CERTIFICATION

AOAC® *Performance Tested*SM

Certificate No.

051303

The AOAC Research Institute hereby certifies that the performance of the test kit known as:

Thermo Scientific™ SureTect™ Salmonella species PCR Assay

manufactured by

Oxoid Ltd, part of Thermo Fisher Scientific
Wade Road
Basingstoke
Hampshire, RG248PW

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 12, 2018 – December 31, 2019). 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 12, 2018
Date

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SUBMITTING COMPANY
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KIT NAME(S)
Thermo Scientific™ SureTect™ Salmonella species PCR Assay

CATALOG NUMBERS
PT0100A

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[2] **Modification August 2015**

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[4] February 2016, November 2018 Modifications

APPLICABILITY OF METHOD
Target organism – *Salmonella* species

Matrices – Original Validation: (25 g; 1:10) raw ground beef, pork frankfurters, raw ground pork, raw chicken breast, bagged lettuce, non-fat dried milk powder, cooked shrimp, chilled ready-to-eat dinner, pasteurized liquid whole egg, and stainless steel
Modification August 2015: (25 g; 1:10) wet cat food, dry dog food, pasteurized 2% milk, bean sprouts, cantaloupe, chilled pizza dough, black peppercorns, peanut butter, ice cream, plastic surface, dark chocolate (85% cocoa solids) and 20% fat raw ground beef (375 g)

Performance claims - Performance equivalent to the reference method.

REFERENCE METHODS
Microbiology of food and animal feeding stuffs-Horizontal method for the detection of Salmonella spp. ISO 6579:2002, including Technical Corrigendum 1:2004 (6)
ISO 6579:2017, Microbiology of the food chain -- Horizontal method for the detection, enumeration and serotyping of Salmonella -- Part 1: Detection of Salmonella spp. (11)

ORIGINAL CERTIFICATION DATE
May 20, 2013

CERTIFICATION RENEWAL RECORD
Renewed annually through December 2019

METHOD MODIFICATION RECORD
1. **August 2015 Level 2**
2. **February 2016 Level 2**
3. **December 2017 Level 1**
4. **April 2018 Level 2**
5. **November 2018 Level 2**
6. **December 2018 Level 1**

SUMMARY OF MODIFICATION
1. **Matrix Extension modification for various foods**
2. **Change in target probe concentration and use of Applied Biosystems 7500 FAST PCR instrument**
3. **Edits to IFUs and labels**
4. **Evaluation of workflow and lyophilization steps**
5. **Evaluation of Applied Biosystems™ QuantStudio™ Real-Time PCR Instrument (with Applied Biosystems™ RapidFinder™ Analysis Software v2.0)**
6. **Updated user manual to include complete AOAC workflow, update template, and minor edits**

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NONE

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NONE

PRINCIPLE OF THE METHOD (1)

The Thermo Scientific SureTect Salmonella species PCR assay is a real-time Polymerase Chain Reaction (PCR) test intended to be used in conjunction with the Thermo Scientific PikoReal™ Real-Time PCR Instrument and the SureTect Software for the detection and identification of *Salmonella* species in human foods, animal feeds and environmental samples.

The assay is supplied as a kit containing all necessary reagents to conduct the sample lysis, including pre-filled Lysis Tubes and lyophilised PCR pellets, containing all necessary PCR reagents (target-specific primers, dye labelled probes and PCR master mix components) to easily conduct the PCR analysis of the sample. PCR Probes are short oligonucleotides with a quencher molecule at one end that, when not bound to target DNA, greatly reduces fluorescence from the dye label at the opposite end of the probe molecule. The oligonucleotides target unique DNA sequences found only in *Salmonella*. If *Salmonella* species are present, the target DNA sequence will be amplified and the increasing fluorescent signal generated will be detected by the PikoReal Real-Time instrument and interpreted by the Thermo Scientific SureTect Software. In addition to detection of any target DNA, the SureTect Salmonella species PCR pellets contain probe, primers and DNA templates for an internal amplification control (IAC). During PCR cycling, the IAC template is amplified whether any target DNA is present or not. The probe used for the IAC uses a different coloured fluorescent dye to the probes used within the assay to detect target DNA and so can be detected by the PikoReal Instrument through a separate dye channel. The result is that after a successful PCR run the instrument will detect amplification of the IAC DNA sequence. In the absence of any target DNA being detected by the assay, the presence of the IAC amplification curve confirms that the PCR process has occurred successfully.

The assays used in the Thermo Scientific SureTect System are based on Solaris™ qPCR technology. The PCR probes have a molecule called Minor Groove Binder (MGB) attached to one end, which enhances the probe-template DNA bond and yields a better signal-to-noise ratio by lowering the background fluorescence. Results from this assay system are achieved in one hour and twenty minutes of loading the prepared sample into the PikoReal Instrument and are displayed on the attached PC screen as simple positive or negative symbols with PCR amplification plots that are easily accessible for review. All results interpreted by the SureTect Software can be stored, printed or downloaded by the user, as required.

DISCUSSION OF THE VALIDATION STUDY (1)

The data presented and discussed in this report, within the statistical uncertainty of the analysis supports the product claims of the SureTect Salmonella species assay for the detection of *Salmonella* from raw ground beef, raw chicken, chilled ready to eat dinner, pork Frankfurters, raw ground pork, cooked shrimps, non-fat dried milk powder, lettuce, pasteurised liquid egg and stainless steel surface. Additional studies conducted as part of the validation show that the assay has excellent inclusivity and is unaffected by high levels of non-target bacteria. The SureTect Salmonella species assay was also shown to have good reproducibility and although accelerated stability testing was conducted, real time studies are on-going and will be reported at the annual method renewal.

Table 1: Inclusivity of the Thermo Scientific SureTect Salmonella species Assay (1)

Isolate	Species or Serotype	O-group	Source	TCC[a] No	SureTect Result
Salmonella bongori	66:z_{41}:-	66	Frog	2274	Positive
Salmonella bongori	66:z_{41}:-	66	Unknown	2275	Positive
Salmonella bongori	48:z_{35}:-	Y	Chicken egg	2402	Positive
Salmonella bongori	48:z_{35}:-	Y	Cheese	2398	Positive
Salmonella enterica	subsp *salamae*	39		1996	Positive
Salmonella enterica	subsp *salamae*	61		2217	Positive
Salmonella enterica	subsp *salamae* Canastel	D1	Gastroenteritis	2270	Positive
Salmonella enterica	subsp *salamae* Tranoroa	55		2353	Positive
Salmonella enterica	subsp *salamae* Humber	53		2037	Positive
Salmonella enterica	subsp *arizoniae*	41		1995	Positive
Salmonella enterica	subsp *arizoniae* 11,33:26:31	Unknown	NCTC 10043	2267	Positive
Salmonella enterica	subsp *arizoniae*	Y		2268	Positive
Salmonella enterica	subsp *diarizoniae*	62		2034	Positive
Salmonella enterica	subsp *diarizoniae*	65		2035	Positive
Salmonella enterica	subsp *diarizoniae*	50		1997	Positive
Salmonella enterica	subsp *diarizoniae* Eilbek 61:i:z	61		2276	Positive
Salmonella enterica	subsp *houtenae*	51	Boa constrictor	2032	Positive
Salmonella enterica	subsp *houtenae*	43		2033	Positive
Salmonella enterica	subsp *houtenae* Wassenaar	Z	Human infection	2272	Positive
Salmonella enterica	subsp *houtenae* Seminole	R		2038	Positive
Salmonella enterica	subsp *indica* Ferlac	H	Desiccated coconut	2269	Positive
Salmonella enterica	subsp *indica* Ferlac	H		2271	Positive
Salmonella enterica	subsp *indica*	Unknown	ATCC® BAA-1578	2360	Positive
Salmonella enterica subsp enterica	Aberdeen	F		1612	Positive
Salmonella enterica subsp enterica	Abortusequi	B		2296	Positive
Salmonella enterica subsp enterica	Adelaide	O		OCC[b] 2536	Positive
Salmonella enterica subsp enterica	Agona	B		1619	Positive
Salmonella enterica subsp enterica	Alabama	D1		1621	Positive
Salmonella enterica subsp enterica	Allerton	E1		1623	Positive
Salmonella enterica subsp enterica	Amherstiana	C2		1624	Positive
Salmonella enterica subsp enterica	Amsterdam	E1		1625	Positive
Salmonella enterica subsp enterica	Anatum	E1	Duck	1626	Positive
Salmonella enterica subsp enterica	Binza	E2		2027	Positive

Salmonella enterica subsp enterica	Bovis-Morbificans	C2		2001	Positive
Salmonella enterica subsp enterica	Braenderup	C1		1630	Positive
Salmonella enterica subsp enterica	Brandenberg	B		1998	Positive
Salmonella enterica subsp enterica	Bredeney	B		2019	Positive
Salmonella enterica subsp enterica	Breukelen	C2	Cuscus	2287	Positive
Salmonella enterica subsp enterica	Cambridge	E2	Gastroenteritis	1632	Positive
Salmonella enterica subsp enterica	Cerro	K		2016	Positive
Salmonella enterica subsp enterica	Cholerasuis	C1		1852	Positive

Salmonella enterica subsp enterica	Colombo	P		2031	Positive
Salmonella enterica subsp enterica	Corvallis	C3		1633	Positive
Salmonella enterica subsp enterica	Dahlem	Y		2036	Positive
Salmonella enterica subsp enterica	Derby	B		2008	Positive
Salmonella enterica subsp enterica	Dublin	D1	Cattle	802	Positive
Salmonella enterica subsp enterica	Dusseldorf	C2	Gastroenteritis	1634	Positive
Salmonella enterica subsp enterica	Ealing	O		1999	Positive
Salmonella enterica subsp enterica	Eastbourne	D1		2023	Positive
Salmonella enterica subsp enterica	Emek	C2		1692	Positive
Salmonella enterica subsp enterica	Enteritidis	D1		1638	Positive
Salmonella enterica subsp enterica	Florida	H		2288	Positive
Salmonella enterica subsp enterica	Gallinarum	D1		1641	Positive
Salmonella enterica subsp enterica	Give	E1		1642	Positive
Salmonella enterica subsp enterica	Hadar	C2		1644	Positive
Salmonella enterica subsp enterica	Heidelberg	B		2011	Positive
Salmonella enterica subsp enterica	Hindmarsh	C2		1648	Positive
Salmonella enterica subsp enterica	Ibadan	G		2297	Positive
Salmonella enterica subsp enterica	Indiana	B	Turkey meat	2295	Positive
Salmonella enterica subsp enterica	Infantis	C1		1650	Positive
Salmonella enterica subsp enterica	Inverness	P		2281	Positive
Salmonella enterica subsp enterica	Java	B		1652	Positive
Salmonella enterica subsp enterica	Javiana	D1		2291	Positive
Salmonella enterica subsp enterica	Kedougou	G2		OCC 2474	Positive
Salmonella enterica subsp enterica	Kentucky	C3		1653	Positive
Salmonella enterica subsp enterica	Kiel	A		1654	Positive
Salmonella enterica subsp enterica	Kottbus	C2		2004	Positive
Salmonella enterica subsp enterica	Krefeld	E4		1655	Positive
Salmonella enterica subsp enterica	Lille	C1		2021	Positive
Salmonella enterica subsp enterica	Livingstone	C1		2005	Positive
Salmonella enterica subsp enterica	London	E1		1656	Positive
Salmonella enterica subsp enterica	Madelia	H	Chicken liver	2030	Positive
Salmonella enterica subsp enterica	Manchester	C2		2022	Positive
Salmonella enterica subsp enterica	Manila	E2		2028	Positive
Salmonella enterica subsp enterica	Mbandaka	C1		2010	Positive
Salmonella enterica subsp enterica	Montevideo	C1		1657	Positive
Salmonella enterica subsp enterica	Moscow	D1		1658	Positive
Salmonella enterica subsp enterica	Muenchen	C2		1660	Positive
Salmonella enterica subsp enterica	Napoli	D1	Clinical isolate	2024	Positive
Salmonella enterica subsp enterica	Narashino	C2		1661	Positive
Salmonella enterica subsp enterica	Newport	C2		1663	Positive
Salmonella enterica subsp enterica	Niloese	E4		1664	Positive
Salmonella enterica subsp enterica	Nitra	A		1693	Positive
Salmonella enterica subsp enterica	Ohio	C1		2000	Positive
Salmonella enterica subsp enterica	Oranienberg	C1		2015	Positive
Salmonella enterica subsp enterica	Orion	E1	Asymptomatic food handler	2026	Positive
Salmonella enterica subsp enterica	Panama	D1		1665	Positive
Salmonella enterica subsp enterica	Pensacola	D1	Clinical	2277	Positive

