



CERTIFICATION

AOAC[®] Performance TestedSM

Certificate No.

081803

The AOAC Research Institute hereby certifies the method known as:

SureFast[®] Salmonella ONE

manufactured by

**CONGEN Biotechnologie GmbH
Robert Roessle Str. 10
D-13125 Berlin
Germany**

This method has been evaluated in the AOAC[®] *Performance Tested Methods*SM Program and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC[®] Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*SM certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above-mentioned method for a period of one calendar year from the date of this certificate (December 10, 2021 – December 31, 2022). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

December 10, 2021

Date

METHOD AUTHORS ORIGINAL VALIDATION: Danièle Sohier and Maryse Rannou JULY 2018 MODIFICATION: Maryse Rannou and Muriel Bernard	SUBMITTING COMPANIES Biotest AG Landsteinerstr. 5 D-63303 Dreieich Germany	CONGEN Biotechnologie GmbH Robert Roessle Str. 10 D-13125 Berlin Germany
--	--	--

METHOD NAME(S) SureFast® Salmonella ONE	CATALOG NUMBERS F5211
---	---------------------------------

INDEPENDENT LABORATORY ADRIA Développement ZA Creac'h Gwen F-29196 Quimper cedex France	AOAC EXPERTS AND PEER REVIEWERS Yi Chen ¹ , Henk Stegeman ² , Thomas Hammock ^{3,6} , Michael Brodsky ^{4,6} , Maria Cristina Fernandez ^{5,6} ¹ US Food and Drug Administration, Center for Food Safety and Applied Nutrition, College Park, MD, USA ² Brodsky Consultants, Thornhill, ON, Canada ³ Consultant, Loganville, GA, USA ⁴ Brodsky Consultants, Thornhill, ON, Canada ⁵ Universidad Maimonides, Buenos Aires, Argentina ⁶ Modification July 2018
--	--

APPLICABILITY OF METHOD Target organism – <i>Salmonella</i> spp. Matrixes – (25 g) - Salami, pork minced meat, bacon, fresh ground chicken, fresh chicken carcass, frozen marinated chicken fillets, semi-skim milk powder, raw goat milk cheese, chocolate ice cream, salad with mayonnaise, paella, cream-based pastry, dehydrated poultry proteins, wheat-based flour, pet food pellets Modification July 2018: (25 g) - raw ground beef, frozen poultry meat, raw milk, fresh spinach, pasteurized liquid whole egg, pet food pellets Performance claims – The test method performed equivalent or better than the reference method.	REFERENCE METHOD NF EN ISO 6579: 2002: Microbiology of food and animal feeding stuffs – Horizontal method for the detection of <i>Salmonella</i> spp.
---	---

ORIGINAL CERTIFICATION DATE April 29, 2011	CERTIFICATION RENEWAL RECORD Renewed annually through December 2022.
--	--

METHOD MODIFICATION RECORD	SUMMARY OF MODIFICATION
1. April 2011 Level 1	1. Test kit name change MMB Salmonella Prep Kit and MMB Salmonella V/R/LC .
2. February 2012 Level 1	2. Test kit name change to SureFood PREP Salmonella & SureFood PATHOGEN Salmonella PLUS V/R/LC.
3. March 2014 Level 1	3. Test kit name change to SureFood PATHOGEN Salmonella PLUS.
4. December 2016 Level 1	4. Test kit name change to SureFast® Salmonella PLUS.
5. January 2018 Level 1	5. Editorial changes.
6. July 2018 Level 2	6. Changes: a) Test kit name change from SureFast® Salmonella PLUS to SureFast® Salmonella ONE; b) Updated catalog numbers; c) DNA extraction method (Prep Salmonella) replaced by a one step lysis buffer; d) Matrix extension study to include raw ground beef, frozen poultry meat, raw milk, fresh spinach, pasteurized liquid whole egg, pet food pellets.
7. August 2018 Level 1	7. Separated Salmonella PLUS (PTM 041103) and Salmonella ONE (PTM 081803) to have two certifications.
8. December 2019 Level 1	8. Editorial/clerical changes.

Under this AOAC® Performance Tested SM License Number, 081803 this method is distributed by: R-Biopharm-AG	Under this AOAC® Performance Tested SM License Number, 081803 this method is distributed as: SureFast® Salmonella ONE
--	---

PRINCIPLE OF THE METHOD (3)

The kit is intended to be used for the fast and simple isolation and detection of *Salmonella* - DNA from enrichment cultures. The enrichment is carried out according to EN ISO 6579:2002 in buffered peptone water (BPW) at 37°C for 18 h ± 2 h. Each reaction contains an internal amplification control (PLUS). The real-time PCR assay can be used with established real-time PCR instruments, equipped for detection of two fluorescence emissions in the FAM and VIC/HEX channel at the same time. The technical validation of instruments was performed on Agilent AriaMx, BioRad CFX 96, Roche LightCycler® 480 II, Applied Biosystems® 7500 and Bio Molecular Systems MIC.

DISCUSSION OF THE VALIDATION STUDY (1)

The SureFast Salmonella PLUS method is selective and specific. The Mc Nemar tests concluded to equivalent performances between both tested methods for a variety of foods, except when taking into account the presumptive positive deviations observed with the tested pet food and all food products. In those two cases, a significant difference between both methods is observed. This difference was justified by the high number of presumptive positive deviations for the alternative method.

The SureFast Salmonella PLUS method shows satisfying relative accuracy, specificity and sensitivity results.

The storage of the BPW at 4°C for 72h prior to analyses gave satisfying results, except for the fresh chicken minced meat: for that matrix, results are statistically significant, concluding to a difference of performances between the ISO 6579 method and the SureFast Salmonella PLUS method.

The relative detection levels of SureFast® Salmonella PLUS method are similar to those of the ISO 6579 method.

The short incubation time of 8h for the raw pork minced meat analysis gave results in agreement with the ISO 6579 method results, as shown with the relative accuracy study and the relative detection level determinations.

The SureFast Salmonella PLUS method performances were globally similar whatever the tested thermocycler.

Results from the lot-to-lot and ruggedness studies correspond to the expected one for all the tested protocols.

*Please note that the original validation was conducted under the name Biotest MMB *Salmonella* method but has changed names several times. The following list is a historical review of kit names:

1. Biotest MMB *Salmonella*
2. MMB Salmonella Prep Kit & MMB Salmonella V/R/LC
3. SureFood® PREP Salmonella & SureFood PATHOGEN Salmonella PLUS V/R/LC
4. SureFood PATHOGEN Salmonella PLUS
5. SureFast® Salmonella PLUS
6. SureFast® Salmonella ONE

Appendix 6 – Inclusivity and exclusivity: raw data (1)

