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## VIDAS® UP Salmonella (SPT) Ultra Performance Summary

Food safety professionals have a variety of test kits to choose from when looking to fill a need in their laboratory. One of the main criteria used in making their decision is an evaluation of the certifications the test kit has received. Validation studies provide a user with confidence in the performance of the test kit. This document summarizes the certifications granted to the bioMérieux VIDAS® UP Salmonella (SPT) test method. The VIDAS SPT method was certified by the AOAC Research Institute *Performance Tested Method*<sup>SM</sup> (PTM) program after the completion of a single laboratory study and an independent laboratory study. These studies included an evaluation of the following parameters: inclusivity, exclusivity, robustness, lot-to-lot/stability and method comparison. The VIDAS SPT method was also adopted as an AOAC Official Method of Analysis (OMA), First Action status after the completion of an inclusivity/exclusivity study and a multi-laboratory method comparison study. Additionally, the VIDAS SPT method has been certified NF VALIDATION (AFNOR) as an alternative method for the detection of *Salmonella* through the completion of an independent single laboratory study and a multi-laboratory study. All of the validation studies demonstrated that the VIDAS SPT method was statistically equivalent to the corresponding reference method for the matrices tested with 95% confidence.

### **AOAC Performance Tested Method: PTM#071101**

In July, 2011, the VIDAS® UP Salmonella (VIDAS SPT) Assay was granted *Performance Tested Method* (PTM) status by the AOAC Research Institute for the detection of *Salmonella* in a variety of foods and selected environmental samples. The VIDAS SPT method was validated according to harmonized PTM and Official Methods of Analysis guidelines (2002). Results of the validation study demonstrated the ability of the VIDAS SPT method to: 1) detect 109 different serotypes of *Salmonella* in the inclusivity study; 2) correctly show negative results for 30 exclusivity organisms; 3) support a 12-month shelf life and quality of the test kit in the lot-to-lot and stability study; 4) perform appropriately after varied protocol parameters including enriched sample boiling time (4, 5, 6 min), sample temperature after boiling (10, 25, 50°C) and time reagents held at room temperature (after refrigeration) prior to performing VIDAS SPT method (0, 30, 60 min); and 5) demonstrate equivalent performance when compared to a reference method for 17 claimed matrices: raw ground beef (25g and 375g), deli roast beef, instant NFDM (25g and 375g), vanilla ice cream, processed American cheese, bagged lettuce (mixed leaves) (25g and 375g), peanut butter, shrimp (cooked, peeled), raw cod, liquid eggs, powdered eggs, ground black pepper, dark chocolate (375g), dry dog food (375g), stainless steel, plastic, and ceramic tile. Independent testing included method comparison studies for 4 matrices: raw ground beef, liquid eggs, peanut butter and stainless steel.

**AOAC Official Method: Certificate No: 2013.01**

In January, 2013, the VIDAS® UP Salmonella (VIDAS SPT) Assay was granted First Action AOAC Official Methods of AnalysisSM (OMA) status by the AOAC Research Institute for the detection of *Salmonella* after the completion of the AOAC PTM evaluation and a collaboratively studied evaluation of raw ground beef at both 25g and 375g. Test portions, for each test portion size, were evaluated by fourteen different laboratories. Twelve replicate test portions from each of the three contamination levels of matrix were analyzed by VIDAS SPT and the USDA/FSIS-MLG 4.05 reference method. Statistical analysis was conducted according to the probability of detection model and showed no statistically significant difference in the number of positive test portions detected by the VIDAS SPT method and the USDA/FSIS-MLG method at the 0.05 level.

**AFNOR – NF Validation: Certificate No: BIO 12/32 – 10/11**

In October 2011, the VIDAS® UP Salmonella (VIDAS SPT) Assay was certified NF validation as an alternative analysis method for the detection of *Salmonella* in all human and animal food products, production environmental samples, and primary production samples. This validation was obtained by comparison with the reference method described in the international standard EN ISO 6579 according to the standard EN ISO 16140.

The independent expert laboratory performed inclusivity, exclusivity, limit of detection and comparative studies. For that last one, VIDAS SPT performances (relative sensitivity, specificity, accuracy) were compared to those of ISO 6579 for the following categories: meat products (including poultry), dairy products, seafood and vegetables, miscellaneous (including egg products, pastry, prepared food and chocolate products), production environment samples, primary production samples and selected 50g - 375g matrices (raw beef and veal, milk powder and derivatives, and chocolate and cocoa). Those studies showed that both methods are considered to be statistically equivalent.

In the inter-laboratory study, test portions were evaluated by 14 different laboratories. Eight replicate test portions from each of the three contamination levels of matrix were analyzed by VIDAS SPT and the EN ISO 6579 reference methods. All test portions were confirmed following plating on selective agar and identification. The results obtained demonstrate that the alternative method and the reference method have equivalent relative accuracy, specificity, and sensitivity values.

**Table of Contents**

<b>VIDAS® UP Salmonella (SPT)</b>	<b>1</b>
Table A. Validation Study Technical Requirements	3
<b>AOAC PTM Validation Study</b>	<b>4</b>
Table B. AOAC PTM Independent Expert Labs Study Details	5
Table C. AOAC PTM Data Summary – Internal Data	6
Table D. AOAC Complete Inclusivity List (AOAC & AFNOR)	7
Table E. AOAC Complete Exclusivity List (AOAC & AFNOR)	9
<b>Official Methods of Analysis (OMA) Validation Study</b>	<b>10</b>
Table F. AOAC OMA Data Summary	11
<b>AFNOR NF Validation Study</b>	<b>12</b>
Table G. AFNOR Independent Expert Labs Study Summary	13
Table H. AFNOR Independent Expert Labs Study Data Summary – Relative Sensitivity	14
Table I. AFNOR Independent Expert Labs Study Data Summary – Relative Level of Detection	16
Table J. AFNOR Inter-laboratory Study – Relative Sensitivity	16
<b>Glossary of Terms</b>	<b>17</b>

## VIDAS® UP Salmonella (SPT)

Catalog Number - REF 30 707



### Contents of the VIDAS SPT Kit

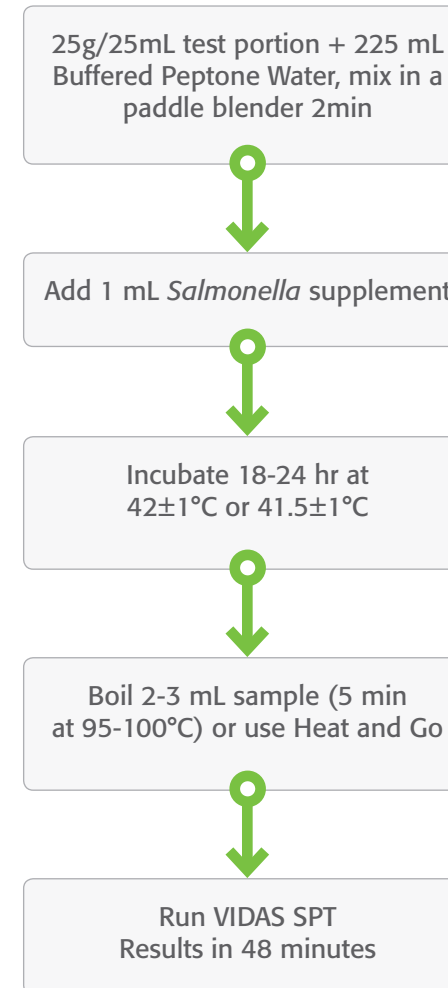
- 60 SPT Strips
- 60 SPT SPR®s
- SPT Standard
- SPT Positive Control
- Negative Control
- 1 Package insert downloadable from [www.biomerieux.com/techlib](http://www.biomerieux.com/techlib)

