	/	+	
3932			+md	+md	-	-	-		-	-	-	-	
3933	High	2.0	+m	+m	/	/	+	4/5	+	+	/	+	4/5
3934			+m	-	-	-	-		+	+	/	+	
3935			+1/2	+m	/	/	+		-	-	-	-	
3936			+m	+m	/	/	+		+	+	/	+	
3937			+1/2	+m	/	/	+		+	+	/	+	

Table 4. RLOD Data Original Study-Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Matrix : Spinach
Strain : Escherichia coli O157:H7 AA18-3
Aerobic mesophilic flora : $2,3.10^8$ cfu/g (2623-2652); $6,2.10^7$ cfu/g (2908-2912)

N° sample	Level	Inoculation level (cfu/25g)	ISO 16654*						GDS E.coli O157:H7 Tq				
			ims 6h		ims 24h		Final Result	Number positive samples/Total	PCR result	Confirmation result-8h 41,5°C	Confirmation result-24h 41,5°C	Final result	Number positive samples/Total
			CT-SMAC	Chromagar O157	CT-SMAC	Chromagar O157							
2623	0	0	+md	+md	+md	+d(1)	-	0/6	-	-	-	-	0/6
2624			+md	+md	-	-	-		+	-	-	-	
2625			-	-	-	-	-		+	-	-	-	
2626			-	-	-	+d(2)	-		-	-	-	-	
2627			-	-	-	-	-		-	-	-	-	
2628	Low	0.5	+1/2	+m	+md	+d(2)	-	7/20	-	-	-	-	8/20
2629			+M	+m	+p	+m	+		-	-	-	-	
2630			+M	+m	+1/2	+m	+		-	-	-	-	
2631			+M	+m	+p	+m	+		+	+	/	+	
2632			+m	+m	-	-	-		-	-	-	-	
2633			+m	+m	-	-	-		-	-	-	-	
2634			+m	+m	-	-	-		+	+	/	+	
2635			+M	+m	+md	+m	+		-	-	-	-	
2636			+M	+m	+1/2	+m	+		-	-	-	-	
2637			+1/2	+m	+pd	+m	+		+	+	/	+	
2638			+1/2	+1/2	-	-	-		+	+	/	+	
2639			+m	+m	-	-	-		-	-	-	-	
2640			+m	+m	-	-	-		+	+	/	+	
2641			+m	+m	-	+d(2)	-		+	+	/	+	
2642			+m	+m	-	-	-		-	-	-	-	
2643			+m	+m	-	-	-		+	+	/	+	
2644			+m	+m	-	-	-		-	-	-	-	
2645			+m	+m	-	+d(1)	-		-	-	-	-	
2646			+M	+1/2	+M	+1/2	+		+	+	/	+	
2647			+1/2	+1/2	-	-	-		-	-	-	-	
2648	High	1.3	-	-	-	-	-	2/5	+	+	/	+	3/5
2649			-	+md	-	-	-		-	-	-	-	
2650			+M	+m	+M	+1/2	+		+	+	/	+	
2651			+m	+m	+M	+m	+		+	+	/	+	
2652			-	+md	-	-	-		-	-	-	-	
2908	High	4.6	+M	+m	/	/	+	5/5	+	+	/	+	5/5
2909			+M	+m	/	/	+		+	+	/	+	
2910			+M	+m	/	/	+		+	+	/	+	
2911			+M	+m	/	/	+		+	+	/	+	
2912			+M	+m	/	/	+		+	+	/	+	

Table 4. RLOD Data Original Study-Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Matrix : Process water
Strain : Escherichia coli O157:H7 B177
Aerobic mesophilic flora : 620 CFU/g

N° sample	Level	Inoculation level (cfu/25g)	ISO 16654*						GDS E.coli O157:H7				
			ims 6h		ims 24h		Final Result	Number positive samples/Total	PCR result	Confirmation result-8h 41,5°C	Confirmation result-24h 41,5°C	Final result	Number positive samples/Total
			CT-SMAC	Chromagar O157	CT-SMAC	Chromagar O157							
3800	0	0	st	st	st	st	-	0/5	-	st	st	-	0/5
3801			st	st	st	st	-		-	st	st	-	
3802			st	st	st	st	-		-	st	st	-	
3803			st	st	st	st	-		-	st	st	-	
3804			st	st	st	st	-		-	st	st	-	
3805	Low	0.9	st	st	st	st	-	1/20	-	st	st	-	11/20
3806			st	st	st	st	-		-	st	st	-	
3807			st	st	st	st	-		+	+p	/	+	
3808			st	st	st	st	-		+	+p	/	+	
3809			st	st	st	st	-		+	+p	/	+	
3810			st	st	st	st	-		-	st	st	-	
3811			st	st	st	st	-		+	+p	/	+	
3812			st	st	st	st	-		-	st	st	-	
3813			st	st	st	st	-		-	st	st	-	
3814			st	st	st	st	-		-	st	st	-	
3815			st	st	st	st	-		-	st	st	-	
3816			st	st	st	st	-		+	+p	/	+	
3817			st	st	st	st	-		+	+p	/	+	
3818			st	st	st	st	-		+	+p	/	+	
3819			st	st	st	st	-		+	+p	/	+	
3820			st	st	st	st	-		-	st	st	-	
3821			st	st	st	st	-		+	+p	/	+	
3822			st	st	st	st	-		-	st	st	-	
3823			+p	+p	/	/	+		+	+p	/	+	
3824			st	st	st	st	-		+	+p	/	+	
3825	Hight	2.3	st	st	st	st	-	0/5	+	+p	/	+	4/5
3826			st	st	st	st	-		+	+p	/	+	
3827			st	st	st	st	-		+	+p	/	+	
3828			st	st	st	st	-		+	+p	/	+	
3829			st	st	st	st	-		-	st	st	-	

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

ANNEX F: Inclusivity and Exclusivity Raw Data- Original Study

Table 5. Inclusivity Raw Data Original Study *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

INCLUSIVITY								
N°	Strain			Origin	Inoculation level (cfu/ml)	mEHEC 8h at 41.5°C		
						PCR result	Confirmation	
							CT-SMAC	Latex (O157/H7)
1	*Escherichia coli*	O157:H7	Ad 485	Ground beef	5	+	+	+
2	*Escherichia coli*	O157:H7	Ad486	Ground beef	3	+	+	+
3	*Escherichia coli*	O157:H7	Ad487	Ground beef	9	+	+	+
4	*Escherichia coli*	O157:H7	Ad488	Ground beef	7	+	+	+
5	*Escherichia coli*	O157:H7	Ad489	Ground beef	3	+	+	+
6	*Escherichia coli*	O157:H7	Ad 552	Slaughterhouse	8	+	+	+
7	*Escherichia coli*	O157:H7	Ad 553	Slaughterhouse	11	+	+	+
8	*Escherichia coli*	O157:H7	Ad 554	Slaughterhouse	7	+	+	+
9	*Escherichia coli*	O157:H7	Ad 555	Slaughterhouse	11	+	+	+
10	*Escherichia coli*	O157:H7	Ad 556	Water purification	13	+	+	+
11	*Escherichia coli*	O157:H7	Ad 557	Water purification	10	+	+	+
12	*Escherichia coli*	O157:H7	Ad 558	Water purification	6	+	+	+
13	*Escherichia coli*	O157:H7	Ad 559	Ground beef	13	+	+	+
14	*Escherichia coli*	O157:H7	Ad 560	Ground beef	3	+	+	+
15	*Escherichia coli*	O157:H7	Ad 561	Ground beef	11	+	+	+
16	*Escherichia coli*	O157:H7	Ad 562	Ground beef	11	+	+	+
17	*Escherichia coli*	O157:H7	Ad 563	Ground beef	14	+	+	+
18	*Escherichia coli*	O157:H7	Ad 564	Ground beef	12	+	+	+
19	*Escherichia coli*	O157:H7	Ad 565	Ground beef	5	+	+	+
20	*Escherichia coli*	O157:H7	Ad 566	Ground beef	6	+	+	+
21	*Escherichia coli*	O157:H7	Ad 567	Slaughterhouse	5	+	+	+
22	*Escherichia coli*	O157:H7	Ad 568	Slaughterhouse	9	+	+	+
23	*Escherichia coli*	O157:H7	Ad 569	Slaughterhouse	8	+	+	+
24	*Escherichia coli*	O157:H7	Ad 570	Slaughterhouse	7	+	+	+
25	*Escherichia coli*	O157:H7	Ad 571	Feces	10	+	+	+
26	*Escherichia coli*	O157:H7	Ad 572	Feces	7	+	+	+
27	*Escherichia coli*	O157:H7	Ad 573	Feces	18	+	+	+
28	*Escherichia coli*	O157:H7	Ad 574	Feces	13	+	+	+
29	*Escherichia coli*	O157:H7	Ad 575	Feces	5	+	+	+
30	*Escherichia coli*	O157:H7	Ad 576	Feces	5	+	+	+
31	*Escherichia coli*	O157:H7	Ad 577	Feces	10	+	+	+
32	*Escherichia coli*	O157:H7	Ad 578	Feces	9	+	+	+
33	*Escherichia coli*	O157:H7	Ad 579	Feces	14	+	+	+
34	*Escherichia coli*	O157:H7	Ad 580	Feces	29	+	+	+
35	*Escherichia coli*	O157:H7	Ad 581	Feces	2	+	+	+
36	*Escherichia coli*	O157:H7	Ad 582	Feces	6	+	+	+

Table 5. Inclusivity Raw Data Original Study- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

INCLUSIVITY								
N°	Strain			Origin	Inoculation level (cfu/ml)	mEHEC 8h at 41.5°C		
						PCR result	Confirmation	
							CT-SMAC	Latex (O157/H7)
37	*Escherichia coli*	O157:H7	Ad 583	Ground beef	8	+	+	+
38	*Escherichia coli*	O157:H7	Ad 584	Ground beef	6	+	+	+
39	*Escherichia coli*	O157:H7	Ad 585	Ground beef	7	+	+	+
40	*Escherichia coli*	O157:H7	Ad 586	Ground beef	4	+	+	+
41	*Escherichia coli*	O157:H7	Ad 587	Ground beef	7	+	+	+
42	*Escherichia coli*	O157:H7	Ad 588	Ground beef	5	+	+	+
43	*Escherichia coli*	O157:H7	Ad 589	Ground beef	1	+	+	+
44	*Escherichia coli*	O157:H7	Ad 590	Ground beef	6	+	+	+
45	*Escherichia coli*	O157:H7	Ad 591	Ground beef	5	+	+	+
46	*Escherichia coli*	O157:H7	EF190	Feces	5	+	+	+
47	*Escherichia coli*	O157:H7	Ad 922	Ground beef with onions	6	+	+	+
48	*Escherichia coli*	O157:H7	CIP103571 (ATCC 35150)	Clinical	3	+	+	+
49	*Escherichia coli*	O157:H7	ATCC 43888	/	1	+	+	+
50	*Escherichia coli*	O157:H7	ATCC 700728	/	7	+	+	+

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 6. Exclusivity Raw Data Original Study *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

EXCLUSIVITY								
N°	Strain			Origin	Inoculation level (cfu/ml)	BPW 20h at 37°C		
						PCR result	Confirmation	
							CT-SMAC	Latex O157
1	*Citrobacter freundii*		25	Frozen raw spinach	4.4 10^5	-		
2	*Escherichia coli*	O104:H21	Ad 516	Clinical origin (USA)	5.3 10^5	-		
3	*Escherichia coli*	O111:H2	Ad 513	Clinical origin (UK)	5.1 10^5	-		
4	*Escherichia coli*	O111:H21	Ad 508	Clinical origin (USA)	3.0 10^5	-		
5	*Escherichia coli*	O111:H8	Ad 511	Clinical origin (USA)	5.3 10^5	-		
6	*Escherichia coli*	O127:H6	Ad 520	Clinical origin (UK)	4.7 10^5	-		
7	*Escherichia coli*	O128:H2	Ad 512	Clinical origin (USA)	5.6 10^5	-		
8	*Escherichia coli*	O128:H7	Ad 514	Clinical origin (USA)	5.6 10^5	-		
9	*Escherichia coli*	O157	Ad525	Feces	4.9 10^5	-		
10	*Escherichia coli*	O157	Ad527	Clinical	4.2 10^5	-		
11	*Escherichia coli*	O157:H-	Ad 535		5.6 10^5	-		
12	*Escherichia coli*	O157:H43	Ad 517		5.1 10^5	-		
13	*Escherichia coli*	O18:K1:H7	Ad 522	Clinical origin	4.6 10^5	-		
14	*Escherichia coli*	O26:H11	Ad 510	Clinical origin (USA)	5.1 10^5	-		
15	*Escherichia coli*	O3:H2	Ad 504	Clinical origin (Chili)	4.2 10^5	-		
16	*Escherichia coli*	O44:H18	Ad 519	Clinical origin (Peru)	5.1 10^5	-		
17	*Escherichia coli*	O55:H6	Ad 521	Clinical origin (USA)	5.6 10^5	-		
18	*Escherichia coli*	O55:H7	Ad 518	Clinical origin (Sri Lanka)	5.1 10^5	+	- (sorbitol +)	-
19	*Escherichia coli*	O6:H10	Ad 507	Clinical origin (Sweden)	5.6 10^5	-		
20	*Escherichia coli*	O6:H6	Ad 506	Human	3.9 10^5	-		
21	*Escherichia coli*	O78:H11	ATCC 35401		3.7 10^5	-		
22	*Escherichia coli*	O78:K80:H12	ATCC 43896	Human	5.6 10^5	-		
23	*Escherichia coli*	O86:H43	Ad 509	Animal origin (elephant USA)	4.9 10^5	-		
24	*Escherichia coli*	O92:H33	Ad 503	Clinical origin (Mexico)	5.3 10^5	-		
25	*Escherichia vulneris*		127	Raw milk	6.4 10^5	-		
26	*Hafnia alvei*		88	Bakery	6.2 10^5	-		
27	*Salmonella*	Landau	Ad499	Food product	2.0 10^5	-		
28	*Salmonella*	Sternhauze	Ad500	Food product	2.3 10^5	-		
29	*Salmonella*	Urbana	Ad501	Food product	4.1 10^5	-		
30	*Salmonella*	Wayne	Ad502	Food product	2.9 10^5	-		

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

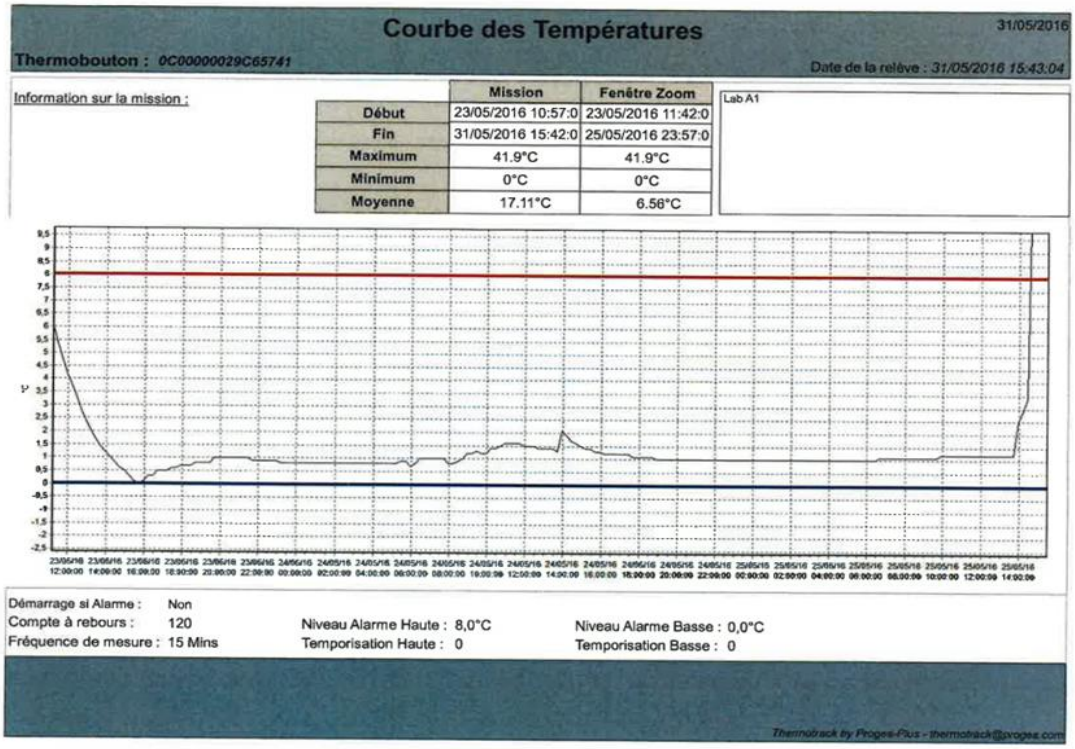
ANNEX G: Inter-Laboratory Study Raw Data- Original Report

Table 7. List of Collaborators *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Laboratories	Country	Adresse	Number of collaborators
Actalia	France	Boulevard du 13 Juin 1944 14310 Villers-Bocage	2
Agrocal	France	8 Avenue du Pays de Caen Site Normandial 14460 Colombelles	1
Aveyron Labo	France	Rue des Artisans ZA Bel Air - BP 3118 12031 Rodez Cedex 9	1
Campden	UK	Station Road, Chipping Campden, Gloucester, UK GL55 6LD	2
Labexia	France	ZAC de Kerdroniou 26Bis Rue Marcel Paul 29000 Quimper	1
Laboratoire de référence Lyon	France	1 avenue Bourgelat 69280 Marcy l'Etoile	1
LILANO	France	23, rue Auguste Grandin 50008 Saint Lô Cedex	1
LVD 24	France	161 Avenue Winston Churchill 24660 Coulounieix Chamiers cedex	2
Merieux Nutri-sciences, Merville	France	Rue du Dr Rousseau ZI du Petit Pacault 59660 Merville	2
RIVM	Netherlands	Antonie van Leeuwenhoeklaan 9 3721 MA Bilthoven The Netherlands	1