INCLUSIVITY								
N°	Strain	Origin	Inoculation level (cfu/225ml EPT)	PCR result (8H incubation)				
				VIC (CT)	FAM (CT)	Result		
1.	<i>Salmonella</i>	Agona	A00V38	Feedstuff	3	N/A	19,52	+
2.	<i>Salmonella</i>	Aberdeen	CIP 105618	/	9	31,07	27,96	+
3.	<i>Salmonella</i>	Abony	CIP 8039	/	11	31,22	28,3	+
4.	<i>Salmonella</i>	Anatum	6140	Bœuf Bourguignon	5	N/A	17,59	+
5.	<i>Salmonella</i>	<i>arizonae</i> 50:z4,z23	CIP 5526	Egg powder	5	N/A	20,71	+
6.	<i>Salmonella</i>	<i>arizonae</i> 51:z4,z23	ATCC 13314	/	9	N/A	19,78	+
7.	<i>Salmonella</i>	<i>arizonae</i> 44:z4,z23,z32:-	CIP 55.22	/	6	31,07	27,79	+
8.	<i>Salmonella</i>	<i>arizonae</i> 18:z4,z23:-	CIP 55.28	/	14	30,63	30,48	+
9.	<i>Salmonella</i>	Bardo	569	Sausage	6	N/A	24,82	+
10.	<i>Salmonella</i>	Blockley	Ad 923	Chicken	8	43,9	22,34	+

11.	<i>Salmonella</i>	Bongori 48:z35	Ad 598	Environment	12	N/A	18,66	+
12.	<i>Salmonella</i>	Bongori 66:z35	Ad 599	Poultry environment	6	43,24	17,9	+
13.	<i>Salmonella</i>	Bovismorbificans	728	Agar	17	42,75	16,38	+
14.	<i>Salmonella</i>	Braenderup	178	/	28	43,78	18,6	+
15.	<i>Salmonella</i>	Brandenburg	Ad 351	Seafood	22	42,51	16,56	+
16.	<i>Salmonella</i>	Brazzaville	CIP 54141	/	4	30,71	27,95	+
17.	<i>Salmonella</i>	Bredeney	396	Ground beef	26	N/A	18,88	+
18.	<i>Salmonella</i>	Carrau	CIP 105619	/	7	31,41	27,51	+

INCLUSIVITY

N°	Strain	Origin	Inoculation level (cfu/225ml EPT)	PCR result (8H incubation)				
				VIC (CT)	FAM (CT)	Result		
19.	<i>Salmonella</i>	Cerro	Ad 689	Dehydrated proteins	2	N/A	17,75	+
20.	<i>Salmonella</i>	Choleraesuis	ATCC 51741		2	43,8	22,77	+
21.	<i>Salmonella</i>	Corvallis	CIP 105342		3	31,4	31,8	+
22.	<i>Salmonella</i>	Cremieu	230	Hare	3	25,69	20,45	+
23.	<i>Salmonella</i>	Dakar	CIP 105620		3	31,95	36,64	+
24.	<i>Salmonella</i>	Derby	Ad 1093	Frozen fish fillet	1	N/A	20,71	+
25.	<i>Salmonella</i>	<i>diarizonae</i> S.IIIb 38:IV:z53	Ad 453	Raw milk cheese	3	N/A	27,66	+
26.	<i>Salmonella</i>	<i>diarizonae</i> S.IIIb 38:IV:z35	Ad 594	Frog leg	8	N/A	19,62	+
27.	<i>Salmonella</i>	<i>diarizonae</i> S.IIIb 50:i:z	Ad 1091	Raw milk cheese	3	N/A	22,27	+
28.	<i>Salmonella</i>	<i>diarizonae</i> S.IIIb 61:i:z53	Ad 595	Cheese	9	N/A	21,89	+

29.	<i>Salmonella</i>	Dublin	Ad 528	Pancake	9	N/A	17,61	+
30.	<i>Salmonella</i>	Duisburg	42	Poultry	18	N/A	24,38	+
31.	<i>Salmonella</i>	Enteritidis	Ad 926	Raw veal meat	7	N/A	18,59	+
32.	<i>Salmonella</i>	Essen	38	Poultry	15	N/A	23,47	+
33.	<i>Salmonella</i>	Falkensee	693	Raw pork sausage	9	N/A	18,74	+
34.	<i>Salmonella</i>	Gallinarum	Ad 300	Poultry slaughterhouse	2	31,8	38,36	+
35.	<i>Salmonella</i>	Garoli	CIP 54139	/	1	30,38	25,33	+
36.	<i>Salmonella</i>	Give	438	Ground beef	2	N/A	18,42	+
37.	<i>Salmonella</i>	Grumpensis	CIP 105621	/	1	30,76	28,5	+

N°	Strain	Origin	INCLUSIVITY		Inoculation level (cfu/225ml EPT)	PCR result t (8H incubation)		
			VIC (CT)	FAM (CT)		Result		
38.	<i>Salmonella</i>	Hadar	35	Poultry	17	N/A	17,97	+
39.	<i>Salmonella</i>	Havana	Ad 930	Poultry	20	N/A	17,16	+
40.	<i>Salmonella</i>	Heidelberg	A00E005	Dairy industry environmental sample	19	N/A	22,27	+
41.	<i>Salmonella</i>	Hessarek	CIP 54140	/	1	31,46	34,44	+
42.	<i>Salmonella</i>	<i>houtenae</i> (sub-group IV) 43:z4z32	Ad 597	Fish	19	N/A	17,3	+
43.	<i>Salmonella</i>	<i>houtenae</i> (sub-group IV) 50:g,z51	Ad 596	Dairy product	10	N/A	20,88	+
44.	<i>Salmonella</i>	Indiana	2	Fish flour	1	32,37	31,94	+
45.	<i>Salmonella</i>	<i>indica</i> (sub-group VI) 1,26,14,25:a:enx	Ad 600	Environment	3	17,92	17,88	+
46.	<i>Salmonella</i>	Infantis	12	Ready to eat food	4	N/A	17,21	+
47.	<i>Salmonella</i>	Kedougou	Ad 929	Environmental sample (Slaughterhouse)	2	N/A	17,91	+

48.	<i>Salmonella</i>	Kentucky	CIP 105623	/	7	31,14	31,07	+
49.	<i>Salmonella</i>	Kottbus	1	Environmental sample (slaughterhouse)	24	N/A	17,38	+
50.	<i>Salmonella</i>	Lagos	173	Sausage	22	N/A	16,17	+
51.	<i>Salmonella</i>	Landau	Ad 499	/	11	N/A	16,61	+
52.	<i>Salmonella</i>	Leipzig	CIP 105624	/	3	35,21	37,17	+
53.	<i>Salmonella</i>	Lille	37	Poultry	15	34,82	21,17	+
54.	<i>Salmonella</i>	Livingstone	E1	Egg white powder	14	N/A	16,07	+
55.	<i>Salmonella</i>	London	326	Ham	6	N/A	16,28	+
56.	<i>Salmonella</i>	Luciana	CIP 105629	/	4	35,01	31,68	+
57.	<i>Salmonella</i>	Manhattan	900	Dairy environmental sample	7	N/A	16,28	+

INCLUSIVITY

N°	Strain	Origin	Inoculation level (cfu/225ml EPT)	PCR result (8H incubation)				
				VIC (CT)	FAM (CT)	Result		
58.	<i>Salmonella</i>	Maracaibo	CIP 54.143	/	2	32,07	32,44	+
59.	<i>Salmonella</i>	Marseille	CIP 105627	/	8	30,97	26,62	+
60.	<i>Salmonella</i>	Mbandaka	Ad 914	Mayonnaise	11	N/A	17,05	+
61.	<i>Salmonella</i>	Meleagris	505	Raw milk	2	N/A	16,72	+
62.	<i>Salmonella</i>	Mikawasima	CIP 107220	/	14	30,93	25,38	+
63.	<i>Salmonella</i>	Minnesota	CIP 105628	/	5	30,39	32,48	+
64.	<i>Salmonella</i>	Montevideo	Ad 912	Raw milk	17	43,05	16,22	+
65.	<i>Salmonella</i>	Muenchen	CIP 106178	/	7	30,86	27,46	+
66.	<i>Salmonella</i>	Muenster	CIP 107859	/	4	30,47	26,92	+

