



CERTIFICATION

AOAC Research Institute

Performance Tested MethodsSM

Certificate No.
081701

The AOAC Research Institute hereby certifies the method known as:

Thermo Scientific™ RapidFinder™ Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit

manufactured by

**Oxford Ltd part of Thermo Fisher Scientific
Wade Rd
Basingstoke, Hampshire
RG24 8PW, UK**

This method has been evaluated in the AOAC Research Institute *Performance Tested Methods*SM Program and found to perform as stated in the applicability of the method. This certificate indicates an AOAC Research Institute Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC Research Institute *Performance Tested Methods*SM certification mark on the above-mentioned method for the period below. Renewal may be granted by the Expiration Date under the rules stated in the licensing agreement.

Bradley A. Sturz

Bradley A. Stawick, Senior Director
Signature for AOAC Research Institute

Issue Date

Expiration Date

January 25, 2024

December 31, 2024

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MODIFICATION OCTOBER 2020 RFA v1.1: Ana-Maria Leonte, Jessica Williams, Marian Teye, Heini Miranto, Laura Vaahtoranta

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SUBMITTING COMPANY

Oxoid Ltd. part of Thermo Fisher Scientific
Wade Rd
Basingstoke, Hampshire
RG24 8PW, UK

METHOD NAMES

Thermo Scientific™ RapidFinder™ Salmonella species, Typhimurium and

Enteritidis Multiplex PCR Kit

Formerly known as Thermo Scientific™ Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit

CATALOG NUMBERS

A33227, A22337KF, A56846, A56847

INDEPENDENT LABORATORY

Q Laboratories, Inc.

1400 Harrison Avenue

Cincinnati, OH 45214 USA

APPLICABILITY OF METHOD

Target Organism – *Salmonella* species, *Salmonella* ser. Typhimurium, and *Salmonella* ser. Enteritidis

Matrixes – (MLG 4.09) (25 g) - raw chicken thighs with skin, raw chicken wings with skin, chicken nuggets, raw pork sausage

(BAM Ch. 5) stainless steel environmental surface (4in x 4in sponge)

MODIFICATION May 2018:

(MLG 4.09) – raw ground turkey (375 g), chicken carcass rinse

(BAM Ch. 5) – shell eggs

REFERENCE METHODS

U.S. Department of Agriculture Food Safety and Inspection Service *Microbiology Laboratory Guidebook 4.09 (2017). Isolation and Identification of Salmonella from Meat, Poultry, Pasteurized Egg, and Siluriformes (Fish) Products and Carcass and Environmental Sponges Revision .09. (2)*

U.S. Food and Drug Administration Bacteriological Analytical Manual Chapter 5: *Salmonella*. (2016) (3)

Performance claims – Method is not significantly different from the reference methods.

ORIGINAL CERTIFICATION DATE

August 18, 2017

CERTIFICATION RENEWAL RECORD

Renewed annually through December 2024.

METHOD MODIFICATION RECORD

1. May 2018 Level 3
2. December 2018 Level 1
3. November 2019 Level 1
4. October 2020 Level 2
5. October 2020 Level 2
6. July 2022 Level 2
7. December 2022 Level 1
8. January 2024 Level 1
9. January 2024 Level 2

SUMMARY OF MODIFICATION

1. Matrix extension; validation of Thermo Scientific™ RapidFinder™ Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit.
2. Edits to include changes from matrix extension (May 2018).
3. Editorial/clerical changes for clarity.
4. Modification to upgrade the software for Thermo Scientific RapidFinder Analysis (RFA) PCR software to v1.1 (designed for use with the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR).
5. Modification to upgrade the software for the Applied Biosystems™ RapidFinder™ Express (RFE) to v2.0 (designed for use with the Applied Biosystems™ 7500 Fast™ Real-Time PCR).
6. Changes made to improve handling steps and visual indicators.
7. Editorial changes to Manual resulting from approval of July 2022 Level 2 modification.
8. Editorial/clerical changes.
9. Addition of automated lysis procedure and PCR setup procedure.

Under this AOAC Performance Tested MethodsSM License Number, 081701 this method is distributed by:
NONE

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NONE

Thermocyclers characteristics to run the Real-Time PCR:

1. Applied Biosystems™ 7500 Fast Real-Time PCR Instrument and equivalents manufactured by Thermo Fisher Scientific and/or subsidiaries with the following characteristics

Characteristics	7500 Fast Real-Time PCR Instrument
Optics	12v 75w halogen bulb
Filters	5 excitation and 5 emission filters
Sample ramp rate	Standard mode: $\pm 1.6^{\circ}\text{C/sec}$ Fast mode: $\pm 3.5^{\circ}\text{C/sec}$
Thermal range	4-100°C
Thermal accuracy	$\pm 0.5^{\circ}\text{C}$
Thermal uniformity	$\pm 1^{\circ}\text{C}$
Format	96-well, 0.1-mL block

2. Applied Biosystems™ QuantStudio™ 5 Real-Time PCR Instrument and equivalents manufactured by Thermo Fisher Scientific and/or subsidiaries with the following characteristics

Characteristics	QuantStudio™ 5 Real-Time PCR Instrument
Optics	Bright white LED
Filters	6 excitation and 6 emission filters
Sample ramp rate	Average: 3.66°C/sec Maximum: 9.0°C/sec
Thermal range	4-99°C
Thermal accuracy	$\pm 0.25^{\circ}\text{C}$
Thermal uniformity	$\pm 0.4^{\circ}\text{C}$
Format	96-well, 0.1-mL block

PRINCIPLE OF THE METHOD (1)

The RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit is a real-time PCR test intended to be used in conjunction with both the Applied Biosystems™ 7500 Fast Real-Time PCR instrument and associated Applied Biosystems RapidFinder™ Express software (version 2.0 or higher) and the Applied Biosystems™ QuantStudio™ 5 Real-Time PCR instrument and associated Applied Biosystems RapidFinder Analysis software (version 1.0) for the detection and differentiation of *Salmonella* species, *S. Typhimurium* and *S. Enteritidis* from poultry and pork meat and production environmental samples (3).

The assay is supplied as a kit containing all necessary reagents to conduct the sample lysis, including prefilled Lysis Tubes and lyophilized 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 *S. Typhimurium* and/or *S. Enteritidis* and/or species are present, the target DNA sequences will be amplified and the increasing fluorescent signal generated will be detected either by the 7500 Fast Real-Time PCR instrument and interpreted by the RapidFinder Express software or by the QuantStudio 5 Real-Time PCR instrument and interpreted by the RapidFinder Analysis software.

In addition to detection of any target DNA, the RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR pellets contain probe, primers, and DNA templates for an internal positive control (IPC). During PCR cycling, the IPC template is amplified whether any target DNA is present or not. The probe used for the IPC is labelled with a different coloured fluorescent dye to the probes used within the assay to detect target DNA, and so can be detected by either the 7500 Fast Real-Time PCR instrument or QuantStudio 5 Real-Time PCR instrument through a separate dye channel. The result is that after a successful PCR run, the instrument will detect amplification of the IPC DNA sequence. If no target DNA is detected by the assay, the presence of the IPC amplification curve confirms that the PCR process has occurred successfully.

The PCR probes used in the RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit are based on TaqMan chemistry. Results from this assay system are achieved in 50 minutes after the prepared sample is loaded into either the 7500 Fast Real-Time PCR instrument or QuantStudio 5 Real-Time PCR instrument and is 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 RapidFinder Express software or RapidFinder Analysis software can be stored, printed, or downloaded by the user, as required.

DISCUSSION OF THE VALIDATION STUDY (1)

The data presented in this report support the product claims that the RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit is suitable for the detection and differentiation of *Salmonella* species, *Salmonella* ser. Typhimurium, and *Salmonella* ser. Enteritidis from raw chicken thighs with skin, raw chicken wings with skin, chicken nuggets, raw pork sausage and stainless steel environmental surface sponges. POD analysis conducted during the validation study demonstrated there were no statistically significant differences between the RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit and the reference methods. Where there were statistically significant differences, these were in favor of the RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit. Additional studies conducted as part of this validation show that the assay detected all *Salmonella* spp. tested and correctly identified all *S. Typhimurium* and *S. Enteritidis* strains tested. The method was negative for all non-*Salmonella* species analysed. The RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit has shown good reproducibility and although real-time stability studies are ongoing, accelerated stability studies have proven to assay to remain stable throughout the proposed one-year shelf life.

Table 1. Inclusivity of the Thermo Scientific RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit (1)

ID number	<i>Salmonella</i> serotype	Group/ comments	Source	Origin	Results - 7500 Fast			Results – QuantStudio 5		
					<i>Salmonella</i> spp. result	<i>Salmonella</i> Enteritidis result	<i>Salmonella</i> Typhimurium result	<i>Salmonella</i> spp. result	<i>Salmonella</i> Enteritidis result	<i>Salmonella</i> Typhimurium result
1726	<i>Salmonella</i> Uphill	II 42:b:e,n,x,z ₁₅	RDCC ^a	unknown ^b	Positive	Negative	Negative	Positive	Negative	Negative
2355	<i>Salmonella</i> Donna	II 53:z ₄ ,z ₂₄ :-	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2830	<i>Salmonella</i> Locarno	II 57:z ₂₉ :z ₄₂	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 10252	<i>Salmonella</i> Tranaroa	II 55:k:z ₃₉	NCTC ^c	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2599	<i>Salmonella</i> salamae	II 58:l,z ₁₃ ,z ₂₈ :z ₆	TCC ^d	unknown	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 8297	<i>Salmonella</i> arizoniae	IIIa 51:z ₄ ,z ₂₃ :-	NCTC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2389	<i>Salmonella</i> arizoniae	S 24, 223:-	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2608	<i>Salmonella</i> arizoniae	IIIa 41:z ₄ ,z ₂₃ :-	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2609	<i>Salmonella</i> arizoniae	IIIa 40:z ₄ ,z ₂₃ :-	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2610	<i>Salmonella</i> arizoniae	IIIa 48:g,z ₅₁ :-	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2386	<i>Salmonella</i> diarizonae	61:k:1,5,7	TCC	Clinical	Positive	Negative	Negative	Positive	Negative	Negative
2388	<i>Salmonella</i> diarizonae	38:l,v:z ₅₃	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2616	<i>Salmonella</i> diarizonae	IIIb 60:r:e,n,x,z ₁₅	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2617	<i>Salmonella</i> diarizonae	IIIb 48:i:z	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2618	<i>Salmonella</i> diarizonae	IIIb 61:k:1,5,(7)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3732	<i>Salmonella</i> houtenae	51:z ₄ ,z ₂₃ :-	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2624	<i>Salmonella</i> houtenae	IV 50:g,z ₅₁ :-	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2625	<i>Salmonella</i> houtenae	IV 48:g,z ₅₁ :-	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2626	<i>Salmonella</i> houtenae	IV 44:z ₄ ,z ₂₃ :-	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2627	<i>Salmonella</i> houtenae	IV 45:g,z ₅₁ :-	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2360	<i>Salmonella</i> indica	45:a:e,n,x	OCC ^e	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2643	<i>Salmonella</i> indica	VI 11:a:1,5	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2640	<i>Salmonella</i> indica	VI 6,14,25:z10:1,(2),7	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2641	<i>Salmonella</i> indica	VI 11:b:1,7	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2642	<i>Salmonella</i> indica	VI 6,7:z41:1,7	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 2215	<i>Salmonella</i> bongori	unkown	NCTC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 12419	<i>Salmonella</i> bongori	66:z41:-	NCTC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3407	<i>Salmonella</i> Stanley	Group O:4 (B)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
5096	<i>Salmonella</i> Abony	Group O:4 (B)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2150	<i>Salmonella</i> Saintpaul	Group O:4 (B)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3377	<i>Salmonella</i> Heidelberg	Group O:4 (B)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2358	<i>Salmonella</i> Agona	Group O:4 (B)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2839	<i>Salmonella</i> Brandenburg	Group O:4 (B)	RDCC	Clinical	Positive	Negative	Negative	Positive	Negative	Negative
2840	<i>Salmonella</i> Indiana	Group O:4 (B)	RDCC	Turkey	Positive	Negative	Negative	Positive	Negative	Negative
2296	<i>Salmonella</i> Abortus-equi	Group O:4 (B)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3016	<i>Salmonella</i> Abortusovis	Group O:4 (B)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3017	<i>Salmonella</i> Schwarzengrund	Group O:4 (B)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3018	<i>Salmonella</i> Stanleyville	Group O:4 (B)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3019	<i>Salmonella</i> Sandiego	Group O:4 (B)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3381	<i>Salmonella</i> Bredeney	Group O:4 (B)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative

