

**NF VALIDATION**  
**Validation of alternative analytical methods**  
*Application in food microbiology*

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

**3M™ Molecular Detection Assay 2 -  
E. coli O157 (including H7)**  
(Certificate number: 3M 01/18 - 05/17)  
for the detection of *Escherichia coli* O157 (including H7)  
in raw beef meats, raw dairy products, raw fruits and vegetables

**Qualitative method**








<i>Expert Laboratory:</i>	<b>ADRIA Développement</b> ZA Creac'h Gwen 29196 Quimper Cedex (France)
<i>For:</i>	<b>3M</b> 2501 Hudson Road Building 275 5W 05 MN 55144 - IWO - St Paul (USA)

This report consists of 83 pages, including 7 appendices.

Only copies including the totality of this report are authorized.

Competencies of the laboratory are certified by COFRAC accreditation for the analyses marked with the symbol♦.

Version 0  
May 6, 2021

<b>1</b>	<b>INTRODUCTION</b>	<b>4</b>
<b>2</b>	<b>METHOD PROTOCOLS</b>	<b>4</b>
<b>2.1</b>	<b>Alternative method</b>	<b>4</b>
2.1.1	<i>Principle</i>	4
2.1.2	<i>Protocol</i>	5
2.1.3	<i>Restrictions</i>	5
<b>2.2</b>	<b>Reference method</b>	<b>6</b>
<b>2.3</b>	<b>Study design</b>	<b>6</b>
<b>3</b>	<b>INITIAL VALIDATION STUDY AND EXTENSION/RENEWAL STUDIES: RESULTS</b>	<b>6</b>
<b>3.1</b>	<b>Method comparison study</b>	<b>6</b>
3.1.1	<i>Sensitivity study</i>	6
3.1.2	<i>Relative level of detection</i>	16
3.1.3	<i>Inclusivity / exclusivity</i>	18
3.1.4	<i>Practicability</i>	19
<b>3.2</b>	<b>Inter-laboratory study</b>	<b>21</b>
3.2.1	<i>Study organisation</i>	21
3.2.2	<i>Experimental parameters controls</i>	22
3.2.3	<i>Results analysis</i>	25
3.2.4	<i>Calculation and interpretation</i>	28
<b>3.3</b>	<b>Conclusion</b>	<b>31</b>
	<i>Appendix 1 – Flow diagram of the alternative method: 3M™ Molecular Detection Assay 2 - E. coli O157 (including H7)</i>	33
	<i>Appendix 2 – Flow diagram of the reference method: ISO 16654 (2011): Microbiology of food and animal feeding stuffs - Horizontal method for the detection of Escherichia coli O157 - Amendment 1 (March 2017): annex B: result of inter-laboratory studies</i>	34
	<i>Appendix 3 – Artificial contamination of samples</i>	35
	<i>Appendix 4 – Sensitivity study: raw data</i>	41
	<i>Appendix 5 – Relative level of detection study: raw data</i>	61
	<i>Appendix 6 – Inclusivity and exclusivity study: raw data</i>	64
	<i>Appendix 7 - Results obtained by the collaborative laboratories and the expert laboratory</i>	68

Quality Assurance documents related to this study can be consulted upon request from **3M**.

The technical protocol and the result interpretation were realized according to the EN ISO 16140-2:2016 and the AFNOR technical rules (PR revision 7).

<b>Validation protocols</b>	<ul style="list-style-type: none"> <li>▪ ISO 16140-1 (2016): Microbiology of the food chain - Method validation — <i>Part 1: Vocabulary</i></li> <li>▪ ISO 16140-2(2016): Microbiology of the food chain - Method validation — <i>Part 2: Protocol for the validation of alternative (proprietary) methods against a reference method</i></li> <li>▪ AFNOR technical rules (PR Revision 7)</li> </ul>
<b>Reference method<sup>♦</sup></b>	<ul style="list-style-type: none"> <li>▪ EN ISO 16654 (July 2001): Microbiology of food and animal feeding stuffs - Horizontal method for the detection of <i>Escherichia coli</i> O157</li> <li>▪ ISO 16654/A1 (March 2017): Microbiology of food and animal feeding stuffs - Horizontal method for the detection of <i>Escherichia coli</i> O157 - Amendment 1: annex B: result of inter-laboratory studies</li> </ul>
<b>Alternative method</b>	<b>3M™ Molecular Detection Assay 2 - <i>E. coli</i> O157 (including H7)</b>
<b>Scope</b>	<ul style="list-style-type: none"> <li><input checked="" type="checkbox"/> <b>Raw beef meats</b></li> <li><input checked="" type="checkbox"/> <b>Raw dairy products</b></li> <li><input checked="" type="checkbox"/> <b>Raw fruits and vegetables</b></li> </ul>
<b>Certification organism</b>	AFNOR Certification ( <a href="http://nf-validation.afnor.org/">http://nf-validation.afnor.org/</a> )

<sup>♦</sup> Analyses performed according to the COFRAC accreditation

## 1 INTRODUCTION

---

The 3M™ Molecular Detection Assay 2 - *E. coli* O157 (including H7) was validated in May 2017 (Certificate number: 3M 01/18 - 05/17), according to the NF EN ISO 16140-2 (June 2016) and the AFNOR technical rules.

The following criteria were evaluated during the method comparison study:

- Sensitivity study,
- Relative level of detection,
- Inclusivity and exclusivity,
- Practicability.

Based on the fact that the changes to the kit concern the lysis solution, and a reduction of the detection run time from 75 minutes to 60 minutes, the inter-laboratory study was not run again, the results of the inter-laboratory study of the first version of the kit was interpreted following to the EN ISO 16140-2:2016.

The method was renewed in April 2021.

## 2 METHOD PROTOCOLS

---

### 2.1 Alternative method

The flow diagram of the alternative method is provided in **Appendix 1**.

#### 2.1.1 Principle

The **3M™ Molecular Detection Assay** uses loop-mediated isothermal amplification to rapidly amplify nucleic acid sequences with high specificity and sensitivity, combined with bioluminescence to detect the amplification.

The software version which was used for the study was the 2.2.0.

The difference between this version of the kit (Issue date: 2016.02) and the previous one of the 3M™ Molecular Detection Assay *E. coli* O157 (including H7) concerns the lysis solution, and a reduction of the run time from 75 minutes to 60 minutes. The detection kit has not been modified and excepting the run time there is no other change in the algorithm.

### 2.1.2 Protocol

The protocol is the following:

- Enrichment step in pre-warmed Buffered Peptone Water (BPW):
  - \* 8 – 24 h at 41.5°C for raw beef meat;
  - \* 18 – 24 h at 41.5°C for raw dairy products, and raw fruits and vegetables;
- Sample lysis on 20 µl enriched sample
- DNA amplification on 20 µl lysate
- **Confirmation:**
  - \* Option 1: Using the ISO 16654 standard starting from the buffered peptone water (BPW) enrichment.
  - \* Option 2: Implementing a confirmation method consisting of the following: streak 50 µl of the BPW enrichment onto CT-SMAC agar plate. Incubate for 24 h ± 3 h at 37°C. Streak characteristic colonies onto nutrient agar and perform latex agglutination test directly onto isolated colonies. If the 3M Molecular Detection Assay *E. coli* O157 (including H7) results are not confirmed, perform an immunomagnetic separation step and then streak 50 µl onto CT-SMAC.
  - \* Option 3: Using nucleic acid probes as described in the EN ISO 7218 standard, performed on isolate colonies (purified or not) from CT-SMAC (see option 1 or 2). The nucleic acid probes must be different from those used in the 3M Molecular Detection Assay *E. coli* O157 (including H7).
  - \* Option 4: Using any other method certified NF VALIDATION, the principle of which must be different from 3M Molecular Detection Assay *E. coli* O157 (including H7). The complete protocol described for this second validated method must be used. All steps prior to the start of confirmation must be common to both methods.

It is possible to store the enrichment and the lysates for 72 h at 5°C ± 3°C in order to offer sufficient practicability to the users.

### 2.1.3 Restrictions

There is no restriction.

## 2.2 Reference method♦

The reference method used for the previous study corresponds to the ISO 16654 method (2001): Microbiology of food and animal feeding stuffs - Horizontal method for the detection of *Escherichia coli* O157.

The reference methods used for the renewal study correspond to the ISO 16654 method (2011): Microbiology of food and animal feeding stuffs - Horizontal method for the detection of *Escherichia coli* O157 and the ISO 16654/A1 (March 2017): Microbiology of food and animal feeding stuffs - Horizontal method for the detection of *Escherichia coli* O157 - Amendment 1: annex B: result of inter-laboratory studies (See **Appendix 2**).

## 2.3 Study design

The study is **an unpaired study design** as the reference and the alternative methods have different enrichment procedures.

# 3 INITIAL VALIDATION STUDY AND EXTENSION/RENEWAL STUDIES: RESULTS

---

## 3.1 Method comparison study

***The method comparison study is a study performed by the expert laboratory to compare the alternative method with the reference method.***

*The study was carried out on a diversity of samples and strains representative of agri-food products. This does not constitute an exhaustive list of the different matrices included in the scope.*

*For any comment on the alternative method, please contact AFNOR Certification at <http://nf-validation.afnor.org/contact-2/>.*

### 3.1.1 Sensitivity study

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

### 3.1.1.1 Number and nature of samples

**187 samples** were analyzed. The distribution per tested category and type is given in Table 1.

**Table 1 – Distribution per tested category and type**

Category		Type	Positive	Negative	Total
1	Raw beef meats (Protocol 8h)	a Raw	11	10	21
		b Frozen	9	11	20
		c Seasoned (raw and frozen)	10	11	21
		Total	30	32	62
	Raw beef meats (Protocol 24h)	a Raw	11	10	21
		b Frozen	9	11	20
		c Seasoned (raw and frozen)	10	11	21
		Total	30	32	62
2	Raw dairy products	a Raw milk	12	9	21
		b Raw milk cheeses	11	9	20
		c Raw milk-based products	11	12	23
		Total	34	30	64
3	Raw fruits and vegetables	a Leafy greens	11	10	21
		b Sprouts	10	10	20
		c Fruit juices and fermented juices	10	10	20
		Total	31	30	61
All categories (Raw meat - 8 h)			95	92	187
All categories (Raw meat - 24 h)			95	92	187

### 3.1.1.2 Artificial contamination of samples

Artificial contaminations were done by seeding. The artificial contaminations are presented in **Appendix 3**.

129 samples were artificially contaminated, using 32 different strains. 95 gave a positive result. 71 samples were inoculated at level  $\leq 3$  CFU and 24 samples were inoculated between 3.2 and 4.6 CFU.

The repartition of the positive samples per inoculation protocol and inoculation level is given in Table 2.

**Table 2 - Repartition of the positive samples per inoculation protocol and inoculation level**

	Naturally contaminated samples	Artificially contaminated samples		Total
		$x \leq 3$ CFU/sample	$3 < x \leq 4.6$ CFU/sample	
Number of samples	0	71	24	95
%	0.0%	74.7%	25.3%	100.0%

25.3% of the samples were inoculated between 3 and 4.6 CFU. According to the AFNOR Technical rules (PR rev 7), only 20 % of the samples should be contaminated between 3 (spiking protocol) or 5 (seeding protocol) and 10 CFU but this percentage was accepted by the AFNOR Technical Committee.

**100 % of the samples were artificially contaminated.**

### 3.1.1.3 Protocols applied during the validation study

#### Incubation time

The minimum and maximum incubation times were applied for the raw beef meat category, *i.e.* 8 h and 24 h and the minimum time, *i.e.* 18 h for the other categories.

#### Confirmations

During the validation, the following confirmatory tests were applied:

- Direct streaking (50  $\mu$ l) of BPW onto CT-SMAC;
- IMS step before streaking (50  $\mu$ l) onto CT-SMAC when no typical colony was observed onto CT-SMAC.

The typical colonies were then tested using latex tests after purification step on non-selective agar plate (O157 and H7) and indole test.

#### Enrichment and lysates storage for 72 h at 5°C $\pm$ 3°C

The enrichment broths and the lysates of positive and discordant samples were stored for 72 h at 5°C  $\pm$  3°C and tested again.



### 3.1.1.4 Test results

Raw data per category are given in **Appendix 4**. The results are given in Table 3.

**Table 3 – Interpretation of sample results between the reference and alternative method (based on the confirmed alternative)**

Category		PA	NA*	PD	ND**	PPND	PPNA
1	Raw beef meats (Protocol 8h)	19	32	4	7	0	0
	Raw beef meats (Protocol 24h)	19	32	4	7	0	0
2	Raw dairy products	24	30	8	2	0	0
3	Raw fruits and vegetables	14	25	11	6	0	5
All categories (Raw meat - 8 h)		57	87	23	15	0	5
All categories (Raw meat - 24 h)		57	87	23	15	0	5

\* PPNA not included

\*\* PPND not included

### 3.1.1.5 Calculation of relative trueness (RT), sensitivity (SE) and false positive ratio (FPR)

The calculations are presented in Table 4.

**Table 4 – Calculation of the relative trueness (RT), the sensitivity (SE) and the false positive ratio (FPR)**

Category		Type	PA	NA*	PD	ND**	PPND	PPNA	SE <sub>alt</sub> %	SE <sub>ref</sub> %	RT %	FPR %
1	Raw beef meats (Protocol 8h)	a Raw	8	10	1	2	0	0	81.8	90.9	85.7	0.0
		b Frozen	7	11	1	1	0	0	88.9	88.9	90.0	0.0
		c Seasoned (raw and frozen)	4	11	2	4	0	0	60.0	80.0	71.4	0.0
		Total	19	32	4	7	0	0	76.7	86.7	82.3	0.0
	Raw beef meats (Protocol 24h)	a Raw	8	10	1	2	0	0	81.8	90.9	85.7	0
		b Frozen	7	11	1	1	0	0	88.9	88.9	90.0	0.0
		c Seasoned (raw and frozen)	4	11	2	4	0	0	60.0	80.0	71.4	0.0
		Total	19	32	4	7	0	0	76.7	86.7	82.3	0.0
2	Raw dairy products	a Raw milk	11	9	0	1	0	0	91.7	100.0	95.2	0.0
		b Raw milk cheeses	5	9	5	1	0	0	90.9	54.5	70.0	0.0
		c Raw milk-based products	8	12	3	0	0	0	100.0	72.7	87.0	0.0
		Total	24	30	8	2	0	0	94.1	76.5	84.4	0.0
3	Raw fruits and vegetables	a Leafy greens	4	10	4	3	0	0	72.7	63.6	66.7	0.0
		b Sprouts	4	9	4	2	0	1	80.0	60.0	70.0	11.1
		c Fruit juices and fermented juices	6	6	3	1	0	4	90.0	70.0	80.0	66.7
		Total	14	25	11	6	0	5	80.6	64.5	72.1	16.7
<b>All categories (Raw meat - 8 h)</b>			<b>57</b>	<b>87</b>	<b>23</b>	<b>15</b>	<b>0</b>	<b>5</b>	<b>84.2</b>	<b>75.8</b>	<b>79.7</b>	<b>5.4</b>
<b>All categories (Raw meat - 24 h)</b>			<b>57</b>	<b>87</b>	<b>23</b>	<b>15</b>	<b>0</b>	<b>5</b>	<b>84.2</b>	<b>75.8</b>	<b>79.7</b>	<b>5.4</b>

\* PPNA not included

\*\* PPND not included

A summary of the results is given in Table 5.

**Table 5 - Summary of results**

		<b>All categories</b> (8 h and 24 h incubation time for raw beef meat)
<b>Sensitivity for the alternative method</b>	$SE_{alt} = \frac{(PA + PD)}{(PA + ND + PD)} \times 100\%$	84.2 %
<b>Sensitivity for the reference method</b>	$SE_{ref} = \frac{(PA + ND +)}{(PA + ND + PD)} \times 100\%$	75.8 %
<b>Relative trueness</b>	$RT = \frac{(PA + NA)}{N} \times 100\%$	79.7 %
<b>False positive ratio for the alternative method*</b> FP = PPNA + PPND	$FPR = \frac{(FP)}{NA} \times 100\%$	5.4 %

With  $ND = ND + PPND$   
 $NA = NA + PPNA$

The false positive ratio (5.4 %) is due to the positive presumptive MDA tests obtained in the raw fruits and vegetables category.

### 3.1.1.6 Analysis of discordant results

The negative deviations are given in Table 6 and the positive deviations in Table 7.

**Table 6 - Negative deviations**

Sample N°	Product	Inoculated strain	Inoculation level (CFU/samples)	MDA test result	Confirmation	Final result	Agreement	Category	Type
7630	Frozen seasoned beef meat	<i>E. coli</i> O157:H7 Ad976	3.0	-	-	-	ND	1	c
7639	Frozen ground beef meat	<i>E. coli</i> O157:H7 Ad1174	3.0	-	-	-	ND	1	b
7910	Raw beef meat	<i>E. coli</i> O157:H7 Ad486	2.2	-	-	-	ND	1	a
8132	Raw beef meat	<i>E. coli</i> O157:H7 Ad585	1.8	-	-	-	ND	1	a
8143	Seasoned raw ground beef	<i>E. coli</i> O157:H7 Ad587	1.0	-	-	-	ND	1	c
8144	Seasoned Carpaccio	<i>E. coli</i> O157:H7 Ad586	2.0	-	-	-	ND	1	c
119	Beef Carpaccio	<i>E. coli</i> O157:H7 Ad560	1.4	-	-	-	ND	1	c
7762	Raw milk	<i>E. coli</i> O157:H7 Ad572	3.0	-	-	-	ND	2	a
252	Raw milk cheese	<i>E. coli</i> O157:H7 Ad1745	1.8	-	-	-	ND	2	b
7767	Green salad	<i>E. coli</i> O157:H7 Ad575	2.6	-	-	-	ND	3	a
7770	Sprouts	<i>E. coli</i> O157:H7 Ad557	2.2	-	-	-	ND	3	b
8036	Salad	<i>E. coli</i> O157:H7 Ad556	3.6	-	-	-	ND	3	a
263	Salad	<i>E. coli</i> O157:H7 Ad580	2.6	-	-	-	ND	3	a
646	Fruit juice	<i>E. coli</i> O157:H7 Ad577	0.8	-	-	-	ND	3	c
843	Sprouts	<i>E. coli</i> O157:H7 Ad577	2.0	-	-	-	ND	3	b

The presence of *E. coli* O157:H7 was not confirmed in the enrichment broth of the samples in negative deviations. These results were probably due to the unpaired study design.

Table 7 - Positive deviations

Sample N°	Product	Inoculated strain	Inoculation level (CFU/samples)	MDA test result	Confirmation	Final result	Agreement	Category	Type
7632	Frozen ground beef meat	<i>E. coli</i> O157:H7 Ad683	1.6	+	+	+	PD	1	b
7905	Seasoned beef	<i>E. coli</i> O157:H7 Ad486	2.2	+	+	+	PD	1	c
8134	Raw ground beef	<i>E. coli</i> O157:H7 Ad585	1.8	+	+	+	PD	1	a
8142	Seasoned raw ground beef	<i>E. coli</i> O157:H7 Ad586	2.0	+	+	+	PD	1	c
7755	Raw milk cheese	<i>E. coli</i> O157:H7 Ad686	2.8	+	+	+	PD	2	b
8024	Raw butter	<i>E. coli</i> O157:H7 Ad567	3.8	+	+	+	PD	2	c
35	Raw milk cheese	<i>E. coli</i> O157:H7 Ad570	2.8	+	+	+	PD	2	b
38	Raw milk cheese	<i>E. coli</i> O157:H7 Ad569	2.2	+	+	+	PD	2	b
254	Raw milk cheese	<i>E. coli</i> O157:H7 Ad1745	1.8	+	+	+	PD	2	b
256	Raw milk cheese	<i>E. coli</i> O157:H7 Ad581	1.4	+	+	+	PD	2	b
651	Fermented milk	<i>E. coli</i> O157:H7 Ad576	2.6	+	+	+	PD	2	c
1403	Fermented milk	<i>E. coli</i> O157:H7 Ad582	3.8	+	+	+	PD	2	c
7763	Lettuce	<i>E. coli</i> O157:H7 Ad575	2.6	+	+	+	PD	3	a
7771	Sprouts	<i>E. coli</i> O157:H7 Ad557	2.2	+	+	+	PD	3	b
8032	Salad	<i>E. coli</i> O157:H7 Ad556	3.6	+	+	+	PD	3	a
8035	Salad	<i>E. coli</i> O157:H7 Ad558	3.6	+	+	+	PD	3	a
8042	Grape juice	<i>E. coli</i> O157:H7 Ad2308	4.0	+	+	+	PD	3	c
8049	Apple juice	<i>E. coli</i> O157:H7 Ad571	3.4	+	+	+	PD	3	c
41	Sprouts	<i>E. coli</i> O157:H7 Ad574	1.6	+	+	+	PD	3	b
46	Sprouts	<i>E. coli</i> O157:H7 Ad573	4.6	+	+	+	PD	3	b
262	Salad	<i>E. coli</i> O157:H7 Ad580	2.6	+	+	+	PD	3	a
648	Fruit juice	<i>E. coli</i> O157:H7 Ad578	0.8	+	+	+	PD	3	c
842	Sprouts	<i>E. coli</i> O157:H7 Ad576	2.0	+	+	+	PD	3	b

The analyses of discordant results according to the EN ISO 16140-2:2016 is the following (See Table 8):

**Table 8 - Analyses of discordant results**

Category		Type	PD	ND	PPND	(ND+PPND)-PD	AL
1	Raw beef meats (Protocol 8h)	a Raw	1	2	0	1	3
		b Frozen	1	1	0	0	
		c Seasoned (raw and frozen)	2	4	0	2	
		Total	4	7	0	3	
	Raw beef meats (Protocol 24h)	a Raw	1	2	0	1	3
		b Frozen	1	1	0	0	
		c Seasoned (raw and frozen)	2	4	0	2	
		Total	4	7	0	3	
2	Raw dairy products	a Raw milk	0	1	0	1	3
		b Raw milk cheeses	5	1	0	-4	
		c Raw milk-based products	3	0	0	-3	
		Total	8	2	0	-6	
3	Raw fruits and vegetables	a Leafy greens	4	3	0	-1	3
		b Sprouts	4	2	0	-2	
		c Fruit juices and fermented juices	3	1	0	-2	
		Total	11	6	0	-5	
All categories (Raw meat - 8 h)			23	15	0	-8	5
All categories (Raw meat - 24 h)			23	15	0	-8	5

**The observed values for ((ND + PPND) - PD) meet the acceptability limit for each category and for all the combined categories.**

### 3.1.1.7 Enrichment broth and lysates storage at $5 \pm 3$ °C for 72 h

The following changes were observed (See Table 9).

**Table 9**

Sample N°	Product	Before BPW storage	Lysate storage	BPW storage
7748	Raw milk	NA	PD	NA
7769	Sprouts	PA	PA	ND

The analyses of discordant results become (See Tables 10 and 11).