67.	<i>Salmonella</i>	Napoli	Ad 928	Bovine	10	N/A	17,19	+
68.	<i>Salmonella</i>	Newport	540	Toulouse sausage	8	N/A	16,83	+
69.	<i>Salmonella</i>	Orion	27	Poultry	7	N/A	21,51	+
70.	<i>Salmonella</i>	Panama	195	Ground beef	16	N/A	16,88	+
71.	<i>Salmonella</i>	Paratyphi A	ATCC 9150	/	1	N/A	16,16	+
72.	<i>Salmonella</i>	Paratyphi B	Ad 301	Clinical	1	N/A	17,89	+
73.	<i>Salmonella</i>	Paratyphi B var java	CIP5626	/	6	42,68	18,52	+
74.	<i>Salmonella</i>	Paratyphi C	ATCC 13428	/	2	N/A	17,83	+
75.	<i>Salmonella</i>	Pomona	CIP 105630	/	18	31,15	30,47	+
76.	<i>Salmonella</i>	Poona	CIP 107125	/	2	31,2	36,64	+

INCLUSIVITY

N°	Strain	Origin	Inoculation level (cfu/225ml EPT)	PCR result (8H incubation)			
				VIC (CT)	FAM (CT)	Result	
77.	<i>Salmonella</i> Regent	328	Duck	7	N/A	16,46	+
78.	<i>Salmonella</i> Rissen	39	Poultry	3	N/A	18,08	+
79.	<i>Salmonella</i> Chester	CIP 103543	/	5	31,07	25,58	+
80.	<i>Salmonella</i> Saintpaul	F31	Pilchard fillet	8	N/A	17,33	+
81.	<i>Salmonella salamae</i> (sub-group II) 42:b:enxz	Ad 593	Cereals	10	N/A	16,83	+
82.	<i>Salmonella salamae</i> (sub-group II) 42:gt:-	Ad 592	Kangaroo	8	N/A	25,26	+
83.	<i>Salmonella</i> Salford	CIP 104917	/	18	81,03	29,62	+
84.	<i>Salmonella</i> Senftenberg	Ad 355	Seafood	16	N/A	16,73	+

85.	<i>Salmonella</i>	Stanley	CIP 106163	/	1	30,96	28,06	+
86.	<i>Salmonella</i>	Sternschanze	Ad 500	Food product	5	N/A	21,88	+
87.	<i>Salmonella</i>	Strasbourg	CIP 105632	/	3	32,27	31,51	+
88.	<i>Salmonella</i>	Tananarive	CIP 54142	/	5	31,1	30,28	+
89.	<i>Salmonella</i>	Tennessee	A00E006	Dairy industry environmental sample	9	N/A	17,01	+
90.	<i>Salmonella</i>	Thompson	AER301	Poultry	9	N/A	17,01	+
91.	<i>Salmonella</i>	Typhi	Ad 302	Clinical	1	N/A	15,12	+
92.	<i>Salmonella</i>	Typhimurium	305	Paella	11	N/A	17,13	+
93.	<i>Salmonella</i>	Urbana	Ad 501	Food product	13	N/A	16,6	+
94.	<i>Salmonella</i>	Veneziana	233	Food product	6	N/A	20,27	+
95.	<i>Salmonella</i>	Virchow	F276	Curry	16	44,17	16,59	+

INCLUSIVITY

N°	Strain	Origin	Inoculation level (cfu/225ml EPT)	PCR result (8H incubation)				
				VIC (CT)	FAM (CT)	Result		
96.	<i>Salmonella</i>	Waycross	CIP 105634	/	8	31,2	29,13	+
97.	<i>Salmonella</i>	Wein	CIP 8122	/	6	31,54	35,4	+
98.	<i>Salmonella</i>	Worthington	3506	Pâté	2	N/A	21,51	+
99.	<i>Salmonella</i>	Zanzibar	CIP 107479	/	12	30,67	25,32	+
100.	<i>Salmonella</i>	Berta	CIP 105682	/	7	30,93	29,45	+

EXCLUSIVITY							
N°	Strain		Origin	Inoculation level (cfu/ml EPT)	PCR result (20H incubation)		
					VIC (CT)	FAM(CT)	Result
1	<i>Citrobacter braakii</i>	Ad833	Raw beef meat	3,1.10 ⁶	33,44	N/A	-
2	<i>Citrobacter diversus</i>	adria 140	Raw milk	3,9.10 ⁵	32,16	N/A	-
3	<i>Citrobacter freundii</i>	adria 23	Raw pork sausage	6,9.10 ⁵	32,32	N/A	-
4	<i>Citrobacter freundii</i>	adria 175	Raw duck meat	7,1.10 ⁵	32,04	N/A	-
5	<i>Citrobacter koseri</i>	adria 71	Frozen vegetables	1,5.10 ⁶	32,23	N/A	-
6	<i>Enterobacter agglomerans</i>	adria 11	Cheese	3,9.10 ⁵	33,4	N/A	-
7	<i>Enterobacter amnigenus</i>	A00C068	Raw poultry meat	4,3.10 ⁵	32,19	N/A	-
8	<i>Enterobacter cloacae</i>	adria 10	Raw milk	5,1.10 ⁵	32,08	N/A	-
9	<i>Enterobacter intermedius</i>	adria 60	Bean	1,2.10 ⁵	32,56	N/A	-
10	<i>Enterobacter kobei</i>	Ad 342	Ham	2,7.10 ⁵	32,24	N/A	-
11	<i>Enterobacter sakazakii</i>	adria 95	Fermented milk	4,8.10 ⁵	32,3	N/A	-
12	<i>Erwinia carotovora</i>	CIP 8283	Potatoes	1,0.10 ⁴	32,11	N/A	-
13	<i>Escherichia coli</i>	adria 19	Greated carrots	2,6.10 ⁵	32,87	N/A	-
14	<i>Escherichia hermanii</i>	Ad 461	Dessert	3,4.10 ⁵	32,22	N/A	-
15	<i>Escherichia vulneris</i>	adria 127	Raw milk	7,6.10 ⁵	32,57	N/A	-
16	<i>Hafnia alvei</i>	adria 167	Raw pork sausage	7,7.10 ⁵	32,4	N/A	-
17	<i>Klebsiella oxytoca</i>	57	Food product	1,4.10 ⁶	32,18	N/A	-
18	<i>Klebsiella pneumoniae</i>	47	Raw turkey meat	3,9.10 ⁵	32,07	N/A	-