### Principle of the Assay

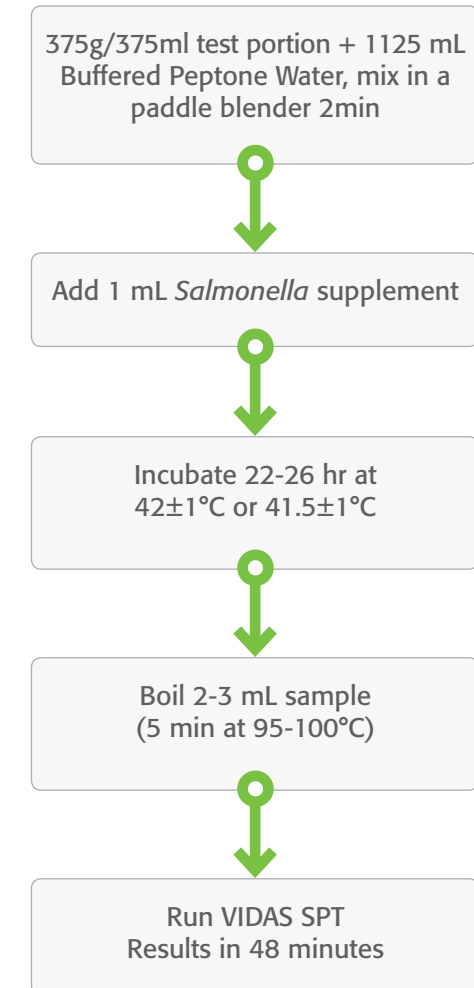
The VIDAS SPT test is a recombinant phage protein based technology designed for use with the automated enzyme-linked fluorescent assay VIDAS® or mini VIDAS® instruments for next day detection of *Salmonella* in a variety of foods, dry dog food, and select environmental samples. The novel method utilizes a single primary enrichment in buffered peptone water (BPW) and a proprietary *Salmonella* enrichment supplement. The Solid Phase Receptacle serves as the solid phase as well as the pipetting device for the assay. The SPR is coated with proprietary detection proteins specific for *Salmonella*. Reagents for the assay are ready-to-use and pre-dispensed in the sealed reagent strips. The instrument performs all of the assay steps automatically. The user places the sample into the reagent strip. Then the sample is cycled in and out of the SPR for a specific length of time. *Salmonella* receptor targets present in the sample will bind to the specific capture proteins, which are coated on the interior of the SPR. Unbound sample components are washed away. Specific proteins conjugated to alkaline phosphatase are cycled in and out of the SPR and will bind to any *Salmonella* receptor targets, which are bound to the capture proteins on the SPR wall. During the final detection step, the substrate (4-Methyl-umbelliferyl phosphate) is cycled in and out of the SPR. The bound enzyme conjugate catalyzes the hydrolysis of this substrate into a fluorescent product (4-Methyl-umbelliferone), the fluorescence of which is measured at 450 nm.

Figure 1. Flow diagrams showing the VIDAS SPT standard protocols – 25g and 375g.

### VIDAS SPT Standard Protocol – 25g



### VIDAS SPT Standard Protocol – 375g



### Performance Tested Method<sup>SM</sup> (PTM)

The AOAC Performance Tested Methods<sup>SM</sup> (PTM) program began in 1992 and is a method certification program for proprietary methods. Methods certified as Performance Tested<sup>SM</sup> were found to perform according to the manufacturer’s documented claims and are used throughout the global market place and within the regulatory arena. The PTM program offers certification as an endpoint for method evaluation or as an entry to method validation for programs requiring increased confidence and method reproducibility information. Validation study protocols are written according to AOAC Microbiology Guidelines (2012) and include the following technical requirements: inclusivity/exclusivity, method developer method comparison, independent laboratory method comparison, robustness, product consistency, product stability and instrument variation (where applicable) studies. More information can be found at [www.aoac.org](http://www.aoac.org).

### Official Methods of Analysis<sup>SM</sup> (OMA)

The Official Methods of Analysis<sup>SM</sup> (OMA) program is offered by AOAC INTERNATIONAL and evaluates chemistry, microbiology, and molecular biology methods. It also evaluates traditional bench-top methods, instrumental methods, and proprietary, commercial, and/or alternative methods. Validation study protocols are written according to AOAC Microbiology Guidelines (2012) and include the following technical requirements: inclusivity/exclusivity, method developer method comparison and collaborative method comparison studies. A PTM study can be used to satisfy the inclusivity/exclusivity and method comparison requirement. More information can be found at [www.aoac.org](http://www.aoac.org).

### AFNOR Validation Study

The NF VALIDATION mark has been widely recognized in France since the 1990s and is now well-established in Europe and internationally. It is a completely separate European certification system, operating alongside the technical validation systems of NordVal (inter-governmental validation system of 5 Nordic countries) and AOAC (North American technical validation system). Validation study protocols are written according to EN ISO 16140 and include the following technical requirements: inclusivity/exclusivity, single laboratory methods comparison and an inter-laboratory studies. More information can be found at <http://www.afnor-validation.com/afnor-validation-food-industry/food-industry.html>.

**Table A. Validation Study Technical Requirements**

Study Type	AOAC PTM	AOAC OMA	AFNOR
Method Developer	●		
Independent	●		●
Collaborative	●	●	●

## AOAC PTM Validation Study

PTM Certification#: 071101

PTM Certified: July 2011

PTM Matrix Extension Certified: March 2012

Guideline document: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Qualitative and Quantitative Food Microbiological Official Methods of Analysis (2002 and 2012)

Reference methods: USDA/FSIS Microbiological Laboratory Guidebook (4.04 original study, 4.05 matrix extension), the US-FDA Bacteriological Analytical Manual Chapter 5 (2007) and AOAC 2000.06

**Independent Expert Labs (Tables C and D):** The Independent Expert Labs study was performed at both the method developer (internal) and independent laboratories. Twenty matrices (internal) and four (independent) were inoculated with *Salmonella* and 20 replicates at one inoculation level (0.2-2 cfu/25g or 375g) and 5 uninoculated replicates were tested by both the VIDAS SPT and appropriate reference method. Primary enrichments for each method were confirmed using the traditional confirmation methods and chromogenic agar.

In the Independent Expert Labs studies there were no significant differences between the VIDAS SPT method and the reference methods using unpaired Chi-square or the POD test at 5% level for the majority of the matrices evaluated. The following matrices showed a significant difference, with the VIDAS SPT method resulting in a higher number of positive test portions: 25g ground beef (BPW+SPT supplement), 375g ground beef (BPW+vancomycin) and 25g powdered eggs (BPW+SPT supplement).

**Inclusivity/Exclusivity (Tables D and E):** The inclusivity studies demonstrated that the VIDAS SPT method could detect all 109 *Salmonella* serotypes tested two different enrichment options: buffered peptone water (BPW) plus *Salmonella* supplement and BPW plus vancomycin (8mg/L). For the exclusivity testing, all 30 non-*Salmonella* tested negative by the VIDAS SPT method.