30151	<i>Salmonella</i> Java	Group O:4 (B)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
30020	<i>Salmonella</i> Paratyphi B	Group O:4 (B)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3399	<i>Salmonella</i> Dublin	Group O:9 (D ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 3747	<i>Salmonella</i> Rostock	Group O:9 (D ₁)	NCTC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
1774	<i>Salmonella</i> Gallinarum	Group O:9 (D ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 9868	<i>Salmonella</i> Alabama	Group O:9 (D ₁)	NCTC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3024	<i>Salmonella</i> Miami	Group O:9 (D ₁)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3025	<i>Salmonella</i> Lomalinda	Group O:9 (D ₁)	TCC	Clinical	Positive	Negative	Negative	Positive	Negative	Negative
3026	<i>Salmonella</i> Israel	Group O:9 (D ₁)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3027	<i>Salmonella</i> Portland	Group O:9 (D ₁)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3028	<i>Salmonella</i> Sendai	Group O:9 (D ₁)	TCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2129	<i>Salmonella</i> Napoli	Group O:9 (D ₁)	RDCC	Clinical	Positive	Negative	Negative	Positive	Negative	Negative
2138	<i>Salmonella</i> Gallinarum	Group O:9 (D ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2139	<i>Salmonella</i> Eastbourne	Group O:9 (D ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2146	<i>Salmonella</i> Javiana	Group O:9 (D ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2360	<i>Salmonella</i> Berta	Group O:9 (D ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
30001	<i>Salmonella</i> Typhi	Group O:9 (D ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
1654	<i>Salmonella</i> Kiel	Group O:2 (A)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2135	<i>Salmonella</i> Ohio	Group O:7 (C ₁)	RDCC	Clinical	Positive	Negative	Negative	Positive	Negative	Negative
2359	<i>Salmonella</i> Montevideo	Group O:7 (C ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2351	<i>Salmonella</i> Virchow	Group O:7 (C ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3400	<i>Salmonella</i> Infantis	Group O:7 (C ₁)	RDCC	Clinical	Positive	Negative	Negative	Positive	Negative	Negative
3402	<i>Salmonella</i> Bovis	Group O:8 (C ₂ -C ₃)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2125	<i>Salmonella</i> Albany	Group O:8 (C ₂ -C ₃)	RDCC	Clinical	Positive	Negative	Negative	Positive	Negative	Negative
2001	<i>Salmonella</i> Bovis-Morbificans	Group O:8 (C ₂ -C ₃)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3734	<i>Salmonella</i> Kentucky	Group O:8 (C ₂ -C ₃)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2087	<i>Salmonella</i> Newport	Group O:8 (C ₂ -C ₃)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2130	<i>Salmonella</i> Muenchen	Group O:8 (C ₂ -C ₃)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2131	<i>Salmonella</i> Hadar	Group O:8 (C ₂ -C ₃)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2132	<i>Salmonella</i> Shanghai	Group O:3,10 (E ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
1623	<i>Salmonella</i> Allerton	Group O:3,10 (E ₁)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2683	<i>Salmonella</i> Muenster	Group O:3,10 (E ₁)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2210	<i>Salmonella</i> Seftenburg	Group O:1,3,19 (E ₄)	RDCC	Feces	Positive	Negative	Negative	Positive	Negative	Negative
1655	<i>Salmonella</i> Krefeld	Group O:1,3,19 (E ₄)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
1612	<i>Salmonella</i> Aberdeen	Group O:11 (F)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3739	<i>Salmonella</i> Rubislaw	Group O:11 (F)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3405	<i>Salmonella</i> Poona	Group O:13 (G)	RDCC	Clinical, gastro-enteritis	Positive	Negative	Negative	Positive	Negative	Negative
2831	<i>Salmonella</i> Ibdam	Group O:13 (G)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
3736	<i>Salmonella</i> Madelia	Group O:6,14 (H)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2453	<i>Salmonella</i> Schalkwijk	Group O:6,14	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative

		(H)								
2671	<i>Salmonella</i> Saphra	Group O:16 (I)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2362	<i>Salmonella</i> Huttingfoss	Group O:16 (I)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2673	<i>Salmonella</i> Michigan	Group O:17 (J)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2127	<i>Salmonella</i> Cerro	Group O:18 (K)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2679	<i>Salmonella</i> Brisbane	Group O:28 (M)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2100	<i>Salmonella</i> Urbana	Group O:30 (N)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2356	<i>Salmonella</i> Matopeni	Group O:30 (N)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2122	<i>Salmonella</i> Adelaide	Group O:35 (O)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2690	<i>Salmonella</i> Alachua	Group O:35 (O)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2120	<i>Salmonella</i> Inverness	Group O:38 (P)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2118	<i>Salmonella</i> Champaign	Group O:39 (Q)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
5372	<i>Salmonella</i> Riogrande	Group O:40 (R)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2685	<i>Salmonella</i> Johannesburg	Group O:40 (R)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2675	<i>Salmonella</i> Vietnam	Group O:41 (S)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2677	<i>Salmonella</i> Gera	Group O:42 (T)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2937	<i>Salmonella</i> Berkeley	Group O:43 (U)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2676	<i>Salmonella</i> Tornow	Group O:45 (W)	OCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
1728	<i>Salmonella</i> Teshi	Group O:47 (X)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
30017	<i>Salmonella</i> Paratyphi A	Group O:2 (A)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
30026	<i>Salmonella</i> Paratyphi C	Group O:7 (C ₁)	RDCC	unknown	Positive	Negative	Negative	Positive	Negative	Negative
2207	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	RDCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
3379	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	RDCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
3729	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	RDCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
3900	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	RDCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
723	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	OCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
1637	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
1638	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
1639	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
1640	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
1986	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
2424	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
2425	<i>Salmonella</i> Enteritidis	9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
2426	<i>Salmonella</i> Enteritidis	9,12:g,m:- (D ₁)	TCC	Guinea pig	Positive	Positive	Negative	Positive	Positive	Negative
2443	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	Raw almonds	Positive	Positive	Negative	Positive	Positive	Negative
2450	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	Clinical, gastroenteritis	Positive	Positive	Negative	Positive	Positive	Negative
2591	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
2668	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
2669	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
2670	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
3372	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	RDCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
3378	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	RDCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative

3383	<i>Salmonella</i> Enteritidis var. Dansyz	1,9,12:g,m:- (D ₁)	RDCC	Clinical, gastroenteritis	Positive	Positive	Negative	Positive	Positive	Negative
1584	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	TCC	unknown	Positive	Positive	Negative	Positive	Positive	Negative
ATCC BAA 1587	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	ATCC ^f	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 10155.1	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL ^g	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 10170.1	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 14255.2	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.40	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.80	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.121	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.184	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.185	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.186	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.278	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.279	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.280	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 1698878.3	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 175599.1	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 182282	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Negative	Negative	Positive	Negative	Negative
QL 182282 (retest) ^h	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 188498.1	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 191569.1	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
QL 194559.3 (IPC failed run) ^j	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Negative	Positive	Negative	Positive	Positive	Negative
QL 194559.3 (retest) ^j	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Positive	Positive	Positive	Negative
CCUG 9563	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 21288	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 25340	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 26522	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 27004	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 27021	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Positive	Positive	Positive	Negative
CCUG 27021 (retest) ^k	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	n/a	n/a	n/a
FSL S5-415	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
FSL S5-483	<i>Salmonella</i> Enteritidis	1,9,12:g,m:- (D ₁)	QL	unknown	Positive	Positive	Negative	Positive	Positive	Negative
962	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive

1793	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2124	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2836	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
3380	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
3384	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
3740	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
3741	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
3897	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	Tissue, animal	Positive	Negative	Positive	Positive	Negative	Positive
3920	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	Dairy (Tiramisu)	Positive	Negative	Positive	Positive	Negative	Positive
3922	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	Chocolate	Positive	Negative	Positive	Positive	Negative	Positive
3924	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	Cocoa beans	Positive	Negative	Positive	Positive	Negative	Positive
4669	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
1585	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
1679	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
1680	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
1681	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	Clinical, gastroenteritis	Positive	Negative	Positive	Positive	Negative	Positive
1683	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
1684	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	RDCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
1880	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2387	<i>Salmonella</i> Typhimurium	1,4,5,12:i:- (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2390	<i>Salmonella</i> Typhimurium	1, 4, 5, 12: - :- (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
ATCC 19585	<i>Salmonella</i> Typhimurium	1,4,5,12 i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
ATCC BAA-1603	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	Tomato	Positive	Negative	Positive	Positive	Negative	Positive
2461	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	Feces	Positive	Negative	Positive	Positive	Negative	Positive
2593	<i>Salmonella</i> Typhimurium	4,5,12:l:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2645	<i>Salmonella</i> Typhimurium	DT104b	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2646	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2647	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2648	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2649	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2650	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2651	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2652	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2653	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2654	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2655	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2656	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2657	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2658	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2659	<i>Salmonella</i> Typhimurium/ DT104	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive

2660	<i>Salmonella</i> Typhimurium/ DT104	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
2661	<i>Salmonella</i> Typhimurium/ DT104	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
1586	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	TCC	unknown	Positive	Negative	Positive	Positive	Negative	Positive
11007-2	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	QL	unknown	Positive	Negative	Positive	Positive	Negative	Positive
11414-2	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	QL	unknown	Positive	Negative	Positive	Positive	Negative	Positive
16078-2A.110	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	QL	unknown	Positive	Negative	Positive	Positive	Negative	Positive
16078-2A.112	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	QL	unknown	Positive	Negative	Positive	Positive	Negative	Positive
16078-2A.1	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	QL	unknown	Positive	Negative	Positive	Positive	Negative	Positive
16078-2A.108	<i>Salmonella</i> Typhimurium	1,4,5,12:i:1,2 (B)	QL	unknown	Positive	Negative	Positive	Positive	Negative	Positive

^a RDCC = Research and Development culture collection – Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.