Salmonella enterica subsp enterica	Plymouth	D2		1994	Positive
Salmonella enterica subsp enterica	Pomona	M	Turkey intestine	1988	Positive
Salmonella enterica subsp enterica	Poona	G1		1611	Positive
Salmonella enterica subsp enterica	Pretoria	F	Pig liver & spleen	2029	Positive
Salmonella enterica subsp enterica	Pullorum	D1		1666	Positive
Salmonella enterica subsp enterica	Reading	B		2006	Positive
Salmonella enterica subsp enterica	Rio-grande	R		2285	Positive
Salmonella enterica subsp enterica	Rostock	D1		1667	Positive
Salmonella enterica subsp enterica	Rubislaw	F		2017	Positive
Salmonella enterica subsp enterica	Saint-Paul	B		2007	Positive
Salmonella enterica subsp enterica	Senftenberg	E4	Faecal sample	2018	Positive
Salmonella enterica subsp enterica	Shanghai	E1		2025	Positive
Salmonella enterica subsp enterica	Simsbury	E4	Faecal sample	1672	Positive
Salmonella enterica subsp enterica	Stanley	B		1673	Positive
Salmonella enterica subsp enterica	Taksony	E4		1678	Positive
Salmonella enterica subsp enterica	Tennessee	C1		2293	Positive
Salmonella enterica subsp enterica	Thompson	C1		2012	Positive
Salmonella enterica subsp enterica	Typhimurium	B	Gastroenteritis	1681	Positive
Salmonella enterica subsp enterica	Umbilo	M		1992	Positive
Salmonella enterica subsp enterica	Urbana	N		1990	Positive
Salmonella enterica subsp enterica	Utrecht	52		2298	Positive
Salmonella enterica subsp enterica	Vellore	B	Faecal sample	2290	Positive
Salmonella enterica subsp enterica	Virchow	C1		1890	Positive
Salmonella enterica subsp enterica	Wandsworth	Q		1685	Positive
Salmonella enterica subsp enterica	Westertede	E4		1686	Positive
Salmonella enterica subsp enterica	Zanzibar	E1	Clinical	1690	Positive
Salmonella enterica subsp enterica	Typhi	D1		NCTC[c] 8385	Positive
Salmonella enterica subsp enterica	Paratyphi A	A		NCTC 5702	Positive
Salmonella enterica subsp enterica	Paratyphi B	B		OCC 149	Positive

[a]TCC. Trials Culture Collection Number-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke
[b]OCC. Oxoid Culture Collection- Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke
[c]NCTC, National Collection of Type Cultures, Health Protection Agency, UK

Table 2: Exclusivity of the Thermo Scientific SureTect Salmonella species Assay (1)

Isolate	Source	TCC[a] No	SureTect Result
Citrobacter freundii		171	Negative
Citrobacter intermedius		181	Negative
Citrobacter koseri	Clinical	2039	Negative
Citrobacter youngae		2043	Negative
Edwardsiella tarda	Clinical	2216	Negative
Enterobacter sakazakii		2053	Negative
Enterobacter aerogenes	Clinical	2200	Negative
Enterobacter amnigenus-Biogroup 1	Clinical	2198	Negative
Enterobacter cloacae		401	Negative
Pantoea agglomerans	Pasteurised milk	409	Negative
Enterobacter faecalis		1388	Negative
Enterobacter intermedius	Clinical	2203	Negative
Escherichia blattae	Cockroach gut	2273	Negative
Escherichia coli		1809	Negative
Escherichia coli O157:H7 VT neg		OCC[b] 1872	Negative
Escherichia hermanii		2047	Negative
Escherichia vulneris	Vegetables	2264	Negative
Hafnia alvei		2044	Negative
Klebsiella aerogenes		1804	Negative
Klebsiella oxytoca	Clinical	593	Negative
Klebsiella pneumoniae		1892	Negative
Klebsiella terrigena	Water isolate	2207	Negative
Morganella morganii	Clinical	1431	Negative
Proteus mirabilis		1566	Negative
Proteus vulgaris		1552	Negative
Providencia alcalifaciens	Clinical	2209	Negative
Providencia rettgeri		2201	Negative
Providencia stuartii	Clinical	418	Negative
Pseudomonas aeruginosa		1903	Negative
Serratia liquifaciens	Milk	2048	Negative
Serratia marcescens	Clinical	414	Negative
Shigella boydii	Clinical	2050	Negative
Shigella flexneri		2052	Negative
Shigella sonnei	Clinical	2051	Negative
Yersinia enterocolitica	Frozen prawn	2215	Negative
Escherichia fergusonii	Sausages	2263	Negative

[a]TCC. Trials Culture Collection Number-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK

[b]OCC. Oxoid Culture Collection- Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK

Table 3: Thermo Scientific SureTect Salmonella species Assay Presumptive vs. Confirmed Result by latex test-POD Analysis (1)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive			SureTect Method Confirmation (Latex) (CC)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cp}[d]	95% CI	X[c]	POD_{cc}[d]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73,1.9)	20	12	0.60	(0.39, 0.78)	12	0.60	(0.39, 0.78)	0.00	(-0.14, 0.14)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Raw ground pork	*Salmonella* Livingstone TCC 2205	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.68 (0.38, 1.2)	20	11	0.55	(0.34, 0.74)	10	0.50	(0.30, 0.70)	0.05	(-0.06, 0.16)
		2.5 (1.2, 6.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Non-fat dried milk	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73, 1.9)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57 ,1.00)	5	1.00	(0.57-, 1.00)	0.00	(-0.45, 0.45)
Pork Frankfurters	*Salmonella* Poona TCC 1611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.38 (0.17, 0.65)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		0.55 (0.25, 1.2)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Cooked Shrimp	*Salmonella* Saint-Paul TCC 2007	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Stainless steel surface	*Salmonella* Newport TCC 1663 With 10X *E. coli*	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ready to eat meal (beef containing)	*Salmonella* Enteritidis TCC 1638	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.3)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive			SureTect Method Confirmation (Latex) (CC)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cp}[d]	95% CI	X[c]	POD_{cc}[d]	95% CI		
Lettuce	*Salmonella* Anatum TCC 1626	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.46, 0.46)
		1.0 (0.48, 1.22)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	-0.05	(-0.06, 0.16)
		1.5 (0.65, 3.37)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.46, 0.46)
Raw ground beef 8 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	8	0.40	(0.22, 0.61)	10	0.50	(0.30, 0.70)	-0.10	(-0.37, 0.19)
		2.3 (1.1, 5.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.47, 0.47)
Raw ground beef 24 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	9	0.45	(0.26, 0.66)	9	0.45	(0.26, 0.66)	0.00	(-0.28, 0.28)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Pasteurised liquid whole egg	*Salmonella* Virchow TCC 1890	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.58 (0.36, 0.98)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		1.35 (0.61, 4.37)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Fresh bagged lettuce[i]	*Salmonella* Thompson ATCC 8391	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.73 (0.42, 1.23)	20	10	0.50	(0.29, 0.70)	9	0.45	(0.25, 0.65)	-0.05	(-0.06, 0.16)
		2.97 (1.25, 7.0)	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)
Pork Frankfurters[i]	*Salmonella* Vellore ATCC 15611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.48 (0.28, 0.75)	20	7	0.35	(0.18, 0.56)	7	0.35	(0.18, 0.56)	0.00	(-0.14, 0.14)
		2.97 (1.25, 7.0)	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)
Stainless steel surface[i]	*Salmonella* Berta ATCC 8392	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		-	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.14, 0.14)
		-	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)

[a]MPN= Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N=Number of test portions
[c]X=Number of positive test portions
[d]PODcp=Candidate method presumptive positive outcomes divided by the total number of portions
[e]PODcc=Candidate confirmation method positive outcomes divided by the total number of portions
[f]dPODcp=Difference between the candidate presumptive result and the candidate method confirmed result POD values
[g]95% CI=If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level
[h]N/A=Not applicable
[i]Independent Laboratory Study

Table 4: Thermo Scientific SureTect Salmonella species Assay Presumptive vs. Confirmed Result by Microbact biochemical gallery-POD Analysis (1)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive			SureTect Method Confirmation (Microbact) (CC)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cp}[d]	95% CI	X[c]	POD_{cc}[d]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73,1.9)	20	12	0.60	(0.39, 0.78)	12	0.60	(0.39, 0.78)	0.00	(-0.14, 0.14)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Raw ground pork	*Salmonella* Livingstone TCC 2205	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.68 (0.38, 1.2)	20	11	0.55	(0.34, 0.74)	10	0.50	(0.30, 0.70)	0.05	(-0.06, 0.16)
		2.5 (1.2, 6.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Non-fat dried milk	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73, 1.9)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pork Frankfurters	*Salmonella* Poona TCC 1611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.38 (0.17, 0.65)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		0.55 (0.25, 1.2)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Cooked Shrimp	*Salmonella* Saint-Paul TCC 2007	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Stainless steel surface	*Salmonella* Newport TCC 1663 With 10X *E. coli*	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ready to eat meal (beef containing)	*Salmonella* Enteritidis TCC 1638	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.3)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Lettuce	*Salmonella* Anatum	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)

	TCC 1626	1.0 (0.48, 1.22)	20	14	0.70	(0.48, 0.85)	13	0.70	(0.48, 0.85)	-0.05	(-0.06, 0.16)
		1.5 (0.65, 3.37)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Raw ground beef 8 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	8	0.40	(0.22, 0.61)	10	0.50	(0.30, 0.70)	-0.10	(-0.37, 0.19)
		2.3 (1.1, 5.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.47, 0.47)
Raw ground beef 24 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	9	0.45	(0.26, 0.66)	9	0.45	(0.26, 0.66)	0.00	(-0.28, 0.28)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Pasteurised liquid whole egg	*Salmonella* Virchow TCC 1890	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.58 (0.36, 0.98)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		1.35 (0.61, 4.37)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Fresh bagged lettuce[i]	*Salmonella* Thompson ATCC 8391	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.73 (0.42, 1.23)	20	10	0.50	(0.29, 0.70)	9	0.45	(0.25, 0.65)	-0.05	(-0.06, 0.16)
		2.97 (1.25, 7.0)	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)
Pork Frankfurters[i]	*Salmonella* Vellore ATCC 15611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.48 (0.28, 0.75)	20	7	0.35	(0.18, 0.56)	7	0.35	(0.18, 0.56)	0.00	(-0.14, 0.14)
		2.97 (1.25, 7.0)	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)
Stainless steel surface[i]	*Salmonella* Thompson ATCC 8392	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		-	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.14, 0.14)
		-	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)

[a]MPN= Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N=Number of test portions
[c]X=Number of positive test portions
[d]PODcp=Candidate method presumptive positive outcomes divided by the total number of portions
[e]PODcc=Candidate confirmation method positive outcomes divided by the total number of portions
[f]dPODcp=Difference between the candidate presumptive result and the candidate method confirmed result POD values
[g]95% CI=If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level
[h]N/A=Not applicable
[i]Independent Laboratory Study

Table 5: Thermo Scientific SureTect Salmonella species Assay Presumptive vs. ISO Reference Confirmation (by microID)-POD Analysis (1)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive			Reference Confirmation (rc)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cp}[d]	95% CI	X[c]	POD_{rc}[d]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73,1.9)	20	12	0.60	(0.39, 0.78)	12	0.60	(0.39, 0.78)	0.00	(-0.14, 0.14)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Raw ground pork	*Salmonella* Livingstone TCC 2205	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.68 (0.38, 1.2)	20	11	0.55	(0.34, 0.74)	10	0.50	(0.30, 0.70)	0.05	(-0.06, 0.16)
		2.5 (1.2, 6.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Non-fat dried milk	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73, 1.9)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pork Frankfurters	*Salmonella* Poona TCC 1611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.38 (0.17, 0.65)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		0.55 (0.25, 1.2)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Cooked Shrimp	*Salmonella* Saint-Paul TCC 2007	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Stainless steel surface	*Salmonella* Newport TCC 1663 With 10X *E. coli*	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ready to eat meal (beef containing)	*Salmonella* Enteritidis TCC 1638	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.3)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Matrix	**Strain**	**MPN[a]/test portion**	**N[b]**	**SureTect Method Presumptive**			**Reference Confirmation (rc)**			**dPODcp[f]**	**95% CI[g]**
				X[c]	**POD_{cc}[d]**	**95% CI**	**X[c]**	**POD_{rc}[d]**	**95% CI**		
Lettuce	*Salmonella* Anatum TCC 1626	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.0	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.14, 0.14)

		(0.48, 1.22)									
		1.5 (0.65, 3.37)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Raw ground beef 8 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	8	0.40	(0.22, 0.61)	10	0.50	(0.30, 0.70)	-0.10	(-0.37, 0.19)
		2.3 (1.1, 5.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.47, 0.47)
Raw ground beef 24 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	9	0.45	(0.26, 0.66)	10	0.50	(0.30, 0.70)	-0.05	(-0.33, 0.24)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Pasteurised liquid whole egg	*Salmonella* Virchow TCC 1890	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.58 (0.36, 0.98)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		1.35 (0.61, 4.37)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)

[a]MPN= Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N=Number of test portions
[c]X=Number of positive test portions
[d]PODcp=Candidate method presumptive positive outcomes divided by the total number of portions
[e]PODcc=Candidate confirmation method positive outcomes divided by the total number of portions
[f]dPODcp=Difference between the candidate presumptive result and the candidate method confirmed result POD values
[g]95% CI=If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level
[h]N/A=Not applicable

Table 6: Thermo Scientific SureTect Salmonella species Assay Confirmation (latex) vs. ISO Reference Confirmation (by microID)-POD Analysis (1)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive (latex)			Reference Confirmation (rc)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cc}[d]	95% CI	X[c]	POD_{rc}[d]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73,1.9)	20	12	0.60	(0.39, 0.78)	12	0.60	(0.39, 0.78)	0.00	(-0.14, 0.14)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Raw ground pork	*Salmonella* Livingstone TCC 2205	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.68 (0.38, 1.2)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.5 (1.2, 6.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Non-fat dried milk	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73, 1.9)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pork Frankfurters	*Salmonella* Poona TCC 1611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.38 (0.17, 0.65)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		0.55 (0.25, 1.2)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Cooked Shrimp	*Salmonella* Saint-Paul TCC 2007	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Stainless steel surface	*Salmonella* Newport TCC 1663 With 10X *E. coli*	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ready to eat meal (beef containing)	*Salmonella* Enteritidis TCC 1638	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.3)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Lettuce	*Salmonella* Anatum TCC 1626	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.0 (0.48, 1.22)	20	13	0.65	(0.43, 0.82)	14	0.70	(0.48, 0.85)	-0.05	(-0.06, 0.16)