**Lot-to-lot/Stability:** Stability and lot-to-lot variation of the VIDAS SPT method was evaluated over 12 months at 2-8°C using *Salmonella* and non-*Salmonella* isolates on three different test kit lots. There was no loss of stability over the 12 months or any difference between the three different test kits supporting the 12 month shelf-life and the quality of the product.

**Ruggedness:** Minor variations to the protocol parameters, including enriched sample boiling time (4, 5, 6 min), sample temperature after boiling (10, 25, 50°C) and time reagents held at room temperature (after refrigeration) prior to performing VIDAS SPT method (0, 30, 60 min). There were no differences seen in the number of positive results with each of the variations in the protocol.

**Table B. AOAC PTM Independent Expert Labs Study Details**

Matrix	Inoculating Organism	Test portion size(s)	Reference Method Comparison
Deli roast beef	<i>Salmonella enterica ser. Bovis-morbificans</i>	25g	USDA/FSIS MLG Ch. 4.04
Chicken carcass rinsate <sup>a</sup>	<i>Salmonella enterica ser. Enteritidis</i>	30 mL	USDA/FSIS MLG Ch. 4.05
Raw ground turkey <sup>a</sup>	<i>Salmonella enterica ser. Hadar</i>	375g	USDA/FSIS MLG Ch. 4.05
Instant NFDM	<i>Salmonella enterica ser. Infantis</i>	25g, 375g	FDA-BAM Ch. 5
Vanilla ice cream	<i>Salmonella enterica ser. Waycross</i>	25g	FDA-BAM Ch. 5
Processed American cheese	<i>Salmonella enterica ser. Montevideo</i>	25g	FDA-BAM Ch. 5
Bagged lettuce	<i>Salmonella enterica ser. Typhimurium</i>	25g <sup>e</sup> , 375g	FDA-BAM Ch. 5
Peanut butter	<i>Salmonella enterica ser. Potsdam</i> <sup>d</sup>	25g	FDA-BAM Ch. 5
Cooked, peeled shrimp	<i>Salmonella enterica ser. Mbandaka</i>	25g	FDA-BAM Ch. 5
Raw cod	<i>Salmonella enterica ser. Newport</i>	25g	FDA-BAM Ch. 5
Liquid eggs	<i>Salmonella enterica ser. Enteritidis</i>	25g <sup>c</sup>	FDA-BAM Ch. 5
Powdered eggs	<i>Salmonella enterica ser. Choleraesuis</i>	25g <sup>c</sup>	FDA-BAM Ch. 5
Ground black pepper	<i>Salmonella enterica ser. Muenchen</i>	25g	AOAC 2000.06
Almonds <sup>a</sup>	<i>Salmonella enterica ser. Montevideo</i>	375g	FDA-BAM Ch. 5
Dark chocolate	<i>Salmonella enterica ser. Senftenberg</i>	375g	FDA-BAM Ch. 5
Dry dog food	<i>Salmonella enterica ser. Tennessee</i>	375g	FDA-BAM Ch. 5
Stainless steel	<i>Salmonella enterica ser. Kahla</i>	Swab	FDA-BAM Ch. 5
Plastic	<i>Salmonella enterica ser. Cubana</i>	Sponge	FDA-BAM Ch. 5
Ceramic	<i>Salmonella enterica ser. Poona</i>	Swab	FDA-BAM Ch. 5

<sup>a</sup> Matrix validated in PTM matrix extension study  
<sup>b</sup> Alternate enrichment testing (BPW+vanco) used *Salmonella enterica ser. Typhimurium*  
<sup>c</sup> Ground beef (375g) and bagged lettuce (25g) were validated using two different enrichment protocols: BPW+SPT supplement and BPW+vancomycin (8mg/L)  
<sup>d</sup> Independent Lab used *Salmonella enterica ser. Tennessee*  
<sup>e</sup> Liquid and powdered eggs were validated using two different enrichment protocols: prewarmed BPW and BPW+SPT supplement

**Table C. AOAC PTM Independent Expert Labs Study – Internal Data**

	INTERNAL LABORATORY DATA	Test portion size	Enrichment broth	VIDAS SPT		Reference	χ <sup>2</sup>	Sensitivity, %	Specificity, %	False pos, %	False neg, %	dPOD CI	
				Presumptive	Confirmed							P vs C <sup>a</sup>	C vs R <sup>b</sup>
				Meat and Poultry	Raw ground beef							25g	BPW+ <i>Salmonella</i> supplement
Raw ground beef	375g	prewarm BPW + <i>Salmonella</i> supplement	14		14	7	4.79	100	100	0	0	-0.27, 0.27	0.04, 0.50
Raw ground beef (ext)	375g	prewarm BPW+Vancomycin	12		12	11	0.10	100	100	0	0	-0.28, 0.28	-0.24, 0.33
Deli roast beef	25g	BPW+ <i>Salmonella</i> supplement	4		4	5	0.14	100	100	0	0	-0.25, 0.25	-0.30, 0.21
Chicken carcass rinsate (ext)	30 mL	BPW+ <i>Salmonella</i> supplement	5		5	3	0.61	100	100	0	0	-0.26, 0.26	-0.15, 0.34
Raw ground turkey (ext)	375g	prewarm BPW + <i>Salmonella</i> supplement	16		16	12	1.86	100	100	0	0	-0.25, 0.25	-0.08, 0.44
Dairy	Instant NFDM	25g	BPW+ <i>Salmonella</i> supplement	9	9	10	0.10	100	100	0	0	-0.28, 0.28	-0.33, 0.24
	Instant NFDM	375g	prewarm BPW + <i>Salmonella</i> supplement	11	11	10	0.10	100	100	0	0	-0.28, 0.28	-0.24, 0.33
	Vanilla ice cream	25g	BPW+ <i>Salmonella</i> supplement	8	8	10	0.39	100	100	0	0	-0.28, 0.28	-0.37, 0.19
Vegetable	Processed American cheese	25g	BPW+ <i>Salmonella</i> supplement	12	12	12	0.00	100	100	0	0	-0.28, 0.28	-0.28, 0.28
	Bagged lettuce	25g	BPW+ <i>Salmonella</i> supplement	5	5	7	0.46	100	100	0	0	-0.26, 0.26	-0.36, 0.18
	Bagged lettuce	25g	prewarm BPW+Vancomycin	10	10	9	0.10	100	100	0	0	-0.28, 0.28	-0.24, 0.33
	Bagged lettuce	375g	prewarm BPW + <i>Salmonella</i> supplement	10	9	9	0.00	90	100	10	0	-0.24, 0.33	-0.28, 0.28
Seafood	Peanut butter	25g	BPW+ <i>Salmonella</i> supplement	6	6	3	1.26	100	100	0	0	-0.27, 0.27	-0.11, 0.39
	Cooked, peeled shrimp	25g	BPW+ <i>Salmonella</i> supplement	9	9	10	0.10	100	100	0	0	-0.28, 0.28	-0.33, 0.24
Eggs	Raw cod	25g	BPW+ <i>Salmonella</i> supplement	11	11	10	0.10	100	100	0	0	-0.28, 0.28	-0.24, 0.33
	Liquid eggs	25g	prewarm BPW	8	8	6	0.43	100	100	0	0	-0.28, 0.28	-0.18, 0.36
	Liquid eggs	25g	BPW+ <i>Salmonella</i> supplement	8	8	6	0.43	100	100	0	0	-0.28, 0.28	-0.18, 0.36
Miscellaneous	Powdered eggs	25g	prewarm BPW	14	14	11	0.94	100	100	0	0	-0.27, 0.27	-0.14, 0.41
	Powdered eggs	25g	BPW+ <i>Salmonella</i> supplement	17	17	11	4.18	100	100	0	0	-0.23, 0.23	0.02, 0.53
	Ground black pepper	25g	BPW+ <i>Salmonella</i> supplement	18	18	13	3.49	100	100	0	0	-0.21, 0.21	-0.01, 0.48
	Almonds (ext)	375g	prewarm BPW + <i>Salmonella</i> supplement	7	7	4	1.10	100	100	0	0	-0.28, 0.28	-0.12, 0.40
Environmental Surface	Dark chocolate	375g	reconstituted NFDM + <i>Salmonella</i> supplement	10	9	5	1.41	90	100	10	0	-0.24, 0.33	-0.09, 0.45
	Dry dog food	375g	prewarm BPW + <i>Salmonella</i> supplement	8	8	8	0.00	100	100	0	0	-0.28, 0.28	-0.28, 0.28
	Stainless steel	Swab	BPW+ <i>Salmonella</i> supplement	8	8	8	0.00	100	100	0	0	-0.28, 0.28	-0.28, 0.28
	Plastic	Sponge	BPW+ <i>Salmonella</i> supplement	8	8	5	1.00	100	100	0	0	-0.28, 0.28	-0.13, 0.40
	Ceramic	Swab	BPW+ <i>Salmonella</i> supplement	9	9	8	0.10	100	100	0	0	-0.28, 0.28	-0.24, 0.33