^b Unknown = Origin of the strain is not listed or provided by the source.

^c NCTC = National Collection of Type Cultures, Health Protection Agency, London, UK.

^dTCC = Trials Culture Collection Number-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.

^aTCC = Thermo Culture Collection Number; ^bProprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK
^cOCC = Oxoid Culture Collection-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK

^f ATCC = American Type Culture Collection, Manassas, Virginia, USA

^g QI = number proprietary to Q Laboratories LLC, Cincinnati, Ohio, USA.

^b Retest results for isolate QL-182282.

First results for isolate QL 1045E0-2 which had an IBC failure

/ First results for isolate QL 194559.3 which had an IPC failure.
/ Retest results for isolate 194559.3 - original test had an IPC failure.

^b Retest results for isolate 194559.3, original test had an IPC failure.

Table 2. Exclusivity of the Thermo Scientific RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit (1)

2273	<i>Escherichia blattae</i>	TCC	Cockroach gut	Negative	Negative	Negative	Negative	Negative	Negative
2050	<i>Shigella boydii</i>	TCC	unknown	Negative	Negative	Negative	Negative	Negative	Negative
2051	<i>Shigella sonnei</i>	TCC	Clinical	Negative	Negative	Negative	Negative	Negative	Negative
2052	<i>Shigella flexneri</i>	TCC	unknown	Negative	Negative	Negative	Negative	Negative	Negative
1872	<i>Escherichia coli</i> O157:H7 VT neg	OCC ^c	unknown	Negative	Negative	Negative	Negative	Negative	Negative
35029	<i>Enterobacter aerogenes</i>	ATCC ^d	unknown	Negative	Negative	Negative	Negative	Negative	Negative
8739	<i>Escherichia coli</i>	ATCC	Faeces	Negative	Negative	Negative	Negative	Negative	Negative
51815	<i>Hafnia alvei</i>	ATCC	Milk	Negative	Negative	Negative	Negative	Negative	Negative
4352	<i>Klebsiella pneumoniae</i>	ATCC	Cow's milk	Negative	Negative	Negative	Negative	Negative	Negative
25829	<i>Morganella morganii</i>	ATCC	Faeces	Negative	Negative	Negative	Negative	Negative	Negative
6380	<i>Proteus vulgaris</i>	ATCC	unknown	Negative	Negative	Negative	Negative	Negative	Negative
9027	<i>Pseudomonas aeruginosa</i>	ATCC	Clinical	Negative	Negative	Negative	Negative	Negative	Negative
13880	<i>Serratia marcescens</i>	ATCC	Water	Negative	Negative	Negative	Negative	Negative	Negative
49397	<i>Yersinia enterocolitica</i>	ATCC	Clinical	Negative	Negative	Negative	Negative	Negative	Negative

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

^b Unknown = Origin of the strain is not listed or provided by the source.^c OCC = Oxoid Culture Collection-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.

^d ATCC = American Type Culture Collection, Manassas, Virginia, USA.

Table 3. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with AB 7500 Fast: Presumptive candidate result (PCR result) vs. confirmed candidate result (using Brilliance Agar confirmation method) POD summary (1)

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit presumptive			RapidFinder Salmonella Multiplex PCR Kit confirmed ^e			dPOD _{CP} ^g	95% CI ^h
				x ^c	POD _{CP} ^d	95% CI	x	POD _{CC} ^f	95% CI		
Raw chicken thighs w/skin	<i>Salmonella</i> spp. total ^l (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.84	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		1.77	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.20	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	<i>S. Kentucky C₃</i>	N/A	5	NR ^j	NR	NR	0	0.00	0.00, 0.28	NR	NR
		1.01	20	NR	NR	NR	11	0.55	0.34, 0.74	NR	NR
		1.51	5	NR	NR	NR	2	0.40	0.12, 0.77	NR	NR
	<i>Salmonella</i> spp. total ^l (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	16	0.80	0.58, 0.92	0.00	-0.25, 0.25
		3.63	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw chicken thighs w/skin (independent lab) ^k	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.39, 0.78	12	0.60	0.37, 0.78	0.00	-0.28, 0.28
		2.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Kentucky C₃</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.81	20	NR	NR	NR	10	0.50	0.30, 0.70	NR	NR
		2.37	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	<i>S. Montevideo C₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.52	20	NR	NR	NR	11	0.55	0.34, 0.74	NR	NR
		1.32	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
Chicken nuggets	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.50	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.01	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
	<i>S. Montevideo C₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.52	20	NR	NR	NR	11	0.55	0.34, 0.74	NR	NR
		1.32	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.50	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.01	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Raw pork sausage	<i>Salmonella</i> spp. total ^l (<i>S. Ohio C₁</i> , <i>S. Typhimurium B</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		0.8	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.36	20	15	0.75	0.53, 0.89	14	0.70	0.48, 0.85	0.05	-0.22, 0.31
		0.27	5	5	1.00	0.57, 1.00	3	0.60	0.23, 0.88	0.40	-0.12, 0.77
	<i>S. Ohio C₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		1.25	20	NR	NR	NR	12	0.60	0.39, 0.78	NR	NR
		4.38	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Stainless	<i>Salmonella</i> spp.	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43

steel	total ^l (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	N/A	20	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
	<i>S. Poona G₁</i>	N/A	20	NR	NR	NR	10	0.50	0.30, 0.70	NR	NR
		N/A	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
		N/A	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Stainless steel (independent lab) ^k	Salmonella spp. total ^l (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	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	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	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
	<i>S. Typhimurium B</i>	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	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	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
	<i>S. Poona G₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	9	0.45	0.26, 0.66	NR	NR
		N/A	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR

^a 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.

^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 trials.

^e All strains were confirmed by serotyping.

^f POD_{CC} = Candidate method confirmed (via Brilliance Salmonella method) positive outcomes divided by the total number of trials.

^g dPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via Brilliance Salmonella method) result POD values.

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

ⁱ RapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between the species.

^j N/A = Not applicable

^k Matrix tested in the independent laboratory.

^l NR = Not reported. *Salmonella* strains that are not a specific PCR target cannot have presumptive PCR results for the specific strain. Therefore POD and dPOD cannot be calculated.

Table 4. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with AB 7500 Fast: Presumptive candidate result (PCR result) vs. confirmed candidate result (using reference confirmation method) POD summary (1)

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit presumptive			RapidFinder Salmonella Multiplex PCR Kit reference method confirmed ^e			dPOD _{CP} ^g	95% CI ^h
				x ^c	POD _{CP} ^d	95% CI	x	POD _{CC} ^f	95% CI		
Raw chicken thighs w/skin	<i>Salmonella</i> spp. total ^l (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A ^j	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.84	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		1.77	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	15 ^j	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.20	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	<i>S. Kentucky C₃</i>	N/A	5	NR ⁿ	NR	NR	0	0.00	0.00, 0.28	NR	NR
		1.01	20	NR	NR	NR	12	0.60	0.39, 0.78	NR	NR
		1.51	5	NR	NR	NR	2	0.40	0.12, 0.77	NR	NR
Raw chicken thighs w/skin (independent lab) ^k	<i>Salmonella</i> spp. total ^l (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	16	0.80	0.58, 0.92	0.00	-0.25, 0.25
		3.63	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.25, 0.25
		2.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Kentucky C₃</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.81	20	NR	NR	NR	10	0.50	0.30, 0.70	NR	NR
		2.37	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Raw chicken wings w/skin	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	<i>S. Montevideo C₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.52	20	NR	NR	NR	11	0.55	0.34, 0.74	NR	NR
		1.32	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
Chicken	<i>S.</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43

nuggets	Typhimurium B	1.50	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.01	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Raw pork sausage	<i>Salmonella</i> spp. total ^j (<i>S. Ohio C₁</i> , <i>S. Typhimurium B</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		0.8	5	4	0.80	0.38, 1.00	3	0.60	0.23, 0.88	0.20	-0.31, 0.62
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.36	20	15	0.75	0.53, 0.89	12 ^m	0.60	0.39, 0.78	0.15	-0.13, 0.40
		0.27	5	5	1.00	0.57, 1.00	3	0.60	0.23, 0.88	0.40	-0.12, 0.77
	<i>S. Ohio C₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		1.25	20	NR	NR	NR	12	0.60	0.39, 0.78	NR	NR
		4.38	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Stainless Steel environmental surface sponges	<i>Salmonella</i> spp. total ^j (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Poona G₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	10	0.50	0.30, 0.70	NR	NR
		N/A	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
Stainless Steel environmental surface sponges (independent lab) ^k	<i>Salmonella</i> spp. total ^j (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	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	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	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
	<i>S. Typhimurium B</i>	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	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	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
	<i>S. Poona G₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	9	0.45	0.26, 0.66	NR	NR
		N/A	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR

^a 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.^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 trials.^e All strains were confirmed by serotyping.^f POD_{CC} = Candidate method confirmed (via reference confirmation method) positive outcomes divided by the total number of trials.^g dPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via reference confirmation method) result POD values.^h 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.ⁱ RapidFinder presumptive PCR result for *Salmonella* species reflects all species present and therefore does not discriminate between the species.^j N/A = Not applicable.^k Matrix tested in the independent laboratory.^l 14 of the 15 positives confirmed using standard confirmation protocol. Additional 1 positive confirmed using extended confirmation protocol.^m 11 of the 12 positives confirmed using standard protocol. An additional 1 positive confirmed by testing more than the recommended 20 colonies.ⁿ NR = Not reported. *Salmonella* strains that are not a specific PCR target cannot have presumptive PCR results for the specific strain, therefore POD and dPOD cannot be calculated.**Table 5. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with AB 7500 Fast: Confirmed candidate result (using Brilliance Agar confirmation method) vs. confirmed candidate result (using reference confirmation method) POD summary (1)**

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit Brilliance Salmonella Agar confirmed ^e			RapidFinder Salmonella Multiplex PCR Kit Reference method confirmed ^f			dPOD _{cc^h}	95% CI ⁱ
				x ^c	POD _{CC} ^d	95% CI	x	POD _{CC} ^g	95% CI		
Raw chicken thighs w/skin	<i>Salmonella</i> spp. total ^j (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.84	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		1.77	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.20	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47