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 8. Temperature Registered During Sample Transport and Storage *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]



Courbe des Températures

31/05/2016

Thermobouton : 0C00000029C65741

Date de la relève : 31/05/2016 15:43:04

Information sur la mission :

	Mission	Fenêtre Zoom
Début	23/05/2016 10:57:0	23/05/2016 11:42:0
Fin	31/05/2016 15:42:0	25/05/2016 23:57:0
Maximum	41.9°C	41.9°C
Minimum	0°C	0°C
Moyenne	17.11°C	6.56°C

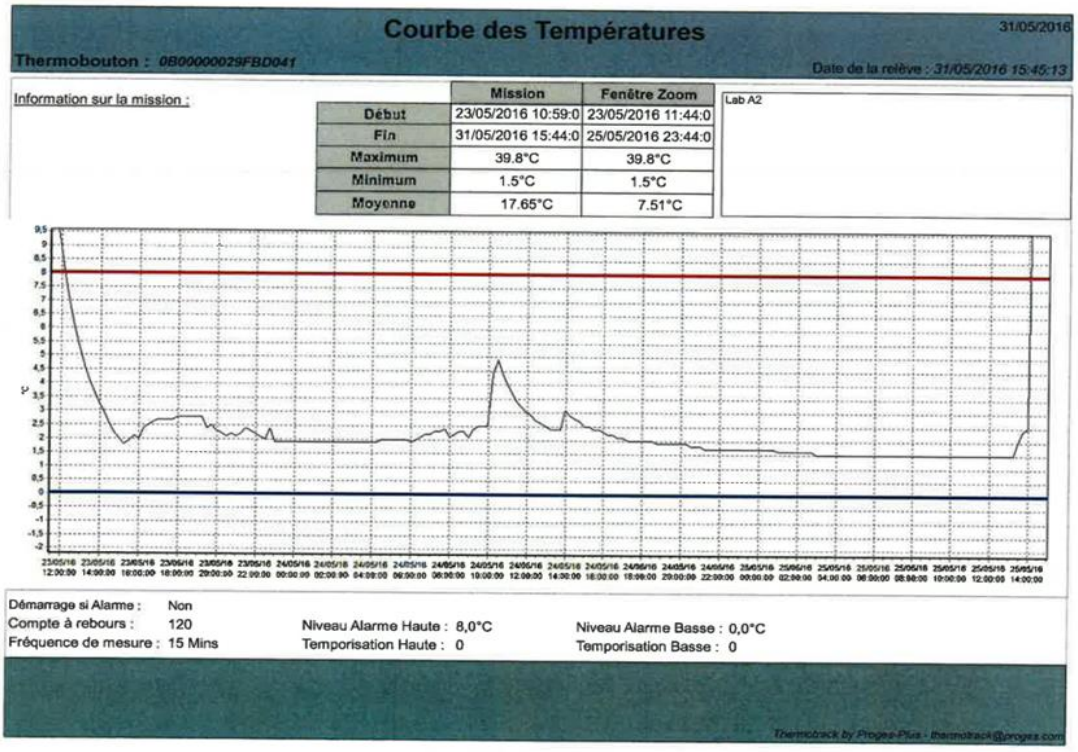
Lab A1

Démarrage si Alarme : Non
Compte à rebours : 120
Fréquence de mesure : 15 Mins

Niveau Alarme Haute : 8,0°C
Temporisation Haute : 0

Niveau Alarme Basse : 0,0°C
Temporisation Basse : 0

Thermotrack by Proges-Plus - thermotrack@proges.com



Courbe des Températures

31/05/2016

Thermobouton : 0B00000029FBD041

Date de la relève : 31/05/2016 15:45:13

Information sur la mission :

	Mission	Fenêtre Zoom
Début	23/05/2016 10:59:0	23/05/2016 11:44:0
Fin	31/05/2016 15:44:0	25/05/2016 23:44:0
Maximum	39.8°C	39.8°C
Minimum	1.5°C	1.5°C
Moyenne	17.65°C	7.51°C

Lab A2

Démarrage si Alarme : Non
Compte à rebours : 120
Fréquence de mesure : 15 Mins

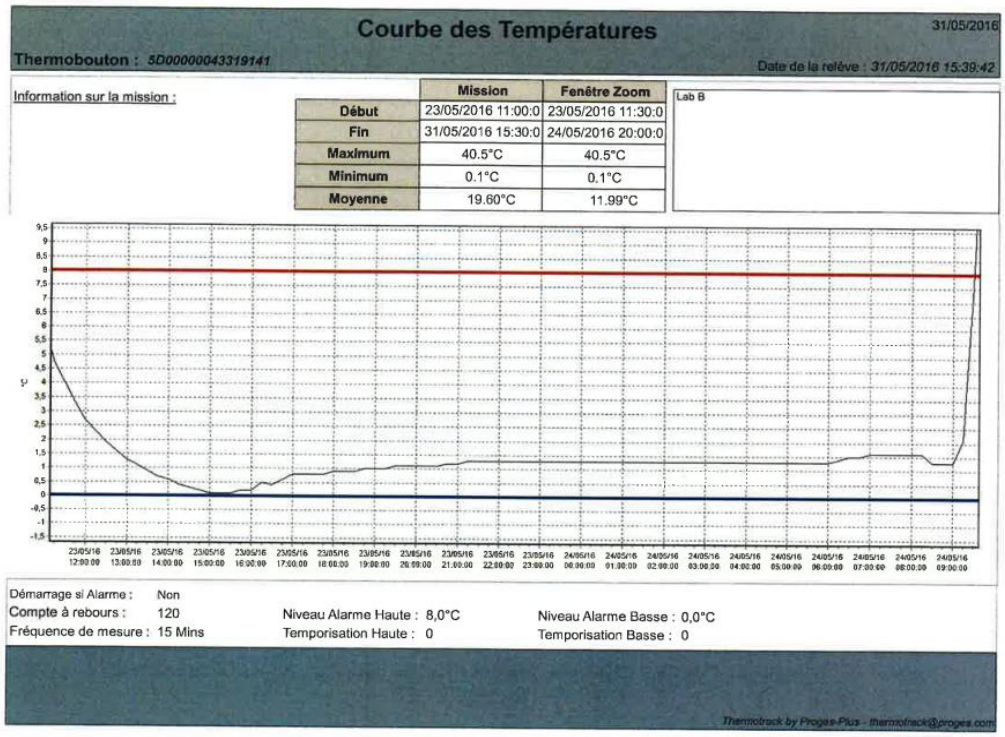
Niveau Alarme Haute : 8,0°C
Temporisation Haute : 0

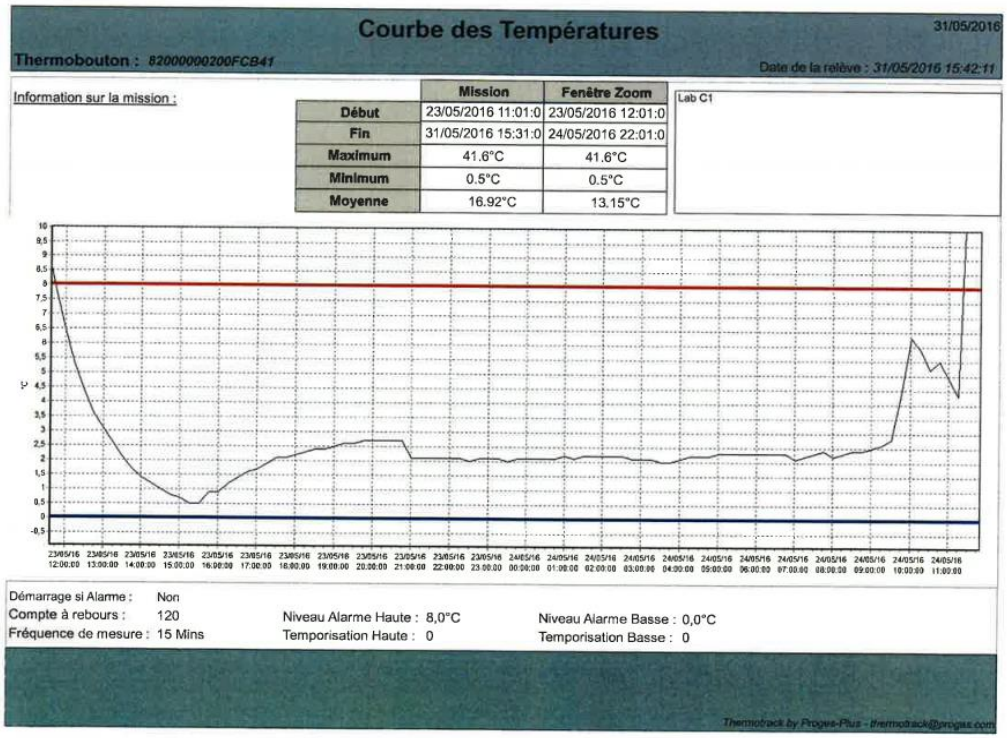
Niveau Alarme Basse : 0,0°C
Temporisation Basse : 0

Thermotrack by Proges-Plus - thermotrack@proges.com

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

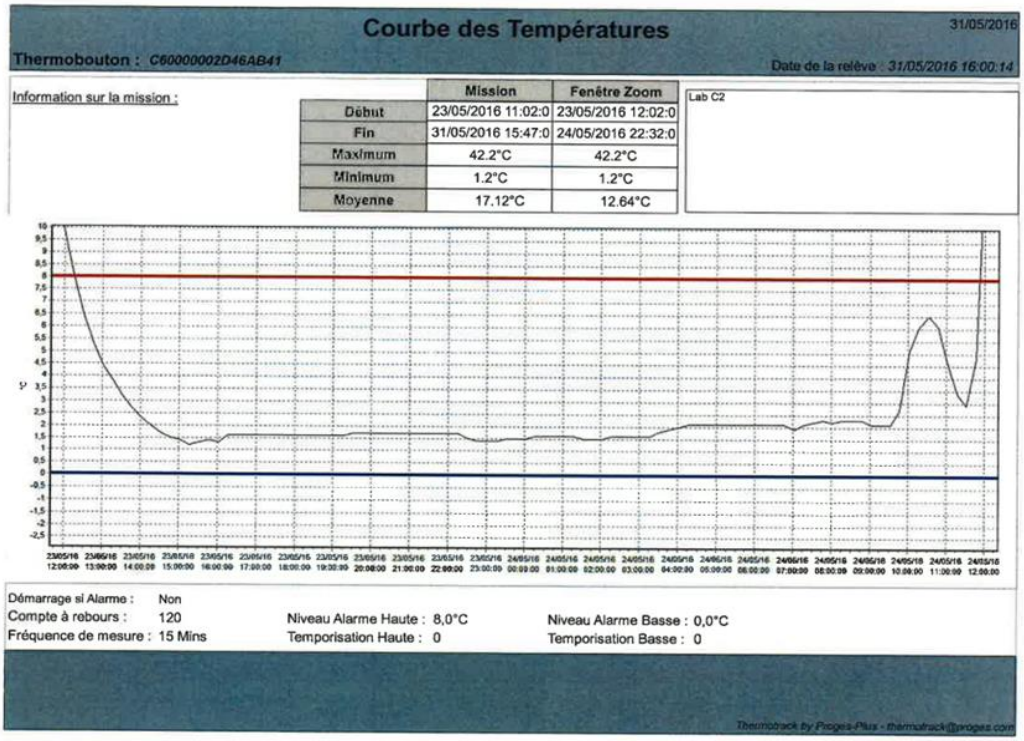
Table 8. Temperature Registered During Sample Transport and Storage- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

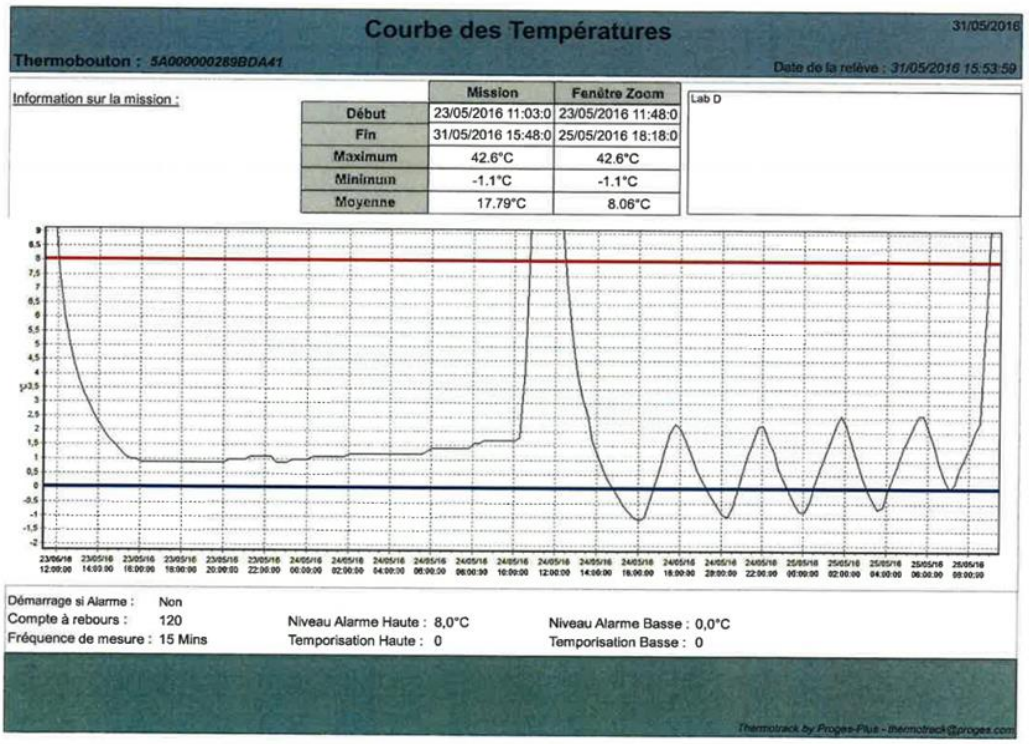




[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

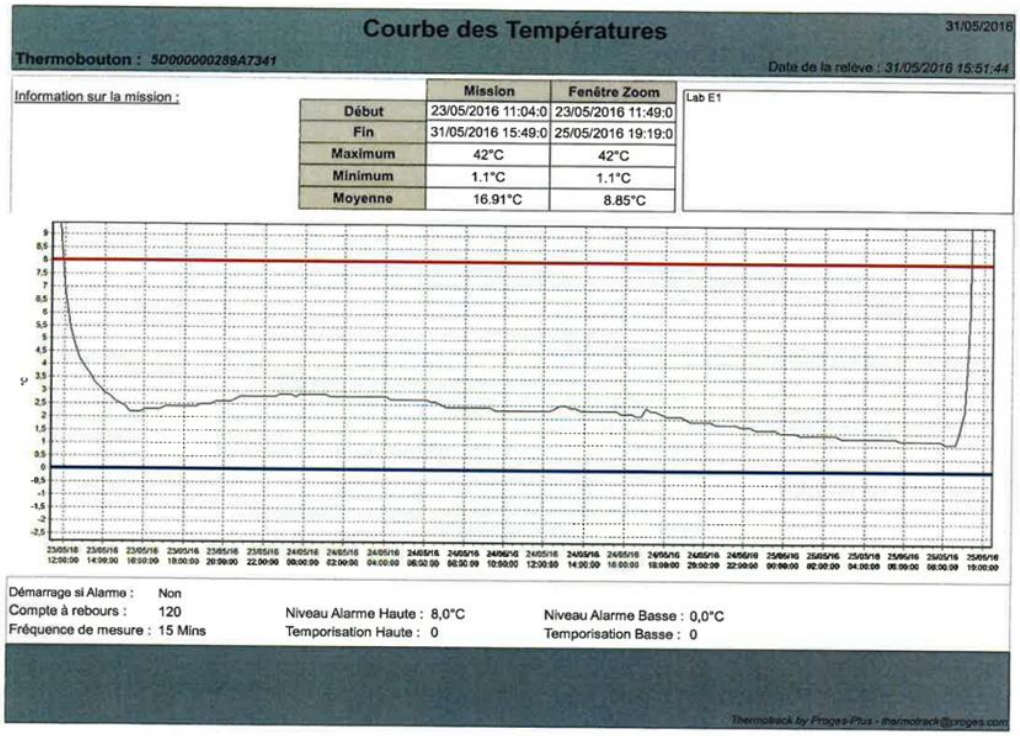
Table 8. Temperature Registered During Sample Transport and Storage- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