**Table 10 - Analyses of discordant results  
after BPW storage for 72 h at 5°C ± 3°C**

Category		Type	PD	ND	PPND	(ND+PPND)-PD	AL
1	Raw beef meats (Protocol 8h)	a Raw	1	2	0		
		b Frozen	1	1	0		
		c Seasoned (raw and frozen)	2	4	0		
	Total		4	7	0	3	3
	Raw beef meats (Protocol 24h)	a Raw	1	2	0		
		b Frozen	1	1	0		
c Seasoned (raw and frozen)		2	4	0			
Total		4	7	0	3	3	
2	Raw dairy products	a Raw milk	0	1	0		
		b Raw milk cheeses	5	1	0		
		c Raw milk-based products	3	0	0		
	Total		8	2	0	-6	3
3	Raw fruits and vegetables	a Leafy greens	4	3	0		
		b Sprouts	4	3	0		
		c Fruit juices and fermented juices	3	1	0		
	Total		11	7	0	-4	3
All products (Raw meat - 8 h)			23	16	0	-7	5
All products (Raw meat - 24 h)			23	16	0	-7	5

**Table 11 - Analysis of discordant results  
after lysates storage for 72 h at 5 ± 3°C**

Category		Type	PD	ND	PPND	(ND+PPND)-PD	AL
1	Raw beef meats (Protocol 8h)	a Raw	1	2	0		
		b Frozen	1	1	0		
		c Seasoned (raw and frozen)	2	4	0		
	Total		4	7	0	3	3
	Raw beef meats (Protocol 24h)	a Raw	1	2	0		
		b Frozen	1	1	0		
c Seasoned (raw and frozen)		2	4	0			
Total		4	7	0	3	3	
2	Raw dairy products	a Raw milk	1	1	0		
		b Raw milk cheeses	5	1	0		
		c Raw milk-based products	3	0	0		
	Total		9	2	0	-7	3
3	Raw fruits and vegetables	a Leafy greens	4	3	0		
		b Sprouts	4	2	0		
		c Fruit juices and fermented juices	3	1	0		
	Total		11	6	0	-5	3
All products (Raw meat - 8 h)			24	15	0	-9	5
All products (Raw meat - 24 h)			24	15	0	-9	5

**The observed values for ((ND + PPND) - PD) meet the acceptability limit for each category and for the combined categories for both enrichment and lysates storage.**

### 3.1.1.8 Confirmation

For raw ground beef, all the positive MDA results were confirmed by direct streaking onto CT-SMAC.

For dairy products, for one sample (n° 246), an IMS step was required to confirm the presence of *E. coli* strain in the enrichment broth and for one sample (n° 245), a regrowth step in BHI for 24 h at 37°C (IMS, BHI, IMS) was necessary to the recovery of the strain.

For fruits and vegetables, 13 samples were not confirmed using direct streaking:

- For one sample (No 262), the *E. coli* O157:H7 strain was recovered when an IMS step was applied prior streaking onto CT-SMAC;
- For seven samples (No 8042, 40, 41, 43, 411, 46 and 842), the presence of *E. coli* O157:H7 was confirmed by proceeding to an IMS on BPW, incubation of immunobeads in BHI for 24 h at 37°C, IMS and streaking onto CT-SMAC;
- For five samples (No 8040, 8043, 8044, 8045 and 45), it was impossible to recover the strain in the enrichment broth. These samples are mainly in type c (fruit juices and fermented juices). The percentage of false positive ratio (FPR) for the category “Raw fruits and vegetables” is 16.7 %.

Additionally, one sample (n° 7748: raw cow milk) which gave a negative MDA test was confirmed by direct streaking onto CT-SMAC.

### 3.1.2 Relative level of detection

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

The RLOD is defined as the ratio of the alternative and reference methods:

$$RLOD = \frac{LOD_{Alt.}}{LOD_{Ref.}}$$



### 3.1.2.1 Experimental design

Three (matrix/strain) pairs were analyzed by the reference method and by the alternative method (See Table 12):

**Table 12 - Defined (matrix/strain) pairs for the RLOD determination**

	Category	Matrix	Inoculated strain	Origin	Storage conditions before analysis
1	Raw beef meats	Ground beef	<i>Escherichia coli</i> O157:H7 Ad486	Ground beef	48 h at 5°C ± 3°C
2	Raw dairy products	Raw milk	<i>Escherichia coli</i> O157:H7 Ad686	Bovine slaughterhouse environment	
3	Raw fruits and vegetables	Raw spinach	<i>Escherichia coli</i> O157:H7 Ad 556	Water treatment plant	

### 3.1.2.2 Calculation and interpretation of the RLOD

The raw data are given in **Appendix 5**.

The RLOD calculations were performed using the Excel spreadsheet available at <http://standards.iso.org/iso/16140> - RLOD (clause 5-1-4-2 Calculation and interpretation of RLOD) version 06.07.2015. The RLOD are given Table 13.

**Table 13 – Presentation of RLOD before and after confirmation of the alternative method results**

Category	Matrix/strain pair	RLOD	RLODL	RLODU	b=ln (RLOD)	sd(b)	z-Test statistic	p-value
1	Raw Ground beef/ <i>E. coli</i> O157:H7 Ad486 (8 h and 24 h incubation times)	1,322	0,549	3,186	0,279	0,440	0,635	0,526
2	Raw milk/ <i>E. coli</i> O157:H7 Ad686	0,563	0,179	1,774	-0,574	0,574	1,001	1,683
3	Raw spinach/ <i>E. coli</i> O157:H7 Ad556	1,186	0,417	3,371	0,170	0,522	0,326	0,744
<b>Combined results</b>		<b>1,000</b>	<b>0,565</b>	<b>1,770</b>	<b>0,000</b>	<b>0,286</b>	<b>0,000</b>	<b>1,000</b>

**The RLOD meet the AL fixed at 2.5 for an unpaired study design for the three tested matrix/strain pairs.**

The LOD<sub>50</sub> % calculations according to Wilrich & Wilrich POD-LOD calculation program - version 10, 2021.03.02 test are given in Table 14.

Table 14 - LOD<sub>50</sub> results

Category	Matrix / strain pair	Level of detection at 50% (CFU / sample size) according to Wilrich & Wilrich <sup>1</sup>	
		Reference method	Alternative method
1	Raw Ground beef/ <i>E. coli</i> O157:H7 Ad486 (8 h and 24 h incubation times)	0,454 [0,250;0,823]	0,597 (0,317;1,124]
2	Raw milk/ <i>E. coli</i> O157:H7 Ad686	1,253 [0,616; 2,551]	0,794 [0,407; 1,551]
3	Raw spinach/ <i>E. coli</i> O157:H7 Ad556	1,332 [0,676;2,627]	1,551 [0,773;3,112]
Combined results		0,918 [0,626; 1,346]	0,924 [0,630; 1,355]

The LOD<sub>50</sub> varies from 0.5 to 1.3 log CFU/test portion for the reference method and from 0.6 to 1.6 log CFU/test portion for the alternative method.

### 3.1.3 Inclusivity / exclusivity

The inclusivity is the ability of the alternative method to detect the target analyte from a wide range of strains. The exclusivity is the lack of interference from a relevant range of non-target strains of the alternative method.

#### 3.1.3.1 Test protocols

##### □ Inclusivity

As the most challenging protocol shall be used, it was proposed to run the inclusivity testing with the **short protocol** dedicated to raw beef (8 h incubation time).

*E. coli* O157 cultures were performed in BHI medium at 37°C. Dilutions were done in order to inoculate 10 cells/225 ml of pre-warmed BPW broth. The broths were incubated for 8 h at 41.5°C ± 1°C before performing the alternative method protocol. The confirmatory tests were applied on the enrichment broths.

<sup>1</sup> Wilrich, C., and P.-Th. Wilrich: Estimation of the POD function and the LOD of a qualitative microbiological measurement method. AOAC International **92** (2009) 1763 - 1772.

### **Exclusivity**

Negative strains cultures were performed in BHI at 37°C. Dilutions were realized in order to inoculate 10<sup>5</sup> cells/ml BPW. The BPW was then incubated for 24 h at 37°C ± 1°C. The alternative method was then performed.

#### 3.1.3.2 *Results*

Raw data are given in **Appendix 6**.

### **Inclusivity**

The 50 target strains gave positive MDA results as well as positive confirmatory tests.

### **Exclusivity**

No cross reaction was observed among the 30 strains tested.

**The 3M™ Molecular Detection Assay 2 - *E. coli* O157 (including H7) is specific and selective.**

#### 3.1.4 *Practicability*

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

<b>Storage conditions and shelf-life</b>	The storage temperature is: 2 – 8°C. The shelf-life is given on the package. All the reagents must be stored at the temperature mentioned on the package.			
<b>Time to result</b>	Steps	Reference Method	Alternative method	
			Protocol 8 h	Protocol 18 h
	<b>Negative samples</b>			
	Sampling / pre-enrichment	Day 0	/	Day 0
	IMS 6 h	Day 0	/	/
	IMS 24 h	Day 1	/	/
	MDA test	/	Day 0	Day 1
	Selective agar plate reading	Day 2	/	/
	Final negative result	Day 2	Day 0	Day 1
	<b>Presumptive positive or positive results</b>			
	Streaking onto CT SMAC	/	Day 0	Day 1
	Streaking onto nutrient agar	Day 1 – Day 2	Day 1	Day 2
	Indole test	Day 2 – Day 3	/	/
Latex test	Day 2 – Day 3	Day 1	Day 2	
<b>Common step with the reference method</b>	No common step			

Negative results are available within the day of initializing the analysis with the 3M™ Molecular Detection Assay 2 - *E. coli* O157 (including H7). Depending on the confirmation protocol, the positive results are available between 1 and 2 days.

The workflow of the 3M™ Molecular Detection Assay 2 - *E. coli* O157 (including H7) method allows shortening the handling time in comparison to the reference method.

## 3.2 Inter-laboratory study

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

### 3.2.1 Study organisation

#### Collaborators number

Samples were sent to 17 laboratories.

#### Matrix and strain used

The study was run with ground beef samples contaminated with *Escherichia coli* O157:H7.

#### Samples

The samples were inoculated and sent on Monday 21<sup>st</sup> January 2013, as described below:

- 24 codified samples (25 g) (red labeled) for *Escherichia coli* O157 research by the 3M™ Molecular *Escherichia coli* O157 (including H7) Test Kit,
- 24 codified samples (25 g) (blue labeled) for analyses by the ISO 16654 (2001) reference method,
- 1 ground beef sample (labeled “Sample for Total Count enumeration”) for aerobic mesophilic flora enumeration by ISO 4833 method,
- **1 water flask labeled “Temperature Control” with a temperature probe, which shall be incubated simultaneously with the samples during analysis (storage and alternative enrichment incubation).**

The analyses were started on Wednesday 23<sup>rd</sup> January 2013.

### *Inoculation*

The targeted inoculation levels were:

- 0 CFU/25 ml,
- 1 – 10 CFU/25 ml,
- 5 – 50 CFU/25 ml.

8 samples were prepared per inoculation level, per method and per laboratory. Each laboratory received 24 samples to analyze by the reference method and 24 samples to analyze by the alternative method.

### *Labeling and shipping*

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

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

Samples were shipped in 24 h to 72 h to the involved laboratories. The temperature conditions had to stay lower or equal to 8.4°C during transport, and between 0°C – 8.4°C in the labs.

### *Analyses*

Collaborators and ADRIA Développement carried out the analyses with the alternative and reference methods at Day 2.

## **3.2.2 Experimental parameters controls**

### *3.2.2.1 Strain stability and background microflora stability*

In order to detect *Escherichia coli* O157, the ISO 16654 method was performed on five ground beef test portions (25 g) before the inoculation. All the results were negative.

Sample stability was checked by inoculating the matrix at 25 CFU/25 g and 3 CFU/g. Enumerations were performed for the high contamination level and

detection analyses were performed for the low contamination level. *Triplicates* were analyzed, and the results were the following (See Table 15).

**Table 15 - Sample stability**

Day	Reference method (detection)			CFU/g (XLD)			Aerobic mesophilic flora (CFU/g)
	Sample 1	Sample 2	Sample 3	Sample 1	Sample 2	Sample 3	
Day 0	+	+	+	102	100	126	2.0 10 <sup>3</sup>
Day 1	-	+	+	92	106	186	2.4 10 <sup>3</sup>
Day 2	-	-	+	100	112	126	1.5 10 <sup>3</sup>

No evolution was observed during storage at 5°C ± 3°C.

### 3.2.2.2 Contamination levels

The contamination levels and the sample codification were the following (see Table 16).

**Table 16 - Contamination levels**

Level	Samples	Theoretical target level (b/25 g)	True level (b/25 g sample)	Low limit / 25 g sample	High limit / 25 g sample
Level 0	4 – 6 – 9 – 12 – 13 – 17 – 22 – 23	/	/	/	/
Low level	1 – 3 – 8 – 10 – 16 – 20 – 21 – 24	3	3	2.4	3.4
High level	2 – 5 – 7 – 11 – 14 – 15 – 18 – 19	25	20.4	17.7	23.5

### 3.2.2.3 Logistic conditions

Temperature conditions are given in Table 17.

**Table 17 - Sample temperatures at receipt**

Laboratories	Temperature measured by the sensor (°C)	Temperature measured at receipt (°C)	Receipt date and time	
A	<i>Register problem encountered with the probe</i>	5.0	22 January 2013	10h00
B	0.5	3.0	22 January 2013	14h00
C	0.	2.1	22 January 2013	11h00
D	1.0	2.3	22 January 2013	09h13
E	1.0	3.0	23 January 2013	10h30
F	0.0	2.1	22 January 2013	07h30
G	0.5	3.9	22 January 2013	09h40
H	1.0	1.5	22 January 2013	11h00
I	0.0	4.0	22 January 2013	11h00
J	0.5	2.7	22 January 2013	09h30
K	1.0	3.8	22 January 2013	11h00
L	<i>Did not participate to the ring trial</i>			
M	<i>Received the samples but did not participate to the ring trial</i>			
N	0.5	1.0	22 January 2013	11h20
O	1.5	3.8	22 January 2013	12h30
P	1.0	1.6	22 January 2013	12h00
Q	2.0	7.7	22 January 2013	09h15

No problem was encountered during the transport or at receipt for 14 labs.

One Lab (E) received its package at Day 2, but in cold conditions (register during shipment, storage and analysis).

Lab L decided to not take part to the ring trial.

Lab M received the samples but did not proceed to the analysis.

**Finally, 15 Labs participated to the ring trial.**



### 3.2.3 Results analysis

The raw data are given in **Appendix 7**.

#### 3.2.3.1 Expert laboratory results

The results obtained by the expert laboratory are given in Table 18.

**Table 18 – Results obtained by the expert Lab.**

Level	Reference method	Alternative method
L0	0/8	0/8
L1	4/8	8/8
L2	8/8	8/8

Fractional positive results were observed for the low inoculation level with the reference method; all the inoculated samples gave positive results with the alternative method.

#### 3.2.3.2 Results observed by the collaborative laboratories

##### **Aerobic mesophilic flora enumeration**

Depending on the Lab results, the enumeration levels varied from  $1.9 \cdot 10^2$  to  $2.5 \cdot 10^3$  CFU/g.

##### **Escherichia coli O157:H7 detection**

15 collaborators participated to the study. The results obtained for the reference method are provided in Table 19 (reference method) and Table 20 (alternative method).

**Table 19 - Positive results by the reference method (ALL the collaborators)**

Laboratory	Contamination level		
	L0	L1	L2
A	0	6	8
B	0	8	8
C	0	8	8
D	0	8	8
E	0	8	8
F	2	7	8
G	1	7	8
H	0	7	8
I	1	7	8
J	1	8	8
K	2	8	8
N	0	7	8
O	1	8	8
P	1	5	8
Q	4	7	8
<b>Total</b>	<b>P<sub>0</sub> = 13</b>	<b>P<sub>1</sub> = 109</b>	<b>P<sub>2</sub> = 120</b>

**Table 20 - Positive results (before and after confirmation) by the alternative methods (ALL the collaborators)**

Laboratory	Contamination level					
	L0		L1		L2	
	Before confirmation	After confirmation	Before confirmation	After confirmation	Before confirmation	After confirmation
A	0	0	7	7	8	8
B	0	0	7	7	8	8
C	1	0	7	7	8	8
D	0	0	8	8	8	8
E	1	0	7	7	8	8
F	0	0	2	2	8	8
G	0	0	8	8	8	8
H	0	0	8	8	8	8
I	0	0	8	8	8	8
J	0	0	6	6	8	8
K	0	0	4	4	6	6
N	0	0	8	8	8	8
O	1	0	5	4	8	8
P	0	0	8	8	8	8
Q	0	0	7	7	8	8
<b>Total</b>	<b>P<sub>0</sub> = 3</b>	<b>CP<sub>0</sub> = 0</b>	<b>P<sub>1</sub> = 100</b>	<b>CP<sub>1</sub> = 99</b>	<b>P<sub>2</sub> = 118</b>	<b>CP<sub>2</sub> = 118</b>

Unexpected data were observed for 8 Labs on unspiked samples using the reference method and for 3 labs using the alternative method (positive MDA tests not confirmed). Unfortunately, it was not possible to run additional testing to explain the observed data.

According to the AFNOR technical rules, it is possible to include the results from a collaborator with maximum one cross contamination at Level 0. For this

study, this rule was applied and the results from 3 Labs (F, K and Q) were excluded.

### 3.2.3.3 Results of the collaborators retained for interpretation

The results obtained with the 12 labs kept for interpretation are presented in Table 21 (reference method) and Table 22 (alternative method).

**Table 21 - Positive results by the reference method (Without Labs F, K and Q)**

Laboratory	Contamination level		
	L0	L1	L2
A	0	6	8
B	0	8	8
C	0	8	8
D	0	8	8
E	0	8	8
G	1	7	8
H	0	7	8
I	1	7	8
J	1	8	8
N	0	7	8
O	1	8	8
P	1	5	8
<b>Total</b>	<b>P<sub>0</sub> = 5</b>	<b>P<sub>1</sub> = 87</b>	<b>P<sub>2</sub> = 96</b>

**Table 22 - Positive results (before and after confirmation)  
by the alternative methods (Without Labs F, K and Q)**

Laboratory	Contamination level					
	L0		L1		L2	
	Before confirmation	After confirmation	Before confirmation	After confirmation	Before confirmation	After confirmation
A	0	0	7	7	8	8
B	0	0	7	7	8	8
C	1	0	7	7	8	8
D	0	0	8	8	8	8
E	1	0	7	7	8	8
G	0	0	8	8	8	8
H	0	0	8	8	8	8
I	0	0	8	8	8	8
J	0	0	6	6	8	8
N	0	0	8	8	8	8
O	1	0	5	4	8	8
P	0	0	8	8	8	8
<b>Total</b>	<b>P<sub>0</sub> = 3</b>	<b>CP<sub>0</sub> = 0</b>	<b>P<sub>1</sub> = 87</b>	<b>CP<sub>1</sub> = 86</b>	<b>P<sub>2</sub> = 96</b>	<b>CP<sub>2</sub> = 96</b>

### 3.2.4 Calculation and interpretation

#### 3.2.4.1 Calculation of the specificity percentage (SP)

The percentage specificities (SP) of the reference method and of the alternative method, using the data after confirmation, based on the results of level L0 are the following (See Table 23).

**Table 23 - Percentage specificity**

Specificity for the reference method	$SP_{ref} = \left(1 - \left(\frac{P_0}{N_-}\right)\right) \times 100 \% =$	94.8 %
Specificity for the alternative method	$SP_{alt} = \left(1 - \left(\frac{CP_0}{N_-}\right)\right) \times 100 \% =$	100.0 %

N: number of all L0 tests

$P_0$  = total number of false-positive results obtained with the blank samples before confirmation

$CP_0$  = total number of false-positive results obtained with the blank samples

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

Fractional positive results were obtained for the low inoculation level (L1). This inoculation level was retained for calculation.

A summary of the results of the collaborators retained for interpretation, and obtained with the reference and the alternative methods for Level 1 is provided in Table 24.

**Table 24 - Summary of the obtained results with the reference method and the alternative method for Level 1**

Response	Reference method positive (R+)	Reference method negative (R-)
Alternative method positive (A+)	Positive agreement (A+/R+) <b>PA = 77</b>	Positive deviation (R-/A+) <b>PD = 9</b>
Alternative method negative (A-)	Negative deviation (A-/R+) <b>ND = 10 (PPND = 1)</b>	Negative agreement (A-/R-) <b>NA = 0 (PPNA = 0)</b>

Based on the data summarized in Table 24, the values of sensitivity of the alternative and reference methods, as well as the relative trueness and false positive ratio for the alternative method taking account the confirmations, are the following (See Table 25).

**Table 25 - Sensitivity, relative trueness and false positive ratio percentages**

Sensitivity for the alternative method:	$SE_{alt} = \frac{(PA+PD)}{(PA+PD+ND)} \times 100\% =$	89.6 %
Sensitivity for the reference method:	$SE_{ref} = \frac{(PA+ND)}{(PA+PD+ND)} \times 100\% =$	90.6 %
Relative trueness	$RT = \frac{(PA+NA)}{N} \times 100\% =$	80.2 %
False positive ratio for the alternative method	$FPR = \frac{FP}{NA} \times 100\% =$	/

### 3.2.4.3 Interpretation of data

The negative deviations are listed in Table 26 for Level 1, and the positive deviations in Table 27 for Level 1.

**Table 26 - Negative deviations for Level 1**

Sample No	MDS Result	Confirmation
A20	-	-
B3	-	-
C8	-/-	-
E8	-	-
J1	-	+
J10	-	+
O1	-	-
O3	+	-
O20	-	-
O21	-	-

**Table 27 - Positive deviations for Level 1**

Sample No	MDS Result	Confirmation
A3	+	+
A8	+	+
G16	+	+
H20	+	+
I16	+	+
N16	+	+
P3	+	+
P21	+	+
P24	+	+

Among the 10 negative deviations obtained, the presence of *E. coli* O157 was confirmed in enrichment broth for 2 samples (J1 and J10).

For an **unpaired study design**, the difference between (ND – PD) is calculated for the level(s) where fractional recovery is obtained (so  $L_1$  and possibly  $L_2$ ). The observed value found for (ND – PD) shall not be higher than the AL. The AL is defined as  $[(ND - PD)_{\max}]$  and calculated per level where fractional recovery is obtained as described below using the following three parameters:

$$(p+)_{\text{ref}} = \frac{P_x}{N_x}$$

where

$P_x$  = number of samples with a positive result obtained with the reference method at level  $x$  ( $L_1$  or  $L_2$ ) for all the collaborators

$N_x$  = number of samples tested at level  $x$  ( $L_1$  or  $L_2$ ) with the reference method by all the collaborators

$$(p+)_{\text{alt}} = \frac{CP_x}{N_x}$$

where

$CP_x$  = number of samples with a confirmed positive result obtained with the alternative method at level  $x$  ( $L_1$  or  $L_2$ ) for all the collaborators;

$N_x$  = number of samples tested at level  $x$  ( $L_1$  or  $L_2$ ) with the alternative method by all the collaborators.

$$(ND-PD)_{\max} = \sqrt{3N_x \times \left( (p+)_{\text{ref}} + (p+)_{\text{alt}} - 2 \left( (p+)_{\text{ref}} \times (p+)_{\text{alt}} \right) \right)}$$

where

$N_x$  = number of samples tested for level  $x$  ( $L_1$  or  $L_2$ ) with the reference method by all the collaborators.

The AL is not met when the observed value is higher than the AL. When the AL is not met, investigations should be made (e.g. root cause analysis) in order to provide an explanation of the observed results. Based on the AL and the additional information, it is decided whether the alternative method is regarded as not fit for purpose. The reasons for acceptance of the alternative method when the AL is not met shall be stated in the study report.

In this study, fractional recovery was observed at Level 1. The calculations are the following, according to the EN ISO 16140-2:2016 (See Table 28).