	S. Kentucky C ₃	N/A	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
	S. Kentucky C ₃	1.01	20	11	0.55	0.34, 0.74	12	0.60	0.39, 0.78	-0.05	-0.33, 0.24
	S. Kentucky C ₃	1.51	5	2	0.44	0.12, 0.77	2	0.40	0.12, 0.77	0.00	-0.46, 0.46
Raw chicken thighs w/skin (independent lab) ^j	Salmonella spp. total ^j (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	16	0.80	0.80, 0.92	0.00	-0.25, 0.25
		3.63	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.39, 0.78	12	0.60	0.50, 0.70	0.00	-0.28, 0.25
		2.28	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43
	S. Kentucky C ₃	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	20	10	0.50	0.30, 0.70	10	0.50	0.60, 0.78	0.00	-0.28, 0.28
		2.37	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43
Raw chicken wings w/skin	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	S. Montevideo C ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.52	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		1.32	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.50	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.01	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Raw pork sausage	Salmonella spp. total ^j (S. Ohio C ₁ , S. Typhimurium B & S. Enteritidis D ₁)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		0.8	5	4	0.80	0.38, 1.00	3	0.60	0.23, 0.88	0.20	-0.16, 0.75
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.36	20	14	0.70	0.48, 0.85	12 ^m	0.60	0.39, 0.78	0.10	-0.18, 0.36
		0.27	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
	S. Ohio C ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.25	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.28, 0.28
		4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless Steel environmental surface sponges	Salmonella spp. total ^j (S. Poona G ₁ & S. Typhimurium B)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Poona G ₁	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	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.28, 0.28
		N/A	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Stainless Steel environmental surface sponges (independent lab) ^j	Salmonella spp. total ^j (S. Poona G ₁ & S. Typhimurium B)	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	15	0.75	0.53, 0.89	15	0.75	0.75, 0.89	0.00	-0.26, 0.26
		N/A	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	10	0.50	0.26, 0.66	10	0.50	0.45, 0.66	0.00	-0.28, 0.28
		N/A	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43
	S. Poona G ₁	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	9	0.45	0.30, 0.70	9	0.45	0.50, 0.70	0.00	-0.28, 0.28
		N/A	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43

^a 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.^b N = Number of test portions.^c x = Number of positive test portions.^d POD_{CC} = Candidate method confirmed (using Brilliance Salmonella Agar method) positive outcomes divided by the total number of trials.^e Candidate method confirmed using Brilliance Salmonella Agar method.^f Candidate method confirmed using reference method. All strains were confirmed by serotyping.^g POD_{CC2} = Candidate method confirmed positive outcomes divided by the total number of trials.^h dPOD_{CC} = Difference between the candidate method confirmed result (using Brilliance Salmonella Agar method) and candidate method confirmed result (using reference method) POD values.ⁱ 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.^j RapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between the species.^k N/A = Not applicable.^l Matrix tested in the independent laboratory.^m 11 of the 12 positives confirmed using standard protocol. An additional 1 positive confirmed by testing more than the recommended 20 colonies.

Table 6. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with AB 7500 Fast: Confirmed candidate result (using Brilliance Agar confirmation method) vs. MLG/BAM reference method POD summary (1)

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit results <i>Brilliance</i> Salmonella Agar confirmed			Reference method results ^c			dPOD _C ^d	95% CI ^e
				x ^f	POD _C ^d	95% CI	x	POD _R ^f	95% CI		
Raw chicken thighs w/skin	<i>Salmonella</i> spp. total ⁱ (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.84	20	19	0.95	0.76, 1.00	18	0.90	0.70, 0.97	0.05	-0.15, 0.26
		1.77	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.28, 0.62
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	8	0.40	0.22, 0.61	0.35	0.04, 0.58
		0.20	5	4	0.80	0.38, 1.00	1	0.20	0.0, 0.62	0.60	0.00, 0.88
	<i>S. Kentucky C₃</i>	N/A	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
		1.01	20	11	0.55	0.34, 0.74	13	0.65	0.43, 0.82	-0.10	-0.37, 0.19
		1.51	5	2	0.40	0.12, 0.77	3	0.60	0.23, 0.88	-0.20	-0.60, 0.32
Raw chicken thighs w/skin (independent lab) ^k	<i>Salmonella</i> spp. total ⁱ (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	17	0.85	0.64, 0.95	-0.05	-0.29, 0.19
		3.63	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.37, 0.19
		2.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Kentucky C₃</i>	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	20	10	0.50	0.30, 0.70	12	0.60	0.39, 0.78	-0.10	-0.32, 0.23
		2.37	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw chicken wings w/skin	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	12	0.60	0.39, 0.78	0.15	-0.13, 0.40
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	<i>S. Montevideo C₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.52	20	11	0.55	0.34, 0.74	8	0.40	0.22, 0.61	0.15	-0.15, 0.41
		1.32	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.50	20	15	0.75	0.53, 0.89	16	0.80	0.58, 0.92	-0.05	-0.30, 0.21
		3.01	5	3	0.60	0.23, 0.88	5	1.00	0.57, 1.00	-0.40	-0.77, 0.12
Raw pork sausage	<i>Salmonella</i> spp. total ⁱ (<i>S. Ohio C₁</i> , <i>S. Typhimurium B</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	19	0.95	0.76, 1.00	0.05	-0.12, 0.24
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		0.8	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.36	20	14	0.70	0.48, 0.85	5	0.25	0.11, 0.47	0.45	0.14, 0.66
		0.27	5	3	0.60	0.23, 0.88	1	0.20	0.00, 0.62	0.40	-0.16, 0.75
	<i>S. Ohio C₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.25	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.32, 0.23
		4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless Steel environmental surface sponges	<i>Salmonella</i> spp. total ⁱ (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	13	0.65	0.43, 0.82	15	0.75	0.53, 0.89	-0.10	-0.36, 0.18
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Poona G₁</i>	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	10	0.50	0.30, 0.70	9	0.45	0.26, 0.66	0.05	-0.24, 0.33
		N/A	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75
Stainless Steel environmental surface sponges (independent lab) ^k	<i>Salmonella</i> spp. total ⁱ (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	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	15	0.75	0.53, 0.89	12	0.60	0.39, 0.78	0.15	-0.13, 0.40
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	10	0.50	0.30, 0.70	8	0.40	0.22, 0.61	0.00	-0.19, 0.37
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Poona G₁</i>	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	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.10	-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

^a 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.^b N = Number of test portions.^c x = Number of positive test portions.^d POD_C = Candidate method presumptive positive outcomes confirmed positive using *Brilliance* Salmonella Agar method.^e Reference methods = MLG 4.09 for poultry and meat products; BAM Ch. 5 for environmental surface sponges.^f POD_R = Reference method confirmed positive outcomes divided by the total number of trials.^g dPOD_C = Difference between the candidate method confirmed (using *Brilliance* Salmonella Agar) and reference method POD values.^h 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.ⁱ RapidFinder presumptive PCR result for *Salmonella* species reflects all species present and therefore does not discriminate between the species. All strains were confirmed by serotyping.^j N/A = Not applicable.^k Matrix tested in the independent laboratory.^l NR = Not reported. *Salmonella* strains that are not a specific PCR target cannot have presumptive PCR results for the specific strain, therefore POD and dPOD cannot be calculated.

Table 7. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with AB 7500 Fast: Confirmed candidate result (using reference confirmation method) vs. MLG/BAM reference method POD summary (1)

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit results reference method confirmed			Reference method results ^e			dPOD _C ^g	95% CI ^h	
				x ^c	POD _C ^d	95% CI	x	POD _R ^f	95% CI			
Raw chicken thighs w/skin	Salmonella spp. total ^l (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
		1.84	20	19	0.95	0.76, 1.00	18	0.90	0.70, 0.97	0.05	-0.15, 0.26	
		1.77	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.28, 0.62	
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.28	0.00	-0.43, 0.43	
		0.34	20	15	0.75	0.53, 0.89	8	0.40	0.22, 0.61	0.35	0.04, 0.58	
		0.20	5	4	0.80	0.38, 1.00	1	0.20	0.00, 0.62	0.60	0.00, 0.88	
	S. Kentucky C ₃	N/A	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.43, 0.43	
		1.01	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.32, 0.23	
		1.51	5	2	0.40	0.12, 0.77	3	0.60	0.23, 0.88	-0.20	-0.60, 0.32	
	Raw chicken thighs w/skin (independent lab) ^k	Salmonella spp. total ^l (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	17	0.85	0.64, 0.95	-0.05	-0.29, 0.19	
		3.63	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
		0.89	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.32, 0.23	
		2.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
Raw chicken wings w/skin	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
		0.99	20	15	0.75	0.53, 0.89	12	0.60	0.39, 0.78	0.15	-0.13, 0.40	
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47	
Chicken nuggets	S. Montevideo C ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
		0.52	20	11	0.55	0.34, 0.74	8	0.40	0.22, 0.61	0.15	-0.15, 0.41	
		1.32	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47	
Chicken nuggets	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
		1.50	20	15	0.75	0.53, 0.89	16	0.80	0.58, 0.92	-0.05	-0.30, 0.21	
		3.01	5	3	0.60	0.23, 0.88	5	1.00	0.57, 1.00	-0.40	-0.77, 0.12	
Raw pork sausage	Salmonella spp. total ^l (S. Ohio C ₁ , S. Typhimurium B & S. Enteritidis D ₁)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
		3.80	20	20	1.00	0.84, 1.00	19	0.95	0.76, 1.00	0.05	-0.12, 0.24	
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
	S. Typhimurium B	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28	
		0.8	5	3	0.60	0.23, 0.88	2	0.40	0.12, 0.77	0.20	-0.32, 0.60	
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
		0.36	20	12 ^l	0.60	0.39, 0.78	5	0.25	0.11, 0.47	0.35	0.04, 0.58	
		0.27	5	3	0.60	0.23, 0.88	1	0.20	0.00, 0.62	0.40	-0.16, 0.75	
	S. Ohio C ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
		1.25	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.32, 0.23	
		4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
Stainless Steel environmental surface sponges	Salmonella spp. total ^l (S. Poona G ₁ & S. Typhimurium B)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23	
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
	S. Typhimurium B	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	13	0.65	0.43, 0.82	15	0.75	0.53, 0.89	-0.10	-0.36, 0.18	
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
	S. Poona G ₁	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	10	0.50	0.30, 0.70	9	0.45	0.26, 0.66	0.05	-0.24, 0.33	
		N/A	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75	
Stainless Steel environmental surface sponges (independent lab) ^k	Salmonella spp. total ^l (S. Poona G ₁ & S. Typhimurium B)	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	15	0.75	0.53, 0.89	12	0.60	0.39, 0.78	0.15	-0.13, 0.40	
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.19, 0.37	
		N/A	20	10	0.50	0.30, 0.70	8	0.40	0.22, 0.61	0.10	-0.43, 0.43	
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
	S. Poona G ₁	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	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	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	

^a 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.^b N = Number of test portions.^c x = Number of positive test portions.^d POD_C = Candidate method presumptive positive outcomes confirmed positive using reference confirmation method.^e Reference methods = MLG 4.09 for poultry and meat products; BAM Ch. 5 for environmental surface sponges.^f POD_R = Reference method confirmed positive outcomes divided by the total number of trials.^g dPOD_C = Difference between the candidate method confirmed (using reference method) and reference method POD values.^h 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.ⁱ RapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between the species. All strains were confirmed by serotyping.^j N/A = Not applicable.^k Matrix tested in the independent laboratory.^l 11 of the 12 positives confirmed using standard protocol. An additional 1 positive confirmed by testing more than the recommended 20 colonies.