EXCLUSIVITY							
N°	Strain		Origin	Inoculation level (cfu/ml EPT)	PCR result (20H incubation)		
					VIC (CT)	FAM(CT)	Result
19	<i>Kluyvera spp</i>	adria 41	Raw milk	3,0.10 ⁵	31,77	N/A	-
20	<i>Morganella morganii</i>	CIP A236	/	5,1.10 ⁵	32,4	N/A	-
21	<i>Pantoea agglomerans</i>	adria 86	Frozen vegetables	7,6.10 ⁵	32,31	N/A	-
22	<i>Proteus mirabilis</i>	Ad639	Mayonnaise	6,3.10 ⁵	31,96	N/A	-
23	<i>Proteus vulgaris</i>	adria 43	Sliced ham	8,4.10 ⁴	32,34	N/A	-
24	<i>Providencia rettgeri</i>	adria 112	White liquid egg	3,7.10 ⁵	31,83	N/A	-
25	<i>Rhanella aquatilis</i>	adria 69	Molluscs	5,6.10 ⁴	32,9	N/A	-
26	<i>Serratia liquefaciens</i>	26	Egg product	2,8.10 ⁵	33,3	N/A	-
27	<i>Serratia proteomaculans</i>	A00C056	Ham	8,0.10 ⁴	32,07	N/A	-
28	<i>Shigella flexneri</i>	CIP 8248	/	3,4.10 ⁵	33,67	N/A	-
29	<i>Shigella sonnei</i>	CIP 8249T (ATCC 29930)	/	4,1.10 ⁵	32,44	N/A	-
30	<i>Yersinia enterocolitica</i>	adria 32	Bacon	2,8.10 ⁵	32,28	N/A	-

Method Comparison (1)

Matrix	Inoculating organism	Level	MPN/25g	N° test portion	Reference	Test kit			Test Kit Performance						
					Positive	Presumptive positive	Confirmed positive	Chi square	Sensitivity rate	False negative rate	Specificity rate	False positive rate	Sensitivity rate alternative**	Sensitivity rate reference**	False positive (PPNC**)
Fermented sausage	Salmonella Give 436	High	2,3[0,5;9,0]	20	5	8	5	/	1,00	0,00	1,00	0,00	1,00	1,00	3,00
		Control	/	5	0	0	0								
Pork minced meat	Salmonella Lagos 173	High	6,0[1,0;24,8]	20	15	15	15	/	1,00	0,00	1,00	0,00	1,00	1,00	0,00
		Control	/	5	0	0	0								
Cured meat	Salmonella Bovimorbificans	High	2,3[0,5;9,0]	20	14	15	15	0,00	1,00	0,00	1,00	0,20	1,00	0,93	0,00
		Control	/	5	0	0	0								
Fresh chicken	Salmonella Braenderup Ad915	High	1,1[0,2;4,5]	20	10	8	8	0,50	0,80	0,25	0,83	0,00	0,80	1,00	0,00
		Control	/	5	0	0	0								
Freh poultry	Salmonella Hadar 24871	High	0,6[0,1;2,4]	20	5	6	5	/	1,00	0,00	1,00	0,00	1,00	1,00	1,00
		Control	/	5	0	0	0								
Frozen	Salmonella Senftenberg Ad934	High	0,6[0,1;2,4]	20	10	10	10	/	1,00	0,00	2,00	0,00	1,00	1,00	0,00
		Control	/	5	0	0	0								
Semi-skim milk powder	Salmonella Anatum Ad298	High	10,8[2,3;45,3]	20	15	16	15	/	1,00	0,00	1,00	0,00	1,00	1,00	1,00
		Control	/	5	0	0	0								
Raw goat milk cheese	Salmonella Illa	High	0,6[0,1;2,4]	20	9	9	9	/	1,00	0,00	1,00	0,00	1,00	1,00	0,00
		Control	/	5	0	0	0								
Chocolate ice cream	Salmonella Montevideo Ad912	High	1,1[0,2;4,5]	20	9	9	9	/	1,00	0,00	1,00	0,00	1,00	1,00	0,00
		Control	/	5	0	0	0								
Salad with	Salmonella Mbandaka Ad914	High	0,6[0,1;2,4]	20	6	6	6	/	1,00	0,00	1,00	0,00	1,00	1,00	0,00
		Control	/	5	0	0	0								
Ready to	Salmonella Virchow F276	High	2,3[0,5;9,0]	20	6	8	7	0,00	1,00	0,00	1,00	0,08	1,00	0,86	1,00
		Control	/	5	0	0	0								
Cream	Salmonella Typhimurium 633	High	0,1[0,0;0,4]	20	7	10	6	0,00	0,86	0,17	0,93	0,00	0,86	1,00	4,00
		Control	/	5	0	0	0								
Dehydrated	Salmonella Cerro Ad689	High	0,6[0,1;2,4]	20	8	8	8	/	1,00	0,00	1,00	0,00	1,00	1,00	0,00
		Control	/	5	0	0	0								
Wheat based flour	Salmonella Derby 630	High	0,6[0,1;2,4]	20	10	10	10	/	1,00	0,00	1,00	0,00	1,00	1,00	0,00
		Control	/	5	0	0	0								
Pet food pellets	Salmonella Agona A00V038	High	0,4[0,1;0,9]	20	5	18	5	0,00	1,00	0,00	1,00	0,00	1,00	1,00	14,00
		Control	/	5	0	2	0								1,00
All matrixes		High		300	134	156	133	0	0,88	0,02	0,98	0,01	0,98	0,99	24,00
		Control		75	0	1	0								

*:taking into account alternative positive deviations that were confirmed with culture-based tests

**PPNC: presumptive positive and non confirmed results

DISCUSSION OF THE MODIFICATION STUDY APPROVED JULY 2018 (3)

Matrix studies, inclusivity/exclusivity were conducted to assess the performances of the SureFast® Salmonella ONE method.

The POD analysis conducted during the validation study demonstrates that there were no statistically significant differences between the SureFast® Salmonella ONE method and the reference method on the matrixes tested.

The data collected in these studies demonstrate that the SureFast® Salmonella ONE method is suitable for *Performance Tested Method*SM certification for rapid and specific detection of *Salmonella* species.

Table 1 - Inclusivity results (3)