**Table 28 - Calculations**

$N_X$	96
$(p^+)_{ref}$	0.91
$(p^+)_{alt}$	0.90
AL = (ND - PD) max	7.17
ND - PD	1
Conclusion	ND - PD $\leq$ AL

**The ISO 16140-2 (2016) requirements are fulfilled as (ND - PD) meet the AL.**

There is indeed no difference between the sensitivity of the compared methods, and the alternative method complies with the reproducibility conditions.

#### 3.2.4.4 Evaluation of the LOD<sub>50%</sub>, LOD<sub>95%</sub> and RLOD between laboratories

The RLOD was calculated using the EN ISO 16140-2:2016 Excel spreadsheet available at [https://standards.iso.org/iso/16140/-5/ed-1/en/RLOD\\_inter-lab-study\\_16140-2\\_AnnexF\\_ver1\\_28-06-2017.xls](https://standards.iso.org/iso/16140/-5/ed-1/en/RLOD_inter-lab-study_16140-2_AnnexF_ver1_28-06-2017.xls). The results are used only for information (see Table 29).

**Table 29 - LOD<sub>50%</sub>, LOD<sub>95%</sub> and RLOD**

Method	LOD 50%	LOD 95%	RLOD
Reference	0,79 [0,55;1,14]	3,41 [2,26;4,91]	1,00 [0,65;1,53]
Alternative	0,79 [0,55;1,14]	3,41 [2,26;4,91]	

### 3.3 Conclusion

The **method comparison study conclusions** are:

- ☒ The method comparison study scheme corresponds to an UNPAIRED STUDY design as the alternative and reference methods have different enrichment procedures.
- ☒ In the sensitivity study, three food categories were tested. The protocol of the alternative method shows 23 positive deviations (PD) and 15 negative deviations (ND) for the three tested categories. The ((ND + PPND) - PD) values are below or equal to the acceptability limits (AL)

whatever the categories, and as well for the three tested categories. The number of PD is higher than the number of ND.

- The Relative Levels of Detection (RLOD) are all below the AL fixed at 2.5 for the unpaired data study whatever the matrix/strain pairs.
- The inclusivity and exclusivity testing did give the expected results for the 50 target strains and the 30 non target strains.
- It is possible to store the enrichment broth and the lysates for 72 h at 5°C ± 3°C.
- The alternative method allows a screening of the negative samples within the day of initializing the analysis for the short protocol dedicated to raw beef meats category.
- The alternative method fulfils all the EN ISO 16140-2:2016 and AFNOR technical rules (PR revision 7).

The **inter-laboratory study conclusions** are:

- The data and interpretations comply with the EN ISO 16140-2:2016 requirements. **The 3M™ Molecular Detection Assay 2 - E. coli O157 (including H7) is considered equivalent to the ISO standard.**

Quimper, 06 May 2021

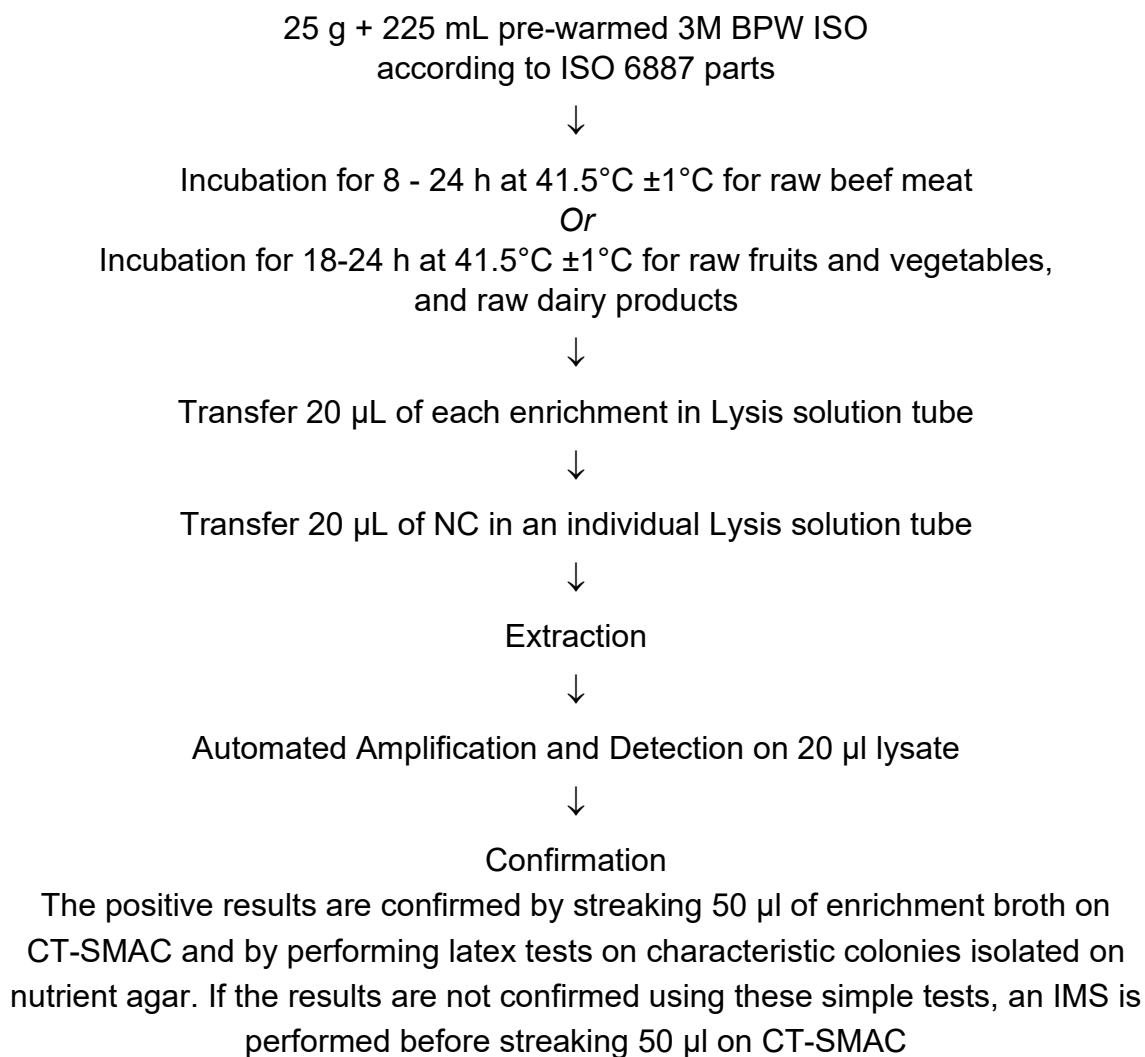
Maryse RANNOU  
Project Manager  
Validation of Alternative methods  
*Food Safety & Quality*



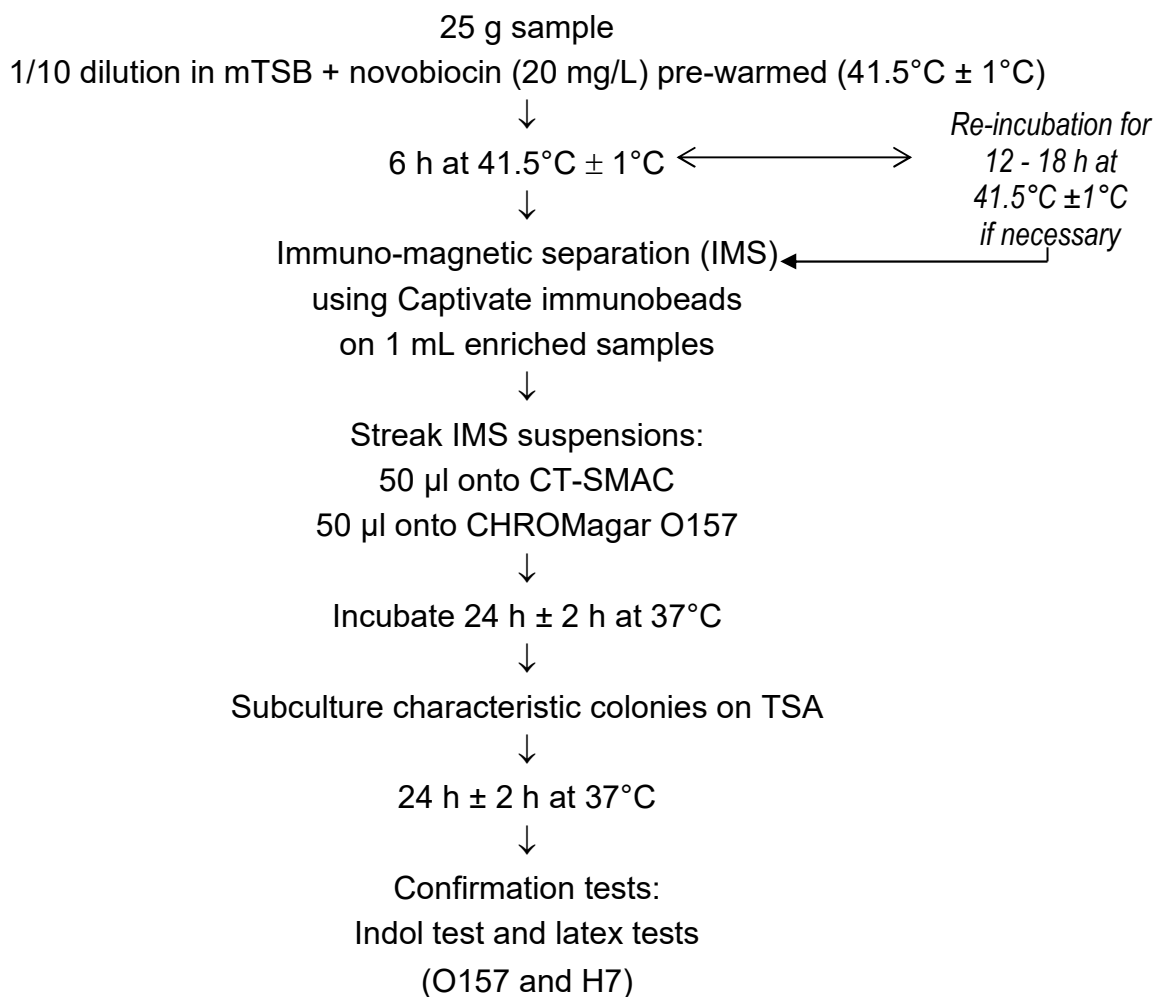
I hereby attest to the validation of the verification of the conformity of the report (opinion and interpretation).



**Appendix 1 – Flow diagram of the alternative method:  
3M™ Molecular Detection Assay 2 - *E. coli* O157 (including H7)**



**Appendix 2 – Flow diagram of the reference method: ISO 16654 (2011):  
Microbiology of food and animal feeding stuffs -  
Horizontal method for the detection of *Escherichia coli* O157 -  
Amendment 1 (March 2017): annex B: result of inter-laboratory studies**



### Appendix 3 – Artificial contamination of samples

Sample N°	Product (French name)	Product	Artificial contamination				Global result 8h
			Strain	Origin	Injury protocol	Inoculation rate/25g	
7628	Pavé de bœuf surgelé	Frozen beef meat	<i>E. coli</i> O157:H7 Ad683	Frozen beef meat	Seeding -20°C 15 days	1-2-1-1-3 (1.6)	+
7629	Effeuilé de charolais surgelé	Frozen beef meat	<i>E. coli</i> O157:H7 Ad683	Frozen beef meat	Seeding -20°C 15 days	1-2-1-1-3 (1.6)	+
7630	Pavé de rumsteak aux trois poivres surgelé	Frozen seasoned beef meat	<i>E. coli</i> O157:H7 Ad976	Beef meat	Seeding -20°C 15 days	5-1-3-1-5 (3.0)	+
7631	Steak haché surgelé	Frozen ground beef meat	<i>E. coli</i> O157:H7 Ad683	Frozen beef meat	Seeding -20°C 15 days	1-2-1-1-3 (1.6)	+
7632	Steak haché surgelé	Frozen ground beef meat	<i>E. coli</i> O157:H7 Ad683	Frozen beef meat	Seeding -20°C 15 days	1-2-1-1-3 (1.6)	+
7633	Steak haché pur bœuf surgelé	Frozen ground beef meat	<i>E. coli</i> O157:H7 Ad683	Frozen beef meat	Seeding -20°C 15 days	1-2-1-1-3 (1.6)	-
7634	Bavette d'ailoyau surgelé	Frozen beef meat	<i>E. coli</i> O157:H7 Ad1174	Frozen ground beef meat	Seeding -20°C 15 days	3-4-1-4-3 (3.0)	+
7636	Pavé de rumsteak à l'échalote poivres surgelé	Frozen seasoned beef meat	<i>E. coli</i> O157:H7 Ad976	Beef meat	Seeding -20°C 15 days	5-1-3-1-5 (3.0)	-
7637	Tendre de bœuf surgelé	Frozen beef meat	<i>E. coli</i> O157:H7 Ad1174	Frozen ground beef meat	Seeding -20°C 15 days	3-4-1-4-3 (3.0)	+
7638	Steak haché pur bœuf surgelé	Frozen ground beef meat	<i>E. coli</i> O157:H7 Ad1174	Frozen ground beef meat	Seeding -20°C 15 days	3-4-1-4-3 (3.0)	+
7639	Haché pur bœuf 20% MG surgelé	Frozen ground beef meat	<i>E. coli</i> O157:H7 Ad1174	Frozen ground beef meat	Seeding -20°C 15 days	3-4-1-4-3 (3.0)	+
7640	Viande hachée pur bœuf surgelé	Frozen ground beef meat	<i>E. coli</i> O157:H7 Ad1174	Frozen ground beef meat	Seeding -20°C 15 days	3-4-1-4-3 (3.0)	+
7904	Carpaccio basilic	Seasoned beef	<i>E. coli</i> O157:H7 Ad976	Beef meat	Seeding 2-8°C 48h	5-1-3-1-5 (3.0)	-
7905	Carpaccio noisette vinaigre balsamique	Seasoned beef	<i>E. coli</i> O157:H7 Ad486	Beef meat	Seeding 2-8°C 48h	5-4-1-1-0 (2.2)	+
7907	Steak haché 5%MG	Raw ground beef	<i>E. coli</i> O157:H7 Ad486	Beef meat	Seeding 2-8°C 48h	5-4-1-1-0 (2.2)	+
7908	Steak de bœuf	Raw beef meat	<i>E. coli</i> O157:H7 Ad486	Beef meat	Seeding 2-8°C 48h	5-4-1-1-0 (2.2)	+
7909	Onglet de bœuf	Raw beef meat	<i>E. coli</i> O157:H7 Ad486	Beef meat	Seeding 2-8°C 48h	5-4-1-1-0 (2.2)	+
7910	Bavette de flanchet	Raw beef meat	<i>E. coli</i> O157:H7 Ad486	Beef meat	Seeding 2-8°C 48h	5-4-1-1-0 (2.2)	+
8124	Viande bovine steak à griller	Raw beef meat	<i>E. coli</i> O157:H7 Ad683	Beef meat	Seeding 2-8°C 48h	1-1-1-1-4 (1.6)	+
8126	Viande bovine pot au feu	Raw beef meat	<i>E. coli</i> O157:H7 Ad683	Beef meat	Seeding 2-8°C 48h	1-1-1-1-4 (1.6)	+

Sample N°	Product (French name)	Product	Artificial contamination				Global result 8h
			Strain	Origin	Injury protocol	Inoculation rate/25g	
8128	Viande bovine bavette de flanchet	Raw beef meat	<i>E. coli</i> O157:H7 Ad585	Beef meat	Seeding 2-8°C 48h	1-2-2-2-2 (1.8)	+
8130	Viande bovine bavette d'aloyau	Raw beef meat	<i>E. coli</i> O157:H7 Ad585	Beef meat	Seeding 2-8°C 48h	1-2-2-2-2 (1.8)	+
8132	Viande bovine pavé en tournedos	Raw beef meat	<i>E. coli</i> O157:H7 Ad585	Beef meat	Seeding 2-8°C 48h	1-2-2-2-2 (1.8)	+
8134	Steak haché pur bœuf 5%MG	Raw ground beef	<i>E. coli</i> O157:H7 Ad585	Beef meat	Seeding 2-8°C 48h	1-2-2-2-2 (1.8)	+
8138	Viande bovine basse côte à griller	Raw beef meat	<i>E. coli</i> O157:H7 Ad585	Beef meat	Seeding 2-8°C 48h	1-2-2-2-2 (1.8)	+
8140	Pavé rumsteak trois poivres	Seasoned raw beef meat	<i>E. coli</i> O157:H7 Ad586	Beef meat	Seeding 2-8°C 48h	5-1-1-1-2 (2.0)	-
8141	Pavé rumsteak trois poivres	Seasoned raw beef meat	<i>E. coli</i> O157:H7 Ad587	Beef meat	Seeding 2-8°C 48h	0-3-0-1-1 (1.0)	-
8142	Viande hachée à la bolognaise	Seasoned raw ground beef	<i>E. coli</i> O157:H7 Ad586	Beef meat	Seeding 2-8°C 48h	5-1-1-1-2 (2.0)	+
8143	Viande hachée à la bolognaise	Seasoned raw ground beef	<i>E. coli</i> O157:H7 Ad587	Beef meat	Seeding 2-8°C 48h	0-3-0-1-1 (1.0)	+
8144	Carpaccio pistou basilic huile d'olive et ail	Seasoned Carpaccio	<i>E. coli</i> O157:H7 Ad586	Beef meat	Seeding 2-8°C 48h	5-1-1-1-2 (2.0)	+
8146	Carpaccio pur bœuf huile d'olive citron	Seasoned Carpaccio	<i>E. coli</i> O157:H7 Ad586	Beef meat	Seeding 2-8°C 48h	5-1-1-1-2 (2.0)	-
8147	Carpaccio pur bœuf huile d'olive citron	Seasoned Carpaccio	<i>E. coli</i> O157:H7 Ad587	Beef meat	Seeding 2-8°C 48h	0-3-0-1-1 (1.0)	+
115	Pavé de bœuf mariné aux trois poivres surgelé	Seasoned beef meat	<i>E. coli</i> O157:H7 Ad559	Beef meat	Seeding 2-8°C 48h	3-3-5-2-3 (3.2)	+
116	Carpaccio de bœuf marinade au pistou surgelé	Frozen seasoned Carpaccio	<i>E. coli</i> O157:H7 Ad559	Beef meat	Seeding 2-8°C 48h	3-3-5-2-3 (3.2)	+
117	Burger à l'oignon surgelé	Frozen seasoned ground beef meat	<i>E. coli</i> O157:H7 Ad559	Beef meat	Seeding 2-8°C 48h	3-3-5-2-3 (3.2)	+
118	Viande hachée à la bolognaise 15%MG	Seasoned raw ground beef meat	<i>E. coli</i> O157:H7 Ad560	Beef meat	Seeding 2-8°C 48h	4-1-1-0-1 (1.4)	-
119	Carpaccio pur bœuf (huile d'olive, citron)	Beef Carpaccio	<i>E. coli</i> O157:H7 Ad560	Beef meat	Seeding 2-8°C 48h	4-1-1-0-1 (1.4)	+
7748	Lait cru de vache	Raw milk	<i>E. coli</i> O157:H7 Ad688	Environmental sample	Seeding 48h 2-8°C	1-2-3-3-4 (2.6)	-
7749	Lait cru fermier	Raw milk	<i>E. coli</i> O157:H7 Ad688	Environmental sample	Seeding 48h 2-8°C	1-2-3-3-4 (2.6)	+

Sample N°	Product (French name)	Product	Artificial contamination				Global result 8h
			Strain	Origin	Injury protocol	Inoculation rate/25g	
7750	Lait cru de vache fermier	Raw milk	<i>E. coli</i> O157:H7 Ad688	Environmental sample	Seeding 48h 2-8°C	1-2-3-3-4 (2.6)	+
7751	Lait cru de vache	Raw milk	<i>E. coli</i> O157:H7 Ad688	Environmental sample	Seeding 48h 2-8°C	1-2-3-3-4 (2.6)	+
7752	Lait cru fermier	Raw milk	<i>E. coli</i> O157:H7 Ad688	Environmental sample	Seeding 48h 2-8°C	1-2-3-3-4 (2.6)	+
7753	Fromage raclette lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad686	Environmental sample	Seeding 48h 2-8°C	4-0-6-2-2 (2.8)	+
7754	Comte au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad686	Environmental sample	Seeding 48h 2-8°C	4-0-6-2-2 (2.8)	+
7755	Tomme de montagne lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad686	Environmental sample	Seeding 48h 2-8°C	4-0-6-2-2 (2.8)	+
7756	Picodon lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad686	Environmental sample	Seeding 48h 2-8°C	4-0-6-2-2 (2.8)	-
7758	Lait cru de vache	Raw milk	<i>E. coli</i> O157:H7 Ad572	Feces	Seeding 48h 2-8°C	4-4-2-4-1 (3.0)	+
7759	Lait cru fermier	Raw milk	<i>E. coli</i> O157:H7 Ad572	Feces	Seeding 48h 2-8°C	4-4-2-4-1 (3.0)	+
7760	Lait cru de vache fermier	Raw milk	<i>E. coli</i> O157:H7 Ad572	Feces	Seeding 48h 2-8°C	4-4-2-4-1 (3.0)	+
7761	Lait cru de vache	Raw milk	<i>E. coli</i> O157:H7 Ad572	Feces	Seeding 48h 2-8°C	4-4-2-4-1 (3.0)	+
7762	Lait cru fermier	Raw milk	<i>E. coli</i> O157:H7 Ad572	Feces	Seeding 48h 2-8°C	4-4-2-4-1 (3.0)	+
7763	Salade laitue	Lettuce	<i>E. coli</i> O157:H7 Ad575	Feces	Seeding 48h 2-8°C	2-3-0-4-4 (2.6)	+
7764	Salade iceberg	Green salad	<i>E. coli</i> O157:H7 Ad575	Feces	Seeding 48h 2-8°C	2-3-0-4-4 (2.6)	+
7765	Mâche	Green salad	<i>E. coli</i> O157:H7 Ad575	Feces	Seeding 48h 2-8°C	2-3-0-4-4 (2.6)	-
7766	Roquette	Green salad	<i>E. coli</i> O157:H7 Ad575	Feces	Seeding 48h 2-8°C	2-3-0-4-4 (2.6)	-
7767	Salade lucas	Green salad	<i>E. coli</i> O157:H7 Ad575	Feces	Seeding 48h 2-8°C	2-3-0-4-4 (2.6)	+
7768	Fines pousses Alfalfa Radis Fenouil	Sprouts	<i>E. coli</i> O157:H7 Ad557	Water treatment plant	Seeding 48h 2-8°C	3-2-3-1-2 (2.2)	-
7769	Fines pousses Alfalfa	Sprouts	<i>E. coli</i> O157:H7 Ad557	Water treatment plant	Seeding 48h 2-8°C	3-2-3-1-2 (2.2)	+
7770	Fines pousses Alfalfa Roquette	Sprouts	<i>E. coli</i> O157:H7 Ad557	Water treatment plant	Seeding 48h 2-8°C	3-2-3-1-2 (2.2)	+
7771	Fines pousses Alfalfa Poireaux lentilles	Sprouts	<i>E. coli</i> O157:H7 Ad557	Water treatment plant	Seeding 48h 2-8°C	3-2-3-1-2 (2.2)	+
8023	Beurre de baratte cru doux	Raw butter	<i>E. coli</i> O157:H7 Ad686	Beef slaughterhouse	Seeding 48h 2-8°C	1-2-7-3-2 (3.0)	+
8024	Beurre de baratte cru doux	Raw butter	<i>E. coli</i> O157:H7 Ad567	Beef slaughterhouse	Seeding 48h 2-8°C	4-3-4-3-5 (3.8)	+
8025	Beurre de baratte cru doux	Raw butter	<i>E. coli</i> O157:H7 Ad568	Beef slaughterhouse	Seeding 48h 2-8°C	2-2-2-3-2 (2.2)	-
8026	Beurre de baratte cru demi-sel	Raw butter	<i>E. coli</i> O157:H7 Ad686	Beef slaughterhouse	Seeding 48h 2-8°C	1-2-7-3-2 (3.0)	-
8028	Beurre de baratte cru demi-sel	Raw butter	<i>E. coli</i> O157:H7 Ad568	Beef slaughterhouse	Seeding 48h 2-8°C	2-2-2-3-2 (2.2)	-
8029	Beurre de baratte cru demi-sel	Raw butter	<i>E. coli</i> O157:H7 Ad686	Beef slaughterhouse	Seeding 48h 2-8°C	1-2-7-3-2 (3.0)	+