<sup>a</sup> VIDAS SPT presumptive vs confirmed  
<sup>b</sup> VIDAS SPT vs reference method  
**Sensitivity** = VIDAS presumptive + (that confirmed +)/VIDAS confirmed +  
**Specificity** = VIDAS presumptive – (that confirmed -)/VIDAS confirmed -  
**False positive** = 100-sensitivity  
**False negative** = 100-specificity

$$\text{Mantel Haenszel Chi sq } (\chi^2) = \frac{(n-1)(ad-bc)^2}{(a+b)(a+c)(b+d)(c+d)}$$

N = total number of samples, a = candidate +, b = candidate -, c = reference +, d = reference -

**Acceptability Criteria**  
 $\chi^2 \leq 3.84$  indicates no significant difference (at the 0.05 level) between the two methods.

**POD** = x/N, where x is the number of positive test portions and N is the total number of test portions  
**dPOD** = the difference between any two POD values

**Acceptability Criteria**  
dPOD CI – 95% confidence interval of the dPOD

**Table C (continued). AOAC PTM Data Summary – Independent Laboratory Data**

INDEPENDENT LABORATORY DATA	Test portion size	Enrichment broth	VIDAS SPT Presumptive	Confirmed	Reference	X <sup>2</sup>	Sensitivity	Specificity	False pos	False neg	dPOD	
											P vs C <sup>a</sup>	C vs R <sup>b</sup>
Raw ground beef	25g	BPW+Salmonella supplement	16	17	12	0.19	100	94	0	6	-0.29, 0.19	-0.03, 0.48
Raw ground beef	375g	prewarm BPW +Salmonella supplement	11	11	10	0.10	100	100	0	0	-0.28, 0.28	-0.24, 0.33
Peanut butter	25g	BPW+Salmonella supplement	16	16	12	0.19	100	100	0	0	-0.25, 0.25	-0.08, 0.44
Liquid eggs	25g	prewarm BPW	6	6	8	0.43	100	100	0	0	-0.27, 0.27	-0.36, 0.18
Liquid eggs	25g	BPW+Salmonella supplement	5	5	8	1.00	100	100	0	0	-0.26, 0.26	-0.40, 0.13
Stainless steel	Swab	BPW+Salmonella supplement	12	12	13	0.10	100	100	0	0	-0.28, 0.28	-0.32, 0.23

<sup>a</sup>VIDAS SPT presumptive vs confirmed

<sup>b</sup>VIDAS SPT vs reference method

$$\text{Mantel Haenszel Chi sq (X}^2\text{)} = \frac{(n-1)(ad-bc)^2}{(a+b)(a+c)(b+d)(c+d)}$$

N = total number of samples, a = candidate +, b = candidate -, c = reference +, d = reference -

**Acceptability Criteria**

X<sup>2</sup> ≤ 3.84 indicates no significant difference (at the 0.05 level) between the two methods.

**Sensitivity** = VIDAS presumptive + (that confirmed +)/VIDAS confirmed +  
**Specificity** = VIDAS presumptive - (that confirmed -)/VIDAS confirmed -  
**False positive** = 100-sensitivity  
**False negative** = 100-specificity

**POD** = x/N, where x is the number of positive test portions and N is the total number of test portions  
**dPOD** = the difference between any two POD values

**Acceptability Criteria**

dPOD CI – 95% confidence interval of the dPOD

**Table D. Complete Inclusivity List (AOAC & AFNOR)**

	Salmonella Serotype		Salmonella Serotype		Salmonella Serotype
1	<i>S. enterica enterica</i> (I) Abortusequi	17	<i>S. enterica enterica</i> (I) Bergedorf	33	<i>S. enterica enterica</i> (I) Derby
2	<i>S. enterica enterica</i> (I) Agona	18	<i>S. enterica enterica</i> (I) Bergen	34	<i>S. enterica enterica</i> (IIIb) Diarizonae
3	<i>S. enterica enterica</i> (I) Ahuza	19	<i>S. enterica enterica</i> (I) Berta	35	<i>S. enterica enterica</i> (I) Dublin
4	<i>S. enterica enterica</i> (I) Alachua	20	<i>S. enterica enterica</i> (I) Blockley	36	<i>S. enterica enterica</i> (I) Duisburg
5	<i>S. enterica enterica</i> (I) Albany	21	<i>S. enterica enterica</i> (I) Bovismorbificans	37	<i>S. enterica enterica</i> (I) Enteritidis
6	<i>S. enterica enterica</i> (I) Amsterdam	22	<i>S. enterica enterica</i> (I) Braenderup	38	<i>S. enterica enterica</i> (I) Florida
7	<i>S. enterica enterica</i> (I) Anatum	23	<i>S. enterica enterica</i> (I) Brandenburg	39	<i>S. enterica enterica</i> (I) Gallinarum
8	<i>S. enterica enterica</i> Arizonae (III a) 48:z4:z23	24	<i>S. enterica enterica</i> (I) Bredeney	40	<i>S. enterica enterica</i> (I) Gaminara
9	<i>S. enterica enterica</i> Arizonae (III a) 18:z4, z23 :-	25	<i>S. enterica enterica</i> (I) Bukavu	41	<i>S. enterica enterica</i> (I) Give
10	<i>S. enterica enterica</i> Arizonae (III a) 50 ;z4 ;z23	26	<i>S. enterica enterica</i> (I) Cerro	42	<i>S. enterica enterica</i> (I) Goldcoast
11	<i>S. enterica enterica</i> (III a) 51 :z4. z23 :-	27	<i>S. enterica enterica</i> (I) Chandans	43	<i>S. enterica enterica</i> (I) Grumpensis
12	<i>S. enterica</i> diarizonae (III b) 38:l.v:z53	28	<i>S. enterica enterica</i> (I) Chester	44	<i>S. enterica enterica</i> (I) Hadar
13	<i>S. enterica</i> diarizonae (III b) 61:k:1.5.7	29	<i>S. enterica enterica</i> (I) Choleraesuis	45	<i>S. enterica enterica</i> (IV) Harmelen
14	<i>S. enterica enterica</i> (V) Bongori	30	<i>S. enterica enterica</i> (I) Coeln	46	<i>S. enterica enterica</i> (I) Hartford
15	<i>S. enterica enterica</i> (I) Bakau	31	<i>S. enterica enterica</i> (I) Cremieu	47	<i>S. enterica enterica</i> (I) Havana
16	<i>S. enterica enterica</i> (I) Bareilly	32	<i>S. enterica enterica</i> (I) Cubana	48	<i>S. enterica enterica</i> (I) Heidelberg