		1.5 (0.65, 3.37)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Raw ground beef 8 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.28, 0.28)
		2.3 (1.1, 5.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.47, 0.47)
Raw ground beef 24 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	9	0.45	(0.26, 0.66)	10	0.50	(0.30, 0.70)	-0.05	(-0.33, 0.24)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Pasteurised liquid whole egg	*Salmonella* Virchow TCC 1890	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.58 (0.36, 0.98)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		1.35 (0.61, 4.37)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)

[a]MPN= Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations calculator with 95% confidence interval.
[b]N=Number of test portions
[c]X=Number of positive test portions
[d]PODcp=Candidate method presumptive positive outcomes divided by the total number of portions
[e]$PODcc_2$=Reference method confirmation positive outcomes divided by the total number of portions
[f]dPODcp=Difference between the candidate presumptive result and the candidate method confirmed result POD values
[g]95% CI=If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level
[h]N/A=Not applicable

Table 7: Thermo Scientific SureTect Salmonella species Assay Confirmation (Microbact) vs. ISO Reference Confirmation (by microID)-POD Analysis (1)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive (Microbact)			Reference Confirmation (rc)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cc}[d]	95% CI	X[c]	POD_{rc}[d]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73,1.9)	20	12	0.60	(0.39, 0.78)	12	0.60	(0.39, 0.78)	0.00	(-0.14, 0.14)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Raw ground pork	*Salmonella* Livingstone TCC 2205	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.68 (0.38, 1.2)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.5 (1.2, 6.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Non-fat dried milk	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.2 (0.73, 1.9)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pork Frankfurters	*Salmonella* Poona TCC 1611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.38 (0.17, 0.65)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		0.55 (0.25, 1.2)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Cooked Shrimp	*Salmonella* Saint-Paul TCC 2007	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Stainless steel surface	*Salmonella* Newport TCC 1663 With 10X *E. coli*	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ready to eat meal (beef containing)	*Salmonella* Enteritidis TCC 1638	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.3)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Lettuce	*Salmonella* Anatum TCC 1626	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.0 (0.48, 1.22)	20	13	0.65	(0.43, 0.82)	14	0.70	(0.48, 0.85)	-0.05	(-0.06, 0.16)

		1.5 (0.65, 3.37)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Raw ground beef 8 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.28, 0.28)
		2.3 (1.1, 5.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.47, 0.47)
Raw ground beef 24 h	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.63 (0.35, 1.1)	20	9	0.45	(0.26, 0.66)	10	0.50	(0.30, 0.70)	-0.05	(-0.33, 0.24)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Pasteurised liquid whole egg	*Salmonella* Virchow TCC 1890	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.58 (0.36, 0.98)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)
		1.35 (0.61, 4.37)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)

[a]MPN= Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N=Number of test portions
[c]X=Number of positive test portions
[d]PODcc=Candidate method confirmed positive outcomes divided by the total number of portions
[e]$PODcc_2$=Reference method confirmation positive outcomes divided by the total number of portions
[f]dPODcp=Difference between the candidate presumptive result and the candidate method confirmed result POD values
[g]95% CI=If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level
[h]N/A=Not applicable

Table 8 Thermo Scientific SureTect Salmonella species Assay Method vs. Reference Confirmation-POD Analysis (1)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Confirmed			Reference Confirmation (R)			dPODc[f]	95% CI[g]	X^{2} [i]
				X[c]	POD_c[d]	95% CI	X[c]	POD_R[d]	95% CI			
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		1.2 (0.73,1.9)	20	12	0.60	(0.39, 0.78)	13	0.65	(0.43, 0.82)	-0.05	(-0.06, 0.16)	0.00
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)	0.00
Raw ground pork	*Salmonella* Livingstone TCC 2205	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		0.68 (0.38, 1.2)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.14, 0.14)	0.00
		2.5 (1.2, 6.0)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)	0.00
Non-fat dried milk	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		1.2 (0.73, 1.9)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)	0.00
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)	0.00
Pork Frankfurters	*Salmonella* Poona TCC 1611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		0.38 (0.17, 0.65)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)	0.00
		0.55 (0.25, 1.2)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)	0.00
Cooked Shrimp	*Salmonella* Saint-PaulTCC 2007	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)	0.00
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)	0.00
Stainless steel surface	*Salmonella* Newport TCC 1663 With 10X *E. coli*	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		N/A	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)	0.00
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)	0.00
Ready to eat meal (beef containing)	*Salmonella* Enteritidis TCC 1638	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		1.3 (0.80, 2.3)	20	15	0.75	(0.53, 0.89)	15	0.75	(0.53, 0.89)	0.00	(-0.14, 0.14)	0.00
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)	0.00

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Confirmed			Reference Confirmation (R)			dPODcp[f]	95% CI[g]	X^{2} [i]
				X[c]	POD_c[d]	95% CI	X_c	POD_{rc}[d]	95% CI			

Lettuce	*Salmonella* Anatum TCC 1626	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		1.0 (0.48, 1.22)	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.14, 0.14)	0.00
		1.5 (0.65, 3.37)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)	0.00
Raw ground beef 8 h (unpaired)	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)	0.00
		0.63 (0.35, 1.1)	20	10	0.50	(0.30, 0.70)	11	0.55	(0.34, 0.74)	-0.05	(-0.24, 0.33)	0.39
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.47, 0.47)	0.00
Raw ground beef 24 h (unpaired)	*Salmonella* Typhimurium TCC 1911	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)	0.00
		0.63 (0.35, 1.1)	20	10	0.50	(0.30, 0.70)	11	0.55	(0.34, 0.74)	-0.05	(-0.24, 0.33)	0.098
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.47, 0.47)	0.00
Pasteurised liquid whole egg	*Salmonella* Virchow TCC 1890	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		0.58 (0.36, 0.98)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.14, 0.14)	0.00
		1.35 (0.61, 4.37)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)	0.00
Fresh bagged lettuce[i]	*Salmonella* Thompson ATCC 8391	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		0.73 (0.42, 1.23)	20	9	0.45	(0.25, 0.65)	10	0.50	(0.29, 0.70)	-0.05	(-0.06, 0.16)	0.00
		2.97 (1.25, 7.0)	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)	0.00
Pork Frankfurters[i]	*Salmonella* Vellore ATCC 15611	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		0.48 (0.28, 0.75)	20	7	0.35	(0.18, 0.56)	7	0.35	(0.18, 0.56)	0.00	(-0.14, 0.14)	0.00
		2.97 (1.25, 7.0)	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)	0.00
Stainless steel surface[i]	*Salmonella* Thompson ATCC 8392	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)	0.00
		-	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.14, 0.14)	0.00
		-	5	5	1.00	(0.56, 1.00)	5	1.00	(0.56, 1.00)	0.00	(-0.45, 0.45)	0.00

[a]MPN= Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N=Number of test portions
[c]X=Number of positive test portions
[d]PODc=Confirmed candidate method positive outcomes divided by the total number of portions
[e]PODr=Confirmed reference method positive outcomes divided by the total number of portions
[f]dPODc=Difference between the candidate presumptive result and the candidate method confirmed result POD values
[g]95% CI=If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level
[h]N/A=Not applicable
[i]Independent Laboratory Study

DISCUSSION OF MODIFICATION APPROVED AUGUST 2015 (8)

The results detailed in this report, within the statistical uncertainty of the analysis support the product claims made for the SureTect Salmonella species PCR assay for the detection of *Salmonella* from an extended range of food matrices covering 25 g samples of; wet cat and dry dog food, pasteurized 2% milk, bean sprouts, cantaloupe, chilled pizza dough, black peppercorns, peanut butter, ice-cream, chocolate, sponge samples from plastic surfaces and 375 g samples of raw ground beef. The SureTect assay offers the benefits of high sensitivity and specificity whilst reducing the overall time to a presumptive result and reduced "hands on" time for laboratory employees undertaking this method compared to culture based methods and other rapid methods, which require more handling steps in their protocols.

Table 5. Thermo Scientific SureTect Salmonella species Assay Presumptive vs. Confirmed Result by latex test – POD Analysis (8)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive			SureTect Method Confirmation (Latex) (CC)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cp}[d]	95% CI	X[c]	POD_{cc}[d]	95% CI		
Plastic surface sponge 4"x4"	*Salmonella* Kentucky ATCC 9263	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	9	0.45	(0.26, 0.66)	9	0.45	(0.26, 0.66)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pasteurised 2% milk	*Salmonella* Stanley ATCC 7308	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.4 (0.85, 2.3)	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Cantaloupe melon	*Salmonella* London ATCC 8389	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.50 (0.25, 0.85)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.5 (1.2, 5.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Dry dog food	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.73 (0.43, 1.2)	20	13	0.65	(0.43, 0.82)	10	0.50	(0.30, 0.70)	0.15	(-0.026, 0.33)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Wet cat food	*Salmonella* Pomona ATCC 10729	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Chilled pizza dough	*Salmonella* Tennessee ATCC 10722	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.55 (0.30, 0.93)	20	11	0.55	(0.34, 0.74)	10	0.50	(0.30, 0.70)	0.05	(-0.06, 0.16)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ice cream (vanilla)	*Salmonella* Oranienburg ATCC 9239	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.90 (0.55, 1.4)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Black peppercorns	*Salmonella* Reading TCC 2006	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.83 (0.48, 1.3)	20	10	0.50	(0.30, 0.70)	11	0.55	(0.34, 0.74)	-0.05	(-0.33, 0.24)
		1.9 (0.85, 4.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Peanut butter	*Salmonella* Minnesota ATCC 9700	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.35 (0.17, 0.63)	20	5	0.25	(0.11, 0.47)	5	0.25	(0.11, 0.47)	0.00	(-0.14, 0.14)
		0.92 (0.45, 1.9)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)

Bean sprouts	*Salmonella* Muenster ATCC BAA-1575	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.60 (0.33, 1.00)	20	6	0.30	(0.15, 0.52)	4	0.20	(0.08, 0.42)	0.10	(-0.17, 0.35)
		1.9 (1.00, 3.80)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
85% Cocoa solids Chocolate	*Salmonella* Braenderup TCC 1628	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.81 (0.47, 1.33)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		1.88 (0.84, 4.93)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.46, 0.46)
Raw ground beef 375 g 9 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	6	0.30	(0.15, 0.52)	7	0.35	(0.18, 0.57)	-0.05	(-0.32, 0.23)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Raw ground beef 375 g 24h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Dry dog food[i]	*Salmonella* Braenderup ATCC BAA-1739	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.46 (0.27, 0.75)	20	6	0.30	(0.14, 0.51)	6	0.30	(0.14, 0.51)	0.00	(-0.13, 0.13)
		1.88 (0.84, 4.18)	5	4	0.80	(0.56, 1.00)	4	0.80	(0.56, 1.00)	0.00	(-0.45, 0.45)
Milk Chocolate (43% cocoa solids)[i]	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.42 (0.22, 0.76)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		4.38 (1.71, 11.20)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]PODcp = Candidate method presumptive positive outcomes divided by the total number of portions.
[e]PODcc = Candidate confirmation method positive outcomes divided by the total number of portions.
[f]dPODcp = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.
[i]Independent Laboratory Study

Table 6. Thermo Scientific SureTect Salmonella species Assay Presumptive vs. Confirmed Result by Microbact biochemical gallery – POD Analysis (8)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive			SureTect Method Confirmation (Microbact) (CC)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cp}[d]	95% CI	X[c]	POD_{cc}[d]	95% CI		
Plastic surface sponge 4"x4"	*Salmonella* Kentucky ATCC 9263	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	9	0.45	(0.26, 0.66)	9	0.45	(0.26, 0.66)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pasteurised 2% milk	*Salmonella* Stanley ATCC 7308	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.4 (0.85, 2.3)	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Cantaloupe melon	*Salmonella* London ATCC 8389	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.50 (0.25, 0.85)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.5 (1.2, 5.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Dry dog food	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.73 (0.43, 1.2)	20	13	0.65	(0.43, 0.82)	10	0.50	(0.30, 0.70)	0.15	(-0.026, 0.33)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Wet cat food	*Salmonella* Pomona ATCC 10729	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Chilled pizza dough	*Salmonella* Tennessee ATCC 10722	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.55 (0.30, 0.93)	20	11	0.55	(0.34, 0.74)	10	0.50	(0.30, 0.70)	0.05	(-0.06, 0.16)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ice cream (vanilla)	*Salmonella* Oranienburg ATCC 9239	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.90 (0.55, 1.4)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Black peppercorns	*Salmonella* Reading TCC 2006	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.83 (0.48, 1.3)	20	10	0.50	(0.30, 0.70)	11	0.55	(0.34, 0.74)	-0.05	(-0.33, 0.24)
		1.9 (0.85, 4.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Peanut butter	*Salmonella* Minnesota ATCC 9700	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.35 (0.17, 0.63)	20	5	0.25	(0.11, 0.47)	5	0.25	(0.11, 0.47)	0.00	(-0.14, 0.14)
		0.92 (0.45, 1.9)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Bean sprouts	*Salmonella* Muenster ATCC BAA-1575	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.60 (0.33, 1.00)	20	6	0.30	(0.15, 0.52)	4	0.20	(0.08, 0.42)	0.10	(-0.17, 0.35)

		1.9 (1.00, 3.80)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
85% Cocoa solids Chocolate	*Salmonella* Braenderup TCC 1628	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.81 (0.47, 1.33)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		1.88 (0.84, 4.93)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.46, 0.46)
Raw ground beef 375 g 9 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	6	0.30	(0.15, 0.52)	7	0.35	(0.18, 0.57)	-0.05	(-0.32, 0.23)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Raw ground beef 375 g 24 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Dry dog food[i]	*Salmonella* Braenderup ATCC BAA-1739	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.46 (0.27, 0.75)	20	6	0.30	(0.14, 0.51)	6	0.30	(0.14, 0.51)	0.00	(-0.13, 0.13)
		1.88 (0.84, 4.18)	5	4	0.80	(0.56, 1.00)	4	0.80	(0.56, 1.00)	0.00	(-0.45, 0.45)
Milk Chocolate (43% cocoa solids)[i]	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.42 (0.22, 0.76)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		4.38 (1.71, 11.20)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]PODcp = Candidate method presumptive positive outcomes divided by the total number of portions.
[e]PODcc = Candidate confirmation method positive outcomes divided by the total number of portions.
[f]dPODcp = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.
[i]Independent Laboratory Study.