Table 8. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with QuantStudio 5: Presumptive candidate result (PCR result) vs. confirmed candidate result (using Brilliance Agar confirmation method) POD summary (1)

Matrix	Inoculating strain(s)	MPN ^a /test portion	RapidFinder Salmonella Multiplex PCR Kit presumptive			RapidFinder Salmonella Multiplex PCR Kit confirmed ^e			dPOD _{C_p} ^g	95% CI ^h	
			N ^b	x ^c	POD _{CP} ^d	95% CI	x	POD _{C_p} ^f	95% CI		
Raw chicken thighs w/skin	Salmonella spp. total ⁱ (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A ^j	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.28, 0.28
		1.84	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		1.77	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.20	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	<i>S. Kentucky C₃</i>	N/A	5	NR ^j	NR	NR	0	0.00	0.00, 0.28	NR	NR
		1.01	20	NR	NR	NR	11	0.55	0.34, 0.74	NR	NR
		1.51	5	NR	NR	NR	2	0.40	0.12, 0.77	NR	NR
Raw chicken thighs w/skin (independent lab) ^k	Salmonella spp. total ⁱ (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	16	0.80	0.58, 0.92	0.00	-0.25, 0.25
		3.63	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.39, 0.78	12	0.60	0.30, 0.70	0.00	-0.28, 0.28
		2.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Kentucky C₃</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.81	20	NR	NR	NR	10	0.50	0.39, 0.78	NR	NR
		2.37	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Raw chicken wings w/skin	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	<i>S. Montevideo C₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.52	20	NR	NR	NR	11	0.55	0.34, 0.74	NR	NR
		1.32	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
Chicken nuggets	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.50	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.01	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Raw pork sausage	Salmonella spp. total ⁱ (<i>S. Ohio C₁</i> , <i>S. Typhimurium B</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		0.8	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.36	20	15	0.75	0.53, 0.89	14	0.70	0.48, 0.85	0.05	-0.22, 0.31
		0.27	5	5	1.00	0.57, 1.00	3	0.60	0.23, 0.88	0.40	-0.12, 0.77
	<i>S. Ohio C₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		1.25	20	NR	NR	NR	12	0.60	0.39, 0.78	NR	NR
		4.38	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Stainless Steel environmental surface sponges	Salmonella spp. total ⁱ (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Typhimurium B</i>	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	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Poona G₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	10	0.50	0.30, 0.70	NR	NR
		N/A	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
Stainless Steel environmental surface sponges (independent lab) ^k	Salmonella spp. total ⁱ (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	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	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	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
	<i>S. Typhimurium B</i>	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	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	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
	<i>S. Poona G₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR

		N/A	20	NR	NR	NR	9	0.45	0.26, 0.66	NR	NR
		N/A	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR

^a 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.^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 trials.^e All strains were confirmed by serotyping.^f POD_{CC} = Candidate method confirmed (via Brilliance Salmonella method) positive outcomes divided by the total number of trials^g dPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via Brilliance Salmonella method) result POD values.^h 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.ⁱ RapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between the species.^j N/A = Not applicable.^k Matrix tested in the independent laboratory.^l NR = Not reported. *Salmonella* strains that are not a specific PCR target cannot have presumptive PCR results for the specific strain, therefore POD and dPOD cannot be calculated.**Table 9. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with QuantStudio 5: Presumptive candidate result (PCR result) vs. confirmed candidate result (using reference confirmation method) POD summary (1)**

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit presumptive			RapidFinder Salmonella Multiplex PCR Kit reference method confirmed ^e			dPOD _{CP} ^g	95% CI ^h
				x ^c	POD _{CP} ^d	95% CI	x	POD _{CC} ^f	95% CI		
Raw chicken thighs w/skin	Salmonella spp. total ^l (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A ⁱ	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
		1.84	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		1.77	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	15 ⁱ	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.20	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	S. Kentucky C ₃	N/A	5	NR ⁿ	NR	NR	0	0.00	0.00, 0.28	NR	NR
		1.01	20	NR	NR	NR	12	0.60	0.39, 0.78	NR	NR
		1.51	5	NR	NR	NR	2	0.40	0.12, 0.77	NR	NR
Raw chicken thighs w/skin (independent lab) ^k	Salmonella spp. total ^l (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	16	0.80	0.58, 0.92	0.00	-0.25, 0.25
		3.63	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.28, 0.28
		2.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Kentucky C ₃	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.81	20	NR	NR	NR	10	0.50	0.30, 0.70	NR	NR
		2.37	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Raw chicken wings w/skin	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	S. Montevideo C ₁	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.52	20	NR	NR	NR	11	0.55	0.34, 0.74	NR	NR
		1.32	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
Chicken nuggets	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.50	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.01	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Raw pork sausage	Salmonella spp. total ^l (S. Ohio C ₁ , S. Typhimurium B & S. Enteritidis D ₁)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		0.8	5	4	0.80	0.38, 1.00	3	0.60	0.23, 0.88	-0.20	-0.31, 0.62
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.36	20	15	0.75	0.53, 0.89	12 ^m	0.60	0.39, 0.78	-0.15	-0.13, 0.40
		0.27	5	5	1.00	0.57, 1.00	3	0.60	0.23, 0.88	-0.40	-0.12, 0.77
	S. Ohio C ₁	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		1.25	20	NR	NR	NR	12	0.60	0.39, 0.78	NR	NR
		4.38	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
Stainless Steel environmental surface sponges	Salmonella spp. total ^l (S. Poona G ₁ & S. Typhimurium B)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		N/A	20	NR	NR	NR	10	0.50	0.30, 0.70	NR	NR

	S. Poona G ₁	N/A	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
Stainless Steel environmental surface sponges (independent lab) ^k	<i>Salmonella</i> spp. total ^l (<i>S. Poona G₁</i> & <i>S. Typhimurium B</i>)	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	15	0.75	0.58, 0.92	15	0.75	0.53, 0.89	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
	<i>S. Typhimurium B</i>	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	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	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
	<i>S. Poona G₁</i>	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	9	0.45	0.26, 0.66	NR	NR
		N/A	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR

^a 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.

^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 trials.

^e All strains were confirmed by serotyping.

^f POD_{CC} = Candidate method confirmed (via Reference confirmation method) positive outcomes divided by the total number of trials.

^g dPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via Reference confirmation method) result POD values.

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

ⁱ RapidFinder presumptive PCR result for *Salmonella* species reflects all species present and therefore does not discriminate between the species.

^j N/A = Not applicable.

^k Matrix tested in the independent laboratory.

^l 14 of the 15 positives confirmed using standard confirmation protocol. Additional 1 positive confirmed using extended confirmation protocol.

^m 11 of the 12 positives confirmed using standard protocol. An additional 1 positive confirmed by testing more than the recommended 20 colonies.

ⁿ NR = Not reported. *Salmonella* strains that are not a specific PCR target cannot have presumptive PCR results for the specific strain, therefore POD and dPOD cannot be calculated.

Table 10. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with QuantStudio 5: Confirmed candidate result (using Brilliance Agar confirmation method) vs. confirmed candidate result (using reference confirmation method) POD summary (1)

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit Brilliance Salmonella Agar confirmed ^e			RapidFinder Salmonella Multiplex PCR Kit Reference method confirmed ^f			dPOD _{CP} ^g ^h	95% CI ⁱ
				x ^c	POD _{CC} ^d	95% CI	x	POD _{CC} ^g	95% CI		
Raw chicken thighs w/skin	<i>Salmonella</i> spp. total ^l (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A ^k	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.28, 0.28
		1.84	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		1.77	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.20	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	<i>S. Kentucky C₃</i>	N/A	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
		1.01	20	11	0.55	0.34, 0.74	12	0.60	0.39, 0.78	-0.05	-0.33, 0.24
		1.51	5	2	0.40	0.12, 0.77	2	0.40	0.12, 0.77	0.00	-0.46, 0.46
Raw chicken thighs w/skin (independent lab) ^l	<i>Salmonella</i> spp. total ^l (<i>S. Kentucky C₃</i> & <i>S. Enteritidis D₁</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	16	0.80	0.80, 0.92	0.00	-0.25, 0.25
		3.63	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43
	<i>S. Enteritidis D₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.39, 0.78	12	0.60	0.60, 0.78	0.00	-0.28, 0.28
		2.28	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43
	<i>S. Kentucky C₃</i>	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	20	10	0.50	0.39, 0.78	10	0.50	0.50, 0.70	0.00	-0.28, 0.28
		2.37	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43
Raw chicken wings w/skin	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	<i>S. Montevideo C₁</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.52	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		1.32	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	<i>S. Typhimurium B</i>	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.50	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		3.01	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46
Raw pork sausage	<i>Salmonella</i> spp. total ^l (<i>S. Ohio C₁</i> , <i>S. Typhimurium B</i> & <i>S.</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

	Enteritidis D ₁)										
S. Typhimurium B	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28	
	0.8	5	4	0.80	0.38, 1.00	3	0.60	0.23, 0.88	0.20	-0.16, 0.75	
S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
	0.36	20	14	0.70	0.48, 0.85	12 ^m	0.60	0.39, 0.78	0.10	-0.18, 0.36	
	0.27	5	3	0.60	0.23, 0.88	3	0.60	0.23, 0.88	0.00	-0.46, 0.46	
S. Ohio C ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43	
	1.25	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.28, 0.28	
	4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
Stainless Steel environmental surface sponges	Salmonella spp. total ^l (S. Poona G ₁ & S. Typhimurium B)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23	
	N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
	S. Typhimurium B	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	13	0.65	0.43, 0.82	13	0.65	0.43, 0.82	0.00	-0.23, 0.23	
	N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43	
	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	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	-0.28, 0.28	
	S. Poona G ₁	N/A	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	Salmonella spp. total ^l (S. Poona G ₁ & S. Typhimurium B)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Stainless Steel environmental surface sponges (independent lab) ^j	N/A	20	15	0.75	0.53, 0.89	15	0.75	0.75, 0.89	0.00	-0.26, 0.26	
	N/A	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43	
	S. Typhimurium B	N/A	20	10	0.50	0.30, 0.70	10	0.50	0.45, 0.66	0.00	-0.28, 0.28
	N/A	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43	
	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	9	0.45	0.26, 0.66	9	0.45	0.50, 0.70	0.00	-0.28, 0.28	
	N/A	5	5	1.00	0.57, 1.00	5	1.00	1.00, 1.00	0.00	-0.43, 0.43	
	S. Poona G ₁	N/A	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	Salmonella spp. total ^l (S. Poona G ₁ & S. Typhimurium B)	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	15	0.75	0.53, 0.89	15	0.75	0.75, 0.89	0.00	-0.26, 0.26	

^a 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.