**Table D (continued). Complete Inclusivity List (AOAC & AFNOR)**

	Salmonella Serotype		Salmonella Serotype		Salmonella Serotype
49	<i>S. enterica enterica</i> (I) Hilversum	75	<i>S. enterica enterica</i> (I) Moscow	101	<i>S. enterica enterica</i> (I) Tennessee
50	<i>S. enterica enterica</i> (IV) Houtanae	76	<i>S. enterica enterica</i> (I) Moulaine	102	<i>S. enterica enterica</i> (I) Thetford
51	<i>S. enterica enterica</i> (I) Ibadan	77	<i>S. enterica enterica</i> (I) Muenchen	103	<i>S. enterica enterica</i> (I) Tilene
52	<i>S. enterica enterica</i> (I) Indiana	78	<i>S. enterica enterica</i> (I) Napoli	104	<i>S. enterica enterica</i> (I) Toucra
53	<i>S. enterica enterica</i> (VI) Indica 1,26,14,25:a:enx	79	<i>S. enterica enterica</i> (I) Newington	105	<i>S. enterica enterica</i> (I) Typhi
54	<i>S. enterica enterica</i> (I) Infantis	80	<i>S. enterica enterica</i> (I) Newport	106	<i>S. enterica enterica</i> (I) Typhimurium
55	<i>S. enterica enterica</i> (I) Javiana	81	<i>S. enterica enterica</i> (I) Orianenburg	107	<i>S. enterica enterica</i> (I) Typhimurium non motile 1,4,[5],12 :-:-
56	<i>S. enterica enterica</i> (I) Johannesburg	82	<i>S. enterica enterica</i> (I) Panama	108	<i>S. enterica enterica</i> (I) Typhimurium, variant monophasique, "Salmonella 1,4, [5], 12 :-:- 1,2"
57	<i>S. enterica enterica</i> (I) Kahla	83	<i>S. enterica enterica</i> (I) Paratyphi A	109	<i>S. enterica enterica</i> (I) Typhimurium,variant monophasique, "Salmonella 1,4, [5], 12 :i -"
58	<i>S. enterica enterica</i> (I) Kedougou	84	<i>S. enterica enterica</i> (I) Paratyphi B	110	<i>S. enterica enterica</i> (I) Typhimurium
59	<i>S. enterica enterica</i> (I) Kottbus	85	<i>S. enterica enterica</i> (I) Paratyphi C	111	<i>S. enterica enterica</i> (I) Urbana
60	<i>S. enterica enterica</i> (I) Landau	86	<i>S. enterica enterica</i> (I) Poona	112	<i>S. enterica enterica</i> (I) Virchow
61	<i>S. enterica enterica</i> (I) Lexington	87	<i>S. enterica enterica</i> (I) Postdam	113	<i>S. enterica enterica</i> (I) Virginia
62	<i>S. enterica enterica</i> (I) Litchfield	88	<i>S. enterica enterica</i> (I) Putten	114	<i>S. enterica enterica</i> (I) Wayne
63	<i>S. enterica enterica</i> (I) Liverpool	89	<i>S. enterica enterica</i> (I) Regent	115	<i>S. enterica enterica</i> (I) Weltvreden
64	<i>S. enterica enterica</i> (I) Livingstone	90	<i>S. enterica enterica</i> (I) Rissen	116	<i>S. enterica enterica</i> (I) Westhampton
65	<i>S. enterica enterica</i> (I) London	91	<i>S. enterica enterica</i> (I) SaintPaul	117	<i>S. enterica enterica</i> (I) Wien
66	<i>S. enterica enterica</i> (I) Luke	92	<i>S. enterica enterica</i> (II) Salamae 42:b:enz	118	<i>S. enterica enterica</i> (I) Worthington
67	<i>S. enterica enterica</i> (I) Manhattan	93	<i>S. enterica enterica</i> (I) San Diego	119	<i>S. enterica enterica</i> (I) Yoruba
68	<i>S. enterica enterica</i> (I) Mbandaka	94	<i>S. enterica enterica</i> (I) Schwarzengrund	120	<i>S. enterica enterica</i> (I) Zanzibar
69	<i>S. enterica enterica</i> (I) Mbao	95	<i>S. enterica enterica</i> (I) Senftenberg	121	Non motile <i>Salmonella</i> C1 6.7:-:-
70	<i>S. enterica enterica</i> (I) Meleagridis	96	<i>S. enterica enterica</i> (IIIa) Shomrom	122	Non motile <i>Salmonella</i> C2 6.8:-:-
71	<i>S. enterica enterica</i> (I) Milwaukee	97	<i>S. enterica enterica</i> (I) Simsbury	133	<i>Salmonella</i> Typhimurium. non motile variant immobile "S.I 1.4.[5].12 :-:-"
72	<i>S. enterica enterica</i> (I) Minnesota	98	<i>S. enterica enterica</i> (I) Sloterdijk	124	<i>Salmonella</i> Typhimurium. monophasique variant "S.I 1.4. [5]. 12 :i :-"
73	<i>S. enterica enterica</i> (I) Mississippi	99	<i>S. enterica enterica</i> (I) Sternschanze	125	<i>Salmonella</i> Typhimurium. monophasique variant "S.I 1.4. [5]. 12 :-:- 1.2 "
74	<i>S. enterica enterica</i> (I) Montevideo	100	<i>S. enterica enterica</i> (I) Stourbridge		