Table 3. Thermo Scientific SureTect Salmonella species Assay Presumptive vs. ISO Reference Confirmation (by Micro-ID) – POD Analysis (8)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive			Reference confirmation (rc)			dPODc p[f]	95% CI[g]
				X[c]	POD_{cp}[d]	95% CI	X[c]	POD_{rc}[d]	95% CI		
Plastic surface sponge 4"x4"	*Salmonella* Kentucky ATCC 9263	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	9	0.45	(0.26, 0.66)	9	0.45	(0.26, 0.66)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pasteurized 2% milk	*Salmonella* Stanley ATCC 7308	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.4 (0.85, 2.3)	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Cantaloupe	*Salmonella* London ATCC 8389	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.50 (0.25, 0.85)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.5 (1.2, 5.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Dry dog food	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.73 (0.43, 1.2)	20	13	0.65	(0.43, 0.82)	10	0.50	(0.30, 0.70)	0.15	(-0.026, 0.33)

		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Wet cat food	*Salmonella* Pomona ATCC 10729	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Chilled pizza dough	*Salmonella* Tennessee ATCC 10722	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.55 (0.30, 0.93)	20	11	0.55	(0.34, 0.74)	10	0.50	(0.30, 0.70)	0.05	(-0.06, 0.16)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ice cream (vanilla)	*Salmonella* Oranienburg ATCC 9239	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.90 (0.55, 1.4)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Black peppercorns	*Salmonella* Reading TCC 2006	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.83 (0.48, 1.3)	20	10	0.50	(0.30, 0.70)	11	0.55	(0.34, 0.74)	-0.05	(-0.33, 0.24)
		1.9 (0.85, 4.3)	5	4	0.80	(0.38, 1.00)	5	1.00	(0.57, 1.00)	-0.20	(-0.62, 0.28)
Peanut butter	*Salmonella* Minnesota ATCC 9700	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.35 (0.17, 0.63)	20	5	0.25	(0.11, 0.47)	5	0.25	(0.11, 0.47)	0.00	(-0.14, 0.14)
		0.92 (0.45, 1.9)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Bean sprouts	*Salmonella* Muenster ATCC BAA-1575	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.60 (0.33, 1.00)	20	6	0.30	(0.15, 0.52)	4	0.20	(0.08, 0.42)	0.10	(-0.17, 0.35)
		1.9 (1.00, 3.80)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
85% Cocoa solids Chocolate	*Salmonella* Braenderup TCC 1628	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.81 (0.47, 1.33)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		1.88 (0.84, 4.93)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.46, 0.46)
Raw ground beef 375 g 9 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	6	0.30	(0.15, 0.52)	7	0.35	(0.18, 0.57)	-0.05	(-0.32, 0.23)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Raw ground beef 375 g 24 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Dry dog food[i]	*Salmonella* Braenderup ATCC BAA-1739	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.46 (0.27, 0.75)	20	6	0.30	(0.14, 0.51)	6	0.30	(0.14, 0.51)	0.00	(-0.13, 0.13)
		1.88 (0.84, 4.18)	5	4	0.80	(0.56, 1.00)	4	0.80	(0.56, 1.00)	0.00	(-0.45, 0.45)
Milk Chocolate (43% cocoa solids)[i]	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.42 (0.22, 0.76)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		4.38 (1.71, 11.20)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a] MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b] N = Number of test portions.
[c] X = Number of positive test portions.
[d] PODcp = Candidate method presumptive positive outcomes divided by the total number of portions.
[e] PODcc = Candidate confirmation method positive outcomes divided by the total number of portions.
[f] dPODcp = Difference between the candidate presumptive result and the candidate method confirmed result POD value.s
[g] 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h] N/A = Not applicable.
[i] Independent Laboratory Study.

Table 4. Thermo Scientific SureTect Salmonella species Assay Confirmation (latex) vs. ISO Reference Confirmation (by Micro-ID) – POD Analysis 8

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive (latex)			Reference confirmation (rc)			dPOD cp[f]	95% CI[g]
				X[c]	POD_{cc}[d]	95% CI	X[c]	POD_{rc}[d]	95% CI		
Plastic surface sponge 4"x4"	*Salmonella* Kentucky ATCC 9263	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	9	0.45	(0.26, 0.66)	9	0.45	(0.26, 0.66)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pasteurized 2% milk	*Salmonella* Stanley ATCC 7308	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.4 (0.85, 2.3)	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Cantaloupe	*Salmonella* London ATCC 8389	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.50 (0.25, 0.85)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.5 (1.2, 5.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Dry dog food	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.73 (0.43, 1.2)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Wet cat food	*Salmonella* Pomona ATCC 10729	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Chilled pizza dough	*Salmonella* Tennessee ATCC 10722	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.55 (0.30, 0.93)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ice cream (vanilla)	*Salmonella* Oranienburg ATCC 9239	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.90 (0.55, 1.4)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Black peppercorns	*Salmonella* Reading TCC 2006	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.83 (0.48, 1.3)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.28, 0.28)
		1.9 (0.85, 4.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Peanut butter	*Salmonella* Minnesota ATCC 9700	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.35 (0.17, 0.63)	20	5	0.25	(0.11, 0.47)	5	0.25	(0.11, 0.47)	0.00	(-0.14, 0.14)
		0.92 (0.45, 1.9)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Bean sprouts	*Salmonella* Muenster ATCC BAA-1575	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.60 (0.33, 1.00)	20	4	0.20	(0.08, 0.42)	4	0.20	(0.08, 0.42)	0.00	(-0.25, 0.25)
		1.9 (1.00, 3.80)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
85% Cocoa solids	*Salmonella* Braenderup	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)

Chocolate	TCC 1628	0.81 (0.47, 1.33)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		1.88 (0.84, 4.93)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.46, 0.46)
Raw ground beef 375 g 9 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Raw ground beef 375 g 24 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Dry dog food[i]	*Salmonella* Braenderup ATCC BAA-1739	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.46 (0.27, 0.75)	20	6	0.30	(0.14, 0.51)	6	0.30	(0.14, 0.51)	0.00	(-0.13, 0.13)
		1.88 (0.84, 4.18)	5	4	0.80	(0.56, 1.00)	4	0.80	(0.56, 1.00)	0.00	(-0.45, 0.45)
Milk Chocolate (43% cocoa solids)[i]	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.42 (0.22, 0.76)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		4.38 (1.71, 11.20)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]PODcp = Candidate method presumptive positive outcomes divided by the total number of portions.
[e]$PODcc_2$ = Reference method confirmation positive outcomes divided by the total number of portions.
[f]dPODcp = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.
[i]Independent Laboratory Study.

Table 5. Thermo Scientific SureTect Salmonella species Assay Confirmation (Microbact) vs. ISO Reference Confirmation (by Micro-ID) – POD Analysis (8)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive (microbact)			Reference confirmation (rc)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cc}[d]	95% CI	X[c]	POD_{rc}[d]	95% CI		
Plastic surface sponge 4"x4"	*Salmonella* Kentucky ATCC 9263	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	9	0.45	(0.26, 0.66)	9	0.45	(0.26, 0.66)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pasteurized 2% milk	*Salmonella* Stanley ATCC 7308	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.4 (0.85, 2.3)	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Cantaloupe	*Salmonella* London ATCC 8389	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.50 (0.25, 0.85)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.5 (1.2, 5.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Dry dog food	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.73 (0.43, 1.2)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)

Wet cat food	*Salmonella* Pomona ATCC 10729	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Chilled pizza dough	*Salmonella* Tennessee ATCC 10722	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.55 (0.30, 0.93)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ice cream (vanilla)	*Salmonella* Oranienburg ATCC 9239	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.90 (0.55, 1.4)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Black peppercorns	*Salmonella* Reading TCC 2006	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.83 (0.48, 1.3)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.28, 0.28)
		1.9 (0.85, 4.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.43, 0.43)
Peanut butter	*Salmonella* Minnesota ATCC 9700	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.35 (0.17, 0.63)	20	5	0.25	(0.11, 0.47)	5	0.25	(0.11, 0.47)	0.00	(-0.14, 0.14)
		0.92 (0.45, 1.9)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Bean sprouts	*Salmonella* Muenster ATCC BAA-1575	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.60 (0.33, 1.00)	20	4	0.20	(0.08, 0.42)	4	0.20	(0.08, 0.42)	0.00	(-0.25, 0.25)
		1.9 (1.00, 3.80)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
85% Cocoa solids Chocolate	*Salmonella* Braenderup TCC 1628	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.81 (0.47, 1.33)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		1.88 (0.84, 4.93)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.46, 0.46)
Raw ground beef 375 g 9 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Raw ground beef 375 g 24 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Dry dog food[i]	*Salmonella* Braenderup ATCC BAA-1739	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.46 (0.27, 0.75)	20	6	0.30	(0.14, 0.51)	6	0.30	(0.14, 0.51)	0.00	(-0.13, 0.13)
		1.88 (0.84, 4.18)	5	4	0.80	(0.56, 1.00)	4	0.80	(0.56, 1.00)	0.00	(-0.45, 0.45)
Milk Chocolate (43% cocoa solids)[i]	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.42 (0.22, 0.76)	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		4.38 (1.71, 11.20)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a] MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b] N = Number of test portions.
[c] X = Number of positive test portions.
[d] PODcc = Candidate method confirmed positive outcomes divided by the total number of portions.
[e] $PODcc_2$ = Reference method confirmation positive outcomes divided by the total number of portions.
[f] dPODcp = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g] 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h] N/A = Not applicable.
[i] Independent Laboratory Study.

Table 6. Thermo Scientific SureTect Salmonella species Assay Method vs. Reference Method – POD Analysis (8)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Confirmed			Reference method (R)			dPODc[f]	95% CI[g]
				X[c]	POD_c[d]	95% CI	X[c]	POD_R[d]	95% CI		
Plastic surface sponge 4"x4"	*Salmonella* Kentucky ATCC 9263	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	9	0.45	(0.26, 0.66)	9	0.45	(0.26, 0.66)	0.00	(-0.14, 0.14)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Pasteurized 2% milk	*Salmonella* Stanley ATCC 7308	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.4 (0.85, 2.3)	20	16	0.80	(0.58, 0.92)	16	0.80	(0.58, 0.92)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Cantaloupe	*Salmonella* London ATCC 8389	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.50 (0.25, 0.85)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.5 (1.2, 5.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Dry dog food	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.73 (0.43, 1.2)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		4.5 (1.7, 11.25)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Wet cat food	*Salmonella* Pomona ATCC 10729	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		1.3 (0.80, 2.1)	20	13	0.65	(0.43, 0.82)	13	0.65	(0.43, 0.82)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Chilled pizza dough	*Salmonella* Tennessee ATCC 10722	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.55 (0.30, 0.93)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.14, 0.14)
		2.3 (1.1, 5.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Ice cream (vanilla)	*Salmonella* Oranienburg ATCC 9239	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.90 (0.55, 1.4)	20	11	0.55	(0.34, 0.74)	11	0.55	(0.34, 0.74)	0.00	(-0.14, 0.14)
		3.0 (1.3, 7.0)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.45, 0.45)
Black peppercorns	*Salmonella* Reading TCC 2006	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.83 (0.48, 1.3)	20	10	0.50	(0.30, 0.70)	11	0.55	(0.34, 0.74)	-0.05	(-0.33, 0.24)
		1.9 (0.85, 4.3)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.45, 0.45)
Peanut butter	*Salmonella* Minnesota ATCC 9700	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.35 (0.17, 0.63)	20	5	0.25	(0.11, 0.47)	5	0.25	(0.11, 0.47)	0.00	(-0.14, 0.14)
		0.92 (0.45, 1.9)	5	3	0.60	(0.23, 0.88)	3	0.60	(0.23, 0.88)	0.00	(-0.45, 0.45)
Bean sprouts	*Salmonella* Muenster ATCC BAA-1575	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.60 (0.33, 1.00)	20	4	0.20	(0.08, 0.42)	9	0.45	(0.26, 0.66)	-0.25	(-0.49, 0.04)
		1.9 (1.00, 3.80)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Confirmed	Reference confirmation (R)	dPODc[f]	95% CI[g]

				X[c]	POD$_c$[d]	95% CI	X[c]	POD$_R$[d]	95% CI		
85% Cocoa solids Chocolate	*Salmonella* Braenderup TCC 1628	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.81 (0.47, 1.33)	20	8	0.40	(0.22, 0.61)	11	0.55	(0.34, 0.74)	-0.15	(-0.41, 0.15)
		1.88 (0.84, 4.93)	5	3	0.60	(0.23, 0.88)	4	0.80	(0.38, 1.00)	-0.20	(-0.62, 0.31)
Raw ground beef 375 g 9 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	6	0.30	(0.15, 0.52)	9	0.45	(0.15, 0.52)	-0.15	(-0.41, 0.14)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Raw ground beef 375 g 24 h	*Salmonella* Ohio TCC 2000	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.44 (0.23, 0.81)	20	7	0.35	(0.18, 0.57)	9	0.45	(0.15, 0.52)	-0.15	(-0.41, 0.14)
		1.67 (0.70, 3.94)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Dry dog food[i]	*Salmonella* Braenderup ATCC BAA-1739	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.46 (0.27, 0.75)	20	6	0.30	(0.14, 0.51)	6	0.30	(0.14, 0.51)	0.00	(-0.13, 0.13)
		1.88 (0.84, 4.18)	5	4	0.80	(0.56, 1.00)	4	0.80	(0.56, 1.00)	0.00	(-0.45, 0.45)
Milk Chocolate (43% cocoa solids)[i]	*Salmonella* Abony NCTC 6017	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		0.42 (0.22, 0.76)	20	8	0.40	(0.22, 0.61)	6	0.30	(0.15, 0.52)	0.10	(-0.18, 0.36)
		4.38 (1.71, 11.20)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]PODc = Confirmed candidate method positive outcomes divided by the total number of portions.
[e]PODr = Confirmed reference method positive outcomes divided by the total number of portions.
[f]dPODc = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.
[i]Independent Laboratory Study.