Sample N°	Product (French name)	Product	Artificial contamination				Global result 8h
			Strain	Origin	Injury protocol	Inoculation rate/25g	
8031	Beurre de baratte cru demi-sel	Raw butter	<i>E. coli</i> O157:H7 Ad568	Beef slaughterhouse	Seeding 48h 2-8°C	2-2-2-3-2 (2.2)	+
8032	Mâche	Salad	<i>E. coli</i> O157:H7 Ad556	Water treatment plant	Seeding 48h 2-8°C	2-3-4-4-5 (3.6)	+
8033	Mâche	Salad	<i>E. coli</i> O157:H7 Ad558	Water treatment plant	Seeding 48h 2-8°C	3-1-1-8-5 (3.6)	-
8035	Roquette	Salad	<i>E. coli</i> O157:H7 Ad558	Water treatment plant	Seeding 48h 2-8°C	3-1-1-8-5 (3.6)	+
8036	Laitue	Salad	<i>E. coli</i> O157:H7 Ad556	Water treatment plant	Seeding 48h 2-8°C	2-3-4-4-5 (3.6)	+
8037	Laitue	Salad	<i>E. coli</i> O157:H7 Ad558	Water treatment plant	Seeding 48h 2-8°C	3-1-1-8-5 (3.6)	+
8038	Petite salade espagnole	Salad	<i>E. coli</i> O157:H7 Ad556	Water treatment plant	Seeding 48h 2-8°C	2-3-4-4-5 (3.6)	+
8039	Petite salade espagnole	Salad	<i>E. coli</i> O157:H7 Ad558	Water treatment plant	Seeding 48h 2-8°C	3-1-1-8-5 (3.6)	+
8040	Cidre de Bretagne Brut	Cider	<i>E. coli</i> O157:H7 Ad2308	Water	Seeding 48h 2-8°C	3-5-5-1-6 (4.0)	-
8041	Cidre de Bretagne Brut	Cider	<i>E. coli</i> O157:H7 Ad571	Feces	Seeding 48h 2-8°C	3-2-2-4-6 (3.4)	-
8042	Jus de raisin 100% pur jus	Grape juice	<i>E. coli</i> O157:H7 Ad2308	Water	Seeding 48h 2-8°C	3-5-5-1-6 (4.0)	+
8043	Cidre bouché brut bio	Cider	<i>E. coli</i> O157:H7 Ad2308	Water	Seeding 48h 2-8°C	3-5-5-1-6 (4.0)	-
8044	Cidre bouché brut bio	Cider	<i>E. coli</i> O157:H7 Ad571	Feces	Seeding 48h 2-8°C	3-2-2-4-6 (3.4)	-
8045	Jus multifruit 100% pur jus	Fruit juice	<i>E. coli</i> O157:H7 Ad2308	Water	Seeding 48h 2-8°C	3-5-5-1-6 (4.0)	-
8046	Jus multifruit 100% pur jus	Fruit juice	<i>E. coli</i> O157:H7 Ad571	Feces	Seeding 48h 2-8°C	3-2-2-4-6 (3.4)	+
8048	Jus d'orange 100% pur jus	Orange juice	<i>E. coli</i> O157:H7 Ad571	Feces	Seeding 48h 2-8°C	3-2-2-4-6 (3.4)	+
8049	Jus de pomme 100% pur jus	Apple juice	<i>E. coli</i> O157:H7 Ad571	Feces	Seeding 48h 2-8°C	3-2-2-4-6 (3.4)	+
33	Camembert au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad570	Beef slaughterhouse	Seeding 48h 2-8°C	5-3-4-1-1 (2.8)	-
34	Camembert au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad569	Beef slaughterhouse	Seeding 48h 2-8°C	2-3-3-0-3 (2.2)	-
35	Rocamadour au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad570	Beef slaughterhouse	Seeding 48h 2-8°C	5-3-4-1-1 (2.8)	+
36	Rocamadour au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad569	Beef slaughterhouse	Seeding 48h 2-8°C	2-3-3-0-3 (2.2)	+
38	Roquefort au lait cru de brebis	Raw milk cheese	<i>E. coli</i> O157:H7 Ad569	Beef slaughterhouse	Seeding 48h 2-8°C	2-3-3-0-3 (2.2)	+
39	Morbier au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad570	Beef slaughterhouse	Seeding 48h 2-8°C	5-3-4-1-1 (2.8)	+
40	Fines pousses Alfalfa Poireaux lentilles	Sprouts	<i>E. coli</i> O157:H7 Ad573	Feces	Seeding 48h 2-8°C	1-8-6-4-4 (4.6)	+
41	Fines pousses Alfalfa Poireaux lentilles	Sprouts	<i>E. coli</i> O157:H7 Ad574	Feces	Seeding 48h 2-8°C	3-1-4-0-0 (1.6)	+
43	Fines pousses Alfalfa Roquettes	Sprouts	<i>E. coli</i> O157:H7 Ad574	Feces	Seeding 48h 2-8°C	3-1-4-0-0 (1.6)	+
44	Fines pousses Alfalfa	Sprouts	<i>E. coli</i> O157:H7 Ad573	Feces	Seeding 48h 2-8°C	1-8-6-4-4 (4.6)	+
45	Fines pousses Alfalfa	Sprouts	<i>E. coli</i> O157:H7 Ad574	Feces	Seeding 48h 2-8°C	3-1-4-0-0 (1.6)	-

Sample N°	Product (French name)	Product	Artificial contamination				Global result 8h
			Strain	Origin	Injury protocol	Inoculation rate/25g	
46	Fines pousses Alfalfa Radis Fenouil	Sprouts	<i>E. coli</i> O157:H7 Ad573	Feces	Seeding 48h 2-8°C	1-8-6-4-4 (4.6)	+
47	Cidre de Bretagne Brut	Cider	<i>E. coli</i> O157:H7 Ad556	Water treatment plant	Seeding 48h 2-8°C	2-2-5-2-3 (2.8)	-
48	Cidre de Bretagne Brut	Cider	<i>E. coli</i> O157:H7 Ad557	Water treatment plant	Seeding 48h 2-8°C	4-3-5-5-6 (4.6)	-
49	100% pur jus de pamplemousse rose et orange	Fruit juice	<i>E. coli</i> O157:H7 Ad556	Water treatment plant	Seeding 48h 2-8°C	2-2-5-2-3 (2.8)	+
50	100% pur jus de pamplemousse rose et orange	Fruit juice	<i>E. coli</i> O157:H7 Ad557	Water treatment plant	Seeding 48h 2-8°C	4-3-5-5-6 (4.6)	+
51	100% pur jus d'orange abricot pomme et mandarine	Fruit juice	<i>E. coli</i> O157:H7 Ad556	Water treatment plant	Seeding 48h 2-8°C	2-2-5-2-3 (2.8)	+
244	Lait cru de vache	Raw milk	<i>E. coli</i> O157:H7 Ad579	Feces	Seeding 48h 2-8°C	4-3-1-3-1 (2.4)	+
245	Lait cru fermier	Raw milk	<i>E. coli</i> O157:H7 Ad579	Feces	Seeding 48h 2-8°C	4-3-1-3-1 (2.4)	+
246	Lait cru	Raw milk	<i>E. coli</i> O157:H7 Ad579	Feces	Seeding 48h 2-8°C	4-3-1-3-1 (2.4)	+
252	Munster au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad1745	Raw milk cheese	Seeding 48h 2-8°C	2-1-0-3-3 (1.8)	+
253	Roquefort au lait cru de brebis	Raw milk cheese	<i>E. coli</i> O157:H7 Ad1745	Raw milk cheese	Seeding 48h 2-8°C	2-1-0-3-3 (1.8)	-
254	Picodon au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad1745	Raw milk cheese	Seeding 48h 2-8°C	2-1-0-3-3 (1.8)	+
255	Roquefort au lait cru de brebis	Raw milk cheese	<i>E. coli</i> O157:H7 Ad581	Feces	Seeding 48h 2-8°C	0-3-1-1-2 (1.4)	+
256	Cantal au lait cru	Raw milk cheese	<i>E. coli</i> O157:H7 Ad581	Feces	Seeding 48h 2-8°C	0-3-1-1-2 (1.4)	+
262	Laitue craquante	Lettuce	<i>E. coli</i> O157:H7 Ad580	Feces	Seeding 48h 2-8°C	2-2-4-4-1 (2.6)	+
263	Salade	Salad	<i>E. coli</i> O157:H7 Ad580	Feces	Seeding 48h 2-8°C	2-2-4-4-1 (2.6)	+
645	Jus d'orange 100% pur jus	Fruit juice	<i>E. coli</i> O157:H7 Ad577	Feces	Seeding 48h 2-8°C	1-1-0-1-1 (0.8)	+
646	Jus d'orange avec pulpe 100% pur jus	Fruit juice	<i>E. coli</i> O157:H7 Ad577	Feces	Seeding 48h 2-8°C	1-1-0-1-1 (0.8)	+
647	Cidre brut de Normandie	Cider	<i>E. coli</i> O157:H7 Ad577	Feces	Seeding 48h 2-8°C	1-1-0-1-1 (0.8)	-
648	Jus d'orange 100% pur jus	Fruit juice	<i>E. coli</i> O157:H7 Ad578	Feces	Seeding 48h 2-8°C	1-0-1-1-1 (0.8)	+
649	Jus d'orange avec pulpe 100% pur jus	Fruit juice	<i>E. coli</i> O157:H7 Ad578	Feces	Seeding 48h 2-8°C	1-0-1-1-1 (0.8)	-
650	Cidre brut	Cider	<i>E. coli</i> O157:H7 Ad578	Feces	Seeding 48h 2-8°C	1-0-1-1-1 (0.8)	-
651	Lait ribot	Fermented milk	<i>E. coli</i> O157:H7 Ad576	Beef feces	Seeding 48h 2-8°C	2-3-1-1-6 (2.6)	+
652	Lait ribot	Fermented milk	<i>E. coli</i> O157:H7 Ad576	Beef feces	Seeding 48h 2-8°C	2-3-1-1-6 (2.6)	-
653	Lait ribot	Fermented milk	<i>E. coli</i> O157:H7 Ad576	Beef feces	Seeding 48h 2-8°C	2-3-1-1-6 (2.6)	-

Sample N°	Product (French name)	Product	Artificial contamination				Global result 8h
			Strain	Origin	Injury protocol	Inoculation rate/25g	
654	Lait fermenté	Fermented milk	<i>E. coli</i> O157:H7 Ad576	Beef feces	Seeding 48h 2-8°C	2-3-1-1-6 (2.6)	-
841	Jeunes pousses radis	Sprouts	<i>E. coli</i> O157:H7 Ad576	Feces	Seeding 48h 2-8°C	2-3-3-2-0 (2.0)	-
842	Jeunes pousses poireaux	Sprouts	<i>E. coli</i> O157:H7 Ad576	Feces	Seeding 48h 2-8°C	2-3-3-2-0 (2.0)	+
843	Jeunes pousses betteraves rouges	Sprouts	<i>E. coli</i> O157:H7 Ad577	Feces	Seeding 48h 2-8°C	3-1-3-3-0 (2.0)	+
1398	Lait ribot	Fermented milk	<i>E. coli</i> O157:H7 Ad579	Feces	Seeding 48h 2-8°C	3-5-2-7-5 (4.4)	+
1399	Lait ribot lait fermenté	Fermented milk	<i>E. coli</i> O157:H7 Ad579	Feces	Seeding 48h 2-8°C	3-5-2-7-5 (4.4)	+
1400	Lait ribot lait fermenté	Fermented milk	<i>E. coli</i> O157:H7 Ad568	Beef slaughterhouse	Seeding 48h 2-8°C	3-1-6-6-4(4.0)	+
1401	Lait fermenté	Fermented milk	<i>E. coli</i> O157:H7 Ad568	Beef slaughterhouse	Seeding 48h 2-8°C	3-1-6-6-4(4.0)	+
1402	Lait fermenté	Fermented milk	<i>E. coli</i> O157:H7 Ad582	Feces	Seeding 48h 2-8°C	3-4-5-4-3 (3.8)	+
1403	Lait ribot	Fermented milk	<i>E. coli</i> O157:H7 Ad582	Feces	Seeding 48h 2-8°C	3-4-5-4-3 (3.8)	+



## Appendix 4 – Sensitivity study: raw data

### **Bold typing : artificially inoculated samples**

#### **E. coli O157 detection results:**

m:	minority level of target analyte
M :	majority level of target analyte
P:	pure culture level of target analyte
1/2 :	50% level of target analyte
-:	no typical colonies but presence of background microflora
st:	plate without any colony
PA:	positive agreement
NA:	negative agreement
ND:	negative deviation
PD:	positive deviation
PPNA:	positive presumptive negative agreement
PPND :	positive presumptive negative deviation
L:	latex test O157:H7
NC:	non-characteristic colony on nutrient agar
d:	doubtful colony
+w:	weak reaction for Latex test
auto:	auto agglutinate strain
Regrowth in BHI:	IMS on the enrichment broth, subculture in BHI, IMS on the BHI

RAW BEEF MEATS																												
Sample N°	Product (French name)	Product	REFERENCE METHOD: NF EN ISO 16654*					ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method																			Category	Type
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 8h at 41.5°C									Pre-warmed 3M BPW ISO - 24h at 41.5°C											
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 TEST		Confirmation				Final result	Agreement 8h	MDA2 TEST		Confirmation				Final result	Agreement 24h					
								Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification latex O157/H7	Indole test			All confirmatory tests	Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification latex O157/H7			Indole test	All confirmatory tests			
7907	Steak haché 5%MG	Raw ground beef	+p	+M	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+M	/	+/+	+	+	+	PA	1	a	
7908	Steak de bœuf	Raw beef meat	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	a	
7909	Onglet de bœuf	Raw beef meat	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	a	
7910	Bavette de flanchet	Raw beef meat	+p	+p	/	/	+	-	+	-	-	/	/	-	-	ND	-	+	-	-	/	/	-	-	ND	1	a	
8124	Viande bovine steak à griller	Raw beef meat	+p	+M	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	a	
8125	Viande bovine steak à griller	Raw beef meat	st	-	st	st	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a	
8126	Viande bovine pot au feu	Raw beef meat	+p	+m	/	/	+	+	+	+1/2	/	+/+	+	+	+	PA	+	+	+1/2	/	+/+	+	+	+	PA	1	a	
8127	Viande bovine pot au feu	Raw beef meat	st	-	st	st	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a	
8128	Viande bovine bavette de flanchet	Raw beef meat	+p	+M	/	/	+	+	+	+M	/	+/+	+	+	+	PA	+	+	+M	/	+/+	+	+	+	PA	1	a	
8129	Viande bovine bavette de flanchet	Raw beef meat	st	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a	
8130	Viande bovine bavette d'loyau	Raw beef meat	+p	+M	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	+p	+/+	+	+	+	PA	1	a	
8131	Viande bovine bavette d'loyau	Raw beef meat	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a	
8132	Viande bovine pavé en tournedos	Raw beef meat	+p	+1/2	/	/	+	-	+	-	-	/	/	-	-	ND	-	+	-	-	/	/	-	-	ND	1	a	
8133	Viande bovine pavé en tournedos	Raw beef meat	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a	
8134	Steak haché pur bœuf 5%MG	Raw ground beef	-	-	-	-	-	+	+	+M	/	+/+	+	+	+	PD	+	+	+	/	+/+	+	+	+	PD	1	a	
8135	Steak haché pur bœuf 5%MG	Raw ground beef	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a	
8137	Steak haché pur bœuf 15%MG	Raw ground beef	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a	
8138	Viande bovine basse côte à griller	Raw beef meat	+M	+1/2	/	/	+	+	+	+M	/	+/+	+	+	+	PA	+	+	+M	/	+/+	+	+	+	PA	1	a	

RAW BEEF MEATS																											
Sample N°	Product (French name)	Product	REFERENCE METHOD: NF EN ISO 16654*					ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method																		Category	Type
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 8h at 41.5°C									Pre-warmed 3M BPW ISO - 24h at 41.5°C										
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 TEST		Confirmation				Final result	Agreement 8h	MDA2 TEST		Confirmation				Final result	Agreement 24h				
								Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification				All confirmatory tests	Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification			All confirmatory tests			
				latex O157/H7	Indole test			Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	latex O157/H7	Indole test	All confirmatory tests													
8139	Viande bovine basse côte à griller	Raw beef meat	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a
104	Viande bovine pot au feu	Raw beef meat	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a
105	Viande bovine bourguignon	Raw beef meat	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	a
7628	Pavé de bœuf surgelé	Frozen beef meat	+p	+M	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+M	/	+/+	+	+	+	PA	1	b
7629	Effeillé de charolais surgelé	Frozen beef meat	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	b
7631	Steak haché surgelé	Frozen ground beef meat	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	b
7632	Steak haché surgelé	Frozen ground beef meat	st	st	st	-	-	+	+	+p	/	+/+	+	+	+	PD	+	+	+p	/	+/+	+	+	+	PD	1	b
7633	Steak haché pur bœuf surgelé	Frozen ground beef meat	st	st	st	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b
7634	Bavette d'ailoyau surgelé	Frozen beef meat	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	b
7637	Tendre de bœuf surgelé	Frozen beef meat	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	b
7638	Steak haché pur bœuf surgelé	Frozen ground beef meat	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	b
7639	Haché pur bœuf 20% MG surgelé	Frozen ground beef meat	+p	+1/2	/	/	+	-	+	-	-	/	/	-	-	ND	-	+	-	-	/	/	-	-	ND	1	b
7640	Viande hachée pur bœuf surgelé	Frozen ground beef meat	+p	+M	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+M	/	+/+	+	+	+	PA	1	b
106	Mon haché bouché 15%MG surgelé	Frozen raw ground beef meat	st	st	-	-	-	-	+	-	st	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b
107	Effeillé de charolais surgelé	Frozen raw beef meat	st	st	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b
108	Steak haché pur bœuf 15%MG surgelé	Raw ground beef meat	st	st	-	-	-	-	+	-	st	/	/	-	-	NA	-	+	-	st	/	/	-	-	NA	1	b
109	Tendre de bœuf surgelé	Frozen raw beef meat	st	st	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b

RAW BEEF MEATS																											
Sample N°	Product (French name)	Product	REFERENCE METHOD: NF EN ISO 16654*				ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method																		Category	Type	
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 8h at 41.5°C									Pre-warmed 3M BPW ISO - 24h at 41.5°C										
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 TEST		Confirmation				Final result	Agreement 8h	MDA2 TEST		Confirmation				Final result	Agreement 24h				
								Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification				All confirmatory tests	Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification			All confirmatory tests			
110	Viande haché 15%MG surgelé	Frozen raw ground beef meat	-	st	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b	
111	Haché moelleux bœuf surgelé	Frozen raw ground beef meat	st	st	st	st	-	+	-	st	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b	
112	Steak haché pur bœuf 15%MG surgelé	Frozen raw ground beef meat	st	st	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b	
113	Haché pur bœuf 20% MG surgelé	Frozen raw ground beef meat	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b	
114	Bavette d'aloyau surgelé	Raw beef meat	st	st	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b	
525	Steak haché congelé 15%MG	Frozen raw ground beef meat	st	-	st	-	-	+	-	st	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	b	
7630	Pavé de rumsteak aux trois poivres surgelé	frozen seasoned beef meat	+p	+M	/	/	+	-	+	-	/	/	-	-	ND	-	+	-	-	/	/	-	-	ND	1	c	
7636	Pavé de rumsteak à l'échalote poivres surgelé	Frozen seasoned beef meat	st	-	st	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	c	
7904	Carpaccio basilica	Seasoned beef	st	st	st	-	-	+	st	st	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	c	
7905	Carpaccio noisette vinaigre balsamique	Seasoned beef	st	st	-	-	-	+	+	+p	/	+/+	+	+	+	+	+	+p	/	+/+	+	+	+	+	PD	1	c
8140	Pavé rumsteak trois poivres	Seasoned raw beef meat	st	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	c	
8141	Pavé rumsteak trois poivres	Seasoned raw beef meat	st	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	c	
8142	Viande hachée à la bolognaise	Seasoned raw ground beef	st	-	-	-	-	+	+	+p	/	+/+	+	+	+	+	+	+M	/	+/+	+	+	+	+	PD	1	c
8143	Viande hachée à la bolognaise	Seasoned raw ground beef	+p	+M	/	/	+	-	+	-	/	/	-	-	ND	-	+	-	-	/	/	-	-	ND	1	c	

RAW BEEF MEATS																											
Sample N°	Product (French name)	Product	REFERENCE METHOD: NF EN ISO 16654*					ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method																	Category	Type	
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 8h at 41.5°C								Pre-warmed 3M BPW ISO - 24h at 41.5°C											
			MDA2 TEST		Confirmation				Final result	Agreement 8h	MDA2 TEST		Confirmation				Final result	Agreement 24h									
			Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS		After purification			All confirmatory tests	Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification			All confirmatory tests								
CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157	Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	latex O157/H7	Indole test	All confirmatory tests	Final result	Agreement 8h	Result	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	latex O157/H7	Indole test	All confirmatory tests	Final result	Agreement 24h						
8144	Carpaccio pistou basilic huile d'olive et ail	Seasoned Carpaccio	+p	+p	/	/	+	-	+	-	-	/	/	-	-	ND	-	+	-	-	/	/	-	-	ND	1	c
8146	Carpaccio pur bœuf huile d'olive citron	Seasoned Carpaccio	st	st	st	-	-	-	+	st	-	/	/	-	-	NA	-	+	st	-	/	/	-	-	NA	1	c
8147	Carpaccio pur bœuf huile d'olive citron	Seasoned Carpaccio	+Md	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+p	/	+/+	+	+	+	PA	1	c
115	Pavé de bœuf mariné aux trois poivres surgelé	Seasoned beef meat	+p	+M	/	/	+	+	+	+1/2	/	+/+	+	+	+	PA	+	+	+m	/	+/+	+	+	+	PA	1	c
116	Carpaccio de bœuf marinade au pistou surgelé	Frozen seasoned Carpaccio	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	+	+	+M	/	+/+	+	+	+	PA	1	c
117	Burger à l'oignon surgelé	Frozen seasoned ground beef meat	+p	+p	/	/	+	+	+	+M	/	+/+	+	+	+	PA	+	+	+M	/	+/+	+	+	+	PA	1	c
118	Viande hachée à la bolognaise 15%MG	Seasoned raw ground beef meat	st	st	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	c
119	Carpaccio pur bœuf (huile d'olive, citron)	Beef Carpaccio	+p	+p	/	/	+	-	+	st	-	/	/	-	-	ND	-	+	st	st	/	/	-	-	ND	1	c
120	Carpaccio pistou basilic huile d'olive et ail	Seasoned Carpaccio	st	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	st	/	/	-	-	NA	1	c
121	Carpaccio basilic et sa marinade	Seasoned Carpaccio	st	st	st	st	-	-	+	-	st	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	c
122	Carpaccio olive et sa marinade	Seasoned Carpaccio	st	-	-	-	-	-	+	-	st	/	/	-	-	NA	-	+	-	st	/	/	-	-	NA	1	c
123	Rumsteak à l'échalotte	Seasoned beef meat	+d(1) (latex-, indole-)	+md (latex-, indole-)	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	c
124	Carpaccio basilic et sa marinade	Seasoned Carpaccio	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	-	+	-	-	/	/	-	-	NA	1	c