**Table E. Complete Exclusivity List (AOAC & AFNOR)**

	Strains	Origin
1	<i>Aeromonas hydrophila</i>	Collection
2	<i>Bacillus cereus</i>	Meat loaf
3	<i>Bacillus licheniformis</i>	Collection
4	<i>Bacillus subtilis</i>	Collection
5	<i>Candida albicans</i>	Collection
6	<i>Citrobacter koseri</i>	Not available
7	<i>Citrobacter freundii</i>	Salad
8	<i>Citrobacter braaki</i>	Not available
9	<i>Citrobacter youngae</i>	Vegetable
10	<i>Enterobacter amnigenus</i>	Environment
11	<i>Enterobacter cloacae</i>	Sausage
12	<i>Enterobacter aerogenes</i>	Collection
13	<i>Enterobacter sakazakii</i>	Collection
14	<i>Escherichia coli</i>	Animal feed
15	<i>Escherichia coli</i>	Raw milk
16	<i>Hafnia alvei</i>	Duck
17	<i>Hafnia alvei</i>	Poultry
18	<i>Klebsiella oxytoca</i>	Not available
19	<i>Klebsiella pneumoniae</i>	Collection
20	<i>Proteus mirabilis</i>	Collection
21	<i>Proteus vulgaris</i>	Collection
22	<i>Pseudomonas aeruginosa</i>	Raw milk
23	<i>Pseudomonas fluorescens</i>	Not available
24	<i>Pseudomonas stutzeri</i>	Not available
25	<i>Serratia marcescens</i>	Not available
26	<i>Serratia fonticola</i>	Collection
27	<i>Shigella flexneri</i>	Collection
28	<i>Shigella sonnei</i>	Not available
29	<i>Staphylococcus aureus</i>	Butter
30	<i>Yersinia enterocolitica</i>	Vegetable
31	<i>Escherichia hermannii</i>	Collection

## Official Methods of Analysis (OMA) Validation Study

Certificate No: 2013.01

Certification date: January 2013

Guideline document: AOAC INTERNATIONAL Methods Committee Guidelines for Validation of Qualitative and Quantitative Food Microbiological Official Methods of Analysis (2002)

Reference Method: USDA/FSIS Microbiological Laboratory Guidebook, 4.05

### Inclusivity/Exclusivity & Method Developer Method Comparison

See the AOAC PTM study sections for evaluation results of these studies.

#### Collaborative Study: Ground beef - 25g (Table F)

Raw ground beef (80% lean, 25g), was analyzed by fourteen laboratories. The matrix was artificially contaminated with *Salmonella enterica* ser. Enteritidis ATCC 13076 at two levels: a high level 4.38 CFU/25g (95% confidence interval of 0.49, 2.46) and a low level of 1.10 CFU/25g (95% confidence interval of 1.71, 11.20). A set of uncontaminated control test portions were also included at 0 CFU/25g. Twelve replicate test portions from each of the three contamination levels of matrix were analyzed. Two sets of test portions (72 total) were sent to each laboratory for analysis by VIDAS SPT and the USDA/FSIS-MLG 4.05 reference method due to different sample enrichments for each method. All test portions were confirmed following two different confirmation protocols: 1) secondary enrichment followed by selective and chromogenic agar (ASAP and IBISA) plating and identification, 2) direct streaking to chromogenic agar (ASAP and IBISA) and identification.

Statistical analysis was conducted according to the probability of detection (POD). Results obtained by the different confirmation protocols showed no significant differences between the options evaluated. A statistically significant difference was observed between the VIDAS SPT method and the reference method for the low inoculum level, where the VIDAS SPT method recovered a higher number of positive results than the reference method.

#### Collaborative Study: Ground beef - 375g (Table F)

Raw ground beef (80% lean, 375g), was analyzed by fourteen laboratories. The matrix was artificially contaminated with *Salmonella enterica* ser. Montevideo ATCC 8387 and at two levels: a high level 2.19 CFU/375g (95% confidence interval of 0.94, 5.12) and a low level of 0.72 CFU/375g (95% confidence interval of 0.31, 1.67). A set of uncontaminated control test portions were also included at 0 CFU/375g. Twelve replicate test portions from each of the three contamination levels of matrix were analyzed. Two sets of test portions (72 total) were sent to each laboratory for analysis by VIDAS SPT and the USDA/FSIS-MLG 4.05 reference method due to different sample enrichments for each method. All test portions were confirmed following two different confirmation protocols: 1) secondary enrichment followed by selective and chromogenic agar (ASAP and IBISA) plating and identification, 2) direct streaking to chromogenic agar (ASAP and IBISA) and identification.

Statistical analysis was conducted according to the probability of detection (POD). Results obtained by the different confirmation protocols showed no significant differences between the options evaluated. With 0.0 within the confidence intervals for the 375 g test portions, there was no statistically significant difference in the number of positive test portions detected by the VIDAS SPT method and the USDA/FSIS-MLG method at the 0.05 level.

**Table F. AOAC OMA Data Summary**

Matrix	Level (CFU/test portion)	VIDAS SPT		Reference (N=144)	X <sup>2a</sup>	Sensitivity	Specificity	False pos	False Neg	dLPOD (CI)	
		Presumptive (N=144)	Confirmed (N=144)							P vs C <sup>a</sup>	C vs R <sup>b</sup>
Raw ground beef-25g	1.10	144	143	84	72.15	99	100	1	0	0.01 (-0.02, 0.04)	0.41 (0.32, 0.49)
<i>Salmonella enterica ser. Enteritidis</i>	4.38	144	144	138	6.11	100	100	0	0	0.00 (-0.03, 0.03)	0.04 (0.01, 0.09)
Raw ground beef-375g	0.72	57	58	54	0.23	98	100	2	0	-0.01 (-0.21, 0.23)	0.03 (-0.18, 0.24)
<i>Salmonella enterica ser. Montevideo</i>	2.19	130	130	131	0.04	100	100	0	0	0.00 (-0.04, 0.04)	-0.01 (-0.05, 0.03)

<sup>a</sup> Candidate method presumptive vs confirmed  
<sup>b</sup> Candidate method vs reference method

$$\text{Mantel Haenszel Chi sq (X}^2\text{)} = \frac{(n-1)(ad-bc)^2}{(a+b)(a+c)(b+d)(c+d)}$$

N = total number of samples, a = candidate +, b = candidate -, c = reference +, d = reference -

**Acceptability Criteria**

X<sup>2</sup> ≤ 3.84 indicates no significant difference (at the 0.05 level) between the two methods.

**Sensitivity** = VIDAS presumptive + (that confirmed +)/VIDAS confirmed +  
**Specificity** = VIDAS presumptive - (that confirmed -)/VIDAS confirmed -  
**False positive** = 100-sensitivity  
**False negative** = 100-specificity

**POD** = x/N, where x is the number of positive test portions and N is the total number of test portions  
**LPOD** = the POD value obtained from combining all valid collaborator data sets for a method for a given matrix at a given analyte level or concentration  
**dLPOD** = the difference between any two LPOD values

**Acceptability Criteria**

**POD** – confidence interval of a dPOD contains zero indicates no significant difference (at the 0.05 level) between the two methods

## AFNOR NF Validation Study

Certificate No: BIO 12/32 – 10/11

Certification date: October 2011

Extension date (specific dairy protocol): February 2012

Extension date (Primary production protocol): July 2012

Extension date (375g protocols): January 2013

Extension date (rapid latex confirmation): January 2014

Guideline document: ISO 16140:2003(E), Microbiology of food and animal feeding stuffs – Protocol for the validation of alternative methods

Reference Methods: EN ISO 6579 (#): Microbiology of food and animal feeding stuffs. Horizontal method for the detection of *Salmonella* spp.

### Independent Expert Labs Study

**Inclusivity/exclusivity (Tables D & E):** The inclusivity studies demonstrated that the VIDAS SPT method could detect 56/57 *Salmonella* serotypes tested after enrichment in BPW plus *Salmonella* supplement in the presence of food matrix (2 mL UHT milk). For the exclusivity testing, 29/30 non-*Salmonella* (approximately 105 cells/mL) tested negative by the VIDAS SPT method after enrichment in BPW plus *Salmonella* supplement.