DISCUSSION OF MODIFICATION FEBRUARY 2016 (9)

The results obtained during this method modification study to validate both the change in target probe concentration within the SureTect Salmonella species PCR kit and the use of the Applied Biosystems 7500 Fast PCR instrument with RapidFinder Express 2.0 Software demonstrated that the reduced target probe concentration performs as well as the currently validated method using both the PikoReal and 7500 Fast PCR instruments.

The inclusivity study showed no difference in the performance of the reduced probe concentration PCR kit when using the PikoReal PCR instrument with SureTect Software, compared to the inclusivity results previously reported (7), or with the use of the 7500 Fast and RapidFinder Express 2.0 Software, as in both cases all 117 of the inclusivity isolates analyzed gave positive results with the SureTect PCR method. Similarly, the exclusivity study conducted using a panel of 36 different exclusivity isolates, covering organisms genetically and phenotypically close to *Salmonella*, gave negative results with the modified SureTect Salmonella PCR Kit.

Matrix studies showed comparable performance between the modified SureTect Salmonella kit and the ISO 6579:2002 reference method (Tables 3–10). A representative set of food matrices deemed to be "challenging" were evaluated, which included 25 g samples of bagged lettuce, raw chicken breast, skimmed milk powder, plastic surface and 375 g samples of raw ground beef. Samples were tested on both the PikoReal and 7500 Fast PCR instruments. Samples analyzed on the PikoReal instrument showed no differences between the SureTect and ISO methods, with the exception of one sample in the high inoculation level of lettuce. The sample was presumptive negative by the SureTect method but was confirmed to be positive for Salmonella. For the samples analyzed on the 7500 Fast instrument, there were three differences; one in the high inoculation level of lettuce (as with the PikoReal instrument), one in the low level inoculation of ground beef at 9 h and one in the low level inoculation of ground beef at 24 h. These samples were presumptive negative by the SureTect method but confirmed to be positive for Salmonella. However, POD analysis with 95% confidence intervals indicated no statistically significant difference in the performance between the SureTect and ISO reference methods with either platform. The negative PCR results with the lettuce and beef matrices may likely have been due to failure of these individual enrichments to achieve the level of detection of the SureTect PCR kit within the enrichment time due to insufficient homogenization of the food matrix before enrichment.

In addition to the evaluation of the PCR portion of the SureTect assay, the sample confirmation protocol prescribed in the SureTect method's IFU was compared to the ISO reference confirmation procedure during the matrix study. Results demonstrated equivalent performance between the two procedures, as there were no differences between the two on either PCR platform.

Lot-to-lot testing showed consistent results across three lots of test kits, on both instruments, proving that the newly formatted kit can be produced consistently. Robustness studies confirmed that the modification to the kit had no impact on the assay's performance when alterations were made to method parameters having the greatest potential impact on assay performance.

Table 7. Inclusivity of the Thermo Scientific SureTect Salmonella species Assay (9)

Isolate	Species or Serotype	O-group	Source	TCC[a] No.	SureTect (PikoReal) Result	SureTect (7500 Fast) Result
Salmonella bongori	66:z_{41}:-	66	Frog	2274	Positive	Positive
Salmonella bongori	66:z_{41}:-	66	Unknown	2275	Positive	Positive
Salmonella bongori	48:z_{35}:-	Y	Chicken egg	2402	Positive	Positive
Salmonella bongori	48:z_{35}:-	Y	Cheese	2398	Positive	Positive
Salmonella enterica	subsp *salamae*	39		1996	Positive	Positive
Salmonella enterica	subsp *salamae*	61		2217	Positive	Positive
Salmonella enterica	subsp *salamae* Canastel	D1	Gastroenteritis	2270	Positive	Positive
Salmonella enterica	subsp *salamae* Tranoroa	55		2353	Positive	Positive
Salmonella enterica	subsp *salamae* Humber	53		2037	Positive	Positive
Salmonella enterica	subsp *arizoniae*	41		1995	Positive	Positive
Salmonella enterica	subsp *arizoniae* 11,33:26:31	Unknown	NCTC 10043	2267	Positive	Positive
Salmonella enterica	subsp *arizoniae*	Y		2268	Positive	Positive
Salmonella enterica	subsp *diarizoniae*	62		2034	Positive	Positive
Salmonella enterica	subsp *diarizoniae*	65		2035	Positive	Positive
Salmonella enterica	subsp *diarizoniae*	50		1997	Positive	Positive
Salmonella enterica	subsp *diarizoniae* Eilbek 61:i:z	61		2276	Positive	Positive
Salmonella enterica	subsp *houtenae*	51	Boa constrictor	2032	Positive	Positive
Salmonella enterica	subsp *houtenae*	43		2033	Positive	Positive
Salmonella enterica	subsp *houtenae* Wassenaar	Z	Human infection	2272	Positive	Positive
Salmonella enterica	subsp *houtenae* Seminole	R		2038	Positive	Positive
Salmonella enterica	subsp *indica* Ferlac	H	Desiccated coconut	2269	Positive	Positive
Salmonella enterica	subsp *indica* Ferlac	H		2271	Positive	Positive
Salmonella enterica	subsp *indica*	Unknown	ATCC[b] BAA-1578	2360	Positive	Positive
Salmonella enterica subsp enterica	Aberdeen	F		1612	Positive	Positive
Salmonella enterica subsp enterica	Abortusequi	B		2296	Positive	Positive
Salmonella enterica subsp enterica	Adelaide	O		OCC[c] 2536	Positive	Positive
Salmonella enterica subsp	Agona	B		1619	Positive	Positive

enterica						
Salmonella enterica subsp enterica	Alabama	D1		1621	Positive	Positive
Salmonella enterica subsp enterica	Allerton	E1		1623	Positive	Positive
Salmonella enterica subsp enterica	Amherstiana	C2		1624	Positive	Positive
Salmonella enterica subsp enterica	Amsterdam	E1		1625	Positive	Positive
Salmonella enterica subsp enterica	Anatum	E1	Duck	1626	Positive	Positive
Salmonella enterica subsp enterica	Binza	E2		2027	Positive	Positive
Salmonella enterica subsp enterica	Bovis-Morbificans	C2		2001	Positive	Positive
Salmonella enterica subsp enterica	Braenderup	C1		1630	Positive	Positive
Salmonella enterica subsp enterica	Brandenberg	B		1998	Positive	Positive
Salmonella enterica subsp enterica	Bredeney	B		2019	Positive	Positive
Salmonella enterica subsp enterica	Breukelen	C2	Cuscus	2287	Positive	Positive
Salmonella enterica subsp enterica	Cambridge	E2	Gastroenteritis	1632	Positive	Positive
Salmonella enterica subsp enterica	Cerro	K		2016	Positive	Positive
Salmonella enterica subsp enterica	Cholerasuis	C1		1852	Positive	Positive
Salmonella enterica subsp enterica	Colombo	P		2031	Positive	Positive
Salmonella enterica subsp enterica	Corvallis	C3		1633	Positive	Positive
Salmonella enterica subsp enterica	Dahlem	Y		2036	Positive	Positive
Salmonella enterica subsp enterica	Derby	B		2008	Positive	Positive
Salmonella enterica subsp enterica	Dublin	D1	Cattle	802	Positive	Positive
Salmonella enterica subsp enterica	Dusseldorf	C2	Gastroenteritis	1634	Positive	Positive
Salmonella enterica subsp enterica	Ealing	O		1999	Positive	Positive
Salmonella enterica subsp enterica	Eastbourne	D1		2023	Positive	Positive
Salmonella enterica subsp enterica	Emek	C2		1692	Positive	Positive
Salmonella enterica subsp enterica	Enteritidis	D1		1638	Positive	Positive
Salmonella enterica subsp enterica	Florida	H		2288	Positive	Positive
Salmonella enterica subsp enterica	Gallinarum	D1		1641	Positive	Positive
Salmonella enterica subsp enterica	Give	E1		1642	Positive	Positive
Salmonella enterica subsp enterica	Hadar	C2		1644	Positive	Positive
Salmonella enterica subsp enterica	Heidelberg	B		2011	Positive	Positive
Salmonella enterica subsp enterica	Hindmarsh	C2		1648	Positive	Positive
Salmonella enterica subsp enterica	Ibadan	G		2297	Positive	Positive
Salmonella enterica subsp enterica	Indiana	B	Turkey meat	2295	Positive	Positive
Salmonella enterica subsp enterica	Infantis	C1		1650	Positive	Positive
Salmonella enterica subsp enterica	Inverness	P		2281	Positive	Positive
Salmonella enterica subsp	Java	B		1652	Positive	Positive

enterica						
Salmonella enterica subsp enterica	Javiana	D1		2291	Positive	Positive
Salmonella enterica subsp enterica	Kedougou	G2		OCC 2474	Positive	Positive
Salmonella enterica subsp enterica	Kentucky	C3		1653	Positive	Positive
Salmonella enterica subsp enterica	Kiel	A		1654	Positive	Positive
Salmonella enterica subsp enterica	Kottbus	C2		2004	Positive	Positive
Salmonella enterica subsp enterica	Krefeld	E4		1655	Positive	Positive
Salmonella enterica subsp enterica	Lille	C1		2021	Positive	Positive
Salmonella enterica subsp enterica	Livingstone	C1		2005	Positive	Positive
Salmonella enterica subsp enterica	London	E1		1656	Positive	Positive
Salmonella enterica subsp enterica	Madelia	H	Chicken liver	2030	Positive	Positive
Salmonella enterica subsp enterica	Manchester	C2		2022	Positive	Positive
Salmonella enterica subsp enterica	Manila	E2		2028	Positive	Positive
Salmonella enterica subsp enterica	Mbandaka	C1		2010	Positive	Positive
Salmonella enterica subsp enterica	Montevideo	C1		1657	Positive	Positive
Salmonella enterica subsp enterica	Moscow	D1		1658	Positive	Positive
Salmonella enterica subsp enterica	Muenchen	C2		1660	Positive	Positive
Salmonella enterica subsp enterica	Napoli	D1	Clinical isolate	2024	Positive	Positive
Salmonella enterica subsp enterica	Narashino	C2		1661	Positive	Positive
Salmonella enterica subsp enterica	Newport	C2		1663	Positive	Positive
Salmonella enterica subsp enterica	Niloese	E4		1664	Positive	Positive
Salmonella enterica subsp enterica	Nitra	A		1693	Positive	Positive
Salmonella enterica subsp enterica	Ohio	C1		2000	Positive	Positive
Salmonella enterica subsp enterica	Oranienburg	C1		2015	Positive	Positive
Salmonella enterica subsp enterica	Orion	E1	Asymptomatic food handler	2026	Positive	Positive
Salmonella enterica subsp enterica	Panama	D1		1665	Positive	Positive
Salmonella enterica subsp enterica	Pensacola	D1	Clinical	2277	Positive	Positive
Salmonella enterica subsp enterica	Plymouth	D2		1994	Positive	Positive
Salmonella enterica subsp enterica	Pomona	M	Turkey intestine	1988	Positive	Positive
Salmonella enterica subsp enterica	Poona	G1		1611	Positive	Positive
Salmonella enterica subsp enterica	Pretoria	F	Pig liver & spleen	2029	Positive	Positive
Salmonella enterica subsp enterica	Pullorum	D1		1666	Positive	Positive
Salmonella enterica subsp enterica	Reading	B		2006	Positive	Positive
Salmonella enterica subsp enterica	Rio-grande	R		2285	Positive	Positive
Salmonella enterica subsp enterica	Rostock	D1		1667	Positive	Positive

Salmonella enterica subsp enterica	Rubislaw	F		2017	Positive	Positive
Salmonella enterica subsp enterica	Saint-Paul	B		2007	Positive	Positive
Salmonella enterica subsp enterica	Senftenberg	E4	Faecal sample	2018	Positive	Positive
Salmonella enterica subsp enterica	Shanghai	E1		2025	Positive	Positive
Salmonella enterica subsp enterica	Simsbury	E4	Faecal sample	1672	Positive	Positive
Salmonella enterica subsp enterica	Stanley	B		1673	Positive	Positive
Salmonella enterica subsp enterica	Taksony	E4		1678	Positive	Positive
Salmonella enterica subsp enterica	Tennessee	C1		2293	Positive	Positive
Salmonella enterica subsp enterica	Thompson	C1		2012	Positive	Positive
Salmonella enterica subsp enterica	Typhimurium	B	Gastroenteritis	1681	Positive	Positive
Salmonella enterica subsp enterica	Umbilo	M		1992	Positive	Positive
Salmonella enterica subsp enterica	Urbana	N		1990	Positive	Positive
Salmonella enterica subsp enterica	Utrecht	52		2298	Positive	Positive
Salmonella enterica subsp enterica	Vellore	B	Faecal sample	2290	Positive	Positive
Salmonella enterica subsp enterica	Virchow	C1		1890	Positive	Positive
Salmonella enterica subsp enterica	Wandsworth	Q		1685	Positive	Positive
Salmonella enterica subsp enterica	Westertede	E4		1686	Positive	Positive
Salmonella enterica subsp enterica	Zanzibar	E1	Clinical	1690	Positive	Positive
Salmonella enterica subsp enterica	Typhi	D1		NCTC[d] 8385	Positive	Positive
Salmonella enterica subsp enterica	Paratyphi A	A		NCTC 5702	Positive	Positive
Salmonella enterica subsp enterica	Paratyphi B	B		OCC 149	Positive	Positive

[a]TCC. Trials Culture Collection Number-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke.