^b N = Number of test portions.

^c x = Number of positive test portions.

^d POD_{CC} = Candidate method confirmed (using Brilliance Salmonella Agar method) positive outcomes divided by the total number of trials.

^e Candidate method confirmed using Brilliance Salmonella Agar method.

^f Candidate method confirmed using reference method. All strains were confirmed by serotyping.

^g POD_{CC2} = Candidate method confirmed positive outcomes divided by the total number of trials.

^h dPOD_{CC} = Difference between the candidate method confirmed result (using Brilliance Salmonella Agar method) and candidate method confirmed result (using reference method) POD values.

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

^j RapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between the species.

^k N/A = Not applicable.

^l Matrix tested in the independent laboratory.

^m 11 of the 12 positives confirmed using standard protocol. An additional 1 positive confirmed by testing more than the recommended 20 colonies.

Table 11. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with QuantStudio 5: Confirmed candidate result (using Brilliance Agar confirmation method) vs. MLG/BAM reference method POD summary (1)

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit results Brilliance Salmonella Agar confirmed			Reference method results ^e			dPOD _{CC} ^g	95% CI ^h
				x ^c	POD _{CC} ^d	95% CI	x	POD _R ^f	95% CI		
Raw chicken thighs w/skin	Salmonella spp. total ^l (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A ⁱ	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.84	20	19	0.95	0.76, 1.00	18	0.90	0.70, 0.97	0.05	-0.15, 0.26
		1.77	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.28, 0.62
	S. Enteritidis D ₁	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	8	0.40	0.22, 0.61	0.35	0.04, 0.58
		0.20	5	4	0.80	0.38, 1.00	1	0.20	0.0, 0.62	0.60	0.00, 0.88
	S. Kentucky C ₃	N/A ⁱ	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
		1.01	20	11	0.55	0.34, 0.74	13	0.65	0.43, 0.82	-0.10	-0.37, 0.19
		1.51	5	2	0.40	0.12, 0.77	3	0.60	0.23, 0.88	-0.20	-0.60, 0.32
Raw chicken thighs w/skin (independent lab) ^k	Salmonella spp. total ^l (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	17	0.85	0.64, 0.95	-0.05	-0.29, 0.19
		3.63	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Enteritidis D ₁	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.32, 0.23
		2.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Kentucky C ₃	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43

		0.81	20	10	0.50	0.30, 0.70	12	0.60	0.39, 0.78	-0.10	-0.37, 0.19
		2.37	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw chicken wings w/skin	S. Typhimurium B	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	12	0.60	0.39, 0.78	0.15	-0.13, 0.40
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
		N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Chicken nuggets	S. Montevideo C ₁	0.52	20	11	0.55	0.34, 0.74	8	0.40	0.22, 0.61	0.15	-0.15, 0.41
		1.32	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
		N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Chicken nuggets	S. Typhimurium B	1.50	20	15	0.75	0.53, 0.89	16	0.80	0.58, 0.92	-0.05	-0.30, 0.21
		3.01	5	3	0.60	0.23, 0.88	5	1.00	0.57, 1.00	-0.40	-0.77, 0.12
		N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Raw pork sausage	Salmonella spp. total ^j (S. Ohio C ₁ , S. Typhimurium B & S. Enteritidis D ₁)	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	19	0.95	0.76, 1.00	0.05	-0.12, 0.24
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.63	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		0.8	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75
	S. Enteritidis D ₁	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.36	20	14	0.70	0.48, 0.85	5	0.25	0.11, 0.47	0.45	0.14, 0.66
		0.27	5	3	0.60	0.23, 0.88	1	0.20	0.00, 0.62	0.40	-0.16, 0.75
	S. Ohio C ₁	N/A ⁱ	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.25	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.32, 0.23
		4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless Steel environmental surface sponges	Salmonella spp. total ^j (S. Poona G ₁ & S. Typhimurium B)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	13	0.65	0.43, 0.82	15	0.75	0.53, 0.89	-0.10	-0.36, 0.18
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Poona G ₁	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	10	0.50	0.30, 0.70	9	0.45	0.26, 0.66	0.05	-0.24, 0.33
		N/A	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75
Stainless Steel environmental surface sponges (independent lab) ^k	Salmonella spp. total ^j (S. Poona G ₁ & S. Typhimurium B)	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	15	0.75	0.53, 0.89	12	0.60	0.39, 0.78	0.15	-0.13, 0.40
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	10	0.50	0.30, 0.70	8	0.40	0.22, 0.61	0.10	-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
	S. Poona G ₁	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	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.19, 0.37
		N/A	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 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 presumptive positive outcomes confirmed positive using Brilliance Salmonella Agar method.

^e Reference methods = MLG 4.09 for poultry and meat products; BAM Ch. 5 for environmental surface sponges.

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

^g dPOD_C = Difference between the candidate method confirmed (using Brilliance Salmonella Agar) and reference method POD values.

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

ⁱ RapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between the species. All strains were confirmed by serotyping.

^j N/A = Not applicable.

^k Matrix tested in the independent laboratory.

Table 12. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results with QuantStudio 5: Confirmed candidate result (using reference confirmation method) vs. MLG/BAM reference method POD summary (1)

Matrix	Inoculating strain(s)	MPN ^a /test portion	N ^b	RapidFinder Salmonella Multiplex PCR Kit results reference method confirmed			Reference method results ^e			dPOD _C ^g	95% CI ^h
				x ^c	POD _C ^d	95% CI	x	POD _R ^f	95% CI		
Raw chicken thighs w/skin	Salmonella spp. total ⁱ (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A ^j	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.84	20	19	0.95	0.76, 1.00	18	0.90	0.70, 0.97	0.05	-0.15, 0.26
		1.77	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.28, 0.62
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
		0.34	20	15	0.75	0.53, 0.89	8	0.40	0.22, 0.61	0.35	0.04, 0.58
		0.20	5	4	0.80	0.38, 1.00	1	0.20	0.00, 0.62	0.60	0.00, 0.88
	S. Kentucky C ₃	N/A	5	0	0.00	0.00, 0.28	0	0.00	0.00, 0.28	0.00	-0.43, 0.43
		1.01	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.32, 0.23
		1.51	5	2	0.40	0.12, 0.77	3	0.60	0.23, 0.88	-0.20	-0.60, 0.32
Raw chicken thighs w/skin (independent lab) ^k	Salmonella spp. total ⁱ (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.87	20	16	0.80	0.58, 0.92	17	0.85	0.64, 0.95	-0.05	-0.29, 0.19
		3.63	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	12	0.60	0.30, 0.70	13	0.65	0.39, 0.78	-0.05	-0.32, 0.23
		2.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Kentucky C ₃	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	20	10	0.50	0.39, 0.78	12	0.60	0.43, 0.82	-0.10	-0.37, 0.19
		2.37	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Raw chicken wings w/skin	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.99	20	15	0.75	0.53, 0.89	12	0.60	0.39, 0.78	0.15	-0.13, 0.40
		3.14	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	S. Montevideo C ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.52	20	11	0.55	0.34, 0.74	8	0.40	0.22, 0.61	0.15	-0.15, 0.41
		1.32	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Chicken nuggets	S. Typhimurium B	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.50	20	15	0.75	0.53, 0.89	16	0.80	0.58, 0.92	-0.05	-0.30, 0.21
		3.01	5	3	0.60	0.23, 0.88	5	1.00	0.57, 1.00	-0.40	-0.77, 0.12
Raw pork sausage	Salmonella spp. total ⁱ (S. Ohio C ₁ , S. Typhimurium B & S. Enteritidis D ₁)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.80	20	20	1.00	0.84, 1.00	19	0.95	0.76, 1.00	0.05	-0.12, 0.24
		>4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		0.8	5	3	0.60	0.23, 0.88	2	0.40	0.12, 0.77	0.20	-0.32, 0.60
	S. Enteritidis D ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.36	20	12 ^j	0.60	0.39, 0.78	5	0.25	0.11, 0.47	0.35	0.04, 0.58
		0.27	5	3	0.60	0.23, 0.88	1	0.20	0.00, 0.62	0.40	-0.16, 0.75
	S. Ohio C ₁	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.25	20	12	0.60	0.39, 0.78	13	0.65	0.43, 0.82	-0.05	-0.32, 0.23
		4.38	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Stainless Steel environmental surface sponges	Salmonella spp. total ⁱ (S. Poona G ₁ & S. Typhimurium B)	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	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	13	0.65	0.43, 0.82	15	0.75	0.53, 0.89	-0.10	-0.36, 0.18
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Poona G ₁	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	10	0.50	0.30, 0.70	9	0.45	0.26, 0.66	0.05	-0.24, 0.33
		N/A	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75
Stainless Steel environmental surface sponges (independent lab) ^k	Salmonella spp. total ⁱ (S. Poona G ₁ & S. Typhimurium B)	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	15	0.75	0.53, 0.89	12	0.60	0.39, 0.78	0.15	-0.13, 0.40
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Typhimurium B	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	10	0.50	0.30, 0.70	8	0.40	0.22, 0.61	0.10	-0.19, 0.37
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	S. Poona G ₁	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	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	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

^a 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.

^b N = Number of test portions.

^c x = Number of positive test portions.

^d POD_C = Candidate method presumptive positive outcomes confirmed positive using Brilliance Salmonella Agar method.

^e Reference methods = MLG 4.09 for poultry and meat products; BAM Ch. 5 for environmental surface sponges.

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

^g dPOD_C = Difference between the candidate method confirmed (using reference method) and reference method POD values.

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

ⁱ RapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between the species.

All strains were confirmed by serotyping.

^j N/A = Not applicable.

^k Matrix tested in the independent laboratory.

^l 11 of the 12 positives confirmed using standard protocol. An additional 1 positive confirmed by testing more than the recommended 20 colonies.