**Relative sensitivity (Tables G & H):** The purpose of these tests was to evaluate the performance of the VIDAS SPT method with respect to the EN ISO 6579 reference method, on test portions naturally and artificially contaminated with *Salmonella*, for the categories falling within the scope. The study evaluated 798 test portions that were inoculated with a wide variety of *Salmonella* serotypes and analyzed at a level to achieve approximately 50% positive test portions with the following breakdown: meat & poultry – 193, dairy – 199, plant products & seafood – 63, miscellaneous – 123, environmental – 64, animal feeding stuffs – 62, primary production – 94. The results obtained demonstrate that the alternative method and the reference method have equivalent relative accuracy, specificity and sensitivity values.

**Relative level of detection (Table I):** The objective of these tests was to determine the level of contamination needed to obtain about 50% of positive results and 50% negative results. Various “food matrix-strain” pairs were studied in parallel with the reference method and the VIDAS® SPT method, for the studied categories. The results showed equivalency between both methods.

### Inter-laboratory Study (Table J)

Paté (25g) was analyzed by sixteen laboratories in this inter-laboratory study. The matrix was artificially contaminated with *Salmonella enterica ser. Derby* at two levels: a high level of 10.85 CFU/25g (95% confidence interval of 10.11, 11.63) and a low level of 1.16 CFU/25g (95% confidence interval of 0.99, 1.34). A set of uncontaminated control test portions were also included for each matrix at 0 CFU/25g. Eight replicate test portions from each of the three contamination levels of matrix were analyzed. Two sets of test portions (48 total) were sent to each laboratory for analysis by VIDAS SPT and the EN ISO 6579 reference method due to different test portion enrichments for each method. All test portions were confirmed following plating on selective agar and identification. The results showed no statistical difference between the two methods.



**Table G. AFNOR Independent Expert Labs Study Summary**

	Matrix	Protocol Type	Enrichment broth	Test portion size	Number Positive	Number Negative	Total
Meat and Poultry	Raw	General	BPW+Salmonella supplement	25g	9	10	19
	Seasoned, prepared poultry meat	General	BPW+Salmonella supplement	25g	10	11	21
	Cold cuts & ground meat	General	BPW+Salmonella supplement	25g	14	12	26
	Raw beef & veal	Specific (375g, Vancomycin)	prewarm BPW+Vancomycin	375g	36	31	67
	Raw beef & veal	Specific (375g)	BPW+Salmonella supplement	375g	30	30	60
			<b>Totals:</b>	<b>99</b>	<b>94</b>	<b>193</b>	
Dairy	Pasteurized milk cheeses	General	BPW+Salmonella supplement	25g	15	14	29
	Pasteurized milks, powdered milks, yogurts	General	BPW+Salmonella supplement	25g	16	16	32
	Raw milk, raw milk cheeses	Specific (25g, dairy)	BPW+Salmonella supplement, 2° enrichment	25g	14	9	23
	Pasteurized milk cheeses	Specific (25g, dairy)	BPW+Salmonella supplement, 2° enrichment	25g	11	11	22
	Pasteurized milks, powdered milks, yogurts	Specific (25g, dairy)	BPW+Salmonella supplement, 2° enrichment	25g	13	15	28
	Milk powder & derivatives	Specific (375g, dairy)	prewarm BPW+Salmonella supplement	375g	31	34	65
			<b>Totals:</b>	<b>100</b>	<b>99</b>	<b>199</b>	
Plant products & seafood	Fresh, ready to eat, seasoned	General	BPW+Salmonella supplement	25g	10	11	21
	Cooked and seasoned	General	BPW+Salmonella supplement	25g	10	11	21
	Fresh fish fillets	General	BPW+Salmonella supplement	25g	10	11	21
				<b>Totals:</b>	<b>30</b>	<b>33</b>	<b>63</b>
Miscellaneous	Pastries	General	BPW+Salmonella supplement	25g	10	10	20
	Egg products	General	BPW+Salmonella supplement	25g	11	10	21
	Prepared foods	General	BPW+Salmonella supplement	25g	11	11	22
	Chocolate & cocoa	Specific (375g, chocolate/cocoa)	reconstituted NFDM+ Salmonella supplement	375g	30	30	60
				<b>Totals:</b>	<b>62</b>	<b>61</b>	<b>123</b>
Environmental Surface	Process water	General	BPW+Salmonella supplement		10	12	22
	Surface samples	General	BPW+Salmonella supplement		8	10	18
	Residue	General	BPW+Salmonella supplement		14	10	24
			<b>Totals:</b>	<b>32</b>	<b>32</b>	<b>64</b>	
Animal feeding stuffs	Cakes	General	BPW+Salmonella supplement	25g	10	10	20
	Granules, animal meals	General	BPW+Salmonella supplement	25g	12	10	22
	Pastes	General	BPW+Salmonella supplement	25g	10	10	20
				<b>Totals:</b>	<b>32</b>	<b>30</b>	<b>62</b>
Primary production	Poultry fecal samples	primary production	BPW+Salmonella supplement, 2° enrichment	25g	10	15	25
	Pig fecal samples	primary production	BPW+Salmonella supplement, 2° enrichment	25g	11	14	25
	Other poultry env. samples	primary production	BPW+Salmonella supplement, 2° enrichment	25g	10	13	23
	Other pig env. samples	primary production	BPW+Salmonella supplement, 2° enrichment	25g	10	11	21
			<b>Totals:</b>	<b>41</b>	<b>53</b>	<b>94</b>	
<b>Overall Totals</b>					<b>396</b>	<b>402</b>	<b>798</b>

**Table H. AFNOR Independent Expert Labs Study Data Summary – Relative Sensitivity**

	PA	NA	ND	PD	N	Relative Sensitivity, %	
						VIDAS SPT	Reference
<b>25g protocol</b>	215	224	6	7	452	97.4	96.9
<b>375g protocol</b>	123	125	4	0	252	96.9	100
<b>Totals:</b>	338	349	10	7	704		
	<b>PA</b>	<b>NA</b>	<b>ND</b>	<b>PD</b>	<b>N</b>		
<b>Meat products</b>	<b>93</b>	<b>94</b>	<b>5</b>	<b>1</b>	<b>193</b>		
General protocol	30	33	2	1	66		
Specific protocol, 375g	34	31	2	0	67		
Specific protocol, 375g Vancomycin	29	30	1	0	60		
<b>Dairy products</b>	<b>99</b>	<b>99</b>	<b>1</b>	<b>0</b>	<b>199</b>		
General protocol	31	30	0	0	61		
Specific protocol, 25g	38	35	0	0	73		
Specific protocol, 375g	30	34	1	0	65		
<b>Miscellaneous</b>	<b>61</b>	<b>61</b>	<b>0</b>	<b>1</b>	<b>123</b>		
General protocol	31	31	0	1	63		
Specific protocol, 375g	30	30	0	0	60		
<b>Plant products &amp; seafood</b>	<b>30</b>	<b>33</b>	<b>0</b>	<b>0</b>	<b>63</b>		
<b>Environment</b>	<b>24</b>	<b>32</b>	<b>4</b>	<b>4</b>	<b>64</b>		
<b>Animal feeding stuffs</b>	<b>31</b>	<b>30</b>	<b>0</b>	<b>1</b>	<b>62</b>		