[b]ATCC, American Type Culture Collection, Manassas, VI.

[c]OCC. Oxoid Culture Collection- Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke.

[d]NCTC, National Collection of Type Cultures, Health Protection Agency, UK.

Table 8. Exclusivity of the Thermo Scientific SureTect Salmonella species Assay (9)

Isolate	Source	TCC[a] No.	SureTect (PikoReal) Result	SureTect (7500 Fast) Result
Citrobacter freundii		171	Negative	Negative
Citrobacter intermedius		181	Negative	Negative
Citrobacter koseri	Clinical	2039	Negative	Negative
Citrobacter youngae		2043	Negative	Negative
Edwardsiella tarda		RDCC[b] 2027	Negative	Negative
Enterobacter sakazakii		2053	Negative	Negative
Enterobacter aerogenes	Clinical	2200	Negative	Negative
Enterobacter amnigenus-Biogroup 1	Clinical	2198	Negative	Negative
Enterobacter cloacae		401	Negative	Negative
Pantoea agglomerans	Pasteurised milk	409	Negative	Negative
Enterobacter faecalis		1388	Negative	Negative
Enterobacter intermedius	Clinical	2203	Negative	Negative
Escherichia blattae	Cockroach gut	2273	Negative	Negative
Escherichia coli		1809	Negative	Negative
Escherichia coli O157:H7 VT neg		OCC[c] 1872	Negative	Negative
Escherichia hermanii		2047	Negative	Negative
Escherichia vulneris	Vegetables	2264	Negative	Negative
Hafnia alvei		2044	Negative	Negative
Klebsiella aerogenes		1804	Negative	Negative
Klebsiella oxytoca	Clinical	593	Negative	Negative
Klebsiella pneumoniae		1892	Negative	Negative
Klebsiella terrigena	Water isolate	2207	Negative	Negative
Morganella morganii	Clinical	1431	Negative	Negative
Proteus mirabilis		1566	Negative	Negative
Proteus vulgaris		1552	Negative	Negative
Providencia alcalifaciens	Clinical	2209	Negative	Negative
Providencia rettgeri		2201	Negative	Negative
Providencia stuartii	Clinical	418	Negative	Negative
Pseudomonas aeruginosa		1903	Negative	Negative
Serratia liquifaciens	Milk	2048	Negative	Negative
Serratia marcescens	Clinical	414	Negative	Negative
Shigella boydii	Clinical	2050	Negative	Negative
Shigella flexneri		2052	Negative	Negative
Shigella sonnei	Clinical	2051	Negative	Negative
Yersinia enterocolitica	Frozen prawn	2215	Negative	Negative
Escherichia fergusonii	Sausages	2263	Negative	Negative

[a]TCC. Trials Culture Collection Number.

[b]RDCC. R&D Culture Collection.

[c]OCC. Oxoid Culture Collection-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.

Table 5. Thermo Scientific SureTect Salmonella species Assay (PikoReal Instrument) Confirmation Method Result (latex or Microbact) vs. ISO Reference Confirmation (API 20E) – POD Analysis (10)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Confirmation Method			ISO Reference Method Confirmation (RC)			dPOD$_{CC}$[f]	95% CI[g]
				X[c]	POD$_{CC}$[d]	95% CI	X	POD$_{RC}$[e]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.51 (0.26, 0.87)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Bagged lettuce	*Salmonella* Anatum TCC 1626	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.40 (0.17,0.71)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.64 (0.79, 3.39)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.43, 0.43)
Skimmed milk powder	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.76 (0.44, 1.26)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.28, 0.28)
		4.37 (1.72, 11.15)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Plastic surface	*Salmonella* Kentucky TCC 1653	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 9 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 24 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]POD$_{CC}$ = Candidate confirmation method positive outcomes divided by the total number of portions.
[e]POD$_{RC}$ = Reference method positive outcomes divided by the total number of portions.
[f]dPOD$_{CC}$ = Difference between the candidate confirmation result and the candidate method confirmed result POD values
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.

Table 6. Thermo Scientific SureTect Salmonella species Assay (PikoReal Instrument) Confirmed Result vs. ISO Reference method Result – POD Analysis (10)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Confirmed Result			ISO Reference Confirmation (R)			dPOD$_C$[f]	95% CI[g]
				X[c]	POD$_C$[d]	95% CI	X[c]	POD$_R$[e]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.51 (0.26, 0.87)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Bagged lettuce	*Salmonella* Anatum TCC 1626	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.40 (0.17,0.71)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.64 (0.79, 3.39)	5	3	0.60	(0.23, 0.88)	4	0.80	(0.38, 1.00)	-0.20	(-0.62, 0.31)
Skimmed milk powder	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.76 (0.44, 1.26)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.28, 0.28)
		4.37 (1.72, 11.15)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Plastic surface	*Salmonella* Kentucky TCC 1653	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 9 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 24 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]POD$_C$ = Candidate method confirmed positive outcomes divided by the total number of portions.
[e]POD$_R$ = Reference method confirmation positive outcomes divided by the total number of portions.
[f]dPOD$_C$ = Difference between the candidate confirmed result and reference method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.

Table 7. Thermo Scientific SureTect Salmonella species Assay Presumptive (7500 Fast Instrument) Result vs. Confirmed Result by latex or Microbact test – POD Analysis (10)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Presumptive Result			SureTect Confirmation Method Result (CC)			dPOD$_{CP}$[f]	95% CI[g]
				X[c]	POD$_{CP}$[d]	95% CI	X[c]	POD$_{CC}$[e]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.51 (0.26, 0.87)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Bagged lettuce	*Salmonella* Anatum TCC 1626	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.40 (0.17,0.71)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.64 (0.79, 3.39)	5	3	0.60	(0.23, 0.88)	4	0.80	(0.38, 1.00)	-0.20	(-0.62, 0.31)
Skimmed milk powder	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.76 (0.44, 1.26)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.28, 0.28)
		4.37 (1.72, 11.15)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Plastic surface	*Salmonella* Kentucky TCC 1653	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 9 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	13	0.65	(0.43, 0.82)	14	0.70	(0.48, 0.85)	-0.05	(-0.32, 0.23)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 24 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	13	0.65	(0.43, 0.82)	14	0.70	(0.48, 0.85)	-0.05	(-0.32, 0.23)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]POD$_{CP}$ = Candidate method presumptive positive outcomes divided by the total number of portions.
[e]PODcc = Candidate confirmation method positive outcomes divided by the total number of portions.
[f]dPODc = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.

Table 8. Thermo Scientific SureTect Salmonella species Assay Presumptive (7500 Fast Instrument) Result vs. ISO Confirmation Result (API 20E) – POD Analysis (10)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Presumptive			Reference Method Confirmation (RC)			dPODcp[f]	95% CI[g]
				X[c]	POD_{cp}[d]	95% CI	X[c]	POD_{RC}[e]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.51 (0.26, 0.87)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Bagged lettuce	*Salmonella* Anatum TCC 1626	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.40 (0.17,0.71)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.64 (0.79, 3.39)	5	3	0.60	(0.23, 0.88)	4	0.80	(0.38, 1.00)	-0.20	(-0.62, 0.31)
Skimmed milk powder	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.76 (0.44, 1.26)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.28, 0.28)
		4.37 (1.72, 11.15)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Plastic surface	*Salmonella* Kentucky TCC 1653	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 9 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	13	0.65	(0.43, 0.82)	14	0.70	(0.48, 0.85)	-0.05	(-0.32, 0.23)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 24 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	13	0.65	(0.43, 0.82)	14	0.70	(0.48, 0.85)	-0.05	(-0.32, 0.23)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]PODc = Confirmed candidate method positive outcomes divided by the total number of portions.
[e]POD_{RC} = Reference method positive outcomes divided by the total number of portions.
[f]dPODc = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.

Table 9: Thermo Scientific SureTect Salmonella species Assay (7500 Fast Instrument) Confirmation Method Result (latex or Microbact) vs. ISO Reference Confirmation (API 20E) – POD Analysis (10)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Confirmation Result			Reference Method Confirmation			dPODcp[f]	95% CI[g]
				X[c]	POD_{CC}[d]	95% CI	X[c]	POD_{RC}[e]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.51 (0.26, 0.87)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Bagged lettuce	*Salmonella* Anatum TCC 1626	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.40 (0.17,0.71)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.64 (0.79, 3.39)	5	4	0.80	(0.38, 1.00)	4	0.80	(0.38, 1.00)	0.00	(-0.42, 0.47)
Skimmed milk powder	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.76 (0.44, 1.26)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.28, 0.28)
		4.37 (1.72, 11.15)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Plastic surface	*Salmonella* Kentucky TCC 1653	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 9 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 24 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	14	0.70	(0.48, 0.85)	14	0.70	(0.48, 0.85)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]PODcc = Candidate method confirmed positive outcomes divided by the total number of portions.
[e]POD_{RC} = Reference method confirmation positive outcomes divided by the total number of portions.
[f]dPODcp = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.

Table 10. Thermo Scientific SureTect Salmonella species Assay (7500 Fast Instrument) Confirmed Results vs. ISO Reference method Result – POD Analysis (10)

Matrix	Strain	MPN[a]/test portion	N[b]	SureTect Method Confirmed Result			ISO Reference Confirmation (R)			dPOD$_C$[f]	95% CI[g]
				X[c]	POD$_C$[d]	95% CI	X[c]	POD$_R$[e]	95% CI		
Raw chicken breast	*Salmonella* Indiana TCC 2295	N/A[h]	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.51 (0.26, 0.87)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Bagged lettuce	*Salmonella* Anatum TCC 1626	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.40 (0.17,0.71)	20	7	0.35	(0.18, 0.57)	7	0.35	(0.18, 0.57)	0.00	(-0.28, 0.28)
		1.64 (0.79, 3.39)	5	3	0.60	(0.23, 0.88)	4	0.80	(0.38, 1.00)	-0.20	(-0.62, 0.31)
Skimmed milk powder	*Salmonella* Infantis TCC 1650	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		0.76 (0.44, 1.26)	20	10	0.50	(0.30, 0.70)	10	0.50	(0.30, 0.70)	0.00	(-0.28, 0.28)
		4.37 (1.72, 11.15)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
Plastic surface	*Salmonella* Kentucky TCC 1653	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.45, 0.45)
		N/A	20	8	0.40	(0.22, 0.61)	8	0.40	(0.22, 0.61)	0.00	(-0.28, 0.28)
		N/A	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 9 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	13	0.65	(0.43, 0.82)	14	0.70	(0.48, 0.85)	-0.05	(-0.32, 0.23)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)
375g raw ground beef 24 h	*Salmonella* Ohio TCC 2135	N/A	5	0	0.00	(0.00, 0.43)	0	0.00	(0.00, 0.43)	0.00	(-0.43, 0.43)
		1.26 (0.79, 2.07)	20	13	0.65	(0.43, 0.82)	14	0.70	(0.48, 0.85)	-0.05	(-0.32, 0.23)
		3.00 (1.31, 6.89)	5	5	1.00	(0.57, 1.00)	5	1.00	(0.57, 1.00)	0.00	(-0.43, 0.43)

[a]MPN = Most Probable number is based on the POD of the reference method test portions using the Least Cost Formulations MPN calculator with 95% confidence interval.
[b]N = Number of test portions.
[c]X = Number of positive test portions.
[d]PODcc = Candidate method confirmed positive outcomes divided by the total number of portions.
[e]POD$_R$ = Reference method confirmation positive outcomes divided by the total number of portions.
[f]dPODcp = Difference between the candidate presumptive result and the candidate method confirmed result POD values.
[g]95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[h]N/A = Not applicable.

DISCUSSION OF MODIFICATION Approved April 2018

The reagents used in the PCR assay are provided to customers in a freeze-dried format (i.e. pellet) to improve the stability and ease-of-use of the assays. To minimize the exposure of the mixture to temperatures above freezing, the lyophilizer is cooled to -50°C prior to loading the plates in the instrument. By pre-cooling the instrument to -50°C the mixed reagents are spending ~30% less time at temperatures above freezing. The pre-cooling of the lyophilizer doesn't change the raw materials, composition or performance of the assays. The inclusivity and exclusivity of the assays remain the same as the primers and probes are not changed. Similarly, the assays´ sensitivity is unaffected as the formulation of the assays is unchanged. The only effect that the change has is that it improves the stability and robustness of the assays.

When the reaction for PCR step is prepared, the user pipettes lysate on top of the freeze-dried pellet containing the PCR reagents. To date no mixing has been applied after the pipetting step. Mixing with a table-top vortex was added to ensure that the reagents are properly dissolved and the solution homogenous. The mixing step of freeze-dried reagents and the lysate doesn't change the raw materials, composition or performance of the assays. The inclusivity and exclusivity of the assays remain the same as the primers and probes are not changed. Similarly, the assays´ sensitivity is unaffected as the formulation of the assays is unchanged. The only effect that the change has is that it improves the robustness of the assays.