DISCUSSION OF THE MODIFICATION STUDY APPROVED MAY 2018 (10)

Inclusivity/exclusivity

Out of 200 inclusivity isolates tested, 198 were correctly detected by the corresponding PCR target within the RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit (Table 1). One *Salmonella* Enteritidis inclusivity isolate (TCC 1639) gave a positive result for the *Salmonella* species target, but gave a negative result for the *Salmonella* Enteritidis PCR target when tested using the Applied Biosystems 7500 Fast PCR Instrument and the Applied Biosystems QuantStudio 5 PCR Instrument. One *Salmonella* Enteritidis inclusivity isolate (TCC 1640) gave negative PCR results for the *Salmonella* species and the *Salmonella* Enteritidis target when tested using the Applied Biosystems QuantStudio 5 PCR Instrument. Both isolates (TCC 1639 and TCC 1640) gave rough colony morphologies and were confirmed by H:g,m presence as they were O:9 negative (10). The O:9 antigen mutation was also seen during the matrix study and was confirmed by gene sequencing for one *Salmonella* Enteritidis isolate (RDCC 3900), further information is detailed in the matrix study discussion. The lack of O antigen causes the cells not binding properly to the Dynabeads during sample lysis using the Thermo Scientific KingFisher Flex instrument, resulting in a false negative result.

All 45 exclusivity isolates tested were correctly excluded by the RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit (Table 2). Three exclusivity isolates (one *Citrobacter freundii* and two *Serratia marcescens*) originally gave a positive PCR result when tested using the Applied Biosystems 7500 Fast Real Time PCR Instrument and an additional two exclusivity isolates (*Escherichia coli* and *Proteus vulgaris*) originally gave a positive PCR result when tested using the Applied Biosystems QuantStudio 5 Real Time PCR Instrument. The five exclusivity isolates were re-incubated in the candidate enrichment broth ((BPW (ISO) with 12 mg/mL novobiocin) for 20-24 hours at 41.5 ± 1 °C and after reanalysis did not produce a positive PCR result on either PCR instrument.

Real-time stability study

The results from the real time stability study have shown there were no statistically significant differences by POD analysis between the performances of lots near expiration (12 month) and near the middle of the expiration period (6 month) to the recently manufactured kit (0 month). The real time stability study has proven that the RapidFinder Salmonella Multiplex pellets are stable for the proposed on-year shelf life.

Matrix Studies

Results from the method developer and independent studies of the RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit for detection and differentiation of *Salmonella* species, *Salmonella* Typhimurium and *Salmonella* Enteritidis from ground turkey, chicken carcass rinse and shell egg samples with both the 7500 Fast Real-Time PCR instrument and associated RapidFinder Express software and the QuantStudio 5 Real-Time PCR instrument and associated RapidFinder Analysis software are summarized in Tables 5-9. Unless specified, results within the tables and discussion are representative of both the Applied Biosystems 7500 Fast PCR Instrument and the Applied Biosystems QuantStudio 5 PCR Instrument.

Throughout the matrix study at the method developer laboratory, dual colony morphology (one small and smooth and another larger and rough) and difficulty in O serological confirmations was observed whilst testing *Salmonella* Enteritidis isolates. The two colony morphologies from a *Salmonella* Enteritidis isolate showing the smooth and rough characteristics (RDCC 3900) were confirmed by gene sequencing which returned high scores for sequence similarity (99.98% and 99.97% for the smooth and rough morphologies respectively). It was found that cells from the rough colony had a mutation which altered the O:9 antigen expression codon into a STOP codon, therefore these cells were not expressing the O:9 antigen. The mutation is likely due to the use of these isolates within a laboratory environment (10). All *Salmonella* Enteritidis isolates were confirmed by H:g,m antigen presence and the data for both rough (O:9-) and smooth (O:9+) colonies have been combined to create one data set.

During the confirmation testing of *Salmonella* Bareilly at the method developer laboratory, dual morphologies were also observed (one rough and one smooth), as seen in the *Salmonella* Enteritidis confirmation testing. Two *Salmonella* Bareilly isolates exhibited rough colonies only during confirmation testing, which were negative for O:7, this is likely due to a mutation in the O antigen expression. The rough colonies were confirmed as *Salmonella* Bareilly via the H:y and H:1,5 antigens. The data for both rough (O:7-) and smooth (O:7+) colonies have been combined to create one data set.

For all matrixes tested, the candidate presumptive PCR results were not statistically different by POD analysis compared to the candidate confirmed results (via *Brilliance* Salmonella Agar) RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit results when tested using the 7500 Fast Real-Time PCR instrument and interpreted by the RapidFinder Express software and the QuantStudio 5 Real-Time PCR instrument and interpreted by the RapidFinder Analysis software.

The POD analysis of the shell egg data has shown statistically significant differences for the detection of *Salmonella* Enteritidis between the candidate method presumptive and candidate method confirmed via FDA BAM Ch. 5, between the candidate method (confirmed via *Brilliance* Salmonella Agar) and both the FDA BAM Ch. 5 method and candidate method confirmed (via FDA BAM Ch. 5), and also between the candidate method confirmed (via FDA BAM Ch.5) and the FDA BAM Ch.5 method. The statistically significant differences are in favor of the candidate method; it is likely that during the FDA BAM Ch.5 enrichment the *Salmonella* Enteritidis and *Salmonella* Heidelberg were competing for growth during dual inoculation, reducing the likelihood of *Salmonella* Enteritidis confirmation via the FDA BAM Ch. 5 method.

There were statistical differences observed in the POD analysis for the detection of *Salmonella* Heidelberg in shell egg samples in favor of the candidate method. The statistically significant differences were between both the candidate method confirmed (via *Brilliance* Salmonella Agar and FDA BAM Ch. 5) and the FDA BAM Ch. 5 reference method.

The POD analysis of the carcass rinse data has shown statistically significant differences for the detection of *Salmonella* Typhimurium between the candidate method confirmed (via *Brilliance* Salmonella Agar, and confirmed via MLG 4.09) and the MLG 4.09 reference method. The statistically significant differences were in favor of the candidate method; it is likely that during the MLG 4.09 enrichment the *Salmonella* Enteritidis and *Salmonella* Typhimurium were competing for growth during the dual inoculation, reducing the likelihood of *Salmonella* Typhimurium confirmation. There were no statistically significant differences in the detection of *Salmonella* Enteritidis between all methods tested.

The original testing of the ground turkey matrix at the method developer laboratory returned non-fractional results for *Salmonella* Bareilly (<25% positivity) when tested as dual inoculation with *Salmonella* Typhimurium. The *Salmonella* Bareilly was later confirmed with acceptable fractional positivity using the dilute-and-spread troubleshooting method described in the manufacturer's guidelines. It is likely that the candidate confirmed method (via *Brilliance* Salmonella Agar) failed to confirm *Salmonella* Bareilly presence due to strain competition during dual inoculation.

The original testing of the ground turkey matrix returned non-fractional results for *Salmonella* Typhimurium (>75% positivity), therefore the *Salmonella* Typhimurium low spike level was repeated as single inoculation in the ground turkey matrix. The original test low spike data (MPN of 2.26) represents the high spike for the repeat test. Both original and repeat sets of data are shown in Tables 5-9.

During the repeat testing of the ground turkey matrix, the MLG 4.09 reference method and candidate method confirmed (via MLG 4.09 method) failed to detect a natural contaminant that was successfully identified by the candidate method presumptive and candidate method confirmed (via the extended confirmation method detailed in the manufacturer guidelines for high background samples; includes RVS and step prior to *Brilliance* Salmonella Agar). This is likely due to the larger sample size of the candidate test portion (375 g) compared to the reference method test portion (25 g) increasing the likelihood of natural contaminant presence. This has led to a statistically significant difference by POD analysis in favor of the candidate method. For the detection of *Salmonella* Typhimurium in ground turkey samples there were no statistically significant differences between all methods tested.

Table 1. Inclusivity of the Thermo Scientific RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit (10)

ID	Salmonella strain	Group/Comments	Source	Origin	Results - 7500 Fast			Results – QuantStudio 5		
					<i>Salmonella</i> spp. result	<i>Salmonella</i> Typhimurium result	<i>Salmonella</i> Enteritidis result	<i>Salmonella</i> spp. result	<i>Salmonella</i> Typhimurium result	<i>Salmonella</i> Enteritidis result
1726	<i>Salmonella salamae</i> Uphill	II 42:b:e,n,x,z ₁₅	RDCC ^a	Unknown ^b	+	-	-	+	-	-
2355	<i>Salmonella salamae</i> Donna	II 53:z ₄ ,Z ₂₄ :-	RDCC	Unknown	+	-	-	+	-	-
2830	<i>Salmonella salamae</i> Locarno	II 57:z ₂₉ :Z ₄₂	RDCC	Unknown	+	-	-	+	-	-
NCTC ^c 10252	<i>Salmonella salamae</i> Tranaroa	II 55:k:Z ₃₉	NCTC	Unknown	+	-	-	+	-	-
2599	<i>Salmonella salamae</i>	II 58:l,z13,z28:z6	TCC ^d	Unknown	+	-	-	+	-	-
NCTC 8297	<i>Salmonella arizoniae</i>	IIIa 51:z4,z23:-	NCTC	Unknown	+	-	-	+	-	-
2389	<i>Salmonella arizoniae</i>	S 24, 223:-	TCC	Unknown	+	-	-	+	-	-
2608	<i>Salmonella arizoniae</i>	IIIa 41:z4,z23:-	TCC	Unknown	+	-	-	+	-	-
2609	<i>Salmonella arizoniae</i>	IIIa 40:z4,z23:-	TCC	Unknown	+	-	-	+	-	-
2610	<i>Salmonella arizoniae</i>	IIIa 48:g,z51:-	TCC	Unknown	+	-	-	+	-	-
2386	<i>Salmonella diarizonae</i>	61:k:1,5,7	TCC	Clinical	+	-	-	+	-	-
2388	<i>Salmonella diarizonae</i>	38:l,v:z53	TCC	Unknown	+	-	-	+	-	-
2616	<i>Salmonella diarizonae</i>	IIIb 60:r:e,n,x,z15	TCC	Unknown	+	-	-	+	-	-
2617	<i>Salmonella diarizonae</i>	IIIb 48:i:z	TCC	Unknown	+	-	-	+	-	-
2618	<i>Salmonella diarizonae</i>	IIIb 61:k:1,5,(7)	TCC	Unknown	+	-	-	+	-	-
3732	<i>Salmonella houtenae</i>	51:z4,z23:-	RDCC	Unknown	+	-	-	+	-	-
2624	<i>Salmonella houtenae</i>	IV 50:g,z51:-	TCC	Unknown	+	-	-	+	-	-
2625	<i>Salmonella houtenae</i>	IV 48:g,z51:-	TCC	Unknown	+	-	-	+	-	-
2626	<i>Salmonella houtenae</i>	IV 44:z4,z23:-	TCC	Unknown	+	-	-	+	-	-
2627	<i>Salmonella houtenae</i>	IV 45:g,z51:-	TCC	Unknown	+	-	-	+	-	-
2360	<i>Salmonella indica</i>	45:a:e,n,x	TCC	Unknown	+	-	-	+	-	-
2643	<i>Salmonella indica</i>	VI 11:a:1,5	TCC	Unknown	+	-	-	+	-	-
2640	<i>Salmonella indica</i>	VI 6,14,25:z10:1,(2),7	TCC	Unknown	+	-	-	+	-	-
2641	<i>Salmonella indica</i>	VI 11:b:1,7	TCC	Unknown	+	-	-	+	-	-
2642	<i>Salmonella indica</i>	VI 6,7:z41:1,7	TCC	Unknown	+	-	-	+	-	-
NCTC 2215	<i>Salmonella bongori</i>		NCTC	Unknown	+	-	-	+	-	-
NCTC 12419	<i>Salmonella bongori</i>	66:z41:-	NCTC	Unknown	+	-	-	+	-	-
3407	<i>Salmonella Stanley</i>	Group O:4 (B)	RDCC	Unknown	+	-	-	+	-	-
5096	<i>Salmonella Abony</i>	Group O:4 (B)	RDCC	Unknown	+	-	-	+	-	-
2150	<i>Salmonella Saintpaul</i>	Group O:4 (B)	RDCC	Unknown	+	-	-	+	-	-
3377	<i>Salmonella Heidelberg</i>	Group O:4 (B)	RDCC	Unknown	+	-	-	+	-	-
2358	<i>Salmonella Agona</i>	Group O:4 (B)	RDCC	Unknown	+	-	-	+	-	-
2839	<i>Salmonella Brandenburg</i>	Group O:4 (B)	RDCC	Clinical	+	-	-	+	-	-
2840	<i>Salmonella Indiana</i>	Group O:4 (B)	RDCC	Turkey	+	-	-	+	-	-
2296	<i>Salmonella Abortus-equii</i>	Group O:4 (B)	TCC	Unknown	+	-	-	+	-	-
3016	<i>Salmonella Abortusovis</i>	Group O:4 (B)	TCC	Unknown	+	-	-	+	-	-
3017	<i>Salmonella</i>	Group O:4 (B)	TCC	Unknown	+	-	-	+	-	-