PA – positive agreement (Candidate +/Reference +)  
 NA – negative agreement (Candidate -/Reference -)  
 ND – negative deviation (Candidate -/Reference +)  
 PD – positive deviation (Candidate +/Reference -)  
 N – total number of samples  
 Relative Sensitivity, (PA + PD)/(PA + PD + ND)

**Table H (continued). AFNOR Independent Expert Labs Study Data Summary – Relative Sensitivity (primary production)**

Compared to ISO 6579/A1							
VIDAS SPT - 6 hr	PA	NA	ND	PD	N	Relative Sensitivity, %	
						VIDAS SPT	Reference
Poultry fecal samples	7	15	2	1	25	85.4	87.8
Pig fecal samples	8	14	1	2	25		
Other poultry env. samples	8	13	1	1	23		
Other pig env. samples	7	11	2	1	21		
<b>Totals:</b>	<b>30</b>	<b>53</b>	<b>6</b>	<b>5</b>	<b>94</b>		
VIDAS SPT - 24 hr	PA	NA	ND	PD	N	Relative Sensitivity, %	
						VIDAS SPT	Reference
Poultry fecal samples	8	15	1	1	25	90.2	87.8
Pig fecal samples	9	14	0	2	25		
Other poultry env. samples	8	13	1	1	23		
Other pig env. samples	7	11	2	1	21		
<b>Totals:</b>	<b>32</b>	<b>53</b>	<b>4</b>	<b>5</b>	<b>94</b>		

PA – positive agreement (Candidate +/Reference +)  
 NA – negative agreement (Candidate -/Reference -)  
 ND – negative deviation (Candidate -/Reference +)  
 PD – positive deviation (Candidate +/Reference -)  
 N – total number of samples  
 Relative Sensitivity, (PA + PD)/(PA + PD + ND)

**Table I. AFNOR Independent Expert Labs Study Data Summary – Relative Level of Detection Limit**

Matrix	Test portion size	Strain	Relative detection level (CFU/25g or 375g) with confidence interval <sup>a</sup> LOD <sub>50</sub>	
			Reference Method	VIDAS SPT Method
Ground poultry meat	25 g	<i>Salmonella enterica ser. Hadar</i>	0.6 [0.3 - 1.1]	0.7 [0.3 - 1.3]
Cream cheese	25 g	<i>Salmonella enterica ser. Typhimurium</i>	0.6 [0.4 - 0.9]	0.4 [0.3 - 0.8]
Raw milk (specific protocol)	25 mL	<i>Salmonella enterica ser. Derby</i>	0.5 [0.3 - 0.8]	0.6 [0.3 - 0.9]
Fish fillet	25 g	<i>Salmonella enterica ser. Kedougou</i>	0.5 [0.3 - 0.9]	0.5 [0.3 - 0.9]
Liquid egg	25 g	<i>Salmonella enterica ser. Enteritidis</i>	0.5 [0.3 - 0.8]	0.5 [0.3 - 0.9]
Wet pet food	25 g	<i>Salmonella enterica ser. Liverpool</i>	0.8 [0.5 - 1.1]	0.5 [0.3 - 0.9]
Process water	25 mL	<i>Salmonella enterica ser. London</i>	0.4 [0.3 - 0.7]	0.5 [0.3 - 0.8]
Raw minced beef	375 g	<i>Salmonella enterica ser. Ohio</i>	0.5 [0.3 - 0.9]	0.5 [0.3 - 0.8]
Raw minced beef	375 g	<i>Salmonella enterica ser. Ohio</i>	0.5 [0.3 - 0.9]	0.4 [0.2 - 0.7]
Milk powder	375 g	<i>Salmonella enterica ser. Enteritidis</i>	0.5 [0.3 - 0.9]	0.5 [0.3 - 0.9]
Chocolate	375 g	<i>Salmonella enterica ser. Anatum</i>	0.4 [0.3 - 0.7]	0.4 [0.3 - 0.7]
Poultry fecal samples	25 g	<i>Salmonella enterica ser. Agona</i>	1.0 [0.6 - 1.5]	0.9 [0.5 - 1.5]

<sup>a</sup>LOD<sub>50</sub>: estimated level of contamination enabling positive detection using the alternative method in 50% of cases.

**Table J. AFNOR Inter-laboratory Study – Relative Sensitivity**

Level	# positive/total		PA	NA	ND	PD	N	Relative Sensitivity, %	
	VIDAS SPT	Reference						VIDAS	Reference
Level 0 (0 CFU/25g)	0/112	0/112	0	336	0	0	336	88.4	92.1
Low level (1.2CFU/25g)	55/112	62/112	152	147	22	15	336		
High level (10.85 CFU/25g)	112/112	112/112	336	0	0	0	336		

PA – positive agreement (Candidate +/Reference +)  
 NA – negative agreement (Candidate -/Reference -)  
 ND – negative deviation (Candidate -/Reference +)  
 PD – positive deviation (Candidate +/Reference -)  
 N – total number of samples  
 Relative Sensitivity, (PA + PD)/(PA + PD + ND)

## Glossary of Terms

**Candidate method** – The method submitted for validation.

**Chi square** – Test for significant difference; results less than 3.84 indicate no significant difference between methods.

**Collaborative Study (AOAC)** – A validation study performed by multiple laboratories to estimate critical candidate method performance parameters. See also Inter-laboratory study.

**Confirmed result** – The qualitative response from the confirmatory phase of a candidate method.

**False negative** – A VIDAS negative test result that was confirmed to be culturally positive from the corresponding VIDAS enrichment.

**False positive** – A VIDAS positive test result that was not confirmed to be culturally positive from the corresponding VIDAS enrichment.

**Fractional recovery** – Validation criterion that is satisfied when an unknown sample yields both positive and negative responses within a set of replicate analyses. The proportion of positive responses should fall within 25% and 75% and should ideally approximate 50% of the total number of replicates in the set.

**Inter-laboratory Study (AFNOR)** – A validation study performed by multiple laboratories to estimate critical candidate method performance parameters. See also collaborative study.

**Limit of detection** – The VIDAS system is able to detect a single target cell in a specific test portion following enrichment.

**Negative agreement** – Results for both the candidate method and the reference method are negative.

**Negative deviation** – Result for the candidate method is negative and the result for the reference method is positive.

**Presumptive result** – The qualitative response from the presumptive phase of a candidate method that includes a confirmatory phase.

**Probability of Detection (POD)** – The proportion of positive analytical outcomes for a qualitative method for a given matrix at a given analyte level or concentration. POD is concentration dependent.

**Positive agreement** – Results for both the candidate method and the reference method are positive.

**Positive deviation** – Result for the candidate method is positive and the result for the reference method is negative.

**Relative sensitivity** – Ability of the alternative method to detect the analyte when it is detected by the reference method

**Sensitivity** – The number of VIDAS positive test results that were confirmed to be positive from the VIDAS enrichment divided by the total number of confirmed positive VIDAS enrichments.

**Specificity** – The number of VIDAS negative test results that were confirmed to be negative from the VIDAS enrichment divided by the total number of confirmed negative VIDAS enrichments.

**Test portion** – A specified quantity of the sample that is taken for analysis by the method.

For more information, please contact your local  
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