DISCUSSION OF MODIFICATION Approved November 2018 (10)

Inclusivity and exclusivity

All 115 inclusivity isolates were successfully detected, and all 36 exclusivity isolates were correctly excluded by the candidate method, results are detailed in table 1 and table 2 respectively.

Matrix testing

Results for the SureTect Salmonella species PCR Assay using the QuantStudio 5 Real-Time PCR Instrument and associated RapidFinder Analysis Software are detailed in Tables 3–6.

For the plastic surface samples, the presumptive PCR results were the same for all three PCR cyclers used for analysis, therefore the results in tables 3 - 6 represent the results from the QuantStudio 5 PCR Instrument, 7500 Fast PCR Instrument, and the PikoReal PCR Instrument.

The raw ground beef and bagged lettuce matrices showed high level of background growth, therefore the candidate method samples underwent the additional confirmation step using a secondary RVS broth enrichment. This RVS broth enrichment was then streaked onto *Brilliance* Salmonella Agar and confirmed with biochemical tests as detailed in the IFU. The confirmation results from the secondary RVS broth step are detailed in tables 3–6.

During the testing for raw ground beef (24 hour enrichment incubation period), one sample was negative for the candidate presumptive PCR result. The sample was positive when confirmed via the reference method and the candidate method. Additionally when testing raw ground beef, a number of samples were negative after 9 hour enrichment but positive after 24 hour enrichment. This increase in the number of positive results between 9 hour and 24 hour enrichment was observed for all methods (reference method, candidate presumptive and candidate confirmed and candidate method confirmed).

For all matrices tested there were no statistically significant differences by POD analysis between the candidate methods (including presumptive results, and confirmed results via candidate and reference methods) and the reference method, or between the candidate presumptive result and the candidate method confirmed (via the candidate method and the reference method).

Table 1. Thermo Scientific SureTect Salmonella Inclusivity Results (10)

ID	Salmonella serotype	Group	Source	Origin	SureTect Salmonella result
2274	*Salmonella bongori*	66:z41:-	Frog	TCC	Positive
2275	*Salmonella bongori*	66:z41:-	Unknown	TCC	Positive
2402	*Salmonella bongori*	48:z35:-	Chicken egg	TCC	Positive
2398	*Salmonella bongori*	48:z35:-	Cheese	TCC	Positive
1996	*Salmonella enterica*	subsp salamae	Unknown	TCC	Positive
2217	*Salmonella enterica*	subsp salamae	Unknown	TCC	Positive
2270	*Salmonella enterica*	subsp salamae Canastel	Gastroenteritis	TCC	Positive
2353	*Salmonella enterica*	subsp salamae Tranoroa	NCTC 10252	TCC	Positive
2037	*Salmonella enterica*	subsp salamae Humber	Unknown	TCC	Positive
1995	*Salmonella enterica*	subsp arizoniae	Unknown	TCC	Positive
2267	*Salmonella enterica*	subsp arizoniae 11, 33:26:31	NCTC 10043b	TCC	Positive
2268	*Salmonella enterica*	subsp arizoniae	NCTC 10044	TCC	Positive
2034	*Salmonella enterica*	subsp diarizoniae	Unknown	TCC	Positive
2035	*Salmonella enterica*	subsp diarizoniae	Unknown	TCC	Positive
1997	*Salmonella enterica*	subsp diarizoniae	Unknown	TCC	Positive
2276	*Salmonella enterica*	subsp diarizoniae Eilbek 61:i:z	NCTC 10381	TCC	Positive
2032	*Salmonella enterica*	subsp houtenae	Boa constrictor	TCC	Positive
2033	*Salmonella enterica*	subsp houtenae	Unknown	TCC	Positive
2272	*Salmonella enterica*	subsp houtenae Wassenaar	Human infection	TCC	Positive
2038	*Salmonella enterica*	subsp houtane Seminole	Unknown	TCC	Positive
2269	*Salmonella enterica*	subsp indica Ferlac	Dessicated coconut	TCC	Positive

2271	*Salmonella enterica*	subsp indica Ferlac	NCTC 12420	TCC	Positive
2360	*Salmonella enterica*	subsp indica	ATCC BAA-1578	TCC	Positive
1612	*Salmonella enterica subsp enterica*	Aberdeen	Unknown	TCC	Positive
2296	*Salmonella enterica subsp enterica*	Abortusequi	Unknown	TCC	Positive
OCCC 2536	*Salmonella enterica subsp enterica*	Adelaide	RDCC 2122	OCC	Positive
1619	*Salmonella enterica subsp enterica*	Agona	Unknown	TCC	Positive
1621	*Salmonella enterica subsp enterica*	Alabama	NCTC 9868	TCC	Positive
1623	*Salmonella enterica subsp enterica*	Allerton	Unknown	TCC	Positive
1624	*Salmonella enterica subsp enterica*	Amherstiana	NCTC 6385	TCC	Positive
1625	*Salmonella enterica subsp enterica*	Amsterdam	Unknown	TCC	Positive
1626	*Salmonella enterica subsp enterica*	Anatum	Duck	TCC	Positive
2027	*Salmonella enterica subsp enterica*	Binza	Unknown	TCC	Positive
2001	*Salmonella enterica subsp enterica*	Bovis-Morbificans	Unknown	TCC	Positive
1630	*Salmonella enterica subsp enterica*	Braenderup	Unknown	TCC	Positive
1998	*Salmonella enterica subsp enterica*	Brandenberg	Unknown	TCC	Positive
2019	*Salmonella enterica subsp enterica*	Bredeney	Unknown	TCC	Positive
2287	*Salmonella enterica subsp enterica*	Breukelen	Cuscus	TCC	Positive
1632	*Salmonella enterica subsp enterica*	Cambridge	Gastroenteritis	TCC	Positive
2016	*Salmonella enterica subsp enterica*	Cerro	Unknown	TCC	Positive
1852	*Salmonella enterica subsp enterica*	Cholerasuis	Unknown	TCC	Positive
2031	*Salmonella enterica subsp enterica*	Colombo	Unknown	TCC	Positive
1633	*Salmonella enterica subsp enterica*	Corvallis	Unknown	TCC	Positive
2036	*Salmonella enterica subsp enterica*	Dahlem	Unknown	TCC	Positive
2008	*Salmonella enterica subsp enterica*	Derby	Unknown	TCC	Positive
802	*Salmonella enterica subsp enterica*	Dublin	Cattle	TCC	Positive
1634	*Salmonella enterica subsp enterica*	Dusseldorf	Gastroenteritis	TCC	Positive
1999	*Salmonella enterica subsp enterica*	Ealing	Unknown	TCC	Positive
2023	*Salmonella enterica subsp enterica*	Eastbourne	NCTC 3378	TCC	Positive
1692	*Salmonella enterica subsp enterica*	Emek	Unknown	TCC	Positive
1638	*Salmonella enterica subsp enterica*	Enteritidis	NCTC 3046	TCC	Positive
2288	*Salmonella enterica subsp enterica*	Florida	Unknown	TCC	Positive
1641	*Salmonella enterica subsp enterica*	Gallinarum	Unknown	TCC	Positive
1642	*Salmonella enterica subsp enterica*	Give	Unknown	TCC	Positive
1644	*Salmonella enterica subsp enterica*	Hadar	Unknown	TCC	Positive
2011	*Salmonella enterica subsp enterica*	Heidelberg	Unknown	TCC	Positive
1648	*Salmonella enterica subsp enterica*	Hindmarsh	Unknown	TCC	Positive
2297	*Salmonella enterica subsp enterica*	Ibadan	Unknown	TCC	Positive
2295	*Salmonella enterica subsp enterica*	Indiana	Turkey meat	TCC	Positive
1650	*Salmonella enterica subsp enterica*	Infantis	Unknown	TCC	Positive
2281	*Salmonella enterica subsp enterica*	Inverness	NCTC 10720	TCC	Positive
2291	*Salmonella enterica subsp enterica*	Javiana	Unknown	TCC	Positive
OCC 2474	*Salmonella enterica subsp enterica*	Kedougou	RDCC 3733	OCC	Positive
1653	*Salmonella enterica subsp enterica*	Kentucky	NCTC 5799	TCC	Positive
1654	*Salmonella enterica subsp enterica*	Kiel	Unknown	TCC	Positive
2004	*Salmonella enterica subsp enterica*	Kottbus	Unknown	TCC	Positive
1655	*Salmonella enterica subsp enterica*	Krefeld	Unknown	TCC	Positive
2021	*Salmonella enterica subsp enterica*	Lille	Unknown	TCC	Positive
2005	*Salmonella enterica subsp enterica*	Livingstone	Unknown	TCC	Positive
1656	*Salmonella enterica subsp enterica*	London	Unknown	TCC	Positive
2030	*Salmonella enterica subsp enterica*	Madelia	Chicken liver	TCC	Positive
2022	*Salmonella enterica subsp enterica*	Manchester	Unknown	TCC	Positive
2028	*Salmonella enterica subsp enterica*	Manila	Unknown	TCC	Positive
2010	*Salmonella enterica subsp enterica*	Mbandaka	Unknown	TCC	Positive

1657	*Salmonella enterica subsp enterica*	Montevideo	NCTC 5747	TCC	Positive
1658	*Salmonella enterica subsp enterica*	Moscow	NCTC 5768	TCC	Positive
1660	*Salmonella enterica subsp enterica*	Muenchen	Unknown	TCC	Positive
2024	*Salmonella enterica subsp enterica*	Napoli	Clinical isolate	TCC	Positive
1661	*Salmonella enterica subsp enterica*	Narashino	NCTC 5756	TCC	Positive
1663	*Salmonella enterica subsp enterica*	Newport	Unknown	TCC	Positive
1664	*Salmonella enterica subsp enterica*	Niloese	NCTC 5789	TCC	Positive
1693	*Salmonella enterica subsp enterica*	Nitra	Unknown	TCC	Positive
2000	*Salmonella enterica subsp enterica*	Ohio	Unknown	TCC	Positive
2015	*Salmonella enterica subsp enterica*	Oranienberg	Unknown	TCC	Positive
2026	*Salmonella enterica subsp enterica*	Orion	Asymptomatic food handler	TCC	Positive
1665	*Salmonella enterica subsp enterica*	Panama	Unknown	TCC	Positive
2277	*Salmonella enterica subsp enterica*	Pensacola	Clinical	TCC	Positive
1994	*Salmonella enterica subsp enterica*	Plymouth	Unknown	TCC	Positive
1988	*Salmonella enterica subsp enterica*	Pomona	Turkey intestine	TCC	Positive
1611	*Salmonella enterica subsp enterica*	Poona	Unknown	TCC	Positive
2029	*Salmonella enterica subsp enterica*	Pretoria	Pig liver and spleen	TCC	Positive
1666	*Salmonella enterica subsp enterica*	Pullorum	Unknown	TCC	Positive
2006	*Salmonella enterica subsp enterica*	Reading	Unknown	TCC	Positive
2285	*Salmonella enterica subsp enterica*	Rio-grande	Unknown	TCC	Positive
1667	*Salmonella enterica subsp enterica*	Rostock	NCTC 3747	TCC	Positive
2017	*Salmonella enterica subsp enterica*	Rubislaw	Unknown	TCC	Positive
2007	*Salmonella enterica subsp enterica*	Saint-Paul	Unknown	TCC	Positive
2018	*Salmonella enterica subsp enterica*	Senftenberg	Fecal sample	TCC	Positive
2025	*Salmonella enterica subsp enterica*	Shanghai	Unknown	TCC	Positive
1672	*Salmonella enterica subsp enterica*	Simsbury	Fecal sample	TCC	Positive
1673	*Salmonella enterica subsp enterica*	Stanley	NCTC 1705	TCC	Positive
1678	*Salmonella enterica subsp enterica*	Taksony	NCTC 6759	TCC	Positive
2293	*Salmonella enterica subsp enterica*	Tennessee	Unknown	TCC	Positive
2012	*Salmonella enterica subsp enterica*	Thompson	Unknown	TCC	Positive
1681	*Salmonella enterica subsp enterica*	Typhimurium	Gastroenteritis, NCTC 30481	TCC	Positive
1992	*Salmonella enterica subsp enterica*	Umbilo	Unknown	TCC	Positive
1990	*Salmonella enterica subsp enterica*	Urbana	NCTC 2428	TCC	Positive
2298	*Salmonella enterica subsp enterica*	Utrecht	Unknown	TCC	Positive
2290	*Salmonella enterica subsp enterica*	Vellore	Fecal sample	TCC	Positive
1890	*Salmonella enterica subsp enterica*	Virchow	Unknown	TCC	Positive
1685	*Salmonella enterica subsp enterica*	Wandsworth	Unknown	TCC	Positive
1686	*Salmonella enterica subsp enterica*	Westertede	Unknown	TCC	Positive
1690	*Salmonella enterica subsp enterica*	Zanzibar	Clinical	TCC	Positive
2610	*Salmonella enterica*	subsp arizoniae	FDA	TCC	Positive
2611	*Salmonella enterica*	subsp arizoniae	FDA	TCC	Positive

Table 2. Thermo Scientific SureTect Salmonella Exclusivity Results (10)