INCLUSIVITY														
No	Strain		O groups	Reference	Origin	Inoculation level cfu/225ml	SureFast® Salmonella ONE method							
							PCR (Cq)					Confirmation		
							CFX96 BIO-RAD	ROCHE LightCycler 480II	Applied Biosystems 7500	MIC	Agilent AriaMx	XLD	ASAP	Latex
1.	Salmonella	Abaetetuba	O:11	Ad2318	unknown	32	+(21,31)	20,3	21,0	20,1	18,6	+	+	+
2.	Salmonella	Aberdeen	O:11	CIP 105618	Human	35	+(19,78)	20,2	20,6	20,3	19,1	+	+	+
3.	Salmonella	Abortusequi	O:4	Ad2321	unknown	7	+(22,1)	23,2	23,8	22,6	22,1	+(H2S-)	st	+
4.	Salmonella	Abortusovis	O:4	Ad2320	Ovine fetus	26	+(25,89)	26,9	27,5	27,2	25,6	+	+(white)	+
5.	Salmonella	Adelaïde	O:35	Ad2319	Turkey breeding environment	49	+(25,00)	24,1	24,5	25,6	22,3	+	+	+(weak)
6.	Salmonella	Agona	O:4	A00V038	Feed for pork	35	+(21,14)	21,2	21,6	21,4	19,2	+	+	+
7.	Salmonella	Anatum	O:3,10	A00E007	Dusts	34	+(19,18)	19,1	19,3	16,6	16,7	+	+	+
8.	Salmonella	arizonae 51:z4,z23	O:51	CIP 5523	Turkey meat	34	+(20,48)	20,4	20,4	20,5	18,9	+	+	+(weak)
9.	Salmonella	arizonae 18:z4,z23:-	O:18	Ad1848	Food product	18	+(19,20)	20,2	20,3	20,4	18,5	+	+	+(weak)
10.	Salmonella	arizonae 41:z4,z23:-	O:41	Ad1849	Primary production	31	+(19,35)	19,4	19,8	19,3	17,8	+	+	+(weak)
11.	Salmonella	arizonae 48:z4,z23:-	O:48	Ad1850	Poultry environmental sample	36	+(20,73)	19,5	20,0	20,3	18,0	+	+	+(weak)
12.	Salmonella	arizonae 50:z4,z23	O:50	CIP5522	unknown	12	+(23,08)	22,3	23,1	22,9	21,4	+(H2S-)	+(blade)	+(weak)
13.	Salmonella	Bardo	O:8	Adria 569	Meat for sausages	34	+(21,79)	21,6	22,0	23,0	20,3	+	+	+
14.	Salmonella	Bareilly	O:7	Ad1687	Chocolate industry	34	+(20,95)	19,7	20,2	19,9	18,0	+	+	+
15.	Salmonella	Blockley	O:8	Ad923	Poultry environment	43	+(18,68)	18,8	19,6	19,5	17,6	+	+	+
16.	Salmonella	bongori 48:z35	O:48	Ad598	Environmental sample	33	+(19,28)	18,3	18,6	19,3	16,6	+(H2S-)	+(white)	+(weak)
17.	Salmonella	bongori 66 :z35	O:66	Ad599	Environmental sample	35	+(18,48)	19,3	19,7	20,7	17,7	+(H2S-)	+(white)	+(weak)
18.	Salmonella	bongori V 1,40:z81:-	O:40	Ad2683	Cooked meal	64	+(19,51)	18,1	18,3	18,8	16,0	+(H2S-)	+(white)	+(weak)
19.	Salmonella	Breanderup	O:7	Adria 111	Pork meat	24	+(22,76)	20,3	20,7	21,3	18,4	+	+	+
20.	Salmonella	Bredeney	O:4	Adria 396	Ground beef	31	+(19,24)	17,2	17,2	18,8	15,6	+	+	+
21.	Salmonella	Caracas	O:6,14	Ad2322	Spice	36	+(20,18)	20,2	20,3	20,6	18,2	+	+	+
22.	Salmonella	Cerro	O:18	Ad689	Dehydrated poultry proteins	34	+(20,11)	19,0	19,5	19,8	17,3	+	+	+
23.	Salmonella	Chester	O:4	CIP 103543	unknown	25	+(20,48)	19,4	19,8	20,4	17,9	+	+	+
24.	Salmonella	Cubana	O:13	Ad2323	Dust feed environment	28	+(21,48)	20,3	21,0	21,7	18,9	+	+	+
25.	Salmonella	Derby	O:4	Ad1093	Fish fillet	30	+(21,61)	20,1	20,8	21,3	18,9	+	+	+
26.	Salmonella	diarizonae 38:lv:z53	O:38	Ad451	Ewe milk cheese	27	+(19,54)	18,0	18,5	20,0	16,6	+(H2S-)	+	+(weak)
27.	Salmonella	diarizonae 61:k:1,57	O:61	Ad1300	Raw ewe milk	47	+(19,61)	18,9	19,3	19,9	17,2	+	+	+
28.	Salmonella	diarizonae 16:z10:enz15	O:16	Ad1853	Food product	30	+(19,25)	19,0	19,0	20,9	17,5	+(yellow)	+	+
29.	Salmonella	diarizonae 48:k:1,5,7	O:48	Ad1852	Food product	60	+(19,19)	18,3	18,5	19,3	16,7	+	+	+
30.	Salmonella	diarizonae 50:i:z	O:50	Ad1851	Raw milk	46	+(18,78)	18,0	18,4	19,7	16,3	+	+	+
31.	Salmonella	Dublin	O:8	Ad529	Beef meat	26	+(19,15)	19,3	19,8	19,9	17,8	+	+(white)	+
32.	Salmonella	Enteritidis	O:8	Ad477	Hen meat	17	+(19,60)	18,9	19,8	20,0	17,4	+	+	+
33.	Salmonella	Gaminara	O:16	Ad2324	Boar meat	18	+(19,80)	19,9	20,7	20,1	18,6	+	+	+
34.	Salmonella	Give	O:3,10	Adria 436	Ground beef	16	+(19,48)	18,5	19,0	19,7	16,9	+	+	+
35.	Salmonella	Guinea	O:44	Adria 29	Human food	31	+(18,38)	16,8	17,0	17,6	15,3	+(H2S-)	+	+
36.	Salmonella	Hadar	O:8	Adria 24871	Chicken meat	45	+(19,16)	19,2	20,0	20,2	18,3	+	+	+
37.	Salmonella	Havana	O:13	Ad930	Poultry environment	44	+(19,45)	18,6	19,4	20,1	17,7	+	+	+
38.	Salmonella	Heidelberg	O:4	A00E005	Dusts from dairy industry	1	+(21,82)	22,5	22,9	24,1	21,0	+	+	+
39.	Salmonella	houtenae 6,14:24,z23:-	O:6,14	Ad1834	Ewe raw milk	3	+(19,46)	18,4	18,9	19,7	17,3	+	+	+
40.	Salmonella	houtenae IV 1,40:z4,z23:-	O:40	Ad2682	Environmental sample	2	+(19,41)	18,3	18,7	18,9	16,7	+	+	+
41.	Salmonella	houtenae 43:z4,z32	O:43	Ad597	Fish product	3	+(20,01)	19,7	20,0	20,3	18,2	+	+(white)	+
42.	Salmonella	houtenae 50:g,z51	O:50	Ad596	Dairy product	2	+(19,75)	18,2	18,3	18,5	16,6	+	+	+

CONGEN SureFast® Salmonella ONE, AOAC® Performance TestedSM Certification Number 081803