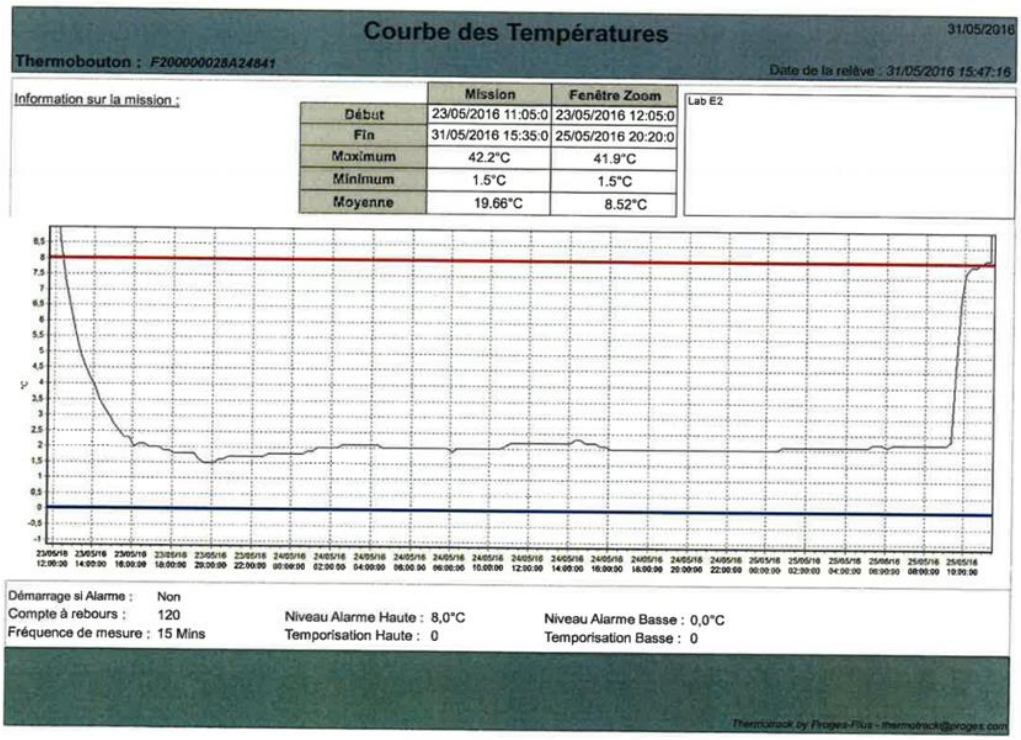




[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 8. Temperature Registered During Sample Transport and Storage- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]





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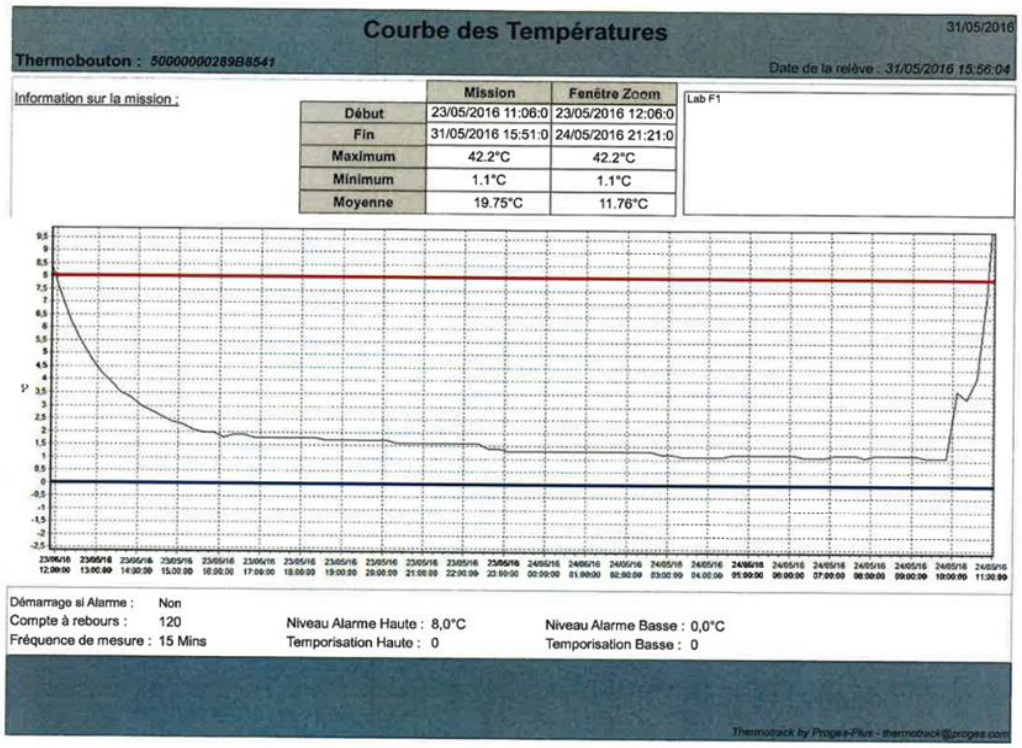

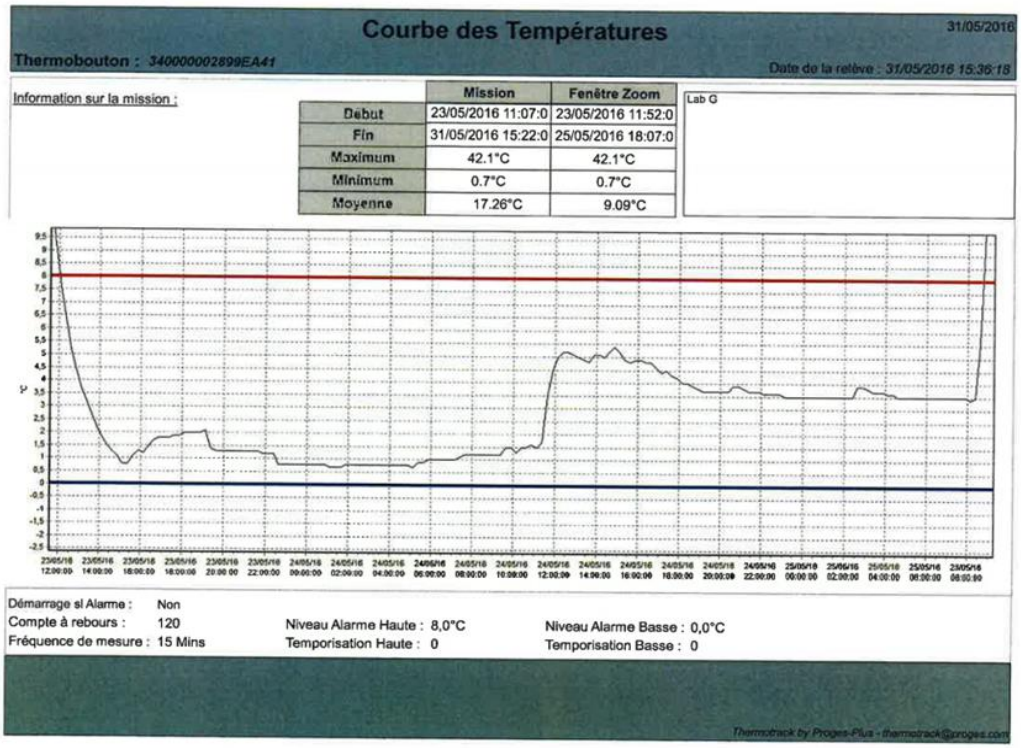

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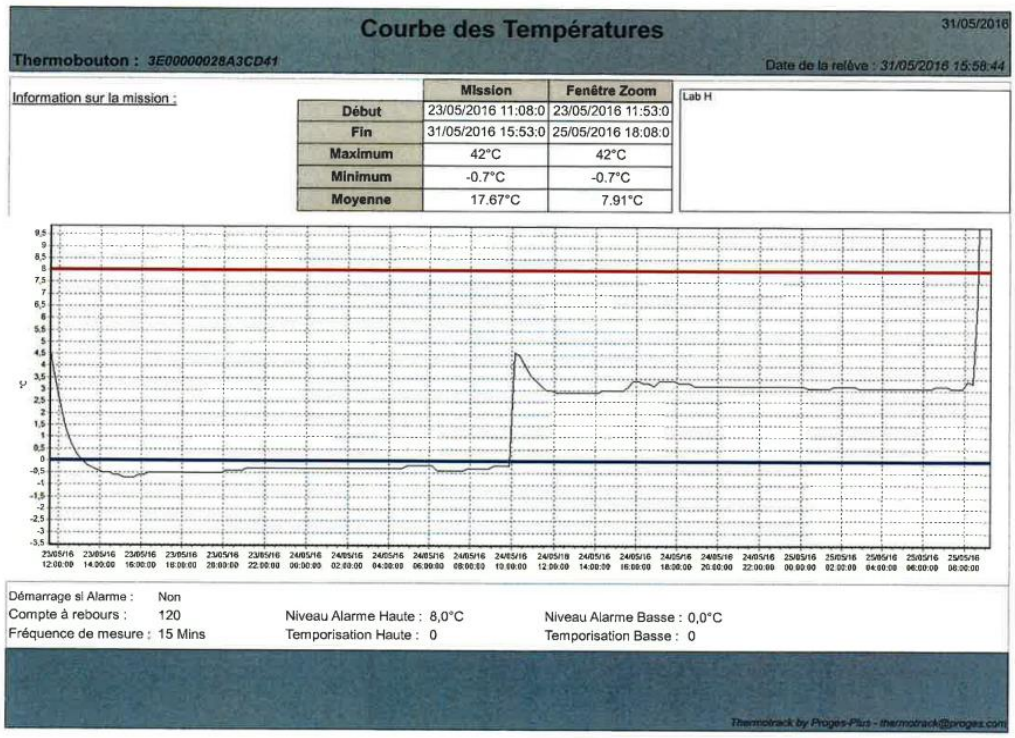

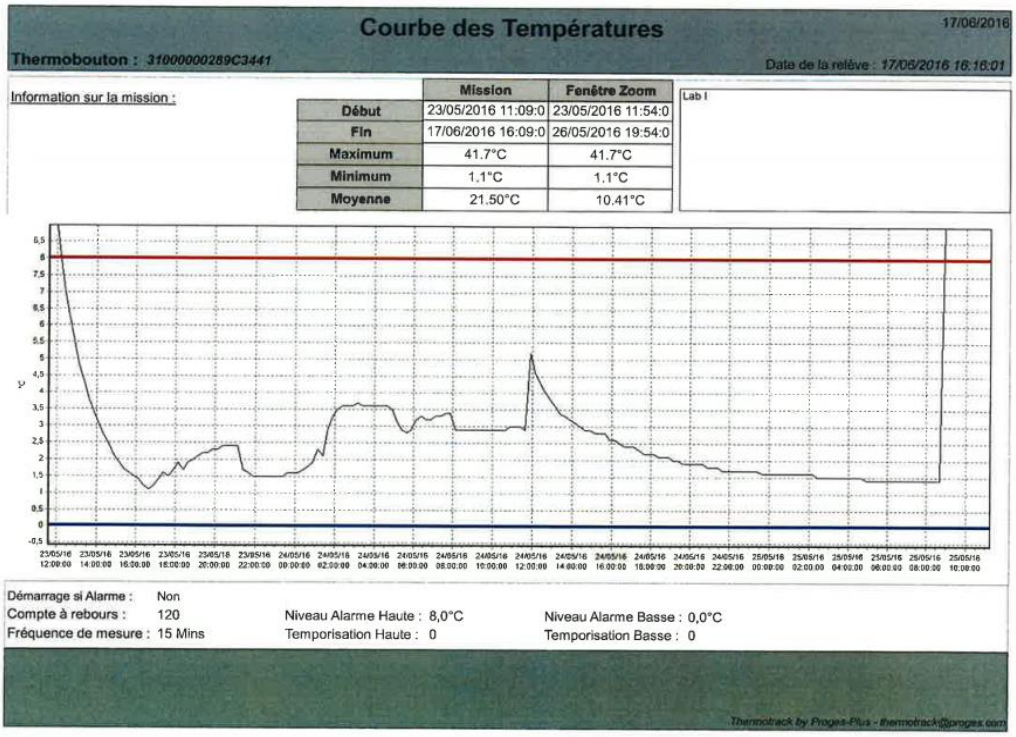

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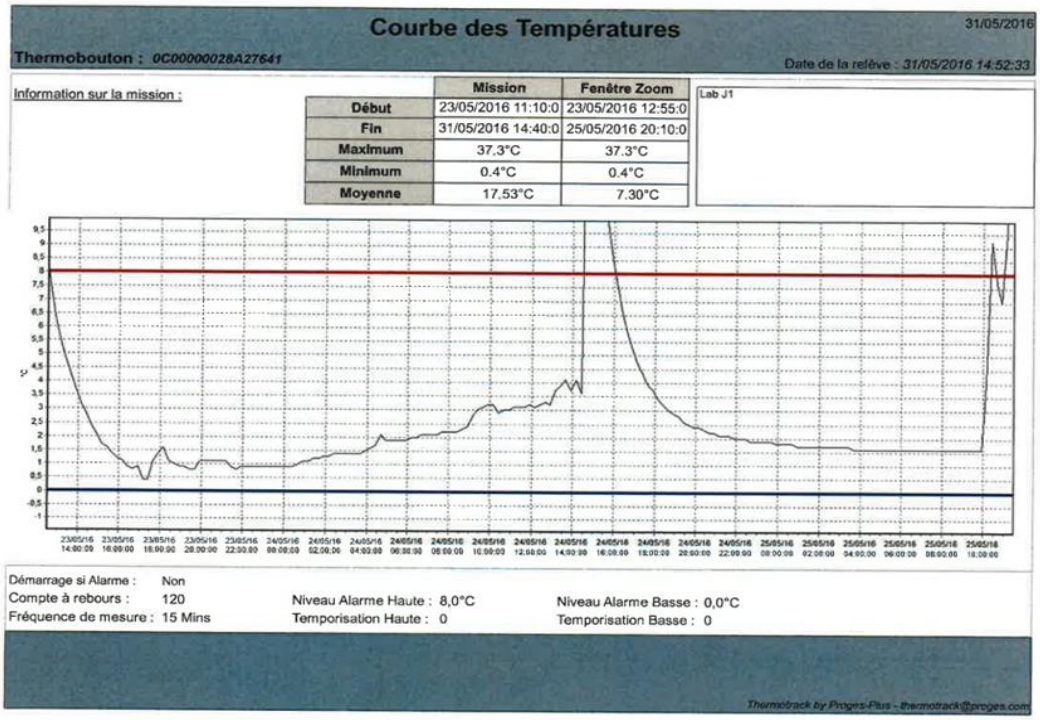

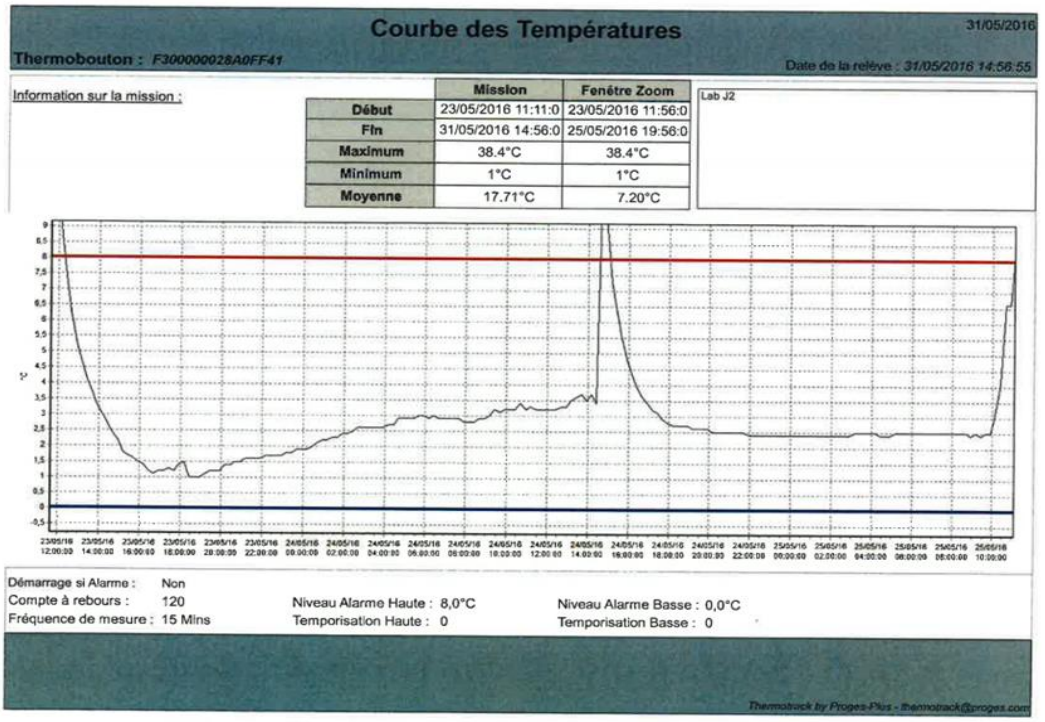

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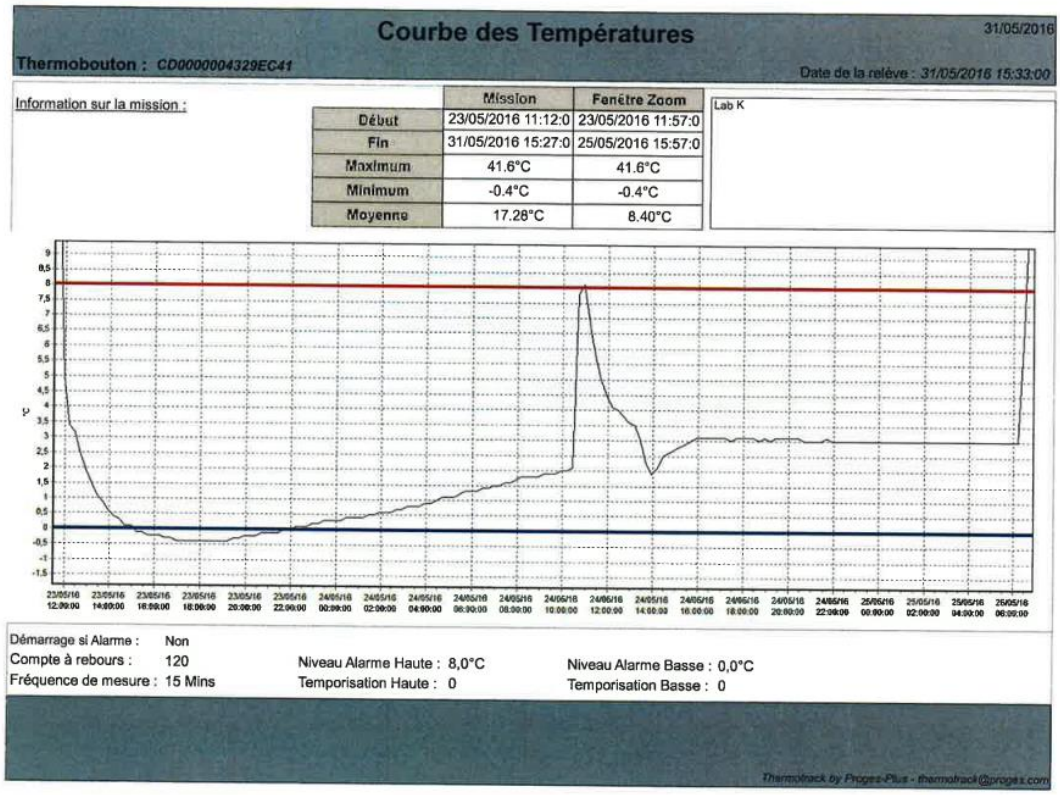