ID	*Isolate*	*Source*	*Origin*	SureTect Salmonella result
171	*Citrobacter freundii*	Unknown	TCC	Negative
181	*Citrobacter intermedius*	Unknown	TCC	Negative
2039	*Citrobacter koseri*	ATCC 25408	TCC	Negative
2043	*Citrobacter youngae*	Unknown	TCC	Negative
RDCC 2027	*Edwardsiella tarda*	Unknown	RDCC	Negative
2053	*Enterobacter sakazakii*	ATCC 29044	TCC	Negative
2200	*Enterobacter aerogenes*	HPA Colindale	TCC	Negative
2198	*Enterobacter amnigenus-Biogroup 1*	Unknown	TCC	Negative
401	*Enterobacter cloacae*	Unknown	TCC	Negative
409	*Pantoea agglomerans*	NCMIB 702072	TCC	Negative
1388	*Enterobacter faecalis*	Unknown	TCC	Negative
2203	*Enterobacter intermedius*	HPA Colindale	TCC	Negative
2273	*Escherichia blattae*	NCTC 10965	TCC	Negative
1809	*Escherichia coli*	ATCC 25922	TCC	Negative
OCC 1872	*Escherichia coli 0157:H7 VT neg*	Unknown	OCC	Negative
2047	*Escherichia hermanii*	Unknown	TCC	Negative
2264	*Escherichia vulneris*	Mixed herbs	TCC	Negative
2044	*Hafnia alvei*	Institut Pasteur	TCC	Negative
1804	*Klebsiella aerogenes*	Unknown	TCC	Negative
593	*Klebsiella oxytoca*	MDGH Scotland	TCC	Negative
1892	*Klebsiella pneumoniae*	Unknown	TCC	Negative
2207	*Klebsiella terrigena*	Water	TCC	Negative
1431	*Morganella morganii*	MDGH Scotland	TCC	Negative
1566	*Proteus mirabilis*	Unknown	TCC	Negative
1552	*Proteus vulgaris*	Unknown	TCC	Negative
2209	*Providencia alcalifaciens*	HPA Colindale	TCC	Negative
2201	*Providencia rettgeri*	HPA Colindale	TCC	Negative
418	*Providencia stuartii*	ATCC 33672	TCC	Negative
1903	*Pseudomonas aeruginosa*	NCTC 10662	TCC	Negative
2048	*Serratia liquifaciens*	Unknown	TCC	Negative
414	*Serratia marcescens*	Unknown	TCC	Negative
2050	*Shigella boydii*	Unknown	TCC	Negative
2052	*Shigella flexneri*	Unknown	TCC	Negative
2051	*Shigella sonnei*	Unknown	TCC	Negative
2215	*Yersinia enterocolitica*	Frozen prawn	TCC	Negative
2263	*Escherichia fergusonii*	Sausages	TCC	Negative

Table 3. SureTect Salmonella PCR Assay Results: candidate presumptive PCR result vs candidate method confirmed (via reference method) (10)

Matrix[a]	Inoculating strain(s)	MPN[b]/ test portion	N[c]	SureTect candidate presumptive PCR			SureTect candidate method confirmed via the reference method			dPOD$_{CPr}$[g]	95% CI[h]
				x[d]	POD$_{CP}$[e]	95% CI	x	POD$_{CR}$[f]	95% CI		
Raw Ground Beef (375 g) - 9 hours[l]	RDCC 2315 *Salmonella* Ohio	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1	20	8	0.40	0.22, 0.61	10	0.50	0.30, 0.70	-0.10	-0.37, 0.17
		1.1	5	3	0.60	0.23, 0.88	4	0.80	0.38, 1.00	-0.20	-0.62, 0.22
Raw Ground Beef (375 g) - 24 hours	RDCC 2315 *Salmonella* Ohio	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1	20	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.28, 0.28
		1.1	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Lettuce	TCC 1626 *Salmonella* Anatum	N/A[j]	5	0	0.00	0.00, 0.43	NR[k]	NR	NR	NR	NR
		0.3	20	5	0.25	0.11, 0.47	NR	NR	NR	NR	NR
		1.8	5	5	1.00	0.57, 1.00	NR	NR	NR	NR	NR
Skimmed Milk Powder	TCC 1650 *Salmonella* Infantis	N/A[j]	5	0	0.00	0.00, 0.43	NR	NR	NR	NR	NR
		1.5	20	15	0.75	0.53, 0.89	NR	NR	NR	NR	NR
		1.5	5	3	0.60	0.23, 0.88	NR	NR	NR	NR	NR
Plastic Surface Swabs (1 x 1")	OCC 722 *Salmonella* Typhimurium	N/A[j]	5	0	0.00	0.00, 0.43	NR	NR	NR	NR	NR
		N/A	20	5	0.25	0.11, 0.47	NR	NR	NR	NR	NR
		N/A	5	3	0.60	0.23, 0.88	NR	NR	NR	NR	NR
Plastic Surface Sponges (4 x 4")	TCC 1653 *Salmonella* Kentucky	N/A[j]	5	0	0.00	0.00, 0.28	NR	NR	NR	NR	NR
		N/A	20	5	0.25	0.11, 0.47	NR	NR	NR	NR	NR
		N/A	5	5	1.00	0.57, 1.00	NR	NR	NR	NR	NR

[a] Matrix = for the stainless steel surface matrices the data is shown combined for PikoReal, 7500 Fast and QuantStudio 5 PCR instruments.
[b] MPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.
[c] N = Number of test portions.
[d] x = Number of positive test portions.
[e] POD$_{CP}$ = Candidate presumptive PCR positive outcomes divided by the total number of trials.
[f] POD$_{CR}$ = Candidate method confirmed (via reference method) positive outcomes divided by the total number of trials.
[g] dPOD$_{CPr}$ = Difference between the candidate presumptive and candidate confirmed (via reference method) results.
[h] 95% CI = If the confidence interval (CI) of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[j] N/A = Not applicable.
[k] NR = Not reported. The candidate confirmation method for these matrices is paired with the reference method.
[l] 9 hour candidate presumptive results compared to the 24 hour candidate confirmed results.

Table 4. SureTect Salmonella PCR Assay Results: candidate presumptive PCR result vs candidate method confirmed (via candidate method) (10)

Matrix[a]	Inoculating strain(s)	MPN[b]/ test portion	N[c]	SureTect candidate presumptive PCR			SureTect candidate method confirmed via the candidate method			dPOD$_{CPc}$[g]	95% CI[h]
				x[d]	POD$_{CP}$[e]	95% CI	x	POD$_{R}$[f]	95% CI		
Raw Ground Beef (375 g) - 9 hours[l]	RDCC 2315 *Salmonella* Ohio	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1	20	8	0.40	0.22, 0.61	10	0.50	0.30, 0.70	-0.10	-0.37, 0.17
		1.1	5	3	0.60	0.23, 0.88	4	0.80	0.38, 1.00	-0.20	-0.62, 0.22
Raw Ground Beef (375 g) - 24 hours	RDCC 2315 *Salmonella* Ohio	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1	20	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.28, 0.28
		1.1	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Lettuce	TCC 1626 *Salmonella* Anatum	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.3	20	5	0.25	0.11, 0.47	5	0.25	0.11, 0.47	0.00	-0.26, 0.26
		1.8	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Skimmed Milk Powder	TCC 1650 *Salmonella* Infantis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.5	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.28, 0.28
		1.5	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Plastic Surface Swabs (1 x 1")	OCC 722 *Salmonella* Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		N/A	20	5	0.25	0.11, 0.47	5	0.25	0.11, 0.47	0.00	-0.26, 0.26
		N/A	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Plastic Surface Sponges (4 x 4")	TCC 1653 *Salmonella* Kentucky	N/A	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.28, 0.28
		N/A	20	5	0.25	0.11, 0.47	5	0.25	0.11, 0.47	0.00	-0.26, 0.25
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 1.00

[a] Matrix = for the stainless steel surface matrices the data is shown combined for PikoReal, 7500 Fast and QuantStudio 5 PCR instruments.
[b] MPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.
[c] N = Number of test portions.
[d] x = Number of positive test portions.
[e] POD$_{CP}$ = Candidate presumptive PCR positive outcomes divided by the total number of trials.
[f] POD$_{CR}$ = Candidate method confirmed (via candidate method) positive outcomes divided by the total number of trials.
[g] dPOD$_{CPc}$ = Difference between the candidate presumptive and candidate confirmed (via candidate method) results.
[h] 95% CI = If the confidence interval (CI) of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[j] N/A = Not applicable.
[l] 9 hour candidate presumptive results compared to the 24 hour candidate confirmed results.

Table 5. SureTect Salmonella PCR Assay Results: candidate method confirmed (via the candidate method) vs Reference method POD summary (10)

Matrix[a]	Inoculating strain(s)	MPN[b]/ test portion	N[c]	SureTect candidate method confirmed via the candidate method			Reference method			dPOD$_{CC}$[g]	95% CI[h]
				x[d]	POD$_{CC}$[e]	95% CI	x	POD$_R$[f]	95% CI		
Raw Ground Beef (375 g) - 9 hours[i]	RDCC 2315 *Salmonella* Ohio	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1	20	8	0.40	0.22, 0.61	12	0.60	0.39, 0.78	-0.20	-0.46, 0.10
		1.1	5	3	0.60	0.23, 0.88	4	0.80	0.38, 1.00	-0.20	-0.62, 0.31
Raw Ground Beef (375 g) - 24 hours	RDCC 2315 *Salmonella* Ohio	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1	20	10	0.50	0.30, 0.70	12	0.60	0.39, 0.78	-0.10	-0.37, 0.19
		1.1	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Lettuce	TCC 1626 *Salmonella* Anatum	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.3	20	5	0.25	0.11, 0.47	6	0.30	0.15, 0.52	-0.05	-0.31, 0.22
		1.8	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Skimmed Milk Powder	TCC 1650 *Salmonella* Infantis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.5	20	15	0.75	0.53, 0.89	16	0.80	0.58, 0.92	-0.05	-0.30, 0.21
		1.5	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Plastic Surface Swabs (1 x 1")	OCC 722 *Salmonella* Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		N/A	20	5	0.25	0.11, 0.47	5	0.25	0.11, 0.47	0.00	-0.26, 0.26
		N/A	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Plastic Surface Sponges (4 x 4")	TCC 1653 *Salmonella* Kentucky	N/A	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.28, 0.28
		N/A	20	5	0.25	0.11, 0.47	5	0.25	0.11, 0.47	0.00	-0.26, 0.26
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

[a] Matrix = for the stainless steel surface matrices the data is shown combined for PikoReal, 7500 Fast and QuantStudio 5 PCR instruments.

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

[c] N = Number of test portions.

[d] x = Number of positive test portions.

[e] POD$_{CC}$ = Candidate method confirmed via the candidate method positive outcomes divided by the total number of trials.

[f] POD$_R$ = Reference method divided by the total number of trials.

[g] dPOD$_{CC}$ = Difference between the candidate method presumptive result and candidate method confirmed result POD values.

[h] 95% CI = If the confidence interval (CI) of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.

[j] N/A = Not applicable.

[i] 9 hour presumptive results compared to the reference method results.

Table 6. SureTect Salmonella PCR Assay Results: candidate method confirmed (via the reference method) vs Reference method POD summary (10)

Matrix[a]	Inoculating strain(s)	MPN[b]/ test portion	N[c]	SureTect candidate method confirmed via the reference method			Reference method			dPOD$_{CR}$[g]	95% CI[h]
				x[d]	POD$_{CR}$[e]	95% CI	x	POD$_R$[f]	95% CI		
Raw Ground Beef (375 g) - 9 hours[l]	RDCC 2315 *Salmonella* Ohio	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1	20	8	0.40	0.22, 0.61	12	0.60	0.39, 0.78	-0.20	-0.46, 0.10
		1.1	5	3	0.60	0.23, 0.88	4	0.80	0.38, 1.00	-0.20	-0.62, 0.31
Raw Ground Beef (375 g) - 24 hours	RDCC 2315 *Salmonella* Ohio	N/A[j]	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1	20	10	0.50	0.30, 0.70	12	0.60	0.39, 0.78	-0.10	-0.37, 0.19
		1.1	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Lettuce	TCC 1626 *Salmonella* Anatum	N/A[j]	5	NR[k]	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.3	20	NR	NR	NR	6	0.30	0.15, 0.52	NR	NR
		1.8	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Skimmed Milk Powder	TCC 1650 *Salmonella* Infantis	N/A[j]	5	NR[k]	NR	NR	0	0.00	0.00, 0.43	NR	NR
		1.5	20	NR	NR	NR	16	0.80	0.58, 0.92	NR	NR
		1.5	5	NR	NR	NR	3	0.60	0.23, 0.88	NR	NR
Plastic Surface Swabs (1 x 1")	OCC 722 *Salmonella* Typhimurium	N/A[j]	5	NR[k]	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	5	0.25	0.11, 0.47	NR	NR
		N/A	5	NR	NR	NR	3	0.60	0.23, 0.88	NR	NR
Plastic Surface Sponges (4 x 4")	TCC 1653 *Salmonella* Kentucky	N/A[j]	5	NR[k]	NR	NR	0	0.00	0.00, 0.28	NR	NR
		N/A	20	NR	NR	NR	5	0.25	0.11, 0.47	NR	NR
		N/A	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR

[a] Matrix = for the stainless steel surface matrices the data is shown combined for PikoReal, 7500 Fast and QuantStudio 5 PCR instruments.
[b] MPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.
[c] N = Number of test portions.
[d] x = Number of positive test portions.
[e] POD$_{CR}$ = Candidate method confirmed (via reference method) positive outcomes divided by the total number of trials.
[f] POD$_R$ = Reference method positive outcomes divided by the total number of trials.
[g] dPOD$_{CR}$ = Difference between the candidate method confirmed via the reference method and the reference method.
[h] 95% CI = If the confidence interval (CI) of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[j] N/A = Not applicable.
[k] NR = Not reported. The candidate confirmation method for these matrices is paired with the reference method (ISO 6579-1:2017).
[l] 9 hour presumptive results compared to the reference method results.

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