43.	Salmonella	houtenae IV 38:z4,z23:-	O:38	Ad2681	Boa	2	+(19,33)	19,4	19,8	20,4	18,1	+(H2S-)	+	+(weak)
44.	Salmonella	Hvittingfoss	O:16	Ad2325	Raw stuff	3	+(20,38)	19,9	20,6	21,1	18,1	+	+	+
45.	Salmonella	Indiana	O:4	Ad174	White cheese	25	+(22,45)	20,5	20,8	21,8	19,0	+	+	+
46.	Salmonella	indica 1,6,14,25:a:e,n,x	O:6,14	Ad600	Environmental sample	10	+(21,57)	19,0	19,2	20,4	17,3	+(H2S-)	+(blade)	+
47.	Salmonella	indica11:b:e,n,x	O:11	Ad2337	Chicken breeding environment	14	+(21,00)	17,9	18,4	18,9	16,8	+	+(blade)	+
48.	Salmonella	Infantis	O:7	F401B	Cheese	29	+(19,82)	17,5	17,9	19,7	16,7	+	+	+
49.	Salmonella	Javiana	O:8	Ad2326	Turkey meat	32	+(18,26)	17,8	18,4	19,2	17,2	+	+	+
50.	Salmonella	Kedougou	O:13	Ad929	Bovine environmental sample	25	+(22,46)	21,8	22,8	23,3	20,0	+	+	+
51.	Salmonella	Kentucky	O:8	CIP 105623	Chicken	20	+(20,51)	20,1	20,9	21,1	18,6	+	+	+
52.	Salmonella	Kottbus	O:8	Adria 1	Poultry environmental sample	30	+(20,26)	20,2	20,9	20,8	18,5	+	+	+
53.	Salmonella	Landau	O:30	Ad499	Human food	2	+(25,08)	24,9	25,5	27,0	23,6	+	+(blade)	+
54.	Salmonella	Lille	O:7	Adria 37	Food product	8	+(21,01)	20,8	21,3	22,5	19,3	+	+	+
55.	Salmonella	Livingstone	O:7	Ad1107	Dusts	42	+(19,75)	19,8	20,5	21,3	18,3	+	+	+
56.	Salmonella	London	O:3,10	Adria 326	Cooked meat sample	1	+(20,09)	19,9	20,6	21,7	18,6	+	+	+
57.	Salmonella	Manhattan	O:8	Adria 900	Dusts from dairy industry	26	+(20,25)	19,8	20,8	20,6	18,2	+	+	+
58.	Salmonella	Mbandaka	O:7	Ad914	Mayonnaise	38	+(20,67)	20,6	21,3	21,1	19,2	+	+	+
59.	Salmonella	Meleagridis	O:3,10	Adria 505	Raw milk	40	+(20,95)	19,8	21,1	21,4	19,0	+	+	+
60.	Salmonella	Michigan	O:17	Ad2327	Low moisture sausage	35	+(19,70)	16,8	18,1	19,1	16,5	+	+	+
61.	Salmonella	Minnesota	O:21	Ad2328	Feed	55	+(20,60)	18,1	18,3	18,8	16,6	+	+	+
62.	Salmonella	Missisipi	O:13	Ad2329	Parakeet	23	+(21,54)	20,2	20,7	21,2	19,1	+	+	+
63.	Salmonella	Montevideo	O:7	Ad912	Raw milk	51	+(21,04)	17,7	17,9	19,2	16,3	+	+	+
64.	Salmonella	Napoli	O:8	Ad928	Clinical	55	+(20,70)	19,6	20,5	21,1	18,2	+	+	+
65.	Salmonella	Ohio	O:7	Ad1482	Raw cow milk	18	+(21,13)	19,3	19,5	20,6	18,0	+	+	+
66.	Salmonella	Oranienburg	O:7	Ad1724	Cereals	58	+(20,38)	18,5	18,9	20,1	17,1	+	+	+
67.	Salmonella	Orion	O:3,10	Adria 27	Human food	22	+(21,98)	21,5	21,5	22,8	19,9	+	+(blade)	+
68.	Salmonella	Ouakam	O:9,46	Ad1647	Compost	22	+(20,06)	18,3	18,6	19,1	16,9	+	+	+
69.	Salmonella	Panama	O:8	Adria 8	Ground beef	16	+(20,96)	21,3	22,0	22,6	19,9	+	+	+
70.	Salmonella	Paratyphi A	O:2	ATCC 9150	unknown	27	+(22,61)	22,5	23,3	22,6	20,7	+(H2S-)	+(blade)	+
71.	Salmonella	Paratyphi B	O:4	Ad301	Clinical	57	+(20,01)	19,4	19,7	20,7	18,5	+	+	+
72.	Salmonella	Paratyphi C	O:7	ATCC 13428	unknown	33	+(18,35)	18,8	19,1	19,7	17,8	+	+(blade)	+
73.	Salmonella	Pomona	O:28	CIP105630	Cock	42	+(19,66)	19,9	20,7	21,3	18,7	+(yellow)	+	+
74.	Salmonella	Putten	O:13	Ad2331	Feed for chicken	55	+(20,48)	20,4	20,9	21,7	18,9	+	+	+
75.	Salmonella	Regent	O:3,10	Adria 328	Duck	32	+(20,18)	20,2	20,8	21,4	18,9	+	+	+
76.	Salmonella	Rissen	O:7	Adria 39	Food product	13	+(21,21)	18,8	18,9	20,2	17,2	+	+	+
77.	Salmonella	Saintpaul	O:4	Adria F31	Pilchard fillets	50	+(19,31)	18,7	19,0	19,8	17,6	+	+	+
78.	Salmonella	salamae 1,13,23:gmt:enx	O:13	Ad450	Ewe milk	33	+(19,68)	19,2	19,4	19,7	17,7	+	+(blade)	+
79.	Salmonella	salamae 42:gt:-	O:42	Ad592	Kangaroo	44	+(21,20)	18,8	18,9	20,3	17,4	+	+(blade)	+
80.	Salmonella	salamae 42:rt:-	O:42	105	Food product	26	+(21,34)	20,9	21,0	21,9	19,5	+	+	+
81.	Salmonella	salamae 42ib:enxz15	O:42	Ad593	Cereals	27	+(19,08)	18,8	19,0	20,5	17,6	+	+	+
82.	Salmonella	salamae 9, g, m, t	O:9,46,27	Ad212	Food product	8	+(22,54)	21,1	21,7	21,6	20,4	+	+	+
83.	Salmonella	Senftenberg	O:1,3,19	Ad355	Seafood cocktail	16	+(19,35)	19,2	20,2	20,4	18,3	+	+	+
84.	Salmonella	Stanley	O:4	CIP106163	unknown	28	+(18,25)	18,5	19,3	20,2	18,3	+	+	+
85.	Salmonella	Stourbridge	O:8	Ad2297	Raw milk cheese	27	+(20,34)	18,9	19,5	20,3	17,7	+	+	+
86.	Salmonella	Strasbourg	O:9,46	CIP105632	Human	17	+(20,29)	19,4	19,8	19,7	18,2	+	+	+
87.	Salmonella	Tananarive	O:8	CIP54142	Pig	31	+(18,75)	20,0	20,4	20,9	18,5	+	+	+
88.	Salmonella	Tennessee	O:7	A00E006	Dusts from dairy industry	40	+(20,31)	20,3	21,0	20,8	19,1	+	+	+
89.	Salmonella	Thompson	O:7	AER301	Poultry	37	+(18,80)	18,9	19,7	19,4	17,6	+	+	+
90.	Salmonella	Typhi	O:9	Ad302	Clinical	34	+(21,76)	20,6	21,0	21,1	19,2	+	+	+
91.	Salmonella	Typhimurium 1,4 [5], l2:-	O:4	Ad1333	Tiramisu	42	+(19,91)	20,2	20,7	20,4	18,8	+	+	+
92.	Salmonella	Typhimurium 1,4 [5], l2:-1,2	O:4	Ad1335	Poultry environmental sample	61	+(20,72)	20,5	19,4	21,2	19,9	+	+	+
93.	Salmonella	Typhimurium 1,4 [5], l12:i:-	O:4	Ad1334	Ready to cook pork	37	+(20,85)	20,0	19,3	21,0	19,3	+	+	+