RAW BEEF MEATS																															
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654* Final result	ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method																								Type			
				Pre-warmed 3M BPW ISO 8h at 41.5°C + 72h at 5°C ± 3°C												Pre-warmed 3M BPW ISO 24h at 41.5°C + 72h at 5°C ± 3°C															
				MDA2 test Lysate		MDA2 test BPW		Confirmation				Final result Lysate	Agreement 8h+72h Lysate	Final result BPW	Agreement 8h+72h BPW	MDA2 test Lysate		MDA2 test BPW		Confirmation				Final result Lysate	Agreement 24h+72h Lysate	Final result BPW	Agreement 24h+72h BPW				
				Re-sult	Matrix control	Re-sult	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification						All confirmatory tests	Re-sult	Matrix control	Re-sult	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification						All confirmatory tests		
						Latex O157/H7	Indole test																								
7907	Steak haché 5%MG	Raw ground beef	+	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+M	/	+/+	+	+	+	+	PA	+	PA	a
7908	Steak de bœuf	Raw beef meat	+	+	+	+	+	+M	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	a
7909	Onglet de bœuf	Raw beef meat	+	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+M	/	+/+	+	+	+	+	PA	+	PA	a
7910	Bavette de flanchet	Raw beef meat	+	-	+	-	+	+1/2d	/	-	-	-	-	ND	-	ND	-	+	-	+	+md	/	-	-	-	-	ND	-	ND	a	
8124	Viande bovine steak à griller	Raw beef meat	+	+	+	+	+	+M	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	a	
8125	Viande bovine steak à griller	Raw beef meat	-																											a	
8126	Viande bovine pot au feu	Raw beef meat	+	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	a	
8127	Viande bovine pot au feu	Raw beef meat	-																											a	
8128	Viande bovine bavette de flanchet	Raw beef meat	+	+	+	+	+	+M	+p	+/+	+	+	+	PA	+	PA	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	a	
8129	Viande bovine bavette de flanchet	Raw beef meat	-																											a	
8130	Viande bovine bavette d'ailoyau	Raw beef meat	+	+	+	+	+	+pd	+p	+/+	+	+	+	PA	+	PA	+	+	+	+	+pd	+p	+/+	+	+	+	PA	+	PA	a	
8131	Viande bovine bavette d'ailoyau	Raw beef meat	-																											a	
8132	Viande bovine pavé en tournedos	Raw beef meat	+	-	+	-	+	+Md	-	-/-	-	-	-	ND	-	ND	-	+	-	+	+Md	-	-/-	-	-	-	ND	-	ND	a	
8133	Viande bovine pavé en tournedos	Raw beef meat	-																											a	
8134	Steak haché pur bœuf 5%MG	Raw ground beef	-	+	+	+	+	+M	+M	+/+	+	+	+	PD	+	PD	+	+	+	+	-	+M	+/+	+	+	+	PD	+	PD	a	
8135	Steak haché pur bœuf 5%MG	Raw ground beef	-																											a	
8137	Steak haché pur bœuf 15%MG	Raw ground beef	-																											a	
8138	Viande bovine basse côte à griller	Raw beef meat	+	+	+	+	+	+M	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	a	

RAW BEEF MEATS																														
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654* Final result	ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method																								Type		
				Pre-warmed 3M BPW ISO 8h at 41.5°C + 72h at 5°C ± 3°C												Pre-warmed 3M BPW ISO 24h at 41.5°C + 72h at 5°C ± 3°C														
				MDA2 test Lysate		MDA2 test BPW		Confirmation				Final result Lysate	Agreement 8h+72h Lysate	Final result BPW	Agreement 8h+72h BPW	MDA2 test Lysate		MDA2 test BPW		Confirmation				Final result Lysate	Agreement 24h+72h Lysate	Final result BPW	Agreement 24h+72h BPW			
				Re-sult	Matrix control	Re-sult	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification						All confirmatory tests	Re-sult	Matrix control	Re-sult	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification						All confirmatory tests	
						Latex O157/H7	Indole test									latex O157/H7	Indole test													
8139	Viande bovine basse côte à griller	Raw beef meat	-																								a			
104	Viande bovine pot au feu	Raw beef meat	-																								a			
105	Viande bovine bourguignon	Raw beef meat	-																								a			
7628	Pavé de bœuf surgelé	Frozen beef meat	+	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	b
7629	Effeillé de charolais surgelé	Frozen beef meat	+	+	+	+	+	+m	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	b
7631	Steak haché surgelé	Frozen ground beef meat	+	+	+	+	+	+M	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	b
7632	Steak haché surgelé	Frozen ground beef meat	-	+	+	+	+	+M	/	+/+	+	+	+	PD	+	PD	+	+	+	+	+p	/	+/+	+	+	+	PD	+	PD	b
7633	Steak haché pur bœuf surgelé	Frozen ground beef meat	-																										b	
7634	Bavette d'aloyau surgelé	Frozen beef meat	+	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	b
7637	Tendre de bœuf surgelé	Frozen beef meat	+	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	b
7638	Steak haché pur bœuf surgelé	Frozen ground beef meat	+	+	+	+	+	+M	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+M	/	+/+	+	+	+	PA	+	PA	b
7639	Haché pur bœuf 20% MG surgelé	Frozen ground beef meat	+	-	+	-	+	-	-	/	/	-	-	ND	-	ND	-	+	-	+	-	-	/	/	-	-	ND	-	ND	b
7640	Viande hachée pur bœuf surgelé	Frozen ground beef meat	+	+	+	+	+	+M	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	b
106	Mon haché bouché 15% MG surgelé	Frozen raw ground beef meat	-																										b	
107	Effeillé de charolais surgelé	Frozen raw beef meat	-																										b	
108	Steak haché pur bœuf 15% MG surgelé	Raw ground beef meat	-																										b	
109	Tendre de bœuf surgelé	Frozen raw beef meat	-																										b	
110	Viande hachée 15% MG surgelé	Frozen raw ground beef meat	-																										b	

RAW BEEF MEATS																															
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654* Final result	ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method																								Type			
				Pre-warmed 3M BPW ISO 8h at 41.5°C + 72h at 5°C ± 3°C												Pre-warmed 3M BPW ISO 24h at 41.5°C + 72h at 5°C ± 3°C															
				MDA2 test Lysate		MDA2 test BPW		Confirmation				Final result Lysate	Agreement 8h+72h Lysate	Final result BPW	Agreement 8h+72h BPW	MDA2 test Lysate		MDA2 test BPW		Confirmation				Final result Lysate	Agreement 24h+72h Lysate	Final result BPW	Agreement 24h+72h BPW				
				Re-sult	Matrix control	Re-sult	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification						All confirmatory tests	Re-sult	Matrix control	Re-sult	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification						All confirmatory tests		
						Latex O157/H7	Indole test																								
111	Haché moelleux bœuf surgelé	Frozen raw ground beef meat	-																								b				
112	Steak haché pur bœuf 15%MG surgelé	Frozen raw ground beef meat	-																								b				
113	Haché pur bœuf 20% MG surgelé	Frozen raw ground beef meat	-																								b				
114	Bavette d'aloyau surgelé	Raw beef meat	-																								b				
525	Steak haché congelé 15%MG	Frozen raw ground beef meat	-																								b				
7630	Pavé de rumstek aux trois poivres surgelé	frozen seasoned beef meat	+	-	+	-	+	-	-	/	/	-	-	ND	-	ND	-	+	-	+	-	-	/	/	-	-	ND	-	ND	c	
7636	Pavé de rumstek à l'échalotte poivres surgelé	Frozen seasoned beef meat	-																									c			
7904	Carpaccio basilic	Seasoned beef	-																									c			
7905	Carpaccio noisette vinaigre balsamique	Seasoned beef	-	+	+	+	+	+p	/	+/+	+	+	+	PD	+	PD	+	+	+	+	+p	/	+/+	+	+	+	+	PD	+	PD	c
8140	Pavé rumsteak trois poivres	Seasoned raw beef meat	-																									c			
8141	Pavé rumsteak trois poivres	Seasoned raw beef meat	-																									c			
8142	Viande hachée à la bolognaise	Seasoned raw ground beef	-	+	+	+	+	+m	/	+/+	+	+	+	PD	+	PD	+	+	+	+	+m	+/+	+	+	+	+	+	PD	+	PD	c
8143	Viande hachée à la bolognaise	Seasoned raw ground beef	+	-	+	-	+	-	-	/	/	-	-	ND	-	ND	-	+	-	+	-	-	/	/	-	-	ND	-	ND	c	
8144	Carpaccio pistou basilic huile d'olive et ail	Seasoned Carpaccio	+	-	+	-	+	+pd	-	-/-	-	-	-	ND	-	ND	-	+	-	+	+pd	-	-/-	-	-	-	ND	-	ND	c	
8146	Carpaccio pur bœuf huile d'olive citron	Seasoned Carpaccio	-																										c		



RAW BEEF MEATS																																
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654* Final result	ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method																									Type			
				Pre-warmed 3M BPW ISO 8h at 41.5°C + 72h at 5°C ± 3°C												Pre-warmed 3M BPW ISO 24h at 41.5°C + 72h at 5°C ± 3°C																
				MDA2 test Lysate		MDA2 test BPW		Confirmation				Final result Lysate	Agreement 8h+72h Lysate	Final result BPW	Agreement 8h+72h BPW	MDA2 test Lysate		MDA2 test BPW		Confirmation				Final result Lysate	Agreement 24h+72h Lysate	Final result BPW	Agreement 24h+72h BPW					
				Re-sult	Matrix control	Re-sult	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification Latex O157/H7	Indole test					All confirmatory tests	Re-sult	Matrix control	Re-sult	Matrix control	CT-SMAC (50µL)	CT-SMAC (50µL) after IMS	After purification latex O157/H7					Indole test		All confirmatory tests		
8147	Carpaccio pur bœuf huile d'olive citron	Seasoned Carpaccio	+	+	+	+	+	+M	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+M	/	+/+	+	+	+	+	+	PA	+	PA	c
115	Pavé de bœuf mariné aux trois poivres surgelé	Seasoned beef meat	+	+	+	+	+	+1/2	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+M	+/+	+	+	+	+	+	+	PA	+	PA	c
116	Carpaccio de bœuf marinade au pistou surgelé	Frozen seasoned Carpaccio	+	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+p	+/+	+	+	+	+	+	+	PA	+	PA	c
117	Burger à l'oignon surgelé	Frozen seasoned ground beef meat	+	+	+	+	+	+p	/	+/+	+	+	+	PA	+	PA	+	+	+	+	+M	+/+	+	+	+	+	+	+	PA	+	PA	c
118	Viande hachée à la bolognaise 15%MG	Seasoned raw ground beef meat	-																												c	
119	Carpaccio pur bœuf (huile d'olive, citron)	Beef Carpaccio	+	-	+	-	+	-	-	/	/	-	-	ND	-	ND	-	+	-	+	st	-	/	/	-	-	ND	-	ND	-	ND	c
120	Carpaccio pistou basilic huile d'olive et ail	Seasoned Carpaccio	-																												c	
121	Carpaccio basilic et sa marinade	Seasoned Carpaccio	-																												c	
122	Carpaccio olive et sa marinade	Seasoned Carpaccio	-																												c	
123	Rumsteak à l'échalotte	Seasoned beef meat	-																												c	
124	Carpaccio basilic et sa marinade	Seasoned Carpaccio	-																												c	

RAW DAIRY PRODUCTS																			
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 ♦					ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method										Category	Type
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 18h at 41.5°C											
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 TEST		Confirmation					Final result	Agreement 18h			
								Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests					
						latex O157/H7	Indole test												
7748	Lait cru de vache	Raw milk	-	-	-	-	-	-/-	+	+1d	+d (5)	+/+	+	+	-	NA	2	a	
7749	Lait cru fermier	Raw milk	+M	-	/	/	+	+	+	+m	/	+/+	+	+	+	PA	2	a	
7750	Lait cru de vache fermier	Raw milk	+M	-	/	/	+	+	+	+m	/	+/+	+	+	+	PA	2	a	
7751	Lait cru de vache	Raw milk	+p	-	/	/	+	+	+	+m	/	+/+	+	+	+	PA	2	a	
7752	Lait cru fermier	Raw milk	+d (2)	+Md	+md	+m	+	+	+	+1/2	/	+/+	+	+	+	PA	2	a	
7758	Lait cru de vache	Raw milk	+m	+m	/	/	+	+	+	+m	/	+/+	+	+	+	PA	2	a	
7759	Lait cru fermier	Raw milk	+M	+m	/	/	+	+	+	+m	/	+/+	+	+	+	PA	2	a	
7760	Lait cru de vache fermier	Raw milk	+M	+m	/	/	+	+	+	+m	/	+/+	+	+	+	PA	2	a	
7761	Lait cru de vache	Raw milk	+M	-	/	/	+	+	+	+m	/	+/+	+	+	+	PA	2	a	
7762	Lait cru fermier	Raw milk	+p	+m	/	/	+	-	+	-	-	/	/	-	-	ND	2	a	
244	Lait cru de vache	Raw milk	+M	+m	/	/	+	+	+	+md/+p	+p	+/+	+	+	+	PA	2	a	
245	Lait cru fermier	Raw milk	+m	+m	/	/	+	+	+	-	+M (after regrowth step in BHI)	+/+	+	+	+	PA	2	a	
246	Lait cru	Raw milk	+m	+m	/	/	+	+	+	-	+m	+/+	+	+	+	PA	2	a	
247	Lait cru de vache	Raw milk	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	a	
248	Lait cru fermier	Raw milk	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	a	
249	Lait cru	Raw milk	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	a	
250	Lait cru fermier	Raw milk	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	a	
251	Lait cru	Raw milk	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	a	
830	Lait cru	Raw milk	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	a	
831	Lait cru	Raw milk	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	a	
832	Lait cru fermier	Raw milk	-	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	a	
7753	Fromage raclette lait cru	Raw milk cheese	+p	-	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	b	
7754	Comte au lait cru	Raw milk cheese	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	b	
7755	Tomme de montagne lait cru	Raw milk cheese	+d (1) (latex-, indole-)	+d (1) (latex-, indole-)	-	-	-	+	+	+m	/	+/+	+	+	+	PD	2	b	
7756	Picodon lait cru	Raw milk cheese	st	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	b	
33	Camembert au lait cru	Raw milk cheese	+md (latex-, indole-)	+md (latex-, indole-)	-	-	-	-	+	+1/2d	-	-/-	-	-	-	NA	2	b	
34	Camembert au lait cru	Raw milk cheese	+md (latex-, indole-)	+md (latex-, indole-)	-	-	-	-	+	+1/2d	-	-/-	-	-	-	NA	2	b	
35	Rocamadour au lait cru	Raw milk cheese	-	-	-	-	-	+	+	+1/2	/	+/+	+	+	+	PD	2	b	
36	Rocamadour au lait cru	Raw milk cheese	+M	+M	/	/	+	+	+	+m	/	+/+	+	+	+	PA	2	b	
38	Roquefort au lait cru de brebis	Raw milk cheese	st	st	st	-	-	+	+	+p	/	+/+	+	+	+	PD	2	b	
39	Morbier au lait cru	Raw milk cheese	+p	+m	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	b	
252	Munster au lait cru	Raw milk cheese	+M	+M	/	/	+	-	+	-	-	/	/	-	-	ND	2	b	

♦ Analyses performed according to the COFRAC accreditation

ADRIA Développement

Summary report (Version 0)

3M MDA 2 - *E. coli* O157 (including H7)

RAW DAIRY PRODUCTS																			
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 ♦					ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method										Category	Type
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 18h at 41.5°C											
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 TEST		Confirmation					Final result	Agreement 18h			
								Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests					
				latex O157/H7	Indole test														
253	Roquefort au lait cru de brebis	Raw milk cheese	st	st	-	-	-	-	+	-	-	/	/	-	-	NA	2	b	
254	Picodon au lait cru	Raw milk cheese	+md (latex-, indole-)	-	-	-	-	+	+	+d	+p	+/+	+	+	+	PD	2	b	
255	Roquefort au lait cru de brebis	Raw milk cheese	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	b	
256	Cantal au lait cru	Raw milk cheese	st	st	-	-	-	+	+	+M	/	+/+	+	+	+	PD	2	b	
257	Munster au lait cru	Raw milk cheese	st	-	-	-	-	-	+	-	-	/	/	-	-	NA	2	b	
258	Roquefort au lait cru de brebis	Raw milk cheese	st	st	-	-	-	-	+	-	-	/	/	-	-	NA	2	b	
259	Picodon au lait cru	Raw milk cheese	-	-	-	-	-	-	+	+d	-	-/-	-	-	-	NA	2	b	
260	Roquefort au lait cru	Raw milk cheese	st	st	-	-	-	-	+	+d	-	-/-	-	-	-	NA	2	b	
261	Cantal au lait cru	Raw milk cheese	st	st	st	-	-	-	+	+d	-	-/-	-	-	-	NA	2	b	
8023	Beurre de baratte cru doux	Raw butter	-	-	+d (latex-, indole-)	+d (latex+, indole+)	+	+	+	+M	/	+/+	+	+	+	PA	2	c	
8024	Beurre de baratte cru doux	Raw butter	-	-	+d (latex-, indole-)	-	-	+	+	+M	/	+/+	+	+	+	PD	2	c	
8025	Beurre de baratte cru doux	Raw butter	+1d (latex-, indole-)	st	+d (latex-, indole-)	-	-	-	+	-	-	/	/	-	-	NA	2	c	
8026	Beurre de baratte cru demi-sel	Raw butter	st	st	st	st	-	-	+	-	st	/	/	-	-	NA	2	c	
8028	Beurre de baratte cru demi-sel	Raw butter	st	st	-	-	-	-	+	st	/	/	/	-	-	NA	2	c	
8029	Beurre de baratte cru demi-sel	Raw butter	+p	+p	/	/	+	+	+	+M	/	+/+	+	+	+	PA	2	c	
8031	Beurre de baratte cru demi-sel	Raw butter	+p	+M	+p	+1/2	+	+	+	+M	/	+/+	+	+	+	PA	2	c	
640	Lait ribot	Fermented milk	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	2	c	
641	Lait ribot	Fermented milk	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	2	c	
642	Lait ribot	Fermented milk	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	2	c	
643	Lait fermenté	Fermented milk	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	2	c	
644	Lait ribot	Fermented milk	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	2	c	
651	Lait ribot	Fermented milk	st	st	st	st	-	+	+	+p	/	+/+	+	+	+	PD	2	c	
652	Lait ribot	Fermented milk	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	2	c	
653	Lait ribot	Fermented milk	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	2	c	
654	Lait fermenté	Fermented milk	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	2	c	
1398	Lait ribot	Fermented milk	+M	+1/2	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	c	
1399	Lait ribot lait fermenté	Fermented milk	+M	+m	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	c	
1400	Lait ribot lait fermenté	Fermented milk	+M	+M	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	c	
1401	Lait fermenté	Fermented milk	+M	+1/2	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	c	
1402	Lait fermenté	Fermented milk	+M	+1/2	/	/	+	+	+	+p	/	+/+	+	+	+	PA	2	c	
1403	Lait ribot	Fermented milk	-	-	-	-	-	+	+	+p	/	+/+	+	+	+	PD	2	c	
1404	Lait ribot	Fermented milk	-	-	-	-	-	-	+	st	-	/	/	-	-	NA	2	c	

RAW FRUITS AND VEGETABLES																			
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 ♦					ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method										Category	Type
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 18h at 41.5°C											
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 TEST		Confirmation					Final result	Agreement 18h			
								Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests					
						latex O157/H7	Indole test												
7763	Salade laitue	Lettuce	+d (1) (latex-, indole-)	-	+md (latex-, indole-)	+md (latex-, indole-)	-	+	+	+1/2	/	+/+	+	+	+	+	PD	3	a
7764	Salade iceberg	Green salad	+p	+1/2	/	/	+	+	+	+M	/	+/+	+	+	+	+	PA	3	a
7765	Mâche	Green salad	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
7766	Roquette	Green salad	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
7767	Salade lucas	Green salad	st	st	+p	+m	+	-	+	-	-	/	/	-	-	-	ND	3	a
8032	Mâche	Salad	-	-	-	-	-	+	+	+M	/	+/+	+	+	+	+	PD	3	a
8033	Mâche	Salad	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
8035	Roquette	Salad	-	-	-	-	-	+	+	+1/2	/	+/+	+	+	+	+	PD	3	a
8036	Laitue	Lettuce	+p	+M	/	/	+	-	+	-	-	/	/	-	-	-	ND	3	a
8037	Laitue	Lettuce	+p	+M	/	/	+	+	+	+m	/	+/+	+	+	+	+	PA	3	a
8038	Petite salade espagnole	Salad	+p	+M	/	/	+	+	+	+1/2	/	+/+	+	+	+	+	PA	3	a
8039	Petite salade espagnole	Salad	+p	+p	/	/	+	+	+	+M	/	+/+	+	+	+	+	PA	3	a
262	Laitue craquante	Salad	-	-	st	-	-	+	+	-	+p	+/+	+	+	+	+	PD	3	a
263	Salade	Salad	+M	+M	/	/	+	-	+	-	-	/	/	-	-	-	ND	3	a
265	Laitue craquante	Salad	-	-	st	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
266	Salade	Salad	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
267	Salade	Salad	st	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
268	Salade	Salad	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
269	Salade mélangée	Salad	st	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
833	Laitue	Salad	st	st	st	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
834	Salade	Salad	-	st	st	-	-	-	+	-	-	/	/	-	-	-	NA	3	a
7768	Fines pousses Alfalfa Radis Fenouil	Sprouts	+md (latex-, indole-)	+1d (latex-, indole-)	-	-	-	-	+	+md	/	-/-	-	-	-	-	NA	3	b
7769	Fines pousses Alfalfa	Sprouts	+m	-	/	/	+	+	+	+m	/	+/+	+	+	+	+	PA	3	b
7770	Fines pousses Alfalfa Roquette	Sprouts	+p	-	+1/2	-	+	-	+	+md	-	-/-	-	-	-	-	ND	3	b
7771	Fines pousses Alfalfa Poireaux lentilles	Sprouts	+md (latex-, indole-)	-	-	-	-	+	+	+m	/	+/+	+	+	+	+	PD	3	b
40	Fines pousses Alfalfa Poireaux lentilles	Sprouts	+1/2	-	+Md (latex+, indole+)	+md (latex+, indole+)	+	+	+	-	+m (after regrowth step in BHI)	+/+	+	+	+	+	PA	3	b
41	Fines pousses Alfalfa Poireaux lentilles	Sprouts	-	-	-	-	-	+	+	-	+m (after regrowth step in BHI)	+/+	+	+	+	+	PD	3	b
43	Fines pousses Alfalfa Roquettes	Sprouts	+md (latex-, indole-)	-	+md (latex+, indole+)	-	+	+	+	-	+md (after regrowth step in BHI)	+/+	+	+	+	+	PA	3	b
44	Fines pousses Alfalfa	Sprouts	+m	-	+m	+m	+	+	+	-	+md (after regrowth step in BHI)	+/+	+	+	+	+	PA	3	b
45	Fines pousses Alfalfa	Sprouts	-	-	-	-	-	+/+/+	+	-	- (- after regrowth step in BHI)	/	/	-	-	-	PPNA	3	b