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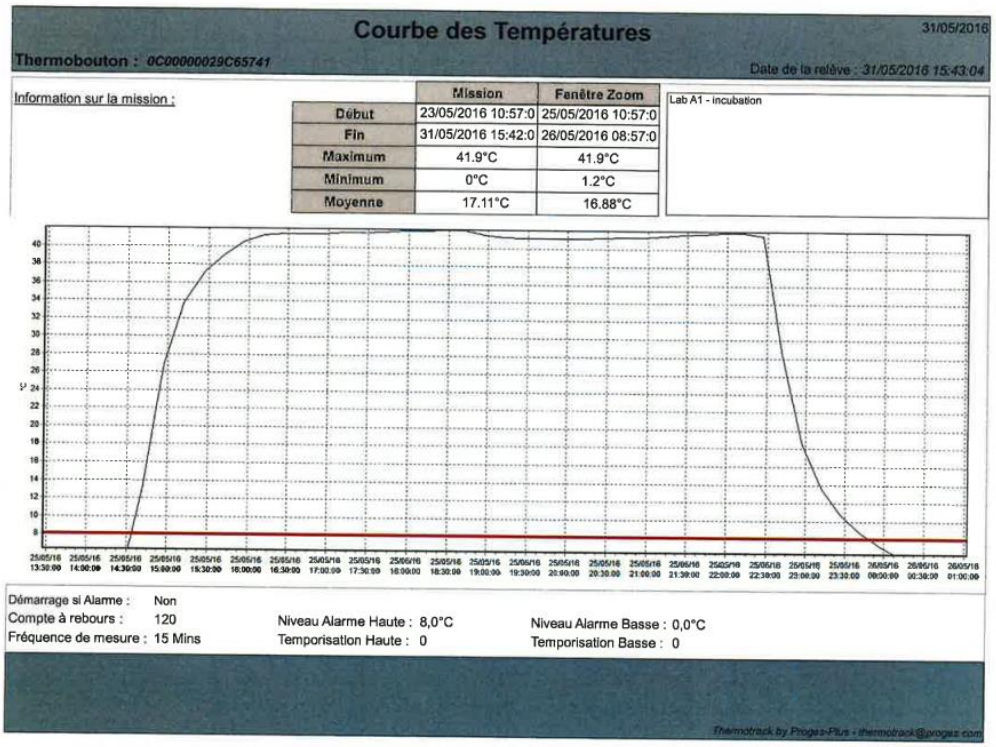

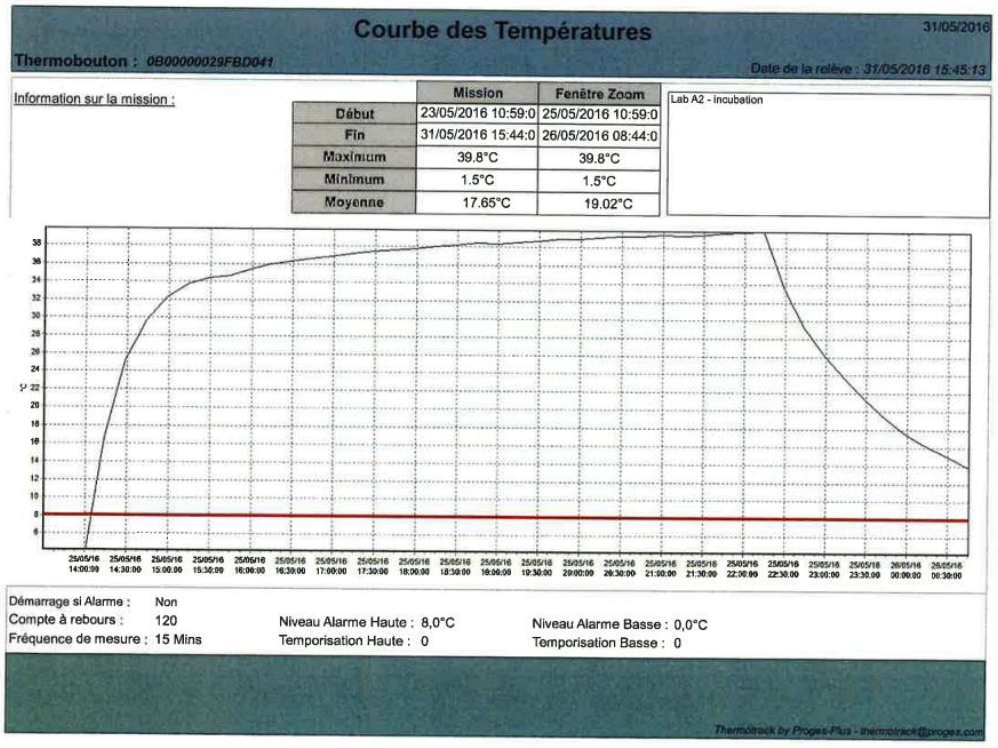

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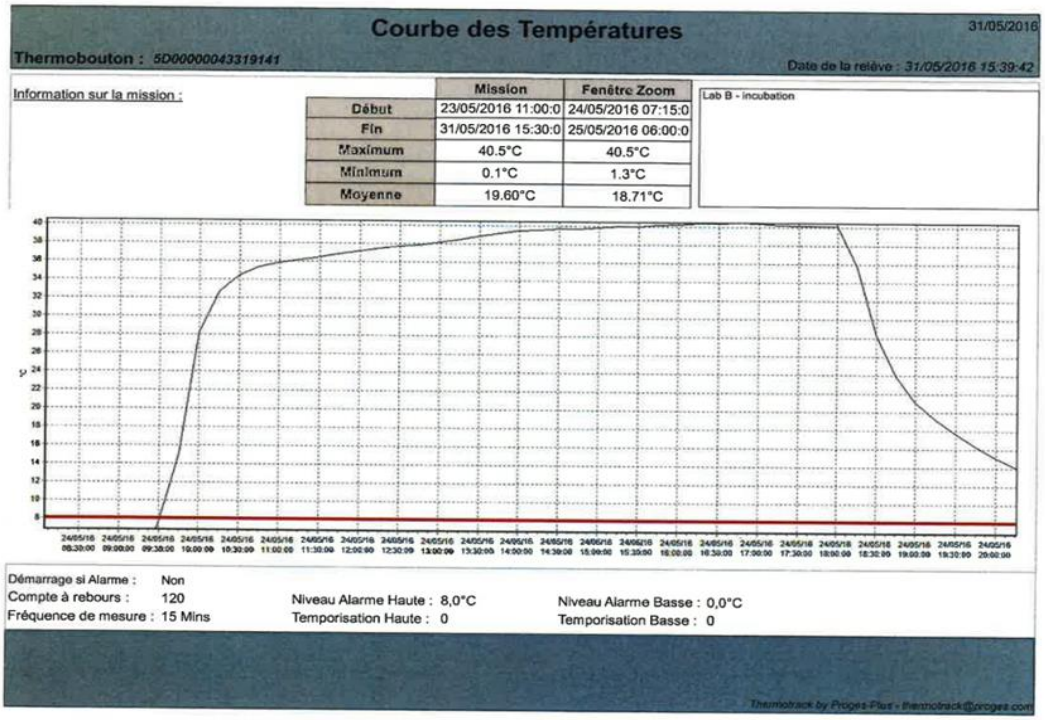

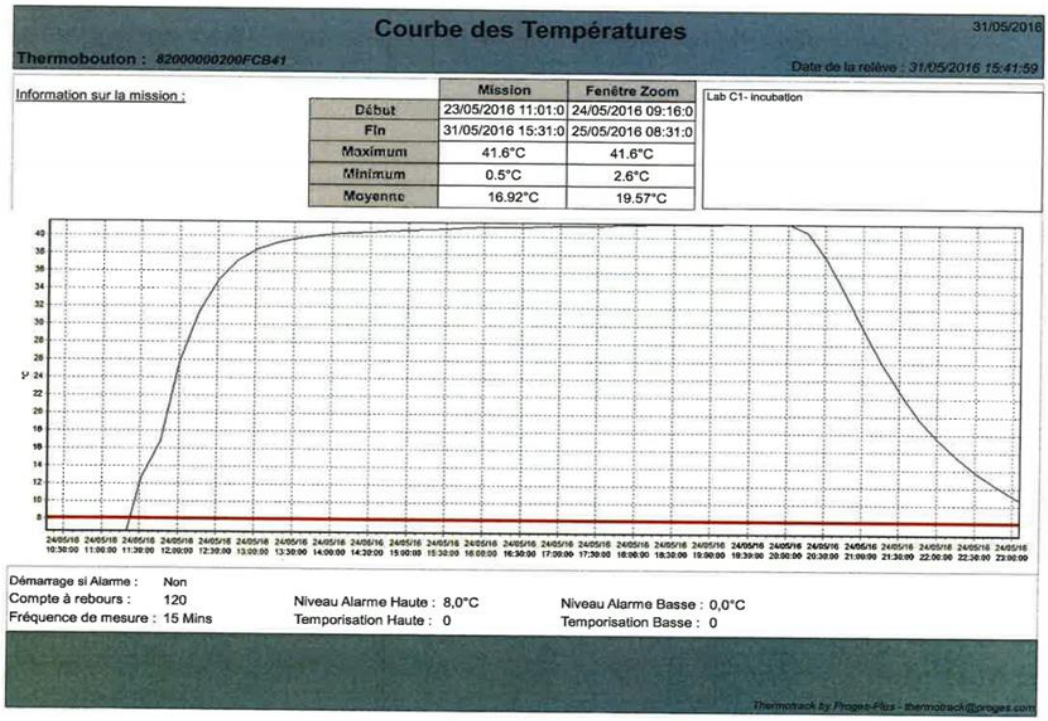

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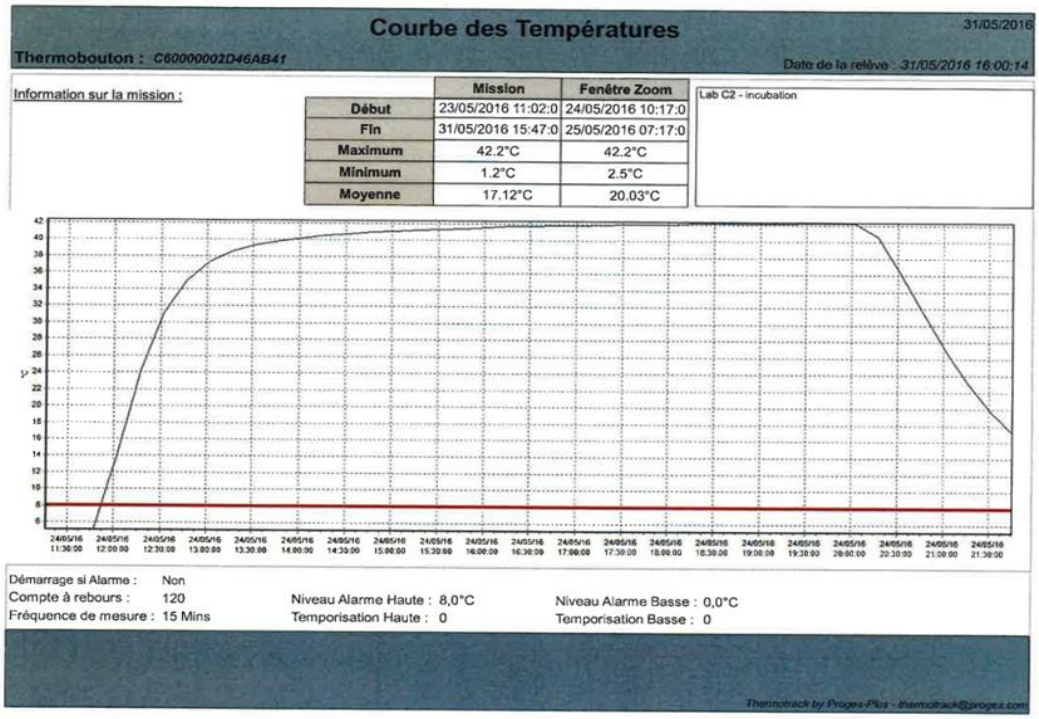

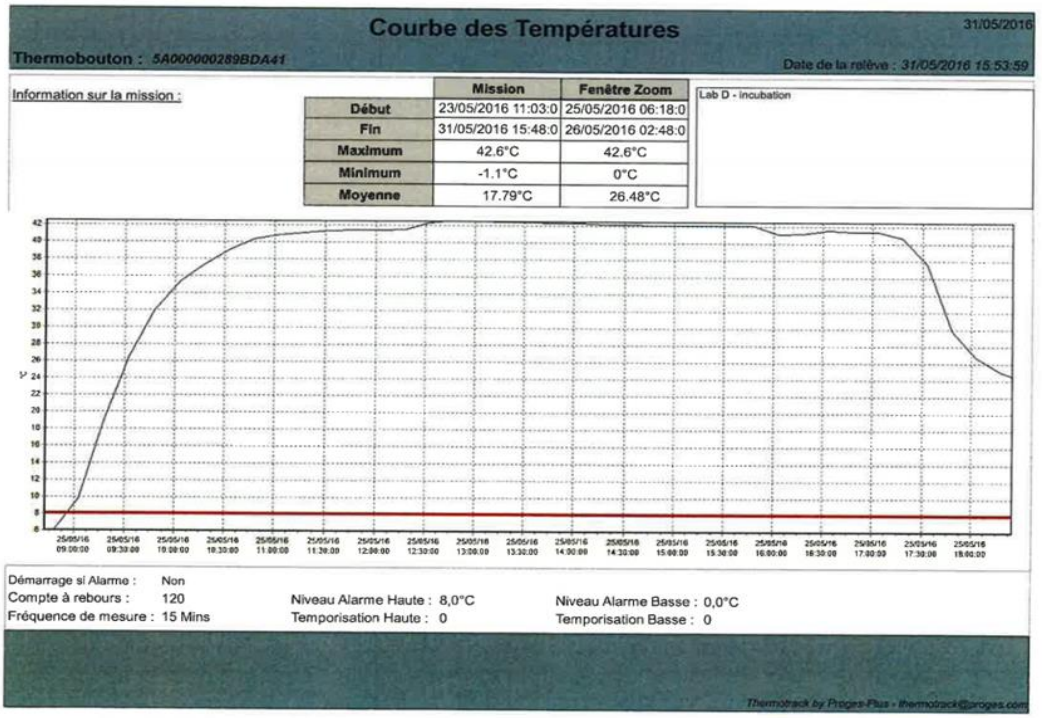

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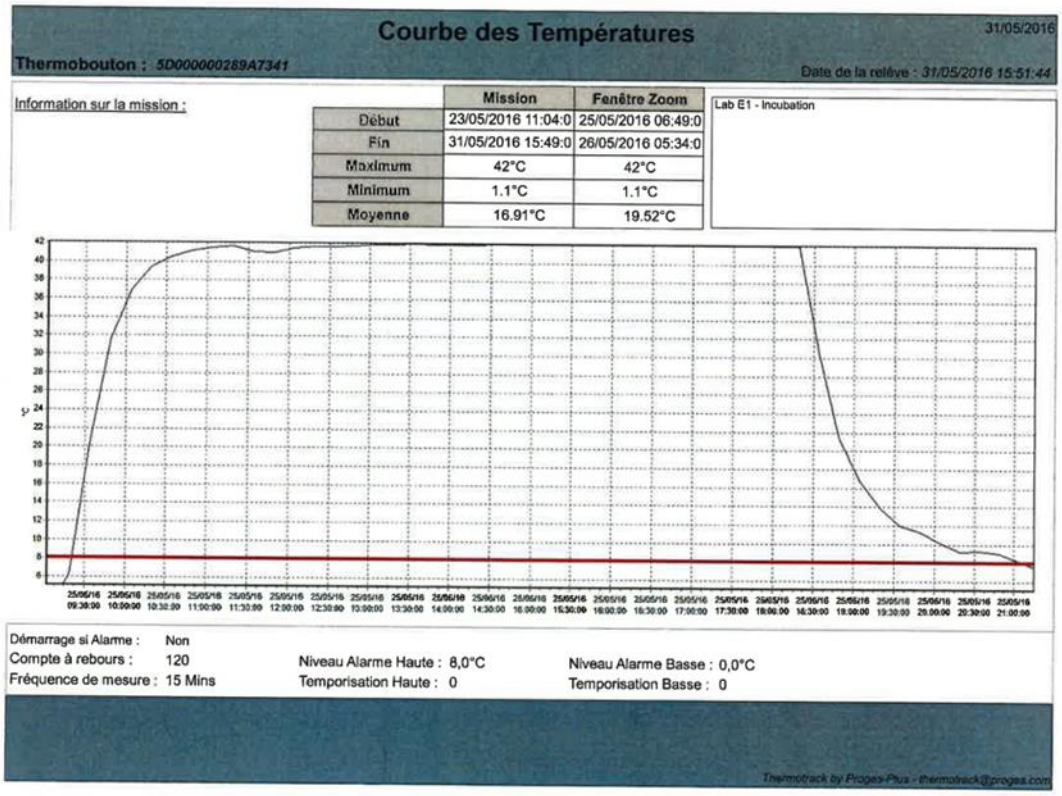