94.	<i>Salmonella</i>	Urbana	O:30	Ad501	Human food	33	+(19,37)	19,3	18,3	20,0	18,7	+	+	+
95.	<i>Salmonella</i>	Veneziana	O:11	Adria 233	Food product	26	+(19,44)	19,3	18,7	20,0	18,8	+	+	+
96.	<i>Salmonella</i>	Virchow	O:7	Adria F276	Curry	31	+(20,18)	21,1	20,2	22,4	20,5	+	+	+
97.	<i>Salmonella</i>	Wandsworth	O:39	Ad2335	Fillet of mullet	24	+(18,96)	19,7	19,0	20,9	19,9	+	+	+
98.	<i>Salmonella</i>	Waycross	O:41	CIP105634	Human	31	+(19,77)	20,7	20,6	20,6	20,5	+	+	+
99.	<i>Salmonella</i>	Wayne	O:30	Ad502	Human food	24	+(20,44)	23,5	22,5	23,9	23,1	+(H2S-)	+	+
100.	<i>Salmonella</i>	Wetlevreden	O:3,10	Ad2336	Treated water	60	+(20,06)	18,7	17,8	19,1	18,3	+	+	+

Strain sources: Ad, Adria or A00 = ADRIA, Quimper, France
 ATCC = American Type Culture Collection, Manassas, VA
 CIP = Collection Institut Pasteur, Paris, France
 Origin: / = Unknown

Table 2 - Exclusivity results (3)

EXCLUSIVITY									
Strain	Reference	Origin	Inoculation level CFU/ml	SureFast® Salmonella ONE method					
				PCR (Cq)					
				CFX96 BIORAD	ROCHE LightCycler 480II	Applied Biosystems 7500	MIC	Agilent AriaMx	
1	<i>Citrobacter braakii</i>	Ad833	Raw beef meat	3,5E+06	-	-	-	-	-
2	<i>Citrobacter Diversus</i>	adria 140	Raw milk	6,0E+06	-	-	-	-	-
3	<i>Citrobacter freundii</i>	adria 23	Raw pork sausage	1,7E+06	-	-	-	-	-
4	<i>Citrobacter farmeri</i>	Ad 1116	Environmental (egg products)	2,9E+06	-	-	-	-	-
5	<i>Citrobacter koseri</i>	adria 71	Frozen vegetables	6,0E+06	-	-	-	-	-
6	<i>Enterobacter agglomerans</i>	adria 11	Cheese	2,4E+06	-	-	-	-	-
7	<i>Enterobacter amnigenus</i>	A00C068	Raw poultry meat	2,4E+06	-	-	-	-	-
8	<i>Enterobacter cloacae</i>	adria 10	Raw milk	1,8E+06	-	-	-	-	-
9	<i>Enterobacter intermedius</i>	adria 60	Bean	1,2E+06	-	-	-	-	-
10	<i>Enterobacter kobei</i>	Ad 342	Ham	2,1E+06	-	-	-	-	-
11	<i>Enterobacter sakazakii</i>	adria 95	Fermented milk	2,7E+06	-	-	-	-	-
12	<i>Erwinia carotovora</i>	CIP 8283	Potatoes	6,0E+04	-	-	-	-	-
13	<i>Escherichia coli</i>	adria 19	Grated carrots	2,6E+06	-	-	-	-	-
14	<i>Escherichia hermanii</i>	Ad 461	Dessert	2,2E+06	-	-	-	-	-
15	<i>Escherichia vulneris</i>	adria 127	Raw milk	1,1E+06	-	-	-	-	-
16	<i>Hafnia alvei</i>	adria 167	Raw pork sausage	6,0E+06	-	-	-	-	-
17	<i>Klebsiella oxytoca</i>	57	Food product	3,1E+06	-	-	-	-	-
18	<i>Klebsiella pneumoniae</i>	47	Raw turkey meat	4,1E+06	-	-	-	-	-
19	<i>Kluyvera spp</i>	adria 41	Raw milk	2,3E+06	-	-	-	-	-
20	<i>Morganella morganii</i>	CIP A236	unknown	4,9E+06	-	-	-	-	-
21	<i>Pantoea agglomerans</i>	adria 86	Frozen vegetables	7,1E+05	-	-	-	-	-

22	<i>Proteus mirabilis</i>	Ad639	Mayonnaise	7,0E+06	-	-	-	-	-
23	<i>Proteus vulgaris</i>	adria 43	Sliced ham	1,5E+06	-	-	-	-	-
24	<i>Providencia rettgeri</i>	adria 112	White liquid egg	3,4E+06	-	-	-	-	-
25	<i>Rhanella aquatilis</i>	adria 69	Molluscs	2,3E+06	-	-	-	-	-
26	<i>Serratia liquefaciens</i>	26	Egg product	1,3E+06	-	-	-	-	-
27	<i>Serratia proteomaculans</i>	A00C056	Ham	4,0E+05	-	-	-	-	-
28	<i>Shigella flexneri</i>	CIP 8248	unknown	1,5E+06	-	-	-	-	-
29	<i>Shigella sonnei</i>	CIP 8249T (ATCC 29930)	unknown	3,2E+06	-	-	-	-	-
30	<i>Yersinia enterocolitica</i>	adria 32	Bacon	2,2E+06	-	-	-	-	-

Strain sources: Ad, Adria or A00 = ADRIA, Quimper, France
 ATCC = American Type Culture Collection, Manassas, VA
 CIP = Collection Institut Pasteur, Paris, France
 Origin: / = Unknown

Table 4 - SureFast Salmonella ONE-Salmonella Presumptive vs. Confirmed (3)

Matrix	Strain ^a	Thermocyclers	Time point	MPN ^b /test portion	N ^c	SureFast® Salmonella ONE			SureFast® Salmonella ONE			dPOD _{CP} ^g	95% CI ^h	SE(dPOD)
						Presumptive Result			Confirmed Result					
						x ^d	POD _{CP} ^e	95% CI	x	POD _C ^f	95% CI			
Frozen poultry meat	<i>Salmonella</i> Derby Ad1337	All thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.47)	0.00	N/A	N/A
			Low	0.4 (0.2,0.7)	20	6	0.30	(0.15,0.52)	7	0.35	(0.18,0.57)	-0.05	(-0.21,0.11)	0.08
			High	2.2 (1.7,4.0)	5	5	1.00	(0.57,1.00)	5	1.00	(0.57,1.00)	0.00	N/A	N/A
Raw ground beef	<i>Salmonella</i> Typhimurium A00C060	All thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	1.0 (0.6,1.6)	20	14	0.70	(0.48,0.85)	14	0.70	(0.48,0.85)	0.00	N/A	N/A
			High	2.8 (1.5,6.5)	5	5	1.00	(0.57,1.00)	5	1.00	(0.57,1.00)	0.00	N/A	N/A
Raw milk	<i>Salmonella</i> Ohio Ad1482	CFX 96 BIORAD	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	0.9 (0.6,1.5)	20	11	0.55	(0.34,0.88)	11	0.55	(0.34,0.74)	0.00	N/A	N/A
			High	1.7 (0.7,5.5)	5	3	0.60	(0.23,0.88)	4	0.80	(0.38,1.00)	-0.20	(-0.76,0.36)	0.29
		Other thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	0.9 (0.6,1.5)	20	9	0.45	(0.26,0.66)	11	0.55	(0.34,0.74)	-0.10	(-0.28,0.08)	0.09
			High	1.7 (0.7,5.5)	5	4	0.80	(0.38,1.00)	4	0.80	(0.38,1.00)	0.00	N/A	N/A
Pasteurized liquid whole egg	<i>Salmonella</i> Enteritidis 657	CFX 96 BIORAD	Uninoculated	N/A	5	1	0.20	(0.00,0.62)	0	0.00	(0.00,0.43)	0.20	(-0.36,0.76)	0.29
			Low	0.5 (0.2,0.8)	20	8	0.40	(0.22,0.61)	7	0.35	(0.18,0.57)	0.05	(-0.11,0.21)	0.08
			High	0.7 (0.2,1.7)	5	3	0.60	(0.23,0.88)	3	0.60	(0.23,0.88)	0.00	N/A	N/A
		Other thermocyclers	Uninoculated	N/A	5	1	0.20	(0.00,0.62)	0	0.00	(0.00,0.43)	0.20	(-0.36,0.76)	0.29
			Low	0.5 (0.2,0.8)	20	9	0.45	(0.26,0.66)	7	0.35	(0.18,0.57)	0.10	(-0.08,0.28)	0.09
			High	0.7 (0.2,1.7)	5	3	0.60	(0.23,0.88)	3	0.60	(0.23,0.88)	0.00	N/A	N/A
Fresh	<i>Salmonella</i>	All	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A