♦ Analyses performed according to the COFRAC accreditation

ADRIA Développement

Summary report (Version 0)

3M MDA 2 - E. coli O157 (including H7)

RAW FRUITS AND VEGETABLES																			
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 *				Final result	ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method										Category	Type
			IMS 6h		IMS 24h			Pre-warmed 3M BPW ISO - 18h at 41.5°C											
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 TEST		Confirmation					Final result	Agreement 18h			
								Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests					
				latex O157/H7	Indole test														
46	Fines pousses Alfalfa Radis Fenouil	Sprouts	-	-	-	-	-	+	+	+md (latex-, indole-)	+m (after regrowth step in BHI)	+/+	+	+	+	+	PD	3	b
835	Jeunes pousses de haricots	Sprouts	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	b
836	Jeunes pousses betteraves rouges	Sprouts	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	b
837	Jeunes pousses poireaux	Sprouts	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	b
838	Jeunes pousses betteraves rouges	Sprouts	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	b
839	Jeunes pousses radis	Sprouts	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	b
840	Jeunes pousses poireaux	Sprouts	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	b
841	Jeunes pousses radis	Sprouts	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	b
842	Jeunes pousses poireaux	Sprouts	-	-	-	-	-	+	+	-	+M (after regrowth step in BHI)	+/+	+	+	+	+	PD	3	b
843	Jeunes pousses betteraves rouges	Sprouts	+M	-	+M	+(3)	+	-	+	-	-	/	/	-	-	-	ND	3	b
1405	Fines pousses ALFALFA	Sprouts	-	-	-	-	-	-	+	-	-	/	/	-	-	-	NA	3	b
8040	Cidre de Bretagne Brut	Cider	st	st	-	-	-	+/+/+	+	-	- (st after regrowth step in BHI)	/	/	-	-	-	PPNA	3	c
8041	Cidre de Bretagne Brut	Cider	st	st	-	-	-	-	+	st	st	/	/	-	-	-	NA	3	c
8042	Jus de raisin 100% pur jus	Grape juice	-	-	-	-	-	+/+/+	+	-	- (+ after regrowth step in BHI at 72h)	+/+	+	+	+	+	PD	3	c
8043	Cidre bouché brut bio	Cider	st	st	-	-	-	+/+/+	+	-	- (st after regrowth step in BHI)	/	/	-	-	-	PPNA	3	c
8044	Cidre bouché brut bio	Cider	st	st	-	-	-	+/-/-	+	st	- (st after regrowth step in BHI)	/	/	-	-	-	PPNA	3	c
8045	Jus multifruit 100% pur jus	Fruit juice	-	-	-	-	-	+/+/+	+	+1d	- (st after regrowth step in BHI)	-/-	-	-	-	-	PPNA	3	c
8046	Jus multifruit 100% pur jus	Fruit juice	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	+	PA	3	c
8048	Jus d'orange 100% pur jus	Orange juice	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	+	PA	3	c
8049	Jus de pomme 100% pur jus	Apple juice	st	st	-	-	-	+	+	+p	/	+/+	+	+	+	+	PD	3	c
47	Cidre de Bretagne Brut	Cider	-	-	st	-	-	-	+	st	-	/	/	-	-	-	NA	3	c
48	Cidre de Bretagne Brut	Cider	-	-	st	-	-	-	+	st	-	/	/	-	-	-	NA	3	c
49	100% pur jus de pamplemousse rose et orange	Fruit juice	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	+	PA	3	c
50	100% pur jus de pamplemousse rose et orange	Fruit juice	st	st	+p	+M	+	+	+	+p	/	+/+	+	+	+	+	PA	3	c
51	100% pur jus d'orange abricot pomme et mandarine	Fruit juice	+p	+M	/	/	+	+	+	+p	/	+/+	+	+	+	+	PA	3	c

RAW FRUITS AND VEGETABLES																			
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 ♦				ALTERNATIVE METHOD: 3M Molecular Detection Assay 2 <i>E.coli</i> O157 (including H7) method										Category	Type	
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 18h at 41.5°C											
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 TEST		Confirmation					Final result	Agreement 18h			
								Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests					
						latex O157/H7	Indole test												
645	Jus d'orange 100% pur jus	Fruit juice	+p	+p	/	/	+	+	+	+p	/	+/+	+	+	+	PA	3	c	
646	Jus d'orange avec pulpe 100% pur jus	Fruit juice	+(4)	+(4)	+p	+p	+	-	+	st	st	/	/	-	-	ND	3	c	
647	Cidre brut de Normandie	Cider	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	3	c	
648	Jus d'orange 100% pur jus	Fruit juice	st	st	st	st	-	+	+	+p	/	+/+	+	+	+	PD	3	c	
649	Jus d'orange avec pulpe 100% pur jus	Fruit juice	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	3	c	
650	Cidre brut	Cider	st	st	st	st	-	-	+	st	st	/	/	-	-	NA	3	c	

RAW DAIRY PRODUCTS																							
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 ♦					Alternative method: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method														Category	Type
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 18 h at 41.5°C + 72 h at 5°C ± 3°C															
								MDA2 test Lysate		MDA2 test BPW		Confirmation					Fina result Lysate	Agreement 18h+72h Lysate	Fina result BPW	Agreement 18h+72h BPW			
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		Result	Matrix control	Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confir-matory tests							
											Latex O157/H7	Indole test											
7748	Lait cru de vache	Raw milk	-	-	-	-	-	+/-	+	-/+	+	-	+m	+/+	+	+	+	+	+	+	+		
7749	Lait cru fermier	Raw milk	+M	-	/	/	+	+	+	+	+	+m	/	+/+	+	+	+	+	+	+	+		
7750	Lait cru de vache fermier	Raw milk	+M	-	/	/	+	+	+	+	+	+1/2	/	+/+	+	+	+	+	+	+	+		
7751	Lait cru de vache	Raw milk	+p	-	/	/	+	+	+	+	+	+m	/	+/+	+	+	+	+	+	+	+		
7752	Lait cru fermier	Raw milk	+d (2)	+Md	+md	+m	+	+	+	+	+	+m	/	+/+	+	+	+	+	+	+	+		
7758	Lait cru de vache	Raw milk	+m	+m	/	/	+	+	+	+	+	+m	/	+/+	+	+	+	+	+	+	+		
7759	Lait cru fermier	Raw milk	+M	+m	/	/	+	+	+	+	+	+M	/	+/+	+	+	+	+	+	+	+		
7760	Lait cru de vache fermier	Raw milk	+M	+m	/	/	+	+	+	+	+	+d	/	+/+	+	+	+	+	+	+	+		
7761	Lait cru de vache	Raw milk	+M	-	/	/	+	+	+	+	+	+m	/	+/+	+	+	+	+	+	+	+		
7762	Lait cru fermier	Raw milk	+p	+m	/	/	+	-	+	-	+	-	-	/	/	-	-	+	+	+	+		
244	Lait cru de vache	Raw milk	+M	+m	/	/	+	+	+	+	+	+M	+M	+/+	+	+	+	+	+	+	+		
245	Lait cru fermier	Raw milk	+m	+m	/	/	+	+	+	+	+	-	+M	+/+	+	+	+	+	+	+	+		
246	Lait cru	Raw milk	+m	+m	/	/	+	+	+	+	+	+m	/	+/+	+	+	+	+	+	+	+		
247	Lait cru de vache	Raw milk	-	-	-	-	-																
248	Lait cru fermier	Raw milk	-	-	-	-	-																
249	Lait cru	Raw milk	-	-	-	-	-																
250	Lait cru fermier	Raw milk	-	-	-	-	-																
251	Lait cru	Raw milk	-	-	-	-	-																
830	Lait cru	Raw milk	-	-	-	-	-																
831	Lait cru	Raw milk	-	-	-	-	-																
832	Lait cru fermier	Raw milk	-	-	-	-	-																
7753	Fromage raclette lait cru	Raw milk cheese	+p	-	/	/	+	+	+	+	+	+p	/	+/+	+	+	+	+	+	+	+		
7754	Comte au lait cru	Raw milk cheese	+p	+p	/	/	+	+	+	+	+	+p	/	+/+	+	+	+	+	+	+	+		
7755	Tomme de montagne lait cru	Raw milk cheese	+d (1) (latex-, indole-)	+d (1) (latex-, indole-)	-	-	-	+	+	+	+	+1/2	/	+/+	+	+	+	+	+	+	+		
7756	Picodon lait cru	Raw milk cheese	st	-	-	-	-																
33	Camembert au lait cru	Raw milk cheese	+md (latex-, indole-)	+md (latex-, indole-)	-	-	-	-	+	-	+	-	-	/	/	-	-	+	+	+	+		
34	Camembert au lait cru	Raw milk cheese	+md (latex-, indole-)	+md (latex-, indole-)	-	-	-	-	+	-	+	-	-	/	/	-	-	+	+	+	+		
35	Rocamadour au lait cru	Raw milk cheese	-	-	-	-	-	+	+	+	+	+m	/	+/+	+	+	+	+	+	+	+		
36	Rocamadour au lait cru	Raw milk cheese	+M	+M	/	/	+	+	+	+	+	+m	/	+/+	+	+	+	+	+	+	+		

RAW DAIRY PRODUCTS																							
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 ♦					Alternative method: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method														Category	Type
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 18 h at 41.5°C + 72 h at 5°C ± 3°C															
								MDA2 test Lysate		MDA2 test BPW		Confirmation					Fina result Lysate	Agreement 18h+72h Lysate	Fina result BPW	Agreement 18h+72h BPW			
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		Result	Matrix control	Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests							
										Latex O157/H7	Indole test												
38	Roquefort au lait cru de brebis	Raw milk cheese	st	st	st	-	-	+	+	+	+	+p	/	+/+	+	+	+	+	PD	+	PD	2	b
39	Morbier au lait cru	Raw milk cheese	+p	+m	/	/	+	+	+	+	+	+M	/	+/+	+	+	+	+	PA	+	PA	2	b
252	Munster au lait cru	Raw milk cheese	+M	+M	/	/	+	-	+	-	+	-	-	/	/	-	-	-	ND	-	ND	2	b
253	Roquefort au lait cru de brebis	Raw milk cheese	st	st	-	-	-															2	b
254	Picodon au lait cru	Raw milk cheese	+md (latex-, indole-)	-	-	-	-	+	+	inspect/inspect/+	+	+M	+m	+/+	+	+	+	+	PD	+	PD	2	b
255	Roquefort au lait cru de brebis	Raw milk cheese	+p	+p	/	/	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	2	b
256	Cantal au lait cru	Raw milk cheese	st	st	-	-	-	+	+	+	+	+m	/	+/+	+	+	+	+	PD	+	PD	2	b
257	Munster au lait cru	Raw milk cheese	st	-	-	-	-															2	b
258	Roquefort au lait cru de brebis	Raw milk cheese	st	st	-	-	-															2	b
259	Picodon au lait cru	Raw milk cheese	-	-	-	-	-															2	b
260	Roquefort au lait cru	Raw milk cheese	st	st	-	-	-															2	b
261	Cantal au lait cru	Raw milk cheese	st	st	st	-	-															2	b
8023	Beurre de baratte cru doux	Raw butter	-	-	+d (latex-, indole-)	+d (latex+, indole+)	+	+	+	+	+	+1/2	/	+/+	+	+	+	+	PA	+	PA	2	c
8024	Beurre de baratte cru doux	Raw butter	-	-	+d (latex-, indole-)	-	-	+	+	+	+	+1/2	/	+/+	+	+	+	+	PD	+	PD	2	c
8025	Beurre de baratte cru doux	Raw butter	+1d (latex-, indole-)	st	+d (latex-, indole-)	-	-															2	c
8026	Beurre de baratte cru demi-sel	Raw butter	st	st	st	st	-															2	c
8028	Beurre de baratte cru demi-sel	Raw butter	st	st	-	-	-															2	c
8029	Beurre de baratte cru demi-sel	Raw butter	+p	+p	/	/	+	+	+	+	+	+M	/	+/+	+	+	+	+	PA	+	PA	2	c
8031	Beurre de baratte cru demi-sel	Raw butter	+p	+M	+p	+1/2	+	+	+	+	+	+M	/	+/+	+	+	+	+	PA	+	PA	2	c
640	Lait ribot	Fermented milk	st	st	st	st	-															2	c
641	Lait ribot	Fermented milk	st	st	st	st	-															2	c
642	Lait ribot	Fermented milk	st	st	st	st	-															2	c
643	Lait fermenté	Fermented milk	st	st	st	st	-															2	c
644	Lait ribot	Fermented milk	st	st	st	st	-															2	c



RAW DAIRY PRODUCTS																							
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 ♦				Final result	Alternative method: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method														Category	Type
			IMS 6h		IMS 24h			Pre-warmed 3M BPW ISO - 18 h at 41.5°C + 72 h at 5°C ± 3°C															
								MDA2 test Lysate		MDA2 test BPW		Confirmation					Fina result Lysate	Agreement 18h+72h Lysate	Fina result BPW	Agreement 18h+72h BPW			
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		Result	Matrix control	Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests							
										Latex O157/H7	Indole test												
651	Lait ribot	Fermented milk	st	st	st	st	-	+	+	+	+	+p	/	+/+	+	+	+	+	PD	+	PD	2	c
652	Lait ribot	Fermented milk	st	st	st	st	-															2	c
653	Lait ribot	Fermented milk	st	st	st	st	-															2	c
654	Lait fermenté	Fermented milk	st	st	st	st	-															2	c
1398	Lait ribot	Fermented milk	+M	+1/2	/	/	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	2	c
1399	Lait ribot lait fermenté	Fermented milk	+M	+m	/	/	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	2	c
1400	Lait ribot lait fermenté	Fermented milk	+M	+M	/	/	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	2	c
1401	Lait fermenté	Fermented milk	+M	+1/2	/	/	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	2	c
1402	Lait fermenté	Fermented milk	+M	+1/2	/	/	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	2	c
1403	Lait ribot	Fermented milk	-	-	-	-	-	+	+	+	+	+p	/	+/+	+	+	+	+	PD	+	PD	2	c
1404	Lait ribot	Fermented milk	-	-	-	-	-															2	c

RAW FRUITS AND VEGETABLES																							
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 ♦					Alternative method: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method														Category	Type
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 18 h at 41.5°C + 72 h at 5°C ± 3°C															
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		MDA2 test Lysate		MDA2 test BPW		Confirmation						Fina result Lysate	Agreement 18h+72h Lysate	Fina result BPW	Agreement 18h+72h BPW		
								Result	Matrix control	Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests							
7763	Salade laitue	Lettuce	+d (1) (latex-, indole-)	-	+md (latex-, indole-)	+md (latex-, indole-)	-	+	+	+	+	+M	/	+/+	+	+	+	+	PD	+	PD	3	a
7764	Salade iceberg	Green salad	+p	+1/2	/	/	+	+	+	+	+	+1/2	/	+/+	+	+	+	+	PA	+	PA	3	a
7765	Mâche	Green salad	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
7766	Roquette	Green salad	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
7767	Salade lucas	Green salad	st	st	+p	+m	+	-	+	-	+	-	-	/	/	-	-	-	ND	-	ND	3	a
8032	Mâche	Salad	-	-	-	-	-	+	+	+	+	+1/2	/	+/+	+	+	+	+	PD	+	PD	3	a
8033	Mâche	Salad	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
8035	Roquette	Salad	-	-	-	-	-	+	+	+	+	+1/2	/	+/+	+	+	+	+	PD	+	PD	3	a
8036	Laitue	Lettuce	+p	+M	/	/	+	-	+	-	+	-	-	/	/	-	-	-	ND	-	ND	3	a
8037	Laitue	Lettuce	+p	+M	/	/	+	+	+	+	+	+m	/	+/+	+	+	+	+	PA	+	PA	3	a
8038	Petite salade espagnole	Salad	+p	+M	/	/	+	+	+	+	+	+1/2	/	+/+	+	+	+	+	PA	+	PA	3	a
8039	Petite salade espagnole	Salad	+p	+p	/	/	+	+	+	+	+	+1/2	/	+/+	+	+	+	+	PA	+	PA	3	a
262	Laitue craquante	Lettuce	-	-	st	-	-	+	+	+	+	+m	/	+/+	+	+	+	+	PD	+	PD	3	a
263	Salade	Salad	+M	+M	/	/	+	-	+	-	+	-	-	/	/	-	-	-	ND	-	ND	3	a
265	Laitue craquante	Salad	-	-	st	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
266	Salade	Salad	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
267	Salade	Salad	st	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
268	Salade	Salad	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
269	Salade mélangée	Salad	st	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
833	Laitue	Salad	st	st	st	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
834	Salade	Salad	-	st	st	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	a
7768	Fines pousses Alfalfa Radis Fenouil	Sprouts	+md (latex-, indole-)	+1d (latex-, indole-)	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	3	b
7769	Fines pousses Alfalfa	Sprouts	+m	-	/	/	+	+	+	-/+	+	+m	/	+/+	+	+	+	+	PA	-	ND	3	b
7770	Fines pousses Alfalfa Roquette	Sprouts	+p	-	+1/2	-	+	-	+	-	+	+md	/	-/-	-	-	-	-	ND	-	ND	3	b
7771	Fines pousses Alfalfa Poireaux lentilles	Sprouts	+md (latex-, indole-)	-	-	-	-	+	+	+	+	+md	/	+/+	+	+	+	+	PD	+	PD	3	b
40	Fines pousses Alfalfa Poireaux lentilles	Sprouts	+1/2	-	+Md (latex+, indole+)	+md (latex+, indole+)	+	+	+	+	+	-	+m (after regrowth step in BHI)	+/+	+	+	+	+	PA	+	PA	3	b
41	Fines pousses Alfalfa Poireaux lentilles	Sprouts	-	-	-	-	-	+	+	+	+	+md (latex-, indole+)	+m (after regrowth step in BHI)	+/+	+	+	+	+	PD	+	PD	3	b

RAW FRUITS AND VEGETABLES																								
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 *					Alternative method: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method														Category	Type	
			IMS 6h		IMS 24h			Final result	Pre-warmed 3M BPW ISO - 18 h at 41.5°C + 72 h at 5°C ± 3°C															
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157	MDA2 test Lysate		MDA2 test BPW		Confirmation					Fina result Lysate	Agreement 18h+72h Lysate	Fina result BPW	Agreement 18h+72h BPW					
							Result		Matrix control	Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification						All confirmatory tests				
										Latex O157/H7	Indole test													
43	Fines pousses Alfalfa Roquettes	Sprouts	+md (latex-, indole-)	-	+md (latex+, indole+)	-	+	+	+	+	+	+md	/	+/+	+	+	+	+	PA	+	PA	3	b	
44	Fines pousses Alfalfa	Sprouts	+m	-	+m	+m	+	+	+	+	+	+md (latex-, indole+)	+m (after regrowth step in BHI)	+/+	+	+	+	+	PA	+	PA	3	b	
45	Fines pousses Alfalfa	Sprouts	-	-	-	-	-	+/+/+	+	+/+/-	+	+md	-	-/-	+			-	PPNA	-	PPNA	3	b	
46	Fines pousses Alfalfa Radis Fenouil	Sprouts	-	-	-	-	-	+	+	+	+	+md	+1	+/+	+	+	+	+	PD	+	PD	3	b	
835	Jeunes pousses de haricots	Sprouts	-	-	-	-	-															3	b	
836	Jeunes pousses betteraves rouges	Sprouts	-	-	-	-	-															3	b	
837	Jeunes pousses poireaux	Sprouts	-	-	-	-	-															3	b	
838	Jeunes pousses betteraves rouges	Sprouts	-	-	-	-	-															3	b	
839	Jeunes pousses radis	Sprouts	-	-	-	-	-															3	b	
840	Jeunes pousses poireaux	Sprouts	-	-	-	-	-															3	b	
841	Jeunes pousses radis	Sprouts	-	-	-	-	-															3	b	
842	Jeunes pousses poireaux	Sprouts	-	-	-	-	-	+	+	+	+	-	+M (after regrowth step in BHI)	+/+	+	+	+	+	PD	+	PD	3	b	
843	Jeunes pousses betteraves rouges	Sprouts	+M	-	+M	+(3)	+	-	+	-	+	-	-	/	/	-	-	-	ND	-	ND	3	b	
1405	Fines pousses ALFALFA	Sprouts	-	-	-	-	-															3	b	
8040	Cidre de Bretagne Brut	Cider	st	st	-	-	-	+/+/+	+	+/+/+	+	-	- (st after regrowth step in BHI)	/	/	-	-	-	PPNA	-	PPNA	3	c	
8041	Cidre de Bretagne Brut	Cider	st	st	-	-	-															3	c	
8042	Jus de raisin 100% pur jus	Grape juice	-	-	-	-	-	+/+/+	+	+/+/+	+	-	+d (2)	+/+	+	+	+	+	PD	+	PD	3	c	
8043	Cidre bouché brut bio	Cider	st	st	-	-	-	+/+/+	+	+/+/+	+	-	- (st after regrowth step in BHI)	/	/	-	-	-	PPNA	-	PPNA	3	c	
8044	Cidre bouché brut bio	Cider	st	st	-	-	-	-/-/	+	-/-/	+	st	st	/	/	-	-	-	NA	-	NA	3	c	
8045	Jus multifruit 100% pur jus	Fruit juice	-	-	-	-	-	+/+/+	+	+/+/+	+	-	- (st after regrowth step in BHI)	/	/	-	-	-	PPNA	-	PPNA	3	c	