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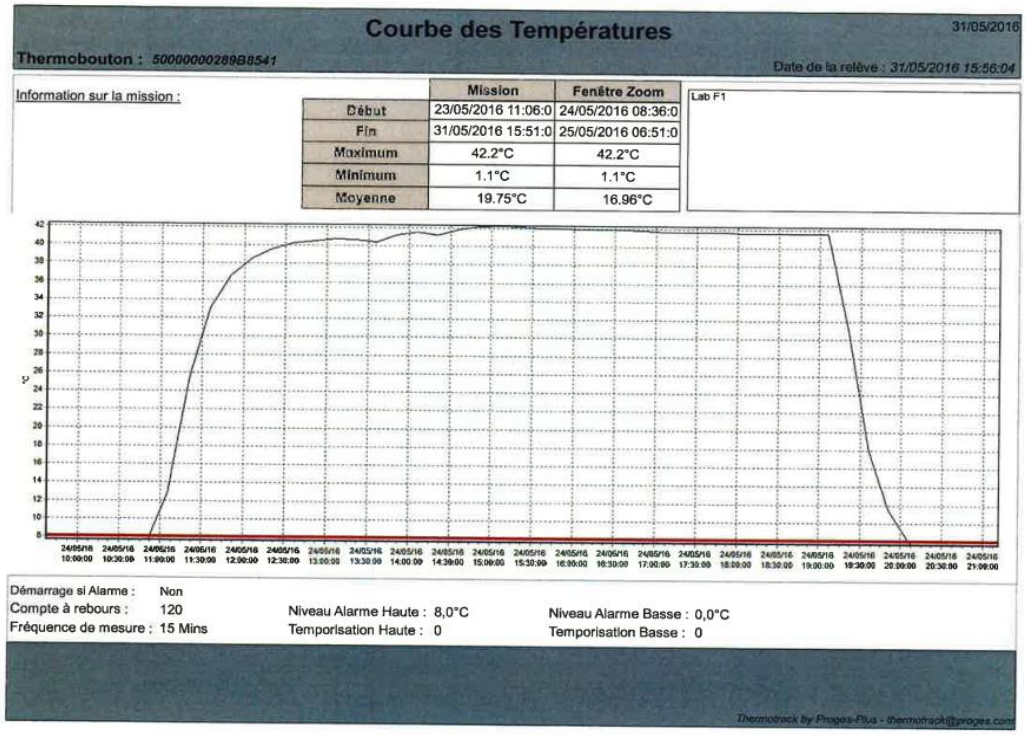

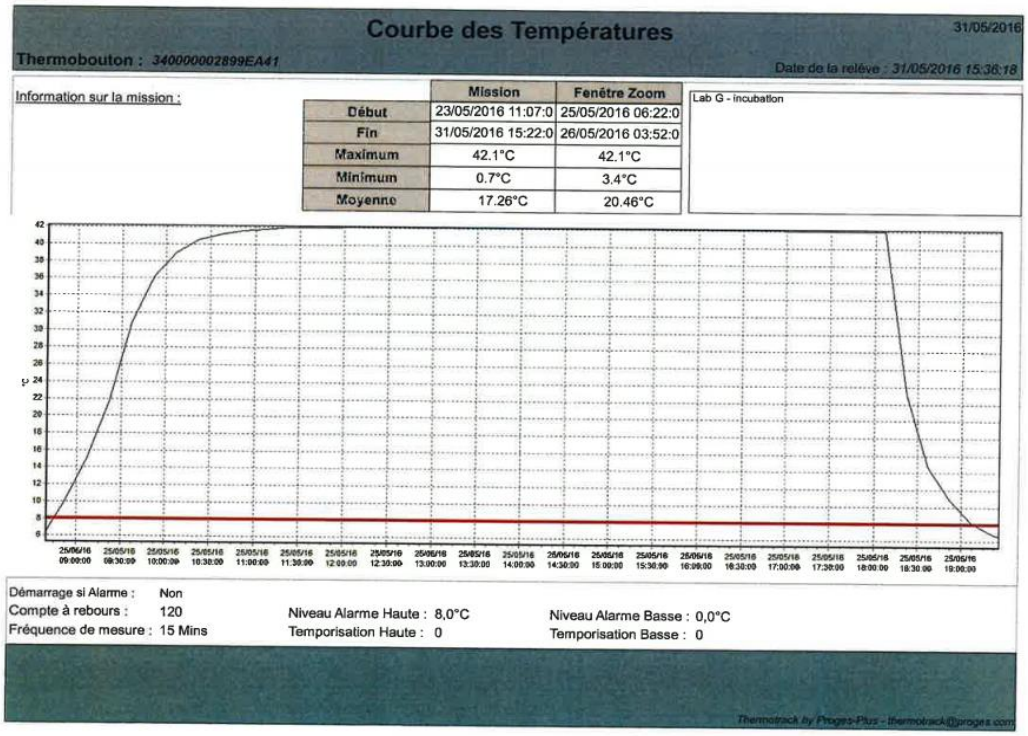

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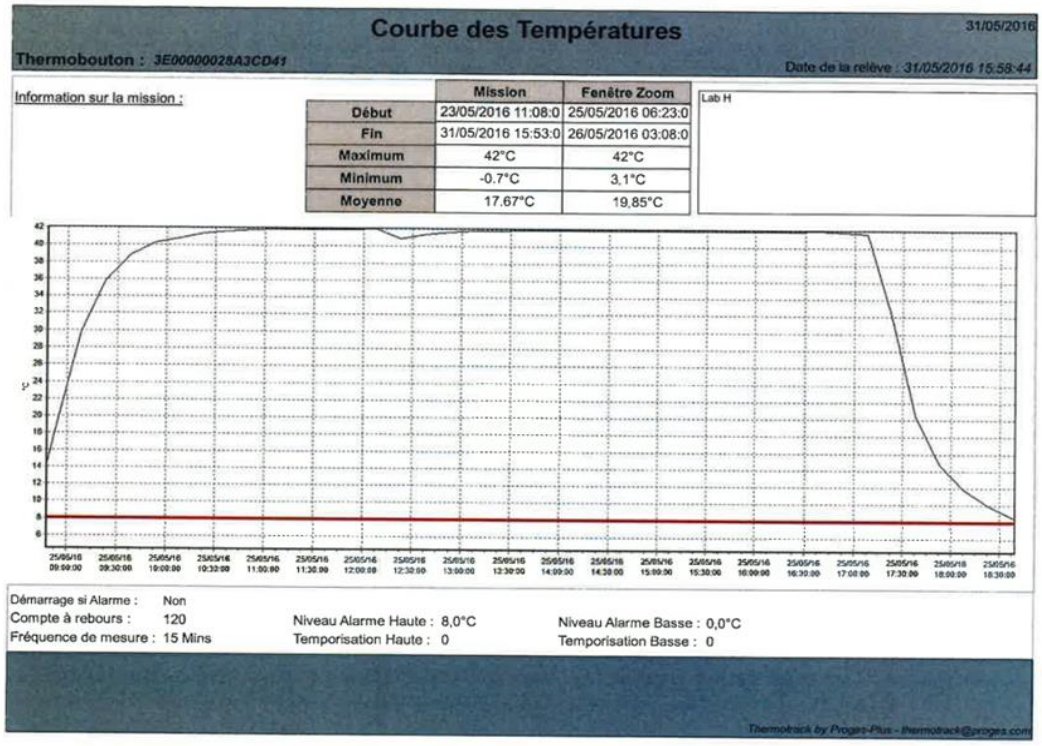

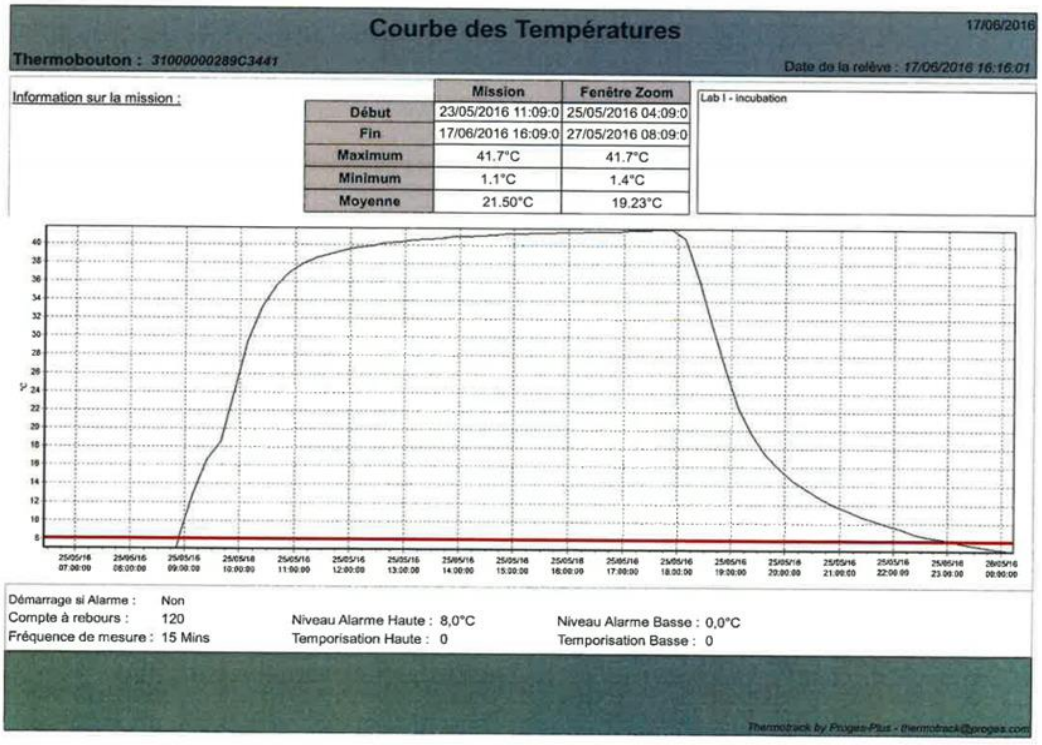

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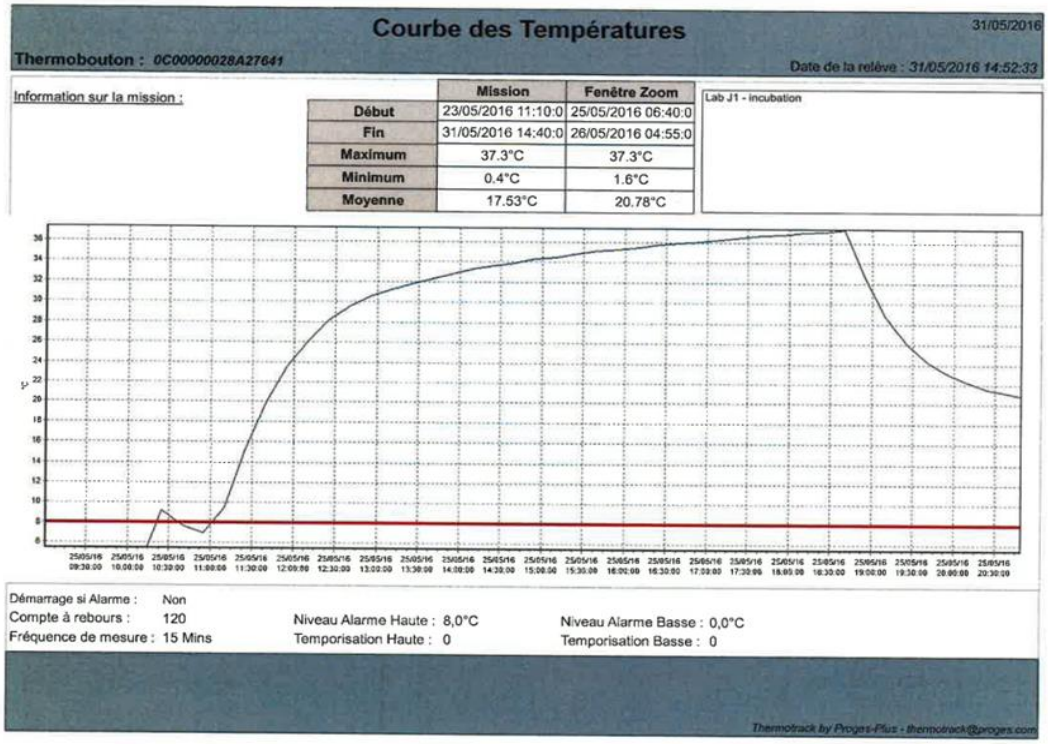

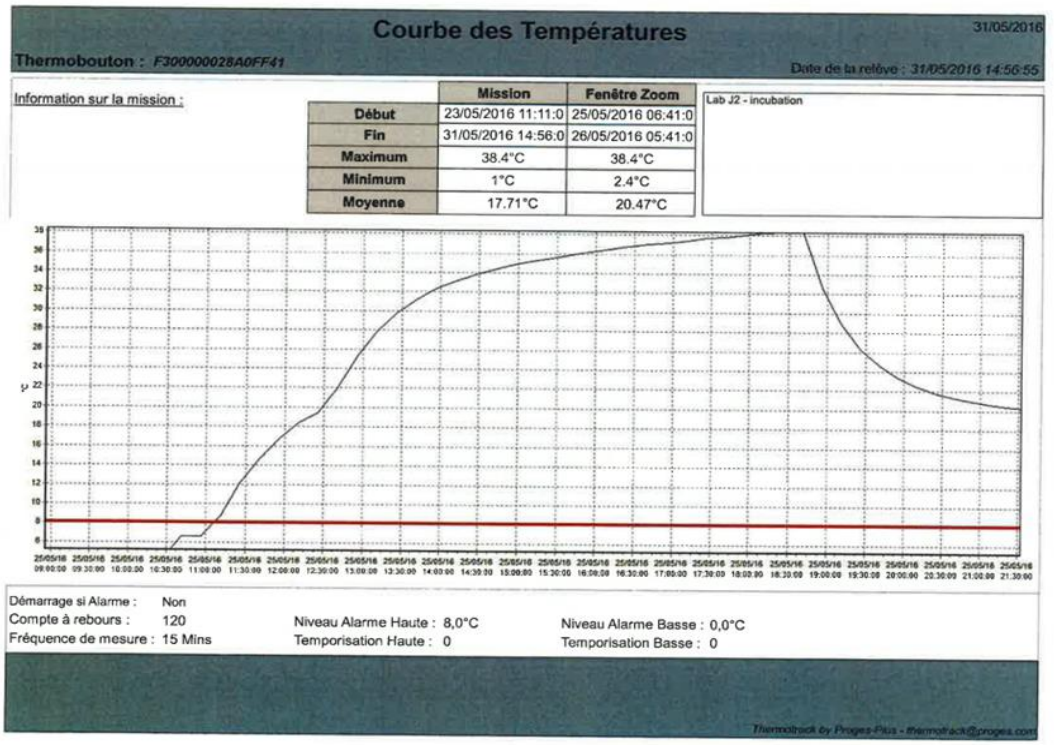

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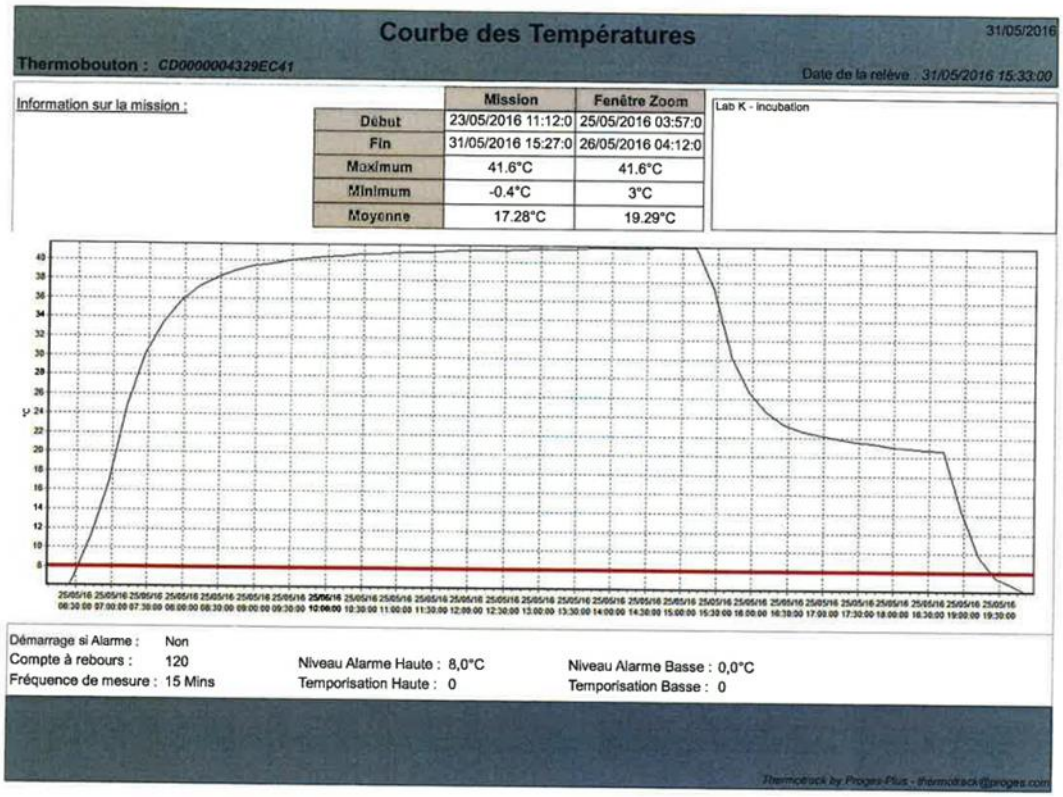