CONGEN SureFast® Salmonella ONE, AOAC® Performance TestedSM Certification Number 081803

spinach	Virchow Ad1721	thermocyclers	Low High	0.7 (0.4,1.2)	20	11	0.55	(0.34,0.74)	11	0.55	(0.34,0.74)	0.00	N/A	N/A
				0.9 (0.2,2.1)	5	3	0.60	(0.23,0.88)	3	0.60	(0.23,0.88)	0.00	N/A	N/A
Dry food dog pellets	Salmonella Derby Ad1503	CFX 96 BIORAD	Uninoculated	N/A	5	1	0.20	(0.00,0.62)	0	0.00	(0.00,0.43)	0.20	(- 0.36,0.76)	0.29
				0.4 (0.2,0.7)	20	7	0.35	(0.18,0.57)	6	0.30	(0.15,0.52)	0.05	(- 0.11,0.21)	0.08
			1.3 (0.8,2.3)	5	5	1.00	(0.57,1.00)	5	1.00	(0.57,1.00)	0.00	N/A	N/A	
		Other thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
				0.4 (0.2,0.7)	20	6	0.30	(0.15,0.52)	6	0.30	(0.15,0.52)	0.00	N/A	N/A
			High	1.3 (0.8,2.3)	5	5	1.00	(0.57,1.00)	5	1.00	(0.57,1.00)	0.00	N/A	N/A

^aStrains sources = Adria Developpement (Ad)

^bMPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.

^cN = Number of test portions.

^dx = Number of positive test portions.

^ePOD_{CP} = Candidate method presumptive positive outcomes divided by the total number of trials.

^fPOD_{CC} = Candidate method confirmed positive outcomes divided by the total number of trials.

^gdPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed result POD values.

^h95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

ⁱN/A = Not applicable.

Table 5 - SureFast Salmonella ONE vs. ISO 6579:2002 Method Comparison (3)

Matrix	Strain ^a	Thermocyclers	Time point	MPN ^b /test portion	N ^c	SureFast® Salmonella ONE			ISO 6579			dPOD _c ^g	95% CI ^h	SE(dPOD)
						Result			Result					
						x ^d	POD _c ^e	95% CI	x	POD _r ^f	95% CI			
Frozen poultry meat	Salmonella Derby Ad1337	All thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.47)	0.00	N/A	N/A
			Low	0.4 (0.2,0.7)	20	6	0.30	(0.15,0.52)	7	0.35	(0.18,0.57)	-0.05	(-0.21,0.11)	0.08
			High	2.2 (1.7,4.0)	5	5	1.00	(0.57,1.00)	5	1.00	(0.57,1.00)	0.00	N/A	N/A
Raw ground beef	Salmonella Typhimurium A00C060	All thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	1.0 (0.6,1.6)	20	14	0.70	(0.48,0.85)	14	0.70	(0.48,0.85)	0.00	N/A	N/A
			High	2.8 (1.5,6.5)	5	5	1.00	(0.57,1.00)	5	1.00	(0.57,1.00)	0.00	N/A	N/A
Raw milk	Salmonella Ohio Ad1482	CFX 96 BIORAD	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	0.9 (0.6,1.5)	20	9	0.45	(0.26,0.66)	11	0.55	(0.34,0.74)	-0.10	(-0.28,0.08)	0.09
			High	1.7 (0.7,5.5)	5	3	0.60	(0.23,0.88)	4	0.80	(0.38,1.00)	-0.20	(0.76,0.36)	0.29
		Other thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	0.9 (0.6,1.5)	20	9	0.45	(0.26,0.66)	11	0.55	(0.34,0.74)	-0.10	(-0.28,0.08)	0.09
			High	1.7 (0.7,5.5)	5	4	0.60	(0.38,1.00)	4	0.80	(0.38,1.00)	0.00	N/A	N/A
Pasteurized liquid whole egg	Salmonella Enteritidis 657	All thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	0.5 (0.2,0.8)	20	7	0.35	(0.18,0.57)	7	0.35	(0.18,0.57)	0.00	N/A	N/A
			High	0.7 (0.2,1.7)	5	3	0.60	(0.23,0.88)	3	0.60	(0.23,0.88)	0.00	N/A	N/A
Fresh spinach	Salmonella Virchow Ad1721	All thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	0.7 (0.4,1.2)	20	11	0.55	(0.34,0.74)	11	0.55	(0.34,0.74)	0.00	N/A	N/A
			High	0.9 (0.2,2.1)	5	3	0.60	(0.23,0.88)	3	0.60	(0.23,0.88)	0.00	N/A	N/A
Dry food dog pellets	Salmonella Derby Ad1503	All thermocyclers	Uninoculated	N/A	5	0	0.00	(0.00,0.43)	0	0.00	(0.00,0.43)	0.00	N/A	N/A
			Low	0.4 (0.2,0.7)	20	6	0.30	(0.15,0.52)	6	0.30	(0.15,0.52)	0.00	N/A	N/A
			High	1.3 (0.8,2.3)	5	5	1.00	(0.57,1.00)	5	1.00	(0.57,1.00)	0.00	N/A	N/A

^aStrain sources = Adria Developpement (Ad), Quimper, France; University of Zurich, Institute for Food Safety and Hygiene (E), Zurich, Switzerland.

^bMPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.

^cN = Number of test portions.

^dx = Number of positive test portions.

^ePOD_c = Candidate method presumptive positive outcomes confirmed positive.

^fPOD_r = Reference method confirmed positive outcomes divided by the total number of trials.

^gdPOD_c = Difference between the candidate method and reference method POD values.

^h95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

N/A = Not applicable.

REFERENCES CITED

1. Sohier, Danièle and Rannou, Maryse., Comparative Evaluation of the Biotest MMB Salmonella method (SureFood PTHOGEN Salmonella PLUS), AOAC® Performance TestedSM certification number 041103.
2. NF EN ISO 6579: 2002: Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Salmonella* spp.
3. Rannou, M. and Bernard, M., Evaluation of the SureFast® Salmonella ONE method, AOAC® Performance TestedSM certification number changed to 081803. Approved July 2018.