RAW FRUITS AND VEGETABLES																										
Sample N°	Product (French name)	Product	Reference method: NF EN ISO 16654 *					Alternative method: 3M Molecular Detection Assay 2 <i>E. coli</i> O157 (including H7) method														Category	Type			
			IMS 6h		IMS 24h		Final result	Pre-warmed 3M BPW ISO - 18 h at 41.5°C + 72 h at 5°C ± 3°C																		
								MDA2 test Lysate		MDA2 test BPW		Confirmation					Fina result Lysate	Agreement 18h+72h Lysate	Fina result BPW	Agreement 18h+72h BPW						
			CT SMAC	CHROMagar O157	CT SMAC	CHROMagar O157		Result	Matrix control	Result	Matrix control	CT SMAC (50µL)	CT SMAC (50µL) after IMS	After purification		All confirmatory tests										
											Latex O157/H7	Indole test														
8046	Jus multifruit 100% pur jus	Fruit juice	+p	+p	/	/	+	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	3	c		
8048	Jus d'orange 100% pur jus	Orange juice	+p	+p	/	/	+	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	3	c		
8049	Jus de pomme 100% pur jus	Apple juice	st	st	-	-	-	+	+	+	+	+	+p	/	+/+	+	+	+	+	PD	+	PD	3	c		
47	Cidre de Bretagne Brut	Cider	-	-	st	-	-																3	c		
48	Cidre de Bretagne Brut	Cider	-	-	st	-	-																	3	c	
49	100% pur jus de pamplemousse rose et orange	Fruit juice	+p	+p	/	/	+	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	3	c		
50	100% pur jus de pamplemousse rose et orange	Fruit juice	st	st	+p	+M	+	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	3	c		
51	100% pur jus d'orange abricot pomme et mandarine	Fruit juice	+p	+M	/	/	+	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	3	c		
645	Jus d'orange 100% pur jus	Fruit juice	+p	+p	/	/	+	+	+	+	+	+	+p	/	+/+	+	+	+	+	PA	+	PA	3	c		
646	Jus d'orange avec pulpe 100% pur jus	Fruit juice	+(4)	+(4)	+p	+p	+	-	+	-	+	st	st	/	/	-	-	-	-	ND	-	ND	3	c		
647	Cidre brut de Normandie	Cider	st	st	st	st	-																	3	c	
648	Jus d'orange 100% pur jus	Fruit juice	st	st	st	st	-	+	+	+	+	+	+p	/	+/+	+	+	+	+	PD	+	PD	3	c		
649	Jus d'orange avec pulpe 100% pur jus	Fruit juice	st	st	st	st	-																	3	c	
650	Cidre brut	Cider	st	st	st	st	-																		3	c

## Appendix 5 – Relative level of detection study: raw data

Matrix : Raw ground beef  
Strain : *E.coli* O157:H7 Ad486

Aerobic mesophilic flora : 4,6.10<sup>3</sup>CFU/g

N° sample	Level	Contamination level- (cfu/sample)	Reference method : ISO 16654*					Number positive samples / Total	Alternative method: 3M™ Molecular Detection Assay 2 - <i>E. coli</i> O157 (including H7)											
			IMS 6h		IMS 24h		Final result		Protocol 8h at 41.5°C ±1°C 3M BPW ISO				Number positive samples / Total	Protocol 24h at 41.5°C± 1°C 3M BPW ISO				Number positive samples /Total		
			CT-SMAC	CHROMagar O157	CT-SMAC	CHROMagar O157			MDA test	Matrix control	Confirmation	Final result		MDA test	Matrix control	Confirmation	Final result			
526	0	/	st	st	st	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
527			st	st	st	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
528			st	st	st	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
529			st	st	st	st	-	-	+	-	-	-	-	-	-	-	-	-	-	
530			st	st	st	-	-	-	+	-	-	-	-	-	-	-	-	-	-	
531	Low	0,6	st	st	-	-	-	+	+	+	+	+	+	+	+	+	+	+		
532			st	st	st	-	-	-	+	-	-	-	-	+	-	-	-	-		
533			+p	+p	/	/	-	-	+	+	-	-	-	-	+	-	-	-	-	
534			+p	+p	/	/	-	-	+	+	+	+	+	+	+	+	+	+	+	+
535			st	st	st	-	-	-	-	+	-	-	-	-	-	+	-	-	-	
536			+p	+p	/	/	-	-	+	+	-	-	-	-	-	+	-	-	-	
537			st	st	st	st	-	-	+	+	+	+	+	+	+	+	+	+	+	
538			st	st	+p	+p	-	-	-	+	-	-	-	-	-	+	-	-	-	
539			st	st	st	-	-	-	+	+	+	+	+	+	+	+	+	+	+	
540			st	st	st	-	-	-	+	+	+	+	+	+	+	+	+	+	+	
541			+p	+p	/	/	-	-	+	+	+	+	+	+	+	+	+	+	+	
542			+p	+p	/	/	-	-	+	+	+	+	+	+	+	+	+	+	+	
543			+p	+p	/	/	-	-	+	+	+	+	+	+	+	+	+	+	+	
544			st	st	st	-	-	-	inspect/+	+	+	+	+	+	+	+	+	+	+	
545			+p	+p	/	/	-	-	-	+	-	-	-	-	-	+	-	-	-	
546			+p	+p	/	/	-	-	+	inspect/-	+	-	-	-	-	+	-	-	-	
547			+p	+p	/	/	-	-	+	+	+	+	+	+	+	+	+	+	+	
548			+p	+p	/	/	-	-	+	+	+	+	+	+	+	+	+	+	+	
549			st	st	st	-	-	-	-	+	-	-	-	-	-	+	-	-	-	
550			+p	+p	/	/	-	-	+	+	+	+	+	+	+	+	+	+	+	
551	High	5,5	+p	+p	/	/	-	+	+	+	+	+	+	+	+	+	+	+		
552			+p	+p	/	/	-	+	+	+	+	+	+	+	+	+	+	+		
553			+p	+p	/	/	-	-	+	+	+	+	+	+	+	+	+	+		
554			+p	+p	/	/	-	-	inspect/+	+	+	+	+	+	+	+	+	+	+	
555			st	st	+p	+p	-	-	inspect/+	+	+	+	+	+	+	+	+	+	+	

Inspect: unusual light output during the run. The user has to repeat a second assay without applying any dilution

\* Analyses performed according to the COFRAC accreditation

ADRIA Développement

Summary report (Version 0)

3M MDA 2 - *E. coli* O157 (including H7)

Matrix : Raw milk  
Strain : *E.coli* O157:H7 Ad686

Aerobic mesophilic flora :  $6.10^7$ CFU/g

N° sample	Level	Contamination level- (cfu/sample)	Reference method: ISO 16654*					Number positive samples/ Total	Alternative method: 3M™ Molecular Detection Assay 2 - <i>E. coli</i> O157 (including H7)				
			IMS 6 h		IMS 24 h		Final result		Protocol 18h at 41,5°C±1°C 3M BPW ISO				Number positive samples/ Total
			CT-SMAC	CHROMagar O157	CT-SMAC	CHROMagar O157			MDA test	Matrix control	Confirmation	Final result	
730	0	/	-	-	-	-	-	-	+	-	-	0/5	
731			-	-	-	-	-	-	+	-	-		
732			-	-	-	-	-	-	-	+	-		-
733			-	-	-	-	-	-	-	+	-		-
734			-	-	-	-	-	-	-	+	-		-
735	Low	0,6	+m	+m	/	/	+	+	+	+	+	8/20	
736			-	-	-	-	-	-	+	-	-		
737			-	-	-	-	-	-	-	+	-		-
738			-	-	-	-	-	-	-	+	-		-
739			-	-	-	-	-	-	+	+	+		+
740			-	-	-	-	-	-	-	+	-		-
741			-	-	-	-	-	-	+	+	+		+
742			-	-	-	-	-	-	+	+	+		+
743			-	-	-	-	-	-	-	+	-		-
744			-	-	-	-	-	-	-	+	-		-
745			-	-	-	-	-	-	-	+	-		-
746			+m	+m	/	/	+	-	+	+	+		+
747			-	-	-	-	-	-	+	+	+		+
748			+m	-	/	/	+	-	+	+	+		+
749			+M	-	+m	+m	+	-	+	-	-		-
750			-	-	-	-	-	-	-	+	-		-
751			-	-	-	-	-	-	+	+	+		+
752			-	+d(2) (NC)	+md (NC)	-	-	-	-	+	-		-
753			-	-	-	-	-	-	-	+	-		-
754	+M	+m	+1/2	+m	+	-	+	+	+	+			
755	High	5,5	+m	+m	/	/	+	+	+	+	+	5/5	
756			+m	+m	/	/	+	+	+	+	+		
757			+m	+m	/	/	+	+	+	+	+		
758			+1/2	+m	/	/	+	+	+	+	+		
759			+1/2	+m	/	/	+	+	+	+	+		

NC: Non characteristic on non-selective agar plate

\* Analyses performed according to the COFRAC accreditation

ADRIA Développement

Summary report (Version 0)

3M MDA 2 - *E. coli* O157 (including H7)

Matrix : Raw spinach  
Strain : *E.coli* O157:H7 Ad556

Aerobic mesophilic flora : 8,2.10<sup>6</sup> CFU/g

N° sample	Level	Contamination level- (cfu/sample)	Reference method : ISO 16654♦					Number positive samples/ Total	Alternative method: 3M™ Molecular Detection Assay 2 - <i>E. coli</i> O157 (including H7)					
			IMS 6h		IMS 24h		Final result		Protocol 18h at 41,5°C±1°C 3M BPW ISO				Number positive samples/ Total	
			CT-SMAC	CHROMagar O157	CT-SMAC	CHROMagar O157			MDA test	Matrix control	Confirmation	Final result		
1067	0	/	-	-	-	-	-	-	+	-	-	0/5		
1068			-	-	-	-	-	-	+	-	-			
1069			-	-	-	-	-	-	-	+	-		-	
1070			-	-	-	-	-	-	-	+	-		-	
1071			-	-	-	-	-	-	-	+	-		-	
1072	Low	1,0	-	-	-	-	-	-	+	-	-	7/20		
1073			-	-	-	-	-	-	-	+	-		-	
1074			-	-	-	-	-	-	-	+	-		-	
1075			-	-	-	-	-	-	-	+	-		-	
1076			-	-	-	-	-	-	-	+	-		-	
1077			-	-	-	-	-	-	-	+	+		+	-
1078			-	-	-	-	-	-	-	+	+		-	-
1079			+m	+m	+m	+m	+	+	+	+	+		+	-
1080			-	-	-	-	-	-	-	+	+		-	-
1081			+M	+1/2	/	/	+	+	+	+	+		+	-
1082			+m	-	+m	-	+	+	+	+	+		+	-
1083			+M	+1/2	/	/	+	+	+	+	+		+	-
1084			+m	-	+m	-	+	+	+	+	+		+	-
1085			-	-	+p	+m	+	+	+	+	+		+	-
1086			+M	+1/2	/	/	+	+	+	+	+		+	-
1087	-	-	-	-	-	+	+	+	+	+	-			
1088	-	-	-	-	-	-	+	+	+	+	-			
1089	-	-	-	-	-	-	+	+	+	+	-			
1090	+M	+1/2	/	/	+	+	+	+	+	+	-			
1091	-	-	-	-	-	+	+	+	+	+	-			
1092	High	10,0	+p	+M	/	/	+	+	+	+	+	5/5		
1093			+p	+1/2	/	/	+	+	+	+	+			
1094			+M	+1/2	/	/	+	+	+	+	+			
1095			+M	+M	/	/	+	+	+	+	+			
1096			+M	+1/2	/	/	+	+	+	+	+			

♦ Analyses performed according to the COFRAC accreditation

ADRIA Développement

Summary report (Version 0)

3M MDA 2 - *E. coli* O157 (including H7)

## Appendix 6 – Inclusivity and exclusivity study: raw data

INCLUSIVITY											
Strains				Origin	3M™ Molecular Detection Assay 2 - <i>E. coli</i> O157 (including H7)						Final result
					Inoculation level (cfu/225ml)	Protocol 8h at 41.5°C ± 1°C 3M BPW ISO					
						MDA test		Confirmation			
MDA	Matrix control	CT-SMAC (50µL)	Latex O157	Latex H7							
1	<i>Escherichia coli</i>	O157:H7	Ad552	Slaughterhouse	42	+	+	+	+	+	+
2	<i>Escherichia coli</i>	O157:H7	Ad553	Slaughterhouse	23	+	+	+	+	+	+
3	<i>Escherichia coli</i>	O157:H7	Ad554	Slaughterhouse	15	+	+	+	+	+	+
4	<i>Escherichia coli</i>	O157:H7	Ad555	Slaughterhouse	20	+	+	+	+	+	+
5	<i>Escherichia coli</i>	O157:H7	Ad556	Water purification	20	+	+	+	+	+	+
6	<i>Escherichia coli</i>	O157:H7	Ad557	Water purification	19	+	+	+	+	+	+
7	<i>Escherichia coli</i>	O157:H7	Ad558	Water purification	29	+	+	+	+	+	+
8	<i>Escherichia coli</i>	O157:H7	Ad559	Ground beef	36	+	+	+	+	+	+
9	<i>Escherichia coli</i>	O157:H7	Ad560	Ground beef	12	+	+	+	+	+	+
10	<i>Escherichia coli</i>	O157:H7	Ad561	Ground beef	27	+	+	+	+	+	+
11	<i>Escherichia coli</i>	O157:H7	Ad562	Ground beef	21	+	+	+	+	+	+
12	<i>Escherichia coli</i>	O157:H7	Ad563	Ground beef	22	+	+	+	+	+	+
13	<i>Escherichia coli</i>	O157:H7	Ad564	Ground beef	13	+	+	+	+	+	+
14	<i>Escherichia coli</i>	O157:H7	Ad567	Slaughterhouse	27	+	+	+	+	+	+
15	<i>Escherichia coli</i>	O157:H7	Ad568	Slaughterhouse	19	+	+	+	+	+	+
16	<i>Escherichia coli</i>	O157:H7	Ad569	Slaughterhouse	27	+	+	+	+	+	+
17	<i>Escherichia coli</i>	O157:H7	Ad570	Slaughterhouse	27	+	+	+	+	+	+
18	<i>Escherichia coli</i>	O157:H7	Ad571	Feces	10	+	+	+	+	+	+
19	<i>Escherichia coli</i>	O157:H7	Ad572	Feces	33	+	+	+	+	+	+
20	<i>Escherichia coli</i>	O157:H7	Ad573	Feces	30	+	+	+	+	+	+
21	<i>Escherichia coli</i>	O157:H7	Ad574	Feces	39	+	+	+	+	+	+



INCLUSIVITY											
Strains				Origin	3M™ Molecular Detection Assay 2 - <i>E. coli</i> O157 (including H7)						Final result
					Inoculation level (cfu/225ml)	Protocol 8h at 41.5°C ± 1°C 3M BPW ISO					
						MDA test		Confirmation			
MDA	Matrix control	CT-SMAC (50µL)	Latex O157	Latex H7							
22	<i>Escherichia coli</i>	O157:H7	Ad575	Feces	19	+	+	+	+	+	+
23	<i>Escherichia coli</i>	O157:H7	Ad576	Feces	32	+	+	+	+	+	+
24	<i>Escherichia coli</i>	O157:H7	Ad577	Feces	28	+	+	+	+	+	+
25	<i>Escherichia coli</i>	O157:H7	Ad578	Feces	20	+	+	+	+	+	+
26	<i>Escherichia coli</i>	O157:H7	Ad579	Feces	29	+	+	+	+	+	+
27	<i>Escherichia coli</i>	O157:H7	Ad580	Feces	35	+	+	+	+	+	+
28	<i>Escherichia coli</i>	O157:H7	Ad585	Ground beef	37	+	+	+	+	+	+
29	<i>Escherichia coli</i>	O157:H7	Ad586	Ground beef	26	+	+	+	+	+	+
30	<i>Escherichia coli</i>	O157:H7	Ad587	Ground beef	26	+	+	+	+	+	+
31	<i>Escherichia coli</i>	O157:H7	Ad588	Ground beef	13	+	+	+	+	+	+
32	<i>Escherichia coli</i>	O157:H7	Ad589	Ground beef	17	+	+	+	+	+	+
33	<i>Escherichia coli</i>	O157:H7	Ad590	Ground beef	35	+	+	+	+	+	+
34	<i>Escherichia coli</i>	O157:H7	Ad591	Ground beef	37	+	+	+	+	+	+
35	<i>Escherichia coli</i>	O157:H7	EF190	Feces	23	+	+	+	+	+	+
36	<i>Escherichia coli</i>	O157:H7	Ad686	Slaughterhouse	25	+	+	+	+	+	+
37	<i>Escherichia coli</i>	O157:H7	CIP103571 (ATCC 35150)	Clinical origin	38	+	+	+	+	+	+
38	<i>Escherichia coli</i>	O157:H7	ATCC 43888	/	23	+	+	+	+	+	+
39	<i>Escherichia coli</i>	O157:H7	Ad486	Ground beef	29	+	+	+	+	+	+
40	<i>Escherichia coli</i>	O157:H7	Ad487	Ground beef	19	+	+	+	+	+	+
41	<i>Escherichia coli</i>	O157:H7	Ad488	Ground beef	20	+	+	+	+	+	+
42	<i>Escherichia coli</i>	O157:H7	Ad489	Ground beef	18	+	+	+	+	+	+
43	<i>Escherichia coli</i>	O157:H7	ATCC 700728	/	38	+	+	+	+	+	+
44	<i>Escherichia coli</i>	O157	Ad524	Environment (dairy products)	18	+	+	+ (red colonies)	+	-	+

INCLUSIVITY											
Strains				Origin	3M™ Molecular Detection Assay 2 - <i>E. coli</i> O157 (including H7)						Final result
					Inoculation level (cfu/225ml)	Protocol 8h at 41.5°C ± 1°C 3M BPW ISO					
						MDA test		Confirmation			
					MDA	Matrix control	CT-SMAC (50µL)	Latex O157	Latex H7		
45	<i>Escherichia coli</i>	O157	Ad525	Feces	26	+	+	+ (red colonies)	+	-	+
46	<i>Escherichia coli</i>	O157	Ad526	Feces	34	+	+	+ (red colonies)	+	-	+
47	<i>Escherichia coli</i>	O157	Ad527	Clinical origin	19	+	+	+ (red colonies)	+	-	+
48	<i>Escherichia coli</i>	O157:H-	Ad535	/	17	+	+	+ (red colonies)	+	-	+
49	<i>Escherichia coli</i>	O157:H-	Ad536	/	31	+	+	+ (red colonies)	+	-	+
50	<i>Escherichia coli</i>	O157:H43	Ad517	Pork (USA)	33	+	+	+ (red colonies)	+	-	+

EXCLUSIVITY								
Strains				Origin	3M™ Molecular Detection Assay 2 - <i>E. coli</i> O157 (including H7)			
					Inoculation level (cfu/ml)	Protocol 24 h at 37°C ± 1°C 3M BPW ISO		Final result
Result		Matrix control						
1	<i>Citrobacter freundii</i>	/	25	Frozen raw spinach	3,02.10 <sup>5</sup>	-	+	-
2	<i>Citrobacter freundii</i>	/	104	Ground beef	2,60.10 <sup>5</sup>	-	+	-
3	<i>Escherichia coli</i>	O92:H33	Ad503	Clinical origin (Mexico)	3,68.10 <sup>5</sup>	-	+	-
4	<i>Escherichia coli</i>	O3:H2	Ad504	Clinical origin (Chili)	3,30.10 <sup>5</sup>	-	+	-
5	<i>Escherichia coli</i>	O78:H11	ATCC 35401	Human origin	2,50.10 <sup>5</sup>	-	+	-
6	<i>Escherichia coli</i>	O6:H6	Ad506	Human origin	3,16.10 <sup>5</sup>	-	+	-
7	<i>Escherichia coli</i>	O6:H10	Ad507	Clinical origin (Sweden)	5,11.10 <sup>5</sup>	-	+	-
8	<i>Escherichia coli</i>	O111:H21	Ad508	Clinical origin (USA)	2,00.10 <sup>5</sup>	-	+	-
9	<i>Escherichia coli</i>	O86:H43	Ad509	Animal origin (elephant USA)	2,40.10 <sup>5</sup>	-	+	-
10	<i>Escherichia coli</i>	O26:H11	Ad510	Clinical origin (USA)	3,40.10 <sup>5</sup>	-	+	-
11	<i>Escherichia coli</i>	O111:H8	Ad511	Clinical origin (USA)	1,60.10 <sup>5</sup>	-	+	-
12	<i>Escherichia coli</i>	O128:H2	Ad512	Clinical origin (USA)	4,00.10 <sup>5</sup>	-	+	-
13	<i>Escherichia coli</i>	O111:H2	Ad513	Clinical origin (UK)	4,00.10 <sup>5</sup>	-	+	-
14	<i>Escherichia coli</i>	O128:H7	Ad514	Clinical origin (USA)	3,02.10 <sup>5</sup>	-	+	-
15	<i>Escherichia coli</i>	O78:K80:H12	ATCC43896	Human origin	3,30.10 <sup>5</sup>	-	+	-
16	<i>Escherichia coli</i>	O104:H21	Ad516	Clinical origin (USA)	5,60.10 <sup>5</sup>	-	+	-
17	<i>Escherichia coli</i>	O26	Ad980	Clinical origin	1,60.10 <sup>5</sup>	-	+	-
18	<i>Escherichia coli</i>	O55:H7	Ad518	Clinical origin (Sri Lanka)	2,89.10 <sup>5</sup>	-	+	-
19	<i>Escherichia coli</i>	O44:H18	Ad519	Clinical origin (Peru)	3,40.10 <sup>5</sup>	-	+	-
20	<i>Escherichia coli</i>	O127:H6	Ad520	Clinical origin (UK)	4,40.10 <sup>5</sup>	-	+	-
21	<i>Escherichia coli</i>	O55:H6	Ad521	Clinical origin (USA)	3,29.10 <sup>5</sup>	-	+	-
22	<i>Escherichia coli</i>	O18:K1:H7	Ad522	Clinical origin	4,00.10 <sup>5</sup>	-	+	-
23	<i>Escherichia coli</i>	O145	Ad983	Clinical origin	2,63.10 <sup>5</sup>	-	+	-
24	<i>Escherichia vulneris</i>	/	127	Raw milk	3,60.10 <sup>5</sup>	-	+	-
25	<i>Hafnia alvei</i>	/	88	Bakery	4,22.10 <sup>5</sup>	-	+	-
26	<i>Pantoea spp.</i>	/	134	Pork	3,55.10 <sup>5</sup>	-	+	-
27	<i>Salmonella</i> Landau		Ad499	/	2,60.10 <sup>5</sup>	-	+	-
28	<i>Salmonella</i> Sternhauze		Ad500	/	2,00.10 <sup>5</sup>	-	+	-
29	<i>Salmonella</i> Urbana		Ad501	/	3,00.10 <sup>5</sup>	-	+	-
30	<i>Salmonella</i> Wayne		Ad502	/	2,08.10 <sup>5</sup>	-	+	-

## Appendix 7 - Results obtained by the collaborative laboratories and the expert laboratory

Laboratory: **A**

Aerobic mesophilic flora 1,9.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
A4	-	-	/	-	-	/	/	-	NA
A6	-	-	/	-	-	/	/	-	NA
A9	-	-	/	-	-	/	/	-	NA
A12	-	-	/	-	-	/	/	-	NA
A13	-	-	/	-	-	/	/	-	NA
A17	-	-	/	-	-	/	/	-	NA
A22	-	-	/	-	-	/	/	-	NA
A23	-	-	/	-	-	/	/	-	NA
A1	+	+	+	+	+	+	+	+	PA
A3	-	-	/	-	+	+	+	+	PD
A8	-	-	/	-	+	+	+	+	PD
A10	+	+	+	+	+	+	+	+	PA
A16	+	+	+	+	+	+	+	+	PA
A20	+	+	+	+	-	-*	/	-	ND
A21	+	+	+	+	+	+	+	+	PA
A24	+	+	+	+	+	+	+	+	PA
A2	+	+	+	+	+	+	+	+	PA
A5	+	+	+	+	+	+	+	+	PA
A7	+	+	+	+	+	+	+	+	PA
A11	+	+	+	+	+	+	+	+	PA
A14	+	+	+	+	+	+	+	+	PA
A15	+	+	+	+	+	+	+	+	PA
A18	+	+	+	+	+	+	+	+	PA
A19	+	+	+	+	+	+	+	+	PA

\* Sample A20(Alt): The streaking of BPW after one-week storage didn't allow to recover the inoculated strain.