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Table 10. Results Obtained by the Collaborators and the Expert Laboratory *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator **A1**

Aerobic mesophilic flora:6,5.10² CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR		CT-SMAC	Latex	Final result	
					Cq	Result				
A6	+d	+d	+	+		-	-		-	ND
A8	-	-	-	-		-	+d	-	-	NA
A12	-	-	-	-		-	+d	-	-	NA
A13	+	-	-	-		-	-	/	-	NA
A18	+	-	-	-		-	+d	-	-	NA
A20	-	-	-	-		-	+d	-	-	NA
A21	-	-	-	-		-	+d	-	-	NA
A22	+	+	-	-		-	+d	-	-	NA
A2	+	+	+	+		+	+	+	+	PA
A3	+	+	+	+		+	+	+	+	PA
A7	+	+	+	+		+	+	+	+	PA
A10	+	+	+	+		+	+	+	+	PA
A15	+	+	+	+		+	+	+	+	PA
A17	+	+	+	+		+	+	+	+	PA
A23	+	+	+	+		+	+	+	+	PA
A24	+	+	+	+		+	+	+	+	PA
A1	+	+	+	+		+	+	+	+	PA
A4	+	+	+	+		+	+	+	+	PA
A5	+	+	+	+		+	+	+	+	PA
A9	+	+	+	+		+	+	+	+	PA
A11	+	+	+	+		+	+	+	+	PA
A14	+	+	+	+		+	+	+	+	PA
A16	+	+	+	+		+	+	+	+	PA
A19	+	+	+	+		+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator **A2**

Aerobic mesophilic flora: 6,5.10² CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
A27	-	-	/	-		-	+d	-	-	NA
A29	-	-	/	-		-	+d	-	-	NA
A33	-	-	/	-		-	-	-	-	NA
A35	-	-	/	-		-	-	-	-	NA
A38	-	-	/	-		+/-	-	/	-	NA
A42	-	-	/	-		+/-	-	/	-	NA
A45	-	-	/	-		-	-	/	-	NA
A48	-	-	/	-		-	-	/	-	NA
A25	+	+	+	+		+	+	+	+	PA
A28	+	+	+	+		+	+	+	+	PA
A31	+	+	+	+		+	+	- (x 5)	-	ND
A34	+	+	+	+		+	+	+	+	PA
A37	+	+	+	+		+	+	+	+	PA
A41	-	-	/	-		+	+	+	+	PD
A44	-	-	/	-		+	+	+	+	PD
A47	+	+	+	+		+	+	+	+	PA
A26	+	+d	+	+		+	+	+	+	PA
A30	-	+	+	+		+	+	+	+	PA
A32	+	+	+	+		+	+	+	+	PA
A36	+	+	+	+		+	+	+	+	PA
A39	+	+	+	+		+	+	+	+	PA
A40	+	+	+	+		+	+	+	+	PA
A43	+	+	+	+		+	+	+	+	PA
A46	+	+	+	+		+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator **B**

Aerobic mesophilic flora: 4,4.10² CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement Individual
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
B6	-	-	/	-		-	-	/	-	NA
B8	+	+	+	+		-	-	/	-	ND
B12	-	-	/	-		-	-	/	-	NA
B13	-	-	/	-		-	-	/	-	NA
B18	-	-	/	-		-	-	/	-	NA
B20	+	+	+	+		+ (late)	-	/	-	ND
B21	-	-	/	-		-	-	/	-	NA
B22	-	-	/	-		-	-	/	-	NA
B2	+	+	+	+		+	+	+	+	PA
B3	+	+	+	+		+	+	+	+	PA
B7	+	+	+	+		+	+	+	+	PA
B10	+	+	+	+		-	-	/	-	ND
B15	+	+	+	+		+	+	+	+	PA
B17	+	+	+	+		+	+	+	+	PA
B23	+	+	+	+		-	-	/	-	ND
B24	+	+	+	+		+	+	+	+	PA
B1	+	+	+	+		+	+	+	+	PA
B4	+	+	+	+		+	+	+	+	PA
B5	+	+	+	+		+	+	+	+	PA
B9	+	+	+	+		+	+	+	+	PA
B11	+	+	+	+		+	+	+	+	PA
B14	+	+	+	+		+	+	+	+	PA
B16	+	+	+	+		+	+	+	+	PA
B19	+	+	+	+		+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator C1

Aerobic mesophilic flora: 1,1. 10^3 CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
C6	+	-	/	-	0	-	-	/	-	NA
C8	+	-	-	-	0	-	-	/	-	NA
C12	+	-	-	-	0	-	-	/	-	NA
C13	+	-	+	+	0	-	-	/	-	ND
C18	+	-	-	-	0	-	-	/	-	NA
C20	-	-	/	-	0	-	-	/	-	NA
C21	+	-	-	-	0	-	-	/	-	NA
C22	+	-	-	-	0	-	-	/	-	NA
C2	+	+	+	+	10.58	+	+	+	+	PA
C3	+	+	+	+	10.24	+	+	+	+	PA
C7	+	+	+	+	11.48	+	+	+	+	PA
C10	+	+	+	+	11.46	+	+	+	+	PA
C15	+	+	+	+	11.12	+	+	+	+	PA
C17	+	+	+	+	14.17	+	+	+	+	PA
C23	+	+	+	+	12.46	+	+	+	+	PA
C24	+	+	+	+	11.63	+	+	+	+	PA
C1	+	+	+	+	10.52	+	+	+	+	PA
C4	+	+	+	+	11.53	+	+	+	+	PA
C5	+	+	+	+	11.52	+	+	+	+	PA
C9	+	+	+	+	11.16	+	+	+	+	PA
C11	+	+	+	+	10.75	+	+	+	+	PA
C14	+	+	+	+	10.56	+	+	+	+	PA
C16	+	+	+	+	13.07	+	+	+	+	PA
C19	+	+	+	+	13,94	+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator C2

Aerobic mesophilic flora: 7,0. 10^2 CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
C27	+	+	+	+	0	-	-	/	-	ND
C29	+	+	+	+	0	-	-	/	-	ND
C33	-	-	/	-	0	-	-	/	-	NA
C35	+	+	+	+	0	-	-	/	-	ND
C38	+	+	+	+	0	-	-	/	-	ND
C42	+	-	+	+	0	-	-	/	-	ND
C45	+	+	+	+	0	-	-	/	-	ND
C48	+	+	+	+	0	-	-	/	-	ND
C25	+	+	+	+	11.97	+	+	+	+	PA
C28	+	+	+	+	8.99	+	+	+	+	PA
C31	+	+	+	+	10.72	+	+	+	+	PA
C34	+	+	+	+	11.5	+	+	+	+	PA
C37	+	+	+	+	11.89	+	+	+	+	PA
C41	+	+	+	+	10.36	+	+	+	+	PA
C44	+	-	+	+	12.08	+	+	+	+	PA
C47	+	+	+	+	0	-	+	-	-	ND
C26	+	+	+	+	12.43	+	+	+	+	PA
C30	+	+	+	+	10.03	+	+	+	+	PA
C32	+	+	+	+	10.42	+	+	+	+	PA
C36	+	+	+	+	10.3	+	+	+	+	PA
C39	+	+	+	+	11.25	+	+	+	+	PA
C40	+	+	+	+	11.79	+	+	+	+	PA
C43	+	+	+	+	9.76	+	+	+	+	PA
C46	+	+	+	+	11.74	+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator D

Aerobic mesophilic flora: 8,7.10² CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
D6	-	-	/	-	0	-	-	/	-	NA
D8	-	-	/	-	0	-	-	/	-	NA
D12	+	+	+	+	0	-	-	/	-	ND
D13	-	-	/	-	0	-	-	/	-	NA
D18	-	-	/	-	0	-	-	/	-	NA
D20	-	-	/	-	0	-	-	/	-	NA
D21	-	-	/	-	0	-	-	/	-	NA
D22	-	-	/	-	0	-	-	/	-	NA
D2	+	+	+	+	11.63	+	+	+	+	PA
D3	+	+	+	+	10.8	+	+	+	+	PA
D7	+	+	+	+	10.33	+	+	+	+	PA
D10	+	+	+	+	10.51	+	+	+	+	PA
D15	+	+	+	+	9.71	+	+	+	+	PA
D17	+	+	+	+	12.3	+	+	+	+	PA
D23	+	+	+	+	0	-	-	/	-	ND
D24	+	+	+	+	11.3	+	+	+	+	PA
D1	+	+	+	+	11.07	+	+	+	+	PA
D4	+	+	+	+	12.81	+	+	+	+	PA
D5	+	+	+	+	12.3	+	+	+	+	PA
D9	+	+	+	+	12.76	+	+	+	+	PA
D11	+	+	+	+	11.09	+	+	+	+	PA
D14	+	+	+	+	12.28	+	+	+	+	PA
D16	+	+	+	+	15.1	+	+	+	+	PA
D19	+	+	+	+	12.25	+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator **E1**

Aerobic mesophilic flora: <10 CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR		CT-SMAC	Latex	Final result	
					Cq	Result				
E6	-	-	/	-	0	-	+	+	-	NA
E8	-	-	/	-	0	-	-	/	-	NA
E12	-	-	/	-	0	-	-	/	-	NA
E13	-	-	/	-	0	-	-	/	-	NA
E18	-	-	/	-	0	-	-	/	-	NA
E20	-	-	/	-	0	-	-	/	-	NA
E21	-	-	/	-	0	-	-	/	-	NA
E22	-	-	/	-	0	-	-	/	-	NA
E2	+	+	+	+	9.4	+	+	+	+	PA
E3	+	+	+	+	9.54	+	+	+	+	PA
E7	+	+	+	+	9.9	+	+	+	+	PA
E10	+	+	+	+	9.72	+	+	+	+	PA
E15	+	+	+	+	0	-	-	/	-	ND
E17	+	+	+	+	11.33	+	+	+	+	PA
E23	+	+	+	+	9.19	+	+	+	+	PA
E24	+	+	+	+	9.86	+	+	+	+	PA
E1	+	+	+	+	9.73	+	+	+	+	PA
E4	+	+	+	+	9.23	+	+	+	+	PA
E5	+	+	+	+	9.78	+	+	+	+	PA
E9	+	+	+	+	13.25	+	+	+	+	PA
E11	+	+	+	+	10.8	+	+	+	+	PA
E14	+	+	+	+	10.31	+	+	+	+	PA
E16	+	+	+	+	10.47	+	+	+	+	PA
E19	+	+	+	+	11.35	+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator E2

Aerobic mesophilic flora: <10 CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR		CT-SMAC	Latex	Final result	
					Cq	Result				
E27	-	-	-	-	0	-	-	/	-	NA
E29	-	-	-	-	0	-	-	/	-	NA
E33	+	-	+	+	0	-	-	/	-	ND
E35	-	-	-	-	0	-	-	/	-	NA
E38	-	-	-	-	0	-	-	/	-	NA
E42	+	+	+	+	0	-	-	/	-	ND
E45	-	+	-	-	21.83	+	-	/	-	NA
E48	-	-	-	-	0	-	-	/	-	NA
E25	+	+	+	+	10.11	+	+	+	+	PA
E28	+	-	-	-	10.64	+	+	+	+	PD
E31	+	+	+	+	9.23	+	+	+	+	PA
E34	+	+	+	+	10.46	+	+	+	+	PA
E37	+	+	+	+	10.06	+	+	+	+	PA
E41	+	-	+	+	11.15	+	+	+	+	PA
E44	+	-	+	+	9.76	+	+	+	+	PA
E47	+	+	+	+	0	-	-		-	ND
E26	+	+	+	+	10.72	+	+	+	+	PA
E30	+	+	+	+	9.84	+	+	+	+	PA
E32	+	+	+	+	8.92	+	+	+	+	PA
E36	+	+	+	+	9.98	+	+	+	+	PA
E39	+	+	+	+	9.15	+	+	+	+	PA
E40	+	+	+	+	9.64	+	+	+	+	PA
E43	+	-	+	+	10.99	+	+	+	+	PA
E46	+	+	+	+	10.88	+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator F1

Aerobic mesophilic flora: 7,2.10² CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR		CT-SMAC	Latex	Final result	
					Cq	Result				
F6	+d	-	-	-	10.1	+	+	+	+	PD
F8	-	-	/	-	9.03/0 (1)	+/-	+d	-	+	PD
F12	+d	-	-	-	0/29.27 (1)	-/+	+	+	-	NA
F13	+d	-	+	+	9.22/0	+/-	-	/	+	PA
F18	-	+d	-	-	9.76	+	+d	+	+	PD
F20	+d	-	+	+	0/30.58 (1)	-/+	+d	+	-	ND
F21	-	-	/	-	0	-	+d	-	-	NA
F22	-	-	/	-	9.65/0 (1)	+/-	+d	-	+	PD
F2	+	+	+	+	9.99	+	+	+	+	PA
F3	+	+	+	+	9.55	+	+	+	+	PA
F7	+	+	+	+	0/12.60 (1)	-/+	+	+	-	ND
F10	+d	-	-	-	9.41	+	+	+	+	PD
F15	+	+	+	+	9.83	+	+	+	+	PA
F17	+	+	+	+	24.41	+	+	+	+	PA
F23	+	+	+	+	30.58	+	+	+	+	PA
F24	+	+	+	+	0	-	+d	-	-	ND
F1	+	+	+	+	11.38	+	+	+	+	PA
F4	+	+	+	+	10.19	+	+	+	+	PA
F5	+	+	+	+	0/12.58 (1)	-/+	+	+	-	ND
F9	+	+	+	+	9.22	+	+	+	+	PA
F11	+	+	+	+	0/13.13 (1)	-/+	+	+	-	ND
F14	+	+	+	+	9.82	+	+	+	+	PA
F16	+	+	+	+	9.55	+	+	+	+	PA
F19	+	+	+	+	0/13.13 (1)	-/+	+	+	-	ND

(1) Second DNA extraction (26 May 2016)

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator **G**

Aerobic mesophilic flora: 1,5.10³ CFU /g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
G6	+	+	+	+		-	*Confirmation not realized*	/	-	ND
G8	+	+	+	+		-		/	-	ND
G12	+	+	+	+		-		/	-	ND
G13	+	+	-	-		-		/	-	NA
G18	+	+	+	+		-		/	-	ND
G20	+	+	+	+		-		/	-	ND
G21	+	+	-	-		-		/	-	NA
G22	+	+	+	+		-		/	-	ND
G2	+	+	+	+		+	+	+	+	PA
G3	+	+	+	+		+	+	+	+	PA
G7	+	+	+	+		+	+	+	+	PA
G10	+	+	+	+		+	+	+	+	PA
G15	-	+	-	-		+	+	+	+	PD
G17	+	+	+	+		+	+	+	+	PA
G23	+	+	+	+		+	+	/	+	PA
G24	+	+	+	+		+	-	/	-	ND
G1	+	+	+	+		+	+	+	+	PA
G4	+	+	+	+		+	+	+	+	PA
G5	+	+	+	+		+	+	+	+	PA
G9	+	+	+	+		+	+	+	+	PA
G11	+	+	+	+		+	+	+	+	PA
G14	+	+	+	+		+	+	+	+	PA
G16	+	+	+	+		+	+	+	+	PA
G19	+	+	+	+		+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator H

Aerobic mesophilic flora: 1,1.10² CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
H6	+d	-	-	-	0	-	-	/	-	NA
H8	+d	+d	-	-	0	-	+d	-	-	NA
H12	+d	-	-	-	0	-	+d	-	-	NA
H13	-	-	/	-	0	-	-	/	-	NA
H18	-	-	/	-	0	-	-	/	-	NA
H20	-	-	/	-	0	-	+d	-	-	NA
H21	-	-	/	-	0	-	-	-	-	NA
H22	-	-	/	-	0	-	+d	-	-	NA
H2	-	-	/	-	0	-	-	/	-	NA
H3	+	+	+	+	8.48	+	+	+	+	PA
H7	+	+	+	+	0	-	-	/	-	ND
H10	+	+	+	+	0	-	-	/	-	ND
H15	+	+	+	+	13.04	+	+	+	+	PA
H17	-	-	/	-	0	-	-	/	-	NA
H23	-	-	/	-	7.6	+	+	+	+	PD
H24	+	+	+	+	13.27	+	+	+	+	PA
H1	+	+	+	+	10.72	+	+	+	+	PA
H4	+	+	+	+	10.31	+	+	+	+	PA
H5	+	+	+	+	8.57	+	+	+	+	PA
H9	+	+	+	+	9.25	+	+	+	+	PA
H11	+	+	+	+	8.95	+	+	+	+	PA
H14	+	-	+	+	9.3	+	+	+	+	PA
H16	+	-	+	+	9.49	+	+	+	+	PA
H19	+	+	+	+	9.78	+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator I

Aerobic mesophilic flora: 10^2 CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
I6	-	-	/	-		-	-	/	-	NA
I8	-	-	/	-		-	-	/	-	NA
I12	-	+ (2)	+	+		-	-	/	-	ND
I13	-	-	/	-		-	-	/	-	NA
I18	-	-	/	-		-	-	/	-	NA
I20	-	-	/	-		-	-	/	-	NA
I21	-	-	/	-		-	-	/	-	NA
I22	-	-	/	-		-	-	/	-	NA
I2	-	-	/	-		+	+	+	+	PD
I3	+	-	+	+		+	+	+	+	PA
I7	-	-	/	-		-	-	-	-	NA
I10	+	+	+	+		+	+	+	+	PA
I15	+	+	+	+		+	+	+	+	PA
I17	+	+	+	+		+	+	+	+	PA
I23	+	+	+	+		+	+	+	+	PA
I24	+	+	+	+		+	+	+	+	PA
I1	+	+	+	+		+	+	+	+	PA
I4	+	+	+	+		+	+	+	+	PA
I5	+	+	+	+		+	+	+	+	PA
I9	+	+	+	+		+	+	- x 4	-	ND
I11	+	+	+	+		+	+	+	+	PA
I14	+	+	+	+		+	+	+	+	PA
I16	+	+	+	+		+	+	+	+	PA
I19	+	+	+	+		+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator **J1**

Aerobic mesophilic flora: 2,1.10² CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
J6	+	+	+	+		+	-	/	-	ND
J8	+	+	+	+		-	-	/	-	ND
J12	-	-	/	-		-	-	/	-	NA
J13	-	-	/	-		-	-	/	-	NA
J18	-	-	/	-		-	-	/	-	NA
J20	-	-	/	-		-	-	/	-	NA
J21	-	-	/	-		-	-	/	-	NA
J22	+	-	-	-		-	-	/	-	NA
J2	+	+	+	+		-	-	/	-	ND
J3	+	+	+	+		+	+	+	+	PA
J7	+	-	-	-		+	+	+	+	PD
J10	+	+	+	+		+	+	+	+	PA
J15	+	+	+	+		+	+	+	+	PA
J17	+	+	+	+		+	+	+	+	PA
J23	+	+	+	+		+	+	+	+	PA
J24	+	+	+	+		+	+	+	+	PA
J1	+	+	+	+		+	+	+	+	PA
J4	+	-	+	+		+	+	+	+	PA
J5	+	+	+	+		+	+	+	+	PA
J9	+	+	+	+		+	+	+	+	PA
J11	-	+	+	+		+	+	+	+	PA
J14	+	+	+	+		+	+	+	+	PA
J16	+	+	+	+		+	+	+	+	PA
J19	+	+	+	+		+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator **J2**

Aerobic mesophilic flora: 7,0.10² CFU/g

N°Sample	Reference method: ISO 16654				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
J27	+	+	+	+		-	-	/	-	ND
J29	+	+	+	+		-	-	/	-	ND
J33	+	+	+	+		-	-	/	-	ND
J35	+	+	+	+		-	-	/	-	ND
J38	+	+	+	+		-	-	/	-	ND
J42	-	+	+	+		-	-	/	-	ND
J45	-	-	/	-		-	-	/	-	NA
J48	+	+	+	+		-	-	/	-	ND
J25	+	+	+	+		+	+	+	+	PA
J28	+	-	-	-		+	+	+	+	PD
J31	+	+	+	+		+	+	+	+	PA
J34	+	+	+	+		+	+	+	+	PA
J37	+	+	+	+		+	+	+	+	PA
J41	+	+	+	+		+	+	+	+	PA
J44	+	-	-	-		+	+	+	+	PD
J47	+	+	+	+		+	+	+	+	PA
J26	+	+	+	+		+	+	+	+	PA
J30	+	+	+	+		+	+	+	+	PA
J32	+	+	+	+		+	+	+	+	PA
J36	+	+	+	+		+	+	+	+	PA
J39	+	+	+	+		+	+	+	+	PA
J40	+	+	+	+		+	+	+	+	PA
J43	+	+	+	+		+	+	+	+	PA
J46	+	+	+	+		+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT.

Table 10. Results Obtained by the Collaborators and the Expert Laboratory- Continued *(Table obtained from original report by ADRIA Développement, Expert Lab)*[1]

Collaborator K(ADRIA)

Aerobic mesophilic flora: 4,5. 10^3 CFU/g

N°Sample	Reference method: ISO 16654♦				Alternative method: GDS *E. coli* O157:H7 Tq					Agreement
	CT-SMAC	Chromagar	Confir-mation	Final result	PCR Cq	PCR Result	CT-SMAC	Latex	Final result	
K6	+d	+d	-	-	0	-	-	/	-	NA
K8	-	-	/	-	0	-	-	/	-	NA
K12	-	-	/	-	0	-	-	/	-	NA
K13	-	-	/	-	0	-	-	/	-	NA
K18	-	-	/	-	0	-	-	/	-	NA
K20	-	-	/	-	0	-	-	/	-	NA
K21	-	-	/	-	0	-	-	/	-	NA
K22	+d	-	-	-	0	-	-	/	-	NA
K2	+	-	+	+	8.3	+	+	+	+	PA
K3	-	-	/	-	8.99	+	+	+	+	PD
K7	+	+	+	+	11.19	+	+	+	+	PA
K10	+	+	+	+	9.34	+	+	+	+	PA
K15	-	-	/	-	9.49	+	+	+	+	PD
K17	-	-	/	-	9.54	+	+	+	+	PD
K23	+	+	+	+	10.61	+	+	+	+	PA
K24	-	-	/	-	11.66	+	+	+	+	PD
K1	+	+	+	+	8.7	+	+	+	+	PA
K4	-	-	/	-	8.83	+	+	+	+	PD
K5	+	+	+	+	8.52	+	+	+	+	PA
K9	+	+	+	+	12.89	+	+	+	+	PA
K11	+	+	+	+	9.88	+	+	+	+	PA
K14	+	+	+	+	9.85	+	+	+	+	PA
K16	+d	-	-	-	8.84	+	+	+	+	PD
K19	+	+	+	+	11.72	+	+	+	+	PA

[1]MicroVal Study 2015LR49 Methods Comparison Study Report, *" ISO 16140-2 validation study of the GDS E. coli O157:H7 Tq detection Kit for the detection of E. coli O157:H7 in raw beef meats (with 25g and 375g sampling), fruits & vegetables (with 25g sampling), dairy products (with 25g sampling), and environmental samples (with 25g sampling or surface)"*, Revision1, December 29, 2016. ADRIA DEVELOPPEMENT

ANNEX H: Alternative Confirmation: Sensitivity Raw Data

Table 11: Alternative Confirmation Sensitivity Raw Data

Category	Item Type	Sample N°	Alternative Confirmation- Initial Enrichment												Alternative Confirmation- Enrichment Broth Storage 48-72 Hrs 4°C											
			10 Hour						14 Hour						10 Hour						14 Hour					
			CHOMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHOMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHOMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHOMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
Fresh beef meats	Raw Ground Beef (85% Lean)	087.1	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Ground Beef (96% Lean)	087.2	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Beef Tips	087.3	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Shaved Beef	087.4	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Beef Serloin	087.5	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
Frozen then thawed beef	Frozen Thawed Quarter Pound Beef Patties	087.6	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Thawed Angus Beef Check Brisket Blend Burgers	087.7	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Thawed 80% Lean Ground Beef Burgers	087.8	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Thawed 100% Angus Beef Patties	087.9	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Thawed Bacon Cheddar Beef Patties	087.10	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
Meats with seasonings	Raw seasoned beef patties	087.11	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Angus Beef Steakhouse Tri Tip	087.12	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Black Peppercorn Ribeye	087.13	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Angus Sweet and Smokey Angus Beef tip	087.14	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Bacon and Black Peppercorn Wrapped Beef Tender	087.15	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA

Table 11: Alternative Confirmation Sensitivity Raw Data- Continued

Category	Item Type	Sample N°	Alternative Confirmation- Initial Enrichment												Alternative Confirmation- Enrichment Broth Storage 48-72 Hrs 4°C											
			10 Hour						14 Hour						10 Hour						14 Hour					
			CHOMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHOMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHOMAgar O157	CT-SMAC	EC 0157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHOMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
Fresh beef meats	Raw Ground Beef (85% Lean)	087.16	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Ground Beef (96% Lean)	087.17	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Beef Tips	087.18	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Shaved Beef	087.19	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Raw Beef Serloin	087.20	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
Frozen then thawed beef	Frozen Thawed Quarter Pound Beef Patties	087.21	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Thawed Angus Beef Check Brisket Blend Burgers	087.22	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Thawed 80% Lean Ground Beef Burgers	087.23	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Thawed 100% Angus Beef Patties	087.24	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Thawed Bacon Cheddar Beef Patties	087.25	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA

Table 11: Alternative Confirmation Sensitivity Raw Data- Continued

Category	Item Type	Sample N°	Alternative Confirmation- Initial Enrichment												Alternative Confirmation- Enrichment Broth Storage 48-72 Hrs 4°C											
			10 Hour						14 Hour						10 Hour						14 Hour					
			CHROMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHROMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHROMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHROMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
Fresh and frozen produces	Chopped Chipotle Salad Kit	087.41	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Chopped Ceasar Salad Kit	087.42	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Garden Salad Kit	087.43	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Fresh Mixed Fruit Bowl	087.44	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Fresh Strawberry and Kiwi Bowl	087.45	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
Fresh and frozen sprouts or baby leafs	Baby Spinach	087.46	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Baby Arugula	087.47	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Baby Kale	087.48	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Baby bean Sprouts	087.49	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Mung Sprouts	087.50	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
Fresh raw, frozen fruit	Grapes	087.51	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Pineapple	087.52	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Apples	087.53	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Peaches	087.54	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Frozen Strawberries	087.55	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA

Table 11: Alternative Confirmation Sensitivity Raw Data- Continued

Category	Item Type	Sample N°	Alternative Confirmation- Initial Enrichment												Alternative Confirmation- Enrichment Broth Storage 48-72 Hrs 4°C											
			10 Hour						14 Hour						10 Hour						14 Hour					
			CHROMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHROMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHROMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result	CHROMAgar O157	CT-SMAC	EC O157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
Surfaces	Swab (food industry) Location 1	087.56	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Sponge (food industry) Location 1	087.57	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Swab (food industry) Location 2	087.58	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Swab (food industry) Location 2	087.59	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Sponge (food industry) Location 2	087.60	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
Process water	Processed Water (food industry) Location 1	087.61	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Processed Water (food industry) Location 2	087.62	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Processed Water (food industry) Location 3	087.63	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Processed Water (food industry) Location 1	087.64	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Processed Water (food industry) Location 3	087.65	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
Dusts	Dust (food industry) Location 1	087.66	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Dust (food industry) Location 2	087.67	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Dust (food industry) Location 3	087.68	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Dust (food industry) Location 3	087.69	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA
	Dust (food industry) Location 1	087.70	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA	+	+	+	+	+	PA

ANNEX I: Alternative Confirmation: Inclusivity and Exclusivity Raw Data

Table 12: Aleternative Confirmation Inclusivity Raw Data

Inclusvity												
Sample No.	Genus	Species	Subspecies/Serovar	Source	Reference No.	Origin	CHOMAgar O157	CT-SMAC	EC 0157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
1	*Escherichia*	*coli*	O157:H7	ATCC	43895	Raw hamburger meat implicated in hemorrhagic colitis outbreak	+	+	+	+	+	Pos
2	*Escherichia*	*coli*	O157:H7	Q Labs	791.1	Raw Chicken	+	+	+	+	+	Pos
3	*Escherichia*	*coli*	O157:H7	MSU	TW00116	Human	+	+	+	+	+	Pos
4	*Escherichia*	*coli*	O157:H7	MSU	TW00975	Human	+	+	+	+	+	Pos
5	*Escherichia*	*coli*	O157:H7	MSU	TW02302	Hamburger	+	+	+	+	+	Pos
6	*Escherichia*	*coli*	O157:H7	MSU	TW04863	Human	+	+	+	+	+	Pos
7	*Escherichia*	*coli*	O157:H7	MSU	TW05356	Human	+	+	+	+	+	Pos
8	*Escherichia*	*coli*	O157:H7	MSU	TW07587	Human	+	+	+	+	+	Pos
9	*Escherichia*	*coli*	O157:H7	ATCC	BAA-460	human feces, 1996, Sakai City Institute of Public Health, Japan	+	+	+	+	+	Pos
10	*Escherichia*	*coli*	O157:H7	NCTC	12900	Not Available	+	+	+	+	+	Pos
11	*Escherichia*	*coli*	O157:H7	NCTC	13126	Not Available	+	+	+	+	+	Pos
12	*Escherichia*	*coli*	O157:H7	NCTC	13127	Not Available	+	+	+	+	+	Pos
13	*Escherichia*	*coli*	O157:H7	NCTC	13128	Not Available	+	+	+	+	+	Pos
14	*Escherichia*	*coli*	O157:H7	ATCC	35150	Human Feces	+	+	+	+	+	Pos
15	*Escherichia*	*coli*	O157:H7	ATCC	43888	Human Feces	+	+	+	+	+	Pos
16	*Escherichia*	*coli*	O157:H7	ATCC	43889	Human Feces	+	+	+	+	+	Pos
17	*Escherichia*	*coli*	O157:H7	ATCC	43890	Human Feces	+	+	+	+	+	Pos
18	*Escherichia*	*coli*	O157:H7	ATCC	43894	Human Feces	+	+	+	+	+	Pos
19	*Escherichia*	*coli*	O157:H7	Q Labs	791.61	Environmental Isolate	+	+	+	+	+	Pos
20	*Escherichia*	*coli*	O157:H7	ATCC	51657	Clinical Isolate	+	+	+	+	+	Pos
21	*Escherichia*	*coli*	O157:H7	ATCC	51657	Clinical Isolate	+	+	+	+	+	Pos
22	*Escherichia*	*coli*	O157:H7	ATCC	51658	Clinical Isolate	+	+	+	+	+	Pos
23	*Escherichia*	*coli*	O157:H7	ATCC	51659	Clinical Isolate	+	+	+	+	+	Pos
24	*Escherichia*	*coli*	O157:H7	ATCC	700531	Clinical Isolate	+	+	+	+	+	Pos
25	*Escherichia*	*coli*	O157:H7	ATCC	700599	Salami	+	+	+	+	+	Pos
26	*Escherichia*	*coli*	O157:H7	ATCC	700728	Not Available	+	+	+	+	+	Pos
27	*Escherichia*	*coli*	O157:H7	ATCC	700927	Not Available	+	+	+	+	+	Pos
28	*Escherichia*	*coli*	O157:H7	MSU	DEC3A	Human	+	+	+	+	+	Pos
29	*Escherichia*	*coli*	O157:H7	MSU	DEC3B	Human	+	+	+	+	+	Pos
30	*Escherichia*	*coli*	O157:H7	MSU	DEC3C	Human	+	+	+	+	+	Pos
31	*Escherichia*	*coli*	O157:H7	MSU	DEC3D	Human	+	+	+	+	+	Pos
32	*Escherichia*	*coli*	O157:H7	MSU	DEC3E	Human	+	+	+	+	+	Pos
33	*Escherichia*	*coli*	O157:H7	MSU	DEC4A	Human	+	+	+	+	+	Pos
34	*Escherichia*	*coli*	O157:H7	MSU	DEC4B	Human	+	+	+	+	+	Pos
35	*Escherichia*	*coli*	O157:H7	MSU	DEC4C	Buffalo	+	+	+	+	+	Pos
36	*Escherichia*	*coli*	O157:H7	MSU	DEC4D	cow, calf	+	+	+	+	+	Pos
37	*Escherichia*	*coli*	O157:H7	MSU	DEC4E	Human	+	+	+	+	+	Pos
38	*Escherichia*	*coli*	O157:H7	Q Labs	QL# 164673	Beef Trim	+	+	+	+	+	Pos
39	*Escherichia*	*coli*	O157:H7	Q Labs	2-202	Meat	+	+	+	+	+	Pos
40	*Escherichia*	*coli*	O157:H7	Q Labs	2-203	Meat	+	+	+	+	+	Pos
41	*Escherichia*	*coli*	O157:H7	Q Labs	2-204	Meat	+	+	+	+	+	Pos
42	*Escherichia*	*coli*	O157:H7	Q Labs	2-205	Meat	+	+	+	+	+	Pos
43	*Escherichia*	*coli*	O157:H7	Q Labs	2-206	Meat	+	+	+	+	+	Pos
44	*Escherichia*	*coli*	O157:H7	Q Labs	2-207	Meat	+	+	+	+	+	Pos
45	*Escherichia*	*coli*	O157:H7	Q Labs	2-214	Meat	+	+	+	+	+	Pos
46	*Escherichia*	*coli*	O157:H7	Q Labs	2-370	Meat	+	+	+	+	+	Pos
47	*Escherichia*	*coli*	O157:H7	Q Labs	2-701	Beef	+	+	+	+	+	Pos
48	*Escherichia*	*coli*	O157:H7	Q Labs	2-704	Beef	+	+	+	+	+	Pos
49	*Escherichia*	*coli*	O157:H7	Q Labs	2-705	Beef	+	+	+	+	+	Pos
50	*Escherichia*	*coli*	O157:H7	Q Labs	2-706	Beef	+	+	+	+	+	Pos