Laboratory:

**B**

Aerobic mesophilic flora

1,9.10<sup>2</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
B4	-	-	/	-	-	/	/	-	NA
B6	-	-	/	-	-	/	/	-	NA
B9	-	-	/	-	-	/	/	-	NA
B12	-	-	/	-	-	/	/	-	NA
B13	-	-	/	-	-	/	/	-	NA
B17	-	-	/	-	-	/	/	-	NA
B22	-	-	/	-	-	/	/	-	NA
B23	-	-	/	-	-	/	/	-	NA
B1	+	+	+	+	+	+	+	+	PA
B3	+	+	+	+	-	-	/	-	ND
B8	+	+	+	+	+	+	+	+	PA
B10	+	+	+	+	+	+	+	+	PA
B16	+	+	+	+	+	+	+	+	PA
B20	+	+	+	+	+	+	+	+	PA
B21	+	+	+	+	+	+	+	+	PA
B24	+	+	+	+	+	+	+	+	PA
B2	+	+	+	+	+	+	+	+	PA
B5	+	+	+	+	+	+	+	+	PA
B7	+	+	+	+	+	+	+	+	PA
B11	+	+	+	+	+	+	+	+	PA
B14	+	+	+	+	+	+	+	+	PA
B15	+	+	+	+	+	+	+	+	PA
B18	+	+	+	+	+	+	+	+	PA
B19	+	+	+	+	+	+	+	+	PA

Laboratory:

**C**

Aerobic mesophilic flora

1,3.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confir- mation	Final result	MDS result	CT SMAC	Latex	Final result	
<b>C4</b>	-	-	/	-	+ / + / - / - / - (low ct values)	-	/	-	<b>PPNA</b>
<b>C6</b>	-	-	/	-	-	/	/	-	<b>NA</b>
<b>C9</b>	-	-	/	-	-	/	/	-	<b>NA</b>
<b>C12</b>	-	-	/	-	-	/	/	-	<b>NA</b>
<b>C13</b>	-	-	/	-	-	/	/	-	<b>NA</b>
<b>C17</b>	-	-	/	-	-	/	/	-	<b>NA</b>
<b>C22</b>	-	-	/	-	-	/	/	-	<b>NA</b>
<b>C23</b>	-	-	/	-	-	/	/	-	<b>NA</b>
<b>C1</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C3</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C8</b>	+	+	+	+	- / - / -	-	/	-	<b>ND</b>
<b>C10</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C16</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C20</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C21</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C24</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C2</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C5</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C7</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C11</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C14</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C15</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C18</b>	+	+	+	+	+	+	+	+	<b>PA</b>
<b>C19</b>	+	+	+	+	+	+	+	+	<b>PA</b>

Laboratory:

D

Aerobic mesophilic flora

7,8.10<sup>2</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confir- mation	Final result	MDS result	CT SMAC	Latex	Final result	
D4	-	-	/	-	-	/	/	-	NA
D6	-	-	/	-	-	/	/	-	NA
D9	-	-	/	-	-	/	/	-	NA
D12	-	-	/	-	-	/	/	-	NA
D13	-	-	/	-	-	/	/	-	NA
D17	-	-	/	-	-	/	/	-	NA
D22	-	-	/	-	-	/	/	-	NA
D23	-	-	/	-	-	/	/	-	NA
D1	+	+	+	+	+	+	+	+	PA
D3	+	+	+	+	+	+	+	+	PA
D8	+	+	+	+	+	+	+	+	PA
D10	+	+	+	+	+	+	+	+	PA
D16	+	+	+	+	+	+	+	+	PA
D20	+	+	+	+	+	+	+	+	PA
D21	+	+	+	+	+	+	+	+	PA
D24	+	+	+	+	+	+	+	+	PA
D2	+	+	+	+	+	+	+	+	PA
D5	+	+	+	+	+	+	+	+	PA
D7	+	+	+	+	+	+	+	+	PA
D11	+	+	+	+	+	+	+	+	PA
D14	+	+	+	+	+	+	+	+	PA
D15	+	+	+	+	+	+	+	+	PA
D18	+	+	+	+	+	+	+	+	PA
D19	+	+	+	+	+	+	+	+	PA

Laboratory:

**E**

Aerobic mesophilic flora

2,3.10<sup>3</sup> CFU/g

N° Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
E4	-	-	/	-	-	/	/	-	NA
E6	-	-	/	-	-	/	/	-	NA
E9	+	+	+ (Latex Auto ADRIA) **	+(-)	-	/	/	-	NA
E12	-	-	/	-	-	/	/	-	NA
E13	-	-	/	-	+	+	+(ADRIA: Latex -) **	-	PPNA
E17	-	-	/	-	-	/	/	-	NA
E22	-	-	/	-	-	/	/	-	NA
E23	-	-	/	-	-	/	/	-	NA
E1	+	+	+	+	+	+	+	+	PA
E3	+	+	+	+	+	+	+	+	PA
E8	+	+	+	+	-	-*	/	-	ND
E10	+	+	+	+	+	+	+(ADRIA: Latex+) **	+	PA
E16	+	+	+	+	+	+	+	+	PA
E20	+	+	+	+	+	+	+	+	PA
E21	+	+	+	+	+	+	+	+	PA
E24	+	+	+	+	+	+	+	+	PA
E2	+	+	+	+	+	+	+	+	PA
E5	+	+	+	+	+	+	+	+	PA
E7	+	+	+	+	+	+	+(Latex+ ADRIA) **	+	PA
E11	+	+	+	+	+	+	+	+	PA
E14	+	+	+	+	+	+	+	+	PA
E15	+	+	+	+	+	+	+	+	PA
E18	+	+	+	+	+	+	+	+	PA
E19	+	+	+	+	+	+	+	+	PA

\* Sample E8: The streaking of BPW after BPW storage didn't allow to recover the inoculated strains.

\*\* Samples E9, E13, E10 and E7: The isolates were tested twice in ADRIA.



Laboratory:

F

Aerobic mesophilic flora

4,7.10<sup>2</sup> CFU/g

N° Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
F4	-	-	/	-	-	+ (ADRIA: +/-)	+ (ADRIA: auto+)	-	NA
F6	+(ADRIA:-)	+	+ (ADRIA:+)	+	-	-	/	-	ND
F9	+(ADRIA:-)	-	+ (+ADRIA:+)	+	-	-	/	-	ND
F12	-	-	/	-	-	-	/	-	NA
F13	-	-	/	-	-	+ (few colonies)	+ (ADRIA:- )	-	NA
F17	-	-	/	-	-	-	/	-	NA
F22	-	-	/	-	-	-	/	-	NA
F23	-	-	/	-	-	-	/	-	NA
F1	+	+	+	+	+	+	+	+	PA
F3	+	+	+	+	+	+	+	+	PA
F8	+	+	+	+	-/+ *	+	+	-	ND
F10	+	+	+	+	-/- *	+ (few colonies)	+	-	ND
F16	-	-	/	-	-/+ *	+	+	-	NA
F20	+	+	+	+	-/- *	-	/	-	ND
F21	+	+	+	+	-/+ *	-	/	-	ND
F24	+	+	+	+	-/- *	+	+	-	ND
F2	+	+	+	+	+	+	+	+	PA
F5	+	+	+	+	+	+	+	+	PA
F7	+	+	+	+	+	+	+	+	PA
F11	+	+	+	+	+	+	+	+	PA
F14	+	+	+	+	+	+	+	+	PA
F15	+	+	+	+	+	+	+	+	PA
F18	+	+	+	+	+	+	+	+	PA
F19	+	+	+	+	+	+	+	+	PA

\* Samples F8-F10-F16-F20-F21-F24: New lysates were tested after 1 week storage of BPW at 4°C. Confirmations were also run by streaking onto CT-SMAC

Streaking performed at ADRIA on BPW provided by the Lab

**Due to the observed unexpected data and the additional testing results, it was decided to exclude this lab.**

Laboratory:

**G**

Aerobic mesophilic flora

2,4.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
G4	-	-	/	-	-	/	/	-	NA
G6	-	-	/	-	-	/	/	-	NA
G9	+	+	+(ADRIA: O157+/H7+) *	+	-	/	/	-	ND
G12	-	-	/	-	-	/	/	-	NA
G13	-	-	/	-	-	/	/	-	NA
G17	-	-	/	-	-	/	/	-	NA
G22	-	-	/	-	-	/	/	-	NA
G23	-	+	-	-	-	/	/	-	NA
G1	+	+	+	+	+	+	+	+	PA
G3	+	+	+	+	+	+	+	+	PA
G8	+	+	+	+	+	+	+	+	PA
G10	+	+	+	+	+	+	+	+	PA
G16	-	-	/	-	+	+	+	+	PD
G20	+	+	+	+	+	+	+	+	PA
G21	+	+	+	+	+	+	+	+	PA
G24	+	+	+	+	+	+	+	+	PA
G2	+	+	+	+	+	+	+	+	PA
G5	+	+	+	+	+	+	+	+	PA
G7	+	+	+	+	+	+	+	+	PA
G11	+	+	+	+	+	+	+	+	PA
G14	+	+	+	+	+	+	+	+	PA
G15	+	+	+	+	+	+	+	+	PA
G18	+	+	+	+	+	+	+	+	PA
G19	+	+	+	+	+	+	+	+	PA

\* The additional test done in ADRIA showed a positive reaction as well.

Laboratory: **H**Aerobic mesophilic flora :  $1,5 \cdot 10^3$  CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
H4	-	-	/	-	-	/	/	-	NA
H6	-	-	/	-	-	/	/	-	NA
H9	-	-	/	-	-	/	/	-	NA
H12	-	-	/	-	-	/	/	-	NA
H13	-	-	/	-	-	/	/	-	NA
H17	-	-	/	-	-	/	/	-	NA
H22	-	-	/	-	-	/	/	-	NA
H23	-	-	/	-	-	/	/	-	NA
H1	+	+	+	+	+	+	+	+	PA
H3	+	+	+	+	+	+	+	+	PA
H8	+	+	+	+	+	+	+	+	PA
H10	+	+	+	+	+	+	+	+	PA
H16	+	-	+	+	+	+	+	+	PA
H20	-	-	/	-	+	+	+	+	PD
H21	+	+	+	+	+	+	+	+	PA
H24	+	+	+	+	+	+	+	+	PA
H2	+	+	+	+	+	+	+	+	PA
H5	+	+	+	+	+	+	+	+	PA
H7	+	+	+	+	+	+	+	+	PA
H11	+	+	+	+	+	+	+	+	PA
H14	+	+	+	+	+	+	+	+	PA
H15	+	+	+	+	+	+	+	+	PA
H18	+	+	+	+	+	+	+	+	PA
H19	+	+	+	+	+	+	+	+	PA

Laboratory: I

Aerobic mesophilic flora 1,7.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
I4	-	-	/	-	-	-	/	-	NA
I6	+	+	+	+	-	-	/	-	ND
I9	-	-	/	-	-	-	/	-	NA
I12	-	-	/	-	-	-	/	-	NA
I13	-	-	/	-	-	-	/	-	NA
I17	-	-	/	-	-	-	/	-	NA
I22	-	-	/	-	-	-	/	-	NA
I23	-	-	/	-	-	-	/	-	NA
I1	+	+	+	+	+	+	+	+	PA
I3	+	+	+	+	+	+	+	+	PA
I8	+	+	+	+	+	+	+	+	PA
I10	+	+	+	+	+	+	+	+	PA
I16	-	-	/	-	+	+	+	+	PD
I20	+	+	+	+	+	+	+	+	PA
I21	+	+	+	+	+	+	+	+	PA
I24	+	+	+	+	+	+	+	+	PA
I2	+	+	+	+	+	+	+	+	PA
I5	+	+	+	+	+	+	+	+	PA
I7	+	+	+	+	+	+	+	+	PA
I11	+	+	+	+	+	+	+	+	PA
I14	+	+	+	+	+	+	+	+	PA
I15	+	+	+	+	+	+	+	+	PA
I18	+	+	+	+	+	+	+	+	PA
I19	+	+	+	+	+	+	+	+	PA

**Laboratory:** J  
 Aerobic mesophilic flora 7,8.10<sup>2</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
J4	+	-	-	-	-	/	/	-	NA
J6	-	-	/	-	-	/	/	-	NA
J9	-	-	/	-	-	/	/	-	NA
J12	+/- *	+/- *	+/- *	+	-	/	/	-	ND
J13	-	-	/	-	-	/	/	-	NA
J17	-	-	/	-	-	/	/	-	NA
J22	-	-	/	-	-	/	/	-	NA
J23	-	-	/	-	-	/	/	-	NA
J1	+	+	+	+	-	+ **	+ **	-	ND
J3	+	+	+	+	+	+	+	+	PA
J8	+	+	+	+	+	+	+	+	PA
J10	+	+	+	+	-	+ **	+ **	-	ND
J16	+	+	+	+	+	+	+	+	PA
J20	+	-	+	+	+	+	+	+	PA
J21	+	+	+	+	+	+	+	+	PA
J24	+	+	+	+	+	+	+	+	PA
J2	+	+	+	+	+	+	+	+	PA
J5	+	+	+	+	+	+	+	+	PA
J7	+	+	+	+	+	+	+	+	PA
J11	+	+	+	+	+	+	+	+	PA
J14	+	+	+	+	+	+	+	+	PA
J15	+	+	+	+	+	+	+	+	PA
J18	+	+	+	+	+	+	+	+	PA
J19	+	+	+	+	+	+	+	+	PA

\* Sample J12 (Ref): A second IMS after 1-week storage of the mTSB gave a negative result.

\*\* Samples J1 and J10 (Alt): Streaking were done twice according to ADRIA recommendations. When coming back again to the lab, it was then not possible anymore to run additional MDS.

Laboratory:

K

Aerobic mesophilic flora 2,5.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
K4	-	-	/	-	-	/	/	-	NA
K6	+	-	+**	+	-	+(IMS)*	+	-	FN
K9	+	-	+**	+	-	/	/	-	ND
K12	-	-	/	-	-	/	/	-	NA
K13	-	-	/	-	-	/	/	-	NA
K17	-	-	/	-	-	/	/	-	NA
K22	-	-	/	-	-	/	/	-	NA
K23	-	-	/	-	-	/	/	-	NA
K1	+	+	+	+	+	+	+	+	PA
K3	+	+	+	+	-	+	+	-	ND
K8	+	+	+	+	+	+	+	+	PA
K10	+	+	+	+	+	+	+	+	PA
K16	+	+	+	+	-	/	/	-	ND
K20	+	+	+	+	-	+(IMS)*	+	-	ND
K21	+	+	+	+	-	+(IMS)*	+	-	ND
K24	+	+	+	+	+	+	+	+	PA
K2	+	+	+	+	+	+	+	+	PA
K5	+	+	+	+	+	+	+	+	PA
K7	+	+	+	+	+	+	+	+	PA
K11	+	+	+	+	+	+	+	+	PA
K14	+	+	+	+	+	+	+	+	PA
K15	+	+	+	+	+	+	+	+	PA
K18	+	+	+	+	-	+	+	-	ND
K19	+	+	+	+	-	+	+	-	ND

\* Samples K3-K6-K18-K19-K20-K21: Confirmatory tests were realized after 1-week storage of BPW. When coming back to the lab, it was too late to repeat the assays related to the unexpected results.

\*\* Samples K6 and K9 (ref: Isolates from were not available for additional testing by ADRIA.

**Due to the observed unexpected data, and the impossibility to run further testing to explain the observed results, it was decided to exclude that Lab.**

Laboratory:

N

Aerobic mesophilic flora

1,5.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
N4	-	-	/	-	-	/	/	-	NA
N6	-	-	/	-	-	/	/	-	NA
N9	-	-	/	-	-	/	/	-	NA
N12	-	-	/	-	-	/	/	-	NA
N13	-	-	/	-	-	/	/	-	NA
N17	-	-	/	-	-	/	/	-	NA
N22	-	-	/	-	-	/	/	-	NA
N23	-	-	/	-	-	/	/	-	NA
N1	+	+	+	+	+	+	+	+	PA
N3	+	+	+	+	+	+	+	+	PA
N8	+	+	+	+	+	+	+	+	PA
N10	+	+	+	+	+	+	+	+	PA
N16	-	-	/	-	+	+	+	+	PD
N20	+	+	+	+	+	+	+	+	PA
N21	+	+	+	+	+	+	+	+	PA
N24	+	+	+	+	+	+	+	+	PA
N2	+	+	+	+	+	+	+	+	PA
N5	+	+	+	+	+	+	+	+	PA
N7	+	+	+	+	+	+	+	+	PA
N11	+	+	+	+	+	+	+	+	PA
N14	+	+	+	+	+	+	+	+	PA
N15	+	+	+	+	+	+	+	+	PA
N18	+	+	+	+	+	+	+	+	PA
N19	+	+	+	+	+	+	+	+	PA

Laboratory: **O**

Aerobic mesophilic flora

1,7.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
O4	-	-	/	-	-	/	/	-	NA
O6	+	+	+	+	+	-/- (IMS)*	/	-	PPND
O9	-	-	/	-	-	/	/	-	NA
O12	-	-	/	-	-	/	/	-	NA
O13	-	-	/	-	-	/	/	-	NA
O17	-	-	/	-	-	/	/	-	NA
O22	-	-	/	-	-	/	/	-	NA
O23	-	-	/	-	-	/	/	-	NA
O1	+	+	+	+	-	-	/	-	ND
O3	+	+	+	+	+	-/- (IMS)*	/	-	PPND
O8	+	+	+	+	+	+	+	+	PA
O10	+	+	+	+	+	+	+	+	PA
O16	+	+	+	+	+	+	+	+	PA
O20	+	+	+	+	-	-/- (IMS)*	/	-	ND
O21	+	+	+	+	-	-/- (IMS)*	/	-	ND
O24	+	+	+	+	+	+	+	+	PA
O2	+	+	+	+	+	+	+	+	PA
O5	+	+	+	+	+	+	+	+	PA
O7	+	+	+	+	+	+	+	+	PA
O11	+	+	+	+	+	+	+	+	PA
O14	+	+	+	+	+	+	+	+	PA
O15	+	+	+	+	+	+	+	+	PA
O18	+	+	+	+	+	+	+	+	PA
O19	+	+	+	+	+	+	+	+	PA

\* Samples O3-O6-O20-O21: The Lab certified that the IMS were negative by running an IMS. But, despite many exchanges with them, the Lab. didn't provide additional test results, as well as the MDS reaction curves.

**Due to the observed unexpected data, and the impossibility to run further testing to explain the observed results, it was decided to exclude that Lab.**



Laboratory:

P

Aerobic mesophilic flora

1,4.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
P4	-	-	/	-	-	/	/	-	NA
P6	-	-	/	-	-	/	/	-	NA
P9	-	-	/	-	-	/	/	-	NA
P12	+	+	+	+	-	/	/	-	ND
P13	-	-	/	-	-	/	/	-	NA
P17	-	-	/	-	-	/	/	-	NA
P22	-	-	/	-	-	/	/	-	NA
P23	-	-	/	-	-	/	/	-	NA
P1	+	+	+	+	+	+	+	+	PA
P3	-	-	/	-	+	+	+	+	PD
P8	+	+	+	+	+	+	+	+	PA
P10	+	+	+	+	+	+	+	+	PA
P16	+	+	+	+	+	+	+	+	PA
P20	+	-	+	+	+	+	+	+	PA
P21	-	-	/	-	+	+	+	+	PD
P24	-	-	/	-	+	+	+	+	PD
P2	+	+	+	+	+	+	+	+	PA
P5	+	+	+	+	+	+	+	+	PA
P7	+	+	+	+	+	+	+	+	PA
P11	+	+	+	+	+	+	+	+	PA
P14	+	+	+	+	+	+	+	+	PA
P15	+	+	+	+	+	+	+	+	PA
P18	+	+	+	+	+	+	+	+	PA
P19	+	+	+	+	+	+	+	+	PA

Laboratory:

Q

Aerobic mesophilic flora

2,1.10<sup>3</sup> CFU/g

N° Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agree- ment
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
Q4	+	-	+ (- ADRIA) *	+ (-)*	-	-	/	-	NA
Q6	+	-	+ (- ADRIA) *	+ (-)*	-	-	/	-	NA
Q9	-	-	-	-	-	-	/	-	NA
Q12	+	+	+ (- ADRIA) *	+ (-)*	-	-	/	-	NA
Q13	-	-	-	-	-	-	/	-	NA
Q17	+	+	+ (- ADRIA) *	+ (-)*	-	-	/	-	NA
Q22	-	-	-	-	-	-	/	-	NA
Q23	-	-	-	-	-	-	/	-	NA
Q1	+	+	+	+	+	+	+	+	PA
Q3	-	-	-	-	+	+	+	+	PD
Q8	+	+	+	+	+	+	+	+	PA
Q10	+	+	+	+	+	+	+	+	PA
Q16	+	+	+	+	-	-	/	-	ND
Q20	+	+	+	+	+	+	+	+	PA
Q21	+	+	+	+	+	+	+	+	PA
Q24	+	+	+	+	+	+	+	+	PA
Q2	+	+	+	+	+	+	+	+	PA
Q5	+	+	+	+	+	+	+	+	PA
Q7	+	+	+	+	+	+	+	+	PA
Q11	+	+	+	+	+	+	+	+	PA
Q14	+	+	+	+	+	+	+	+	PA
Q15	+	+	+	+	+	+	+	+	PA
Q18	+	+	+	+	+	+	+	+	PA
Q19	+	+	+	+	+	+	+	+	PA

\* Additional testing done in ADRIA provided negative reaction test.

Laboratory: **R (ADRIA)**

Aerobic mesophilic flora

1,5.10<sup>3</sup> CFU/g

N°Sample	Reference method: ISO 16654				Alternative method 3M MDA 2 - <i>E. coli</i> O157 (including H7)				Agreement
	CT SMAC	CHROMagar O157	Confirmation	Final result	MDS result	CT SMAC	Latex	Final result	
R4	st	-	/	-	-	st	/	-	NA
R6	-	-	/	-	-	-	/	-	NA
R9	st	-	/	-	-	st	/	-	NA
R12	st	-	/	-	-	-	/	-	NA
R13	st	-	/	-	-	st	/	-	NA
R17	-	-	/	-	-	st	/	-	NA
R22	st	-	/	-	-	st	/	-	NA
R23	-	-	/	-	-	-	/	-	NA
R1	st	-	/	-	+	+	+	+	PD
R3	st	-	/	-	+	+	+	+	PD
R8	+	+	+	+	+	+	+	+	PA
R10	-	-	/	-	+	+	+	+	PD
R16	+	+	+	+	+	+	+	+	PA
R20	+	+	+	+	+	+	+	+	PA
R21	+	+	+	+	+	+	+	+	PA
R24	st	st	/	-	+	+	+	+	PD
R2	+	+	+	+	+	+	+	+	PA
R5	+	+	+	+	+	+	+	+	PA
R7	+	+	+	+	+	+	+	+	PA
R11	+	+	+	+	+	+	+	+	PA
R14	+	+	+	+	+	+	+	+	PA
R15	+	+	+	+	+	+	+	+	PA
R18	+	+	+	+	+	+	+	+	PA
R19	+	+	+	+	+	+	+	+	PA

st: sterile