Table 12: Aleternative Confirmation Inclusivity Raw Data-Continued

Inclusvity												
Sample No.	Genus	Species	Subspecies/Serovar	Source	Reference No.	Origin	CHOMAgar O157	CT-SMAC	EC 0157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
51	*Escherichia*	*coli*	O157:H7	Q Labs	2-707	Beef	+	+	+	+	+	Pos
52	*Escherichia*	*coli*	O157:H7	Q Labs	2-708	Beef	+	+	+	+	+	Pos
53	*Escherichia*	*coli*	O157:H7	Q Labs	791.16	Meat	+	+	+	+	+	Pos
54	*Escherichia*	*coli*	O157:H7	Q Labs	2-709	Beef	+	+	+	+	+	Pos
55	*Escherichia*	*coli*	O157:H7	Q Labs	2-710	Beef	+	+	+	+	+	Pos
56	*Escherichia*	*coli*	O157:H7	Q Labs	14077.1	Meat	+	+	+	+	+	Pos
57	*Escherichia*	*coli*	O157:H7	Q Labs	14077.2	Meat	+	+	+	+	+	Pos
58	*Escherichia*	*coli*	O157:H7	Q Labs	14077.3	Salami	+	+	+	+	+	Pos
59	*Escherichia*	*coli*	O157:H7	Q Labs	14077.4	Apple Cider	+	+	+	+	+	Pos
60	*Escherichia*	*coli*	O157:H7	Q Labs	14077.5	Ground Beef	+	+	+	+	+	Pos
61	*Escherichia*	*coli*	O157:H7	Q Labs	14077.6	Environmental Sample	+	+	+	+	+	Pos
62	*Escherichia*	*coli*	O157:H7	Q Labs	14077.7	Ground Beef	+	+	+	+	+	Pos
63	*Escherichia*	*coli*	O157:H7	Q Labs	14077.8	Ground Beef	+	+	+	+	+	Pos
64	*Escherichia*	*coli*	O157:H7	Q Labs	62918.1	Chicken Breast	+	+	+	+	+	Pos
65	*Escherichia*	*coli*	O157:H7	Q Labs	62918.5	Environmental Sample	+	+	+	+	+	Pos
66	*Escherichia*	*coli*	O157:H7	Q Labs	62918.11	Environmental Sample	+	+	+	+	+	Pos
67	*Escherichia*	*coli*	O157:H7	Q Labs	62918.1	Beef Trim	+	+	+	+	+	Pos
68	*Escherichia*	*coli*	O157:H7	Q Labs	62918.36	Ground Beef	+	+	+	+	+	Pos
69	*Escherichia*	*coli*	O157:H7	Q Labs	62918.69	Spinach	+	+	+	+	+	Pos
70	*Escherichia*	*coli*	O157:H7	Q Labs	62918.74	Baby spinach leaf	+	+	+	+	+	Pos
71	*Escherichia*	*coli*	O157:H7	Q Labs	62918.95	Environmental Sample	+	+	+	+	+	Pos
72	*Escherichia*	*coli*	O157:H7	Q Labs	62918.42	Environmental Sample	+	+	+	+	+	Pos
73	*Escherichia*	*coli*	O157:H7	Q Labs	62918.6	Environmental Sample	+	+	+	+	+	Pos
74	*Escherichia*	*coli*	O157:H7	Q Labs	62918.91	Chicken Breast	+	+	+	+	+	Pos
75	*Escherichia*	*coli*	O157:H7	Q Labs	62918.76	Beef Trim	+	+	+	+	+	Pos
76	*Escherichia*	*coli*	O157:H7	Q Labs	71318.1	Beef Trim	+	+	+	+	+	Pos
77	*Escherichia*	*coli*	O157:H7	Q Labs	71318.5	Ground Beef	+	+	+	+	+	Pos
78	*Escherichia*	*coli*	O157:H7	Q Labs	71318.15	Chicken Feces	+	+	+	+	+	Pos
79	*Escherichia*	*coli*	O157:H7	Q Labs	71318.2	Environmental Sample	+	+	+	+	+	Pos
80	*Escherichia*	*coli*	O157:H7	Q Labs	71318.26	Environmental Sample	+	+	+	+	+	Pos
81	*Escherichia*	*coli*	O157:H7	Q Labs	71318.32	Spinach	+	+	+	+	+	Pos
82	*Escherichia*	*coli*	O157:H7	Q Labs	71318.43	Chicken feces	+	+	+	+	+	Pos
83	*Escherichia*	*coli*	O157:H7	Q Labs	71318.45	Chicken feces	+	+	+	+	+	Pos
84	*Escherichia*	*coli*	O157:H7	Q Labs	71318.65	Environmental Sample	+	+	+	+	+	Pos
85	*Escherichia*	*coli*	O157:H7	Q Labs	71318.87	Ground Beef	+	+	+	+	+	Pos
86	*Escherichia*	*coli*	O157:H7	Q Labs	71318.94	Chicken Breast	+	+	+	+	+	Pos
87	*Escherichia*	*coli*	O157:H7	Q Labs	71318.75	Environmental Sample	+	+	+	+	+	Pos
88	*Escherichia*	*coli*	O157:H7	Q Labs	71318.62	Environmental Sample	+	+	+	+	+	Pos
89	*Escherichia*	*coli*	O157:H7	Q Labs	71318.58	Spinach	+	+	+	+	+	Pos
90	*Escherichia*	*coli*	O157:H7	Q Labs	71318.22	Ground Beef	+	+	+	+	+	Pos
91	*Escherichia*	*coli*	O157:H7	Q Labs	52818.3	Chicken feces	+	+	+	+	+	Pos
92	*Escherichia*	*coli*	O157:H7	Q Labs	52818.4	Environmental Sample	+	+	+	+	+	Pos
93	*Escherichia*	*coli*	O157:H7	Q Labs	52818.6	Chicken Breast	+	+	+	+	+	Pos
94	*Escherichia*	*coli*	O157:H7	Q Labs	52818.22	Beef Trim	+	+	+	+	+	Pos
95	*Escherichia*	*coli*	O157:H7	Q Labs	52818.8	Ground Beef	+	+	+	+	+	Pos
96	*Escherichia*	*coli*	O157:H7	Q Labs	52818.29	Environmental Sample	+	+	+	+	+	Pos
97	*Escherichia*	*coli*	O157:H7	Q Labs	52818.31	Chicken feces	+	+	+	+	+	Pos
98	*Escherichia*	*coli*	O157:H7	Q Labs	52818.52	Chicken feces	+	+	+	+	+	Pos
99	*Escherichia*	*coli*	O157:H7	Q Labs	52818.18	Spinach	+	+	+	+	+	Pos
100	*Escherichia*	*coli*	O157:H7	Q Labs	52818.43	Ground Beef	+	+	+	+	+	Pos

Table 13: Alternative Confirmation Exclusivity Data

Exclusivity												
Sample No.	Genus	Species	Subspecies/Serovar	Source	Reference No.	Origin	CHROMAgar O157	CT-SMAC	EC 0157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
1	*Escherichia*	*coli*	O111	MSU	TW07926	Human	-	-	-	-	-	Neg
2	*Escherichia*	*coli*	O111	MSU	DEC8D	Human Infant	-	-	-	-	-	Neg
3	*Escherichia*	*coli*	O111	MSU	TW14960	Human	-	-	-	-	-	Neg
4	*Escherichia*	*coli*	O111	MSU	TW06296	Human Child	-	-	-	-	-	Neg
5	*Escherichia*	*coli*	O111	MSU	TW06315	Human	-	-	-	-	-	Neg
6	*Escherichia*	*coli*	O111	MSU	DEC12A	Human Infant	-	-	-	-	-	Neg
7	*Escherichia*	*coli*	O111	MSU	DEC15A	Human	-	-	-	-	-	Neg
8	*Escherichia*	*coli*	O111	MSU	TW05614	Human	-	-	-	-	-	Neg
9	*Escherichia*	*coli*	O111	MSU	TW00186	Human	-	-	-	-	-	Neg
10	*Escherichia*	*coli*	O111	MSU	TW01387	Human	-	-	-	-	-	Neg
11	*Escherichia*	*coli*	O111	MSU	TW07502	Human	-	-	-	-	-	Neg
12	*Escherichia*	*coli*	O103	NCTC	8196	Not Available	-	-	-	-	-	Neg
13	*Escherichia*	*coli*	O111:H12	MSU	DEC6A	Human, Infant	-	-	-	-	-	Neg
14	*Escherichia*	*coli*	O111:H8	MSU	DEC6C	Human	-	-	-	-	-	Neg
15	*Escherichia*	*coli*	O113	NCTC	9113	Not Available	-	-	-	-	-	Neg
16	*Escherichia*	*coli*	O115	NCTC	10444	Mammal, Calf	-	-	-	-	-	Neg
17	*Escherichia*	*coli*	O117	NCTC	9117	Not Available	-	-	-	-	-	Neg
18	*Escherichia*	*coli*	O118	NCTC	9118	Not Available	-	-	-	-	-	Neg
19	*Escherichia*	*coli*	O121	NCTC	9121	Human	-	-	-	-	-	Neg
20	*Escherichia*	*coli*	O142	NCTC	10089	Not Available	-	-	-	-	-	Neg
21	*Escherichia*	*coli*	O145	NCTC	10279	Not Available	-	-	-	-	-	Neg
22	*Escherichia*	*coli*	O146	NCTC	10677	Not Available	-	-	-	-	-	Neg
23	*Escherichia*	*coli*	O103	MSU	TW08101	Human	-	-	-	-	-	Neg
24	*Escherichia*	*coli*	O103	MSU	TW07971	Human	-	-	-	-	-	Neg
25	*Escherichia*	*coli*	O103	MSU	TW11239	Human, Child	-	-	-	-	-	Neg
26	*Escherichia*	*coli*	O103	MSU	TW07697	Human	-	-	-	-	-	Neg
27	*Escherichia*	*coli*	O103	MSU	TW05997	Human	-	-	-	-	-	Neg
28	*Escherichia*	*coli*	O145	MSU	TW09153	Human	-	-	-	-	-	Neg
29	*Escherichia*	*coli*	O145	MSU	TW07596	Human	-	-	-	-	-	Neg
30	*Escherichia*	*coli*	O145	MSU	TW01664	Human	-	-	-	-	-	Neg
31	*Escherichia*	*coli*	O145	MSU	TW09356	Human	-	-	-	-	-	Neg
32	*Escherichia*	*coli*	O26	MSU	TW07814	Human	-	-	-	-	-	Neg
33	*Escherichia*	*coli*	O26	MSU	TW00971	Feces, Human	-	-	-	-	-	Neg
34	*Escherichia*	*coli*	O26	MSU	TW04270	Human	-	-	-	-	-	Neg
35	*Escherichia*	*coli*	O26	MSU	TW04284	Human Child	-	-	-	-	-	Neg
36	*Escherichia*	*coli*	O26	MSU	DEC9F	Human	-	-	-	-	-	Neg
37	*Escherichia*	*coli*	O26	MSU	TW05992	Human	-	-	-	-	-	Neg
38	*Escherichia*	*coli*	O26	MSU	TW08031	Human	-	-	-	-	-	Neg
39	*Escherichia*	*coli*	O26	MSU	DEC9A	Human	-	-	-	-	-	Neg
40	*Escherichia*	*coli*	O26	MSU	DEC 10B	Human	-	-	-	-	-	Neg
41	*Escherichia*	*coli*	O26	MSU	DEC 10C	Human, Infant	-	-	-	-	-	Neg
42	*Escherichia*	*coli*	O55	MSU	TW00585	Feces, Human Infant	-	-	-	-	-	Neg
43	*Escherichia*	*coli*	O103	MSU	TW04162	Human	-	-	-	-	-	Neg
44	*Escherichia*	*coli*	O103	MSU	TW08101	Human	-	-	-	-	-	Neg
45	*Escherichia*	*coli*	O121	MSU	TW07614	Human	-	-	-	-	-	Neg
46	*Escherichia*	*coli*	O121	MSU	TW08023	Human	-	-	-	-	-	Neg
47	*Escherichia*	*coli*	O121	MSU	TW08039	Human	-	-	-	-	-	Neg
48	*Escherichia*	*coli*	O121	MSU	TW07931	Human	-	-	-	-	-	Neg
49	*Escherichia*	*coli*	O121	MSU	MT#2	Human	-	-	-	-	-	Neg
50	*Escherichia*	*coli*	O26	MSU	TW02295	Human, Infant	-	-	-	-	-	Neg

Table 13: Alternative Confirmation Exclusivity Data-Continued

Exclusivity												
Sample No.	Genus	Species	Subspecies/Serovar	Source	Reference No.	Origin	CHROMAgar O157	CT-SMAC	EC 0157:H7 ChromoSelect	Abraxis Latex Agglutination Result	OXOID Latex Agglutination Result	Final Result
51	*Escherichia*	*coli*	O26	MSU	TW07862	Calf, Cow	-	-	-	-	-	Neg
52	*Escherichia*	*coli*	O45	MSU	TW09183	Human	-	-	-	-	-	Neg
53	*Escherichia*	*coli*	O45	MSU	TW10121	Human	-	-	-	-	-	Neg
54	*Escherichia*	*coli*	O45	MSU	TW14003	Human	-	-	-	-	-	Neg
55	*Escherichia*	*coli*	O45	MSU	TW07947	Human	-	-	-	-	-	Neg
56	*Escherichia*	*coli*	O45	MSU	DEC 11C	Human	-	-	-	-	-	Neg
57	*Escherichia*	*coli*		NBRC	13500	Not Available	-	-	-	-	-	Neg
58	*Escherichia*	*coli*		Q Labs	030716-1A	Ground Beef	-	-	-	-	-	Neg
59	*Escherichia*	*coli*		Q Labs	17041-11	Raw Milk Isolate	-	-	-	-	-	Neg
60	*Escherichia*	*coli*	O163	NCTC	11021	Feces	-	-	-	-	-	Neg
61	*Escherichia*	*coli*	O26:H11	MSU	DEC10E	Calf, Cow	-	-	-	-	-	Neg
62	*Escherichia*	*coli*	O55:H6	MSU	DEC1A	Feces, Human Infant	-	-	-	-	-	Neg
63	*Escherichia*	*coli*	O91	NCTC	9091	Not Available	-	-	-	-	-	Neg
64	*Escherichia*	*coli*	O103	PSU	5.1658	Not Available	-	-	-	-	-	Neg
65	*Escherichia*	*coli*	O103	PSU	7.1691	Not Available	-	-	-	-	-	Neg
66	*Escherichia*	*coli*	O103	PSU	9.0036	Not Available	-	-	-	-	-	Neg
67	*Escherichia*	*coli*	O111:H8	Q Labs	12289-3A	Not Available	-	-	-	-	-	Neg
68	*Escherichia*	*coli*	O121	PSU	5.0959	Not Available	-	-	-	-	-	Neg
69	*Escherichia*	*coli*	O121	PSU	7.1686	Not Available	-	-	-	-	-	Neg
70	*Escherichia*	*coli*	O121	PSU	7.1709	Not Available	-	-	-	-	-	Neg
71	*Escherichia*	*coli*	O121	PSU	7.1732	Not Available	-	-	-	-	-	Neg
72	*Escherichia*	*coli*	O121	PSU	10.0709	Not Available	-	-	-	-	-	Neg
73	*Escherichia*	*coli*	O145	PSU	7.1711	Not Available	-	-	-	-	-	Neg
74	*Escherichia*	*coli*	O145	PSU	10.0707	Not Available	-	-	-	-	-	Neg
75	*Escherichia*	*coli*	O145	PSU	10.0708	Not Available	-	-	-	-	-	Neg
76	*Escherichia*	*coli*	O145	PSU	10.1438	Not Available	-	-	-	-	-	Neg
77	*Escherichia*	*coli*	O45	PSU	1.2622	Not Available	-	-	-	-	-	Neg
78	*Escherichia*	*coli*	O45	PSU	1.2635	Not Available	-	-	-	-	-	Neg
79	*Escherichia*	*coli*	O45	PSU	2.0164	Not Available	-	-	-	-	-	Neg
80	*Escherichia*	*coli*	O45	PSU	6.3127	Not Available	-	-	-	-	-	Neg
81	*Aeromonas*	*hydrophila*		ATCC	49140	Clinical Isolate	-	-	-	N/A	N/A	Neg
82	*Alcaligenes*	*faecalis*		ATCC	8750	Not Available	-	-	-	N/A	N/A	Neg
83	*Cronobacter*	*sakazakii*		QL	17031.4	Infant Formula	-	-	-	-	-	Neg
84	*Edwardsiella*	*tarda*		ATCC	15947	feces, human	-	-	-	-	-	Neg
85	*Escherichia*	*blattae*		ATCC	29907	insect (hindgut of cockroach)	-	-	-	-	-	Neg
86	*Escherichia*	*hermannii*		ATCC	33650	Mouse Brain	-	-	-	-	-	Neg
87	*Escherichia*	*vulneris*		ATCC	29943	Human Wound	-	-	-	-	-	Neg
88	*Haemophilus*	*influenzae*		ATCC	19418	Not Available	-	-	-	N/A	N/A	Neg
89	*Hafnia*	*alvei*		ATCC	51815	milk, Minnesota	-	-	-	-	-	Neg
90	*Klebsiella*	*pneumoniae*		ATCC	4352	Not Available	-	-	-	-	-	Neg
91	*Kluyvera*	*intermedia*		ATCC	33110	surface water	-	-	-	-	-	Neg
92	*Mycobacterium*	*smegmatis*		ATCC	19420	Not Available	-	-	-	-	-	Neg
93	*Pantoea*	*agglomerans*		ATCC	19552	sewage	-	-	-	-	-	Neg
94	*Proteus*	*mirabilis*		ATCC	7002	Urine	-	-	-	-	-	Neg
95	*Providencia*	*rettgeri*		ATCC	14505	Not Available	-	-	-	-	-	Neg
96	*Serratia*	*marcescens*		ATCC	13880	Not Available	-	-	-	-	-	Neg
97	*Shigella*	*boydii*		ATCC	9290	Pork Liver	-	-	-	-	-	Neg
98	*Siccibacter*	*turicensis*		CCUG	54945	Not Available	-	-	-	N/A	N/A	Neg
99	*Sphingomonas*	*paucimobilis*		ATCC	29837	Hospital Respirator	-	-	-	N/A	N/A	Neg
100	*Vibrio*	*vunificus*		QL	02111-1A	Seafood Product	-	-	-	N/A	N/A	Neg