	Schwarzengrund										
3018	<i>Salmonella</i> Stanleyville	Group O:4 (B)	TCC	Unknown	+	-	-	+	-	-	
3019	<i>Salmonella</i> Sandiego	Group O:4 (B)	TCC	Unknown	+	-	-	+	-	-	
3381	<i>Salmonella</i> Bredeney	Group O:4 (B)	RDCC	Unknown	+	-	-	+	-	-	
1774	<i>Salmonella</i> Gallinarum	Group O:9 (D1)	RDCC	Unknown	+	-	-	+	-	-	
NCTC 9868	<i>Salmonella</i> Alabama	Group O:9 (D1)	NCTC	Unknown	+	-	-	+	-	-	
3024	<i>Salmonella</i> Miami	Group O:9 (D1)	TCC	Unknown	+	-	-	+	-	-	
3025	<i>Salmonella</i> Lomalinda	Group O:9 (D1)	TCC	Clinical	+	-	-	+	-	-	
3026	<i>Salmonella</i> Israel	Group O:9 (D1)	TCC	Unknown	+	-	-	+	-	-	
3027	<i>Salmonella</i> Portland	Group O:9 (D1)	TCC	Unknown	+	-	-	+	-	-	
3028	<i>Salmonella</i> Sendai	Group O:9 (D1)	TCC	Unknown	+	-	-	+	-	-	
2129	<i>Salmonella</i> Napoli	Group O:9 (D1)	RDCC	Clinical	+	-	-	+	-	-	
2138	<i>Salmonella</i> Gallinarum	Group O:9 (D1)	RDCC	Unknown	+	-	-	+	-	-	
2139	<i>Salmonella</i> Eastbourne	Group O:9 (D1)	RDCC	Unknown	+	-	-	+	-	-	
2146	<i>Salmonella</i> Javiana	Group O:9 (D1)	RDCC	Unknown	+	-	-	+	-	-	
2360	<i>Salmonella</i> Berta	Group O:9 (D1)	RDCC	Unknown	+	-	-	+	-	-	
1654	<i>Salmonella</i> Kiel	Group O:2 (A)	TCC	Unknown	+	-	-	+	-	-	
2135	<i>Salmonella</i> Ohio	Group O:7 (C1)	RDCC	Clinical	+	-	-	+	-	-	
2359	<i>Salmonella</i> Montevideo	Group O:7 (C1)	RDCC	Unknown	+	-	-	+	-	-	
2351	<i>Salmonella</i> Virchow	Group O:7 (C1)	RDCC	Unknown	+	-	-	+	-	-	
3400	<i>Salmonella</i> Infantis	Group O:7 (C1)	RDCC	Clinical	+	-	-	+	-	-	
3402	<i>Salmonella</i> Bovis	Group O:8 (C2-C3)	RDCC	Unknown	+	-	-	+	-	-	
2125	<i>Salmonella</i> Albany	Group O:8 (C2-C3)	RDCC	Clinical	+	-	-	+	-	-	
2001	<i>Salmonella</i> Bovis-Morbificans	Group O:8 (C2-C3)	TCC	Unknown	+	-	-	+	-	-	
3734	<i>Salmonella</i> Kentucky	Group O:8 (C2-C3)	RDCC	Unknown	+	-	-	+	-	-	
2087	<i>Salmonella</i> Newport	Group O:8 (C2-C3)	RDCC	Unknown	+	-	-	+	-	-	
2130	<i>Salmonella</i> Muenchen	Group O:8 (C2-C3)	RDCC	Unknown	+	-	-	+	-	-	
2131	<i>Salmonella</i> Hadar	Group O:8 (C2-C3)	RDCC	Unknown	+	-	-	+	-	-	
2132	<i>Salmonella</i> Shanghai	Group O:3,10 (E1)	RDCC	Unknown	+	-	-	+	-	-	
1623	<i>Salmonella</i> Allerton	Group O:3,10 (E1)	TCC	Unknown	+	-	-	+	-	-	
2683	<i>Salmonella</i> Muenster	Group O:3,10 (E1)	TCC	Unknown	+	-	-	+	-	-	
2210	<i>Salmonella</i> Senftenburg	Group O:1,3,19 (E4)	RDCC	Feces	+	-	-	+	-	-	
1655	<i>Salmonella</i> Krefeld	Group O:1,3,19 (E4)	TCC	Unknown	+	-	-	+	-	-	
1612	<i>Salmonella</i> Aberdeen	Group O:11 (F)	TCC	Unknown	+	-	-	+	-	-	
3739	<i>Salmonella</i> Rubislaw	Group O:11 (F)	RDCC	Unknown	+	-	-	+	-	-	
3405	<i>Salmonella</i> Poona	Group O:13 (G)	RDCC	Clinical, gastroenteritis	+	-	-	+	-	-	
2831	<i>Salmonella</i> Ibidam	Group O:13 (G)	RDCC	Unknown	+	-	-	+	-	-	
3736	<i>Salmonella</i> Madelia	Group O:6,14 (H)	RDCC	Unknown	+	-	-	+	-	-	
2453	<i>Salmonella</i> Schalkwijk	Group O:6,14 (H)	TCC	Unknown	+	-	-	+	-	-	
2671	<i>Salmonella</i> Saphra	Group O:16 (I)	TCC	Unknown	+	-	-	+	-	-	
2362	<i>Salmonella</i> Hvttingfoss	Group O:16 (I)	RDCC	Unknown	+	-	-	+	-	-	
2673	<i>Salmonella</i> Michigan	Group O:17 (J)	TCC	Unknown	+	-	-	+	-	-	
2127	<i>Salmonella</i> Cerro	Group O:18 (K)	RDCC	Unknown	+	-	-	+	-	-	

2679	<i>Salmonella</i> Brisbane	Group O:28 (M)	TCC	Unknown	+	-	-	-	+	-	-
2100	<i>Salmonella</i> Urbana	Group O:30 (N)	RDCC	Unknown	+	-	-	-	+	-	-
2356	<i>Salmonella</i> Matopeni	Group O:30 (N)	RDCC	Unknown	+	-	-	-	+	-	-
2122	<i>Salmonella</i> Adelaide	Group O:35 (O)	RDCC	Unknown	+	-	-	-	+	-	-
2690	<i>Salmonella</i> Alachua	Group O:35 (O)	TCC	Unknown	+	-	-	-	+	-	-
2120	<i>Salmonella</i> Inverness	Group O:38 (P)	RDCC	Unknown	+	-	-	-	+	-	-
2118	<i>Salmonella</i> Champaign	Group O:39 (Q)	RDCC	Unknown	+	-	-	-	+	-	-
5372	<i>Salmonella</i> RioGrande	Group O:40 (R)	RDCC	Unknown	+	-	-	-	+	-	-
2685	<i>Salmonella</i> Johannesburg	Group O:40 (R)	TCC	Unknown	+	-	-	-	+	-	-
2675	<i>Salmonella</i> Vietnam	Group O:41 (S)	TCC	Unknown	+	-	-	-	+	-	-
2677	<i>Salmonella</i> Gera	Group O:42 (T)	TCC	Unknown	+	-	-	-	+	-	-
2937	<i>Salmonella</i> Berkeley	Group O:43 (U)	RDCC	Unknown	+	-	-	-	+	-	-
2676	<i>Salmonella</i> Tornow	Group O:45 (W)	TCC	Unknown	+	-	-	-	+	-	-
1728	<i>Salmonella</i> Teshi	Group O:47 (X)	RDCC	Unknown	+	-	-	-	+	-	-
6539	<i>Salmonella</i> Typhi	ATCC	ATCC ^e	Unknown	+	-	-	-	+	-	-
9150	<i>Salmonella</i> Paratyphi A	ATCC	ATCC	Unknown	+	-	-	-	+	-	-
10719	<i>Salmonella</i> Paratyphi B	ATCC	ATCC	Unknown	+	-	-	-	+	-	-
2207	<i>Salmonella</i> Enteritidis		RDCC	Unknown	+	-	-	-	+	-	+
3379	<i>Salmonella</i> Enteritidis		RDCC	Unknown	+	-	-	-	+	-	+
3729	<i>Salmonella</i> Enteritidis		RDCC	Unknown	+	-	-	-	+	-	+
3900	<i>Salmonella</i> Enteritidis		RDCC	Unknown	+	-	-	-	+	-	+
723	<i>Salmonella</i> Enteritidis	OCC ^f	Unknown	+	-	-	-	+	+	-	+
1637	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	+	-	+
1638	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	+	-	+
1639	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	g	-	-g
1640	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	g	-	-g
1986	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	+	-	+
2424	<i>Salmonella</i> Enteritidis	1,9, 12: g,m:-	TCC	Unknown	+	-	-	-	+	-	+
2425	<i>Salmonella</i> Enteritidis	9, 12: g,m:-	TCC	Unknown	+	-	-	-	+	-	+
2426	<i>Salmonella</i> Enteritidis	9, 12: g,m:-	TCC	Guinea pig	+	-	-	-	+	-	+
2443	<i>Salmonella</i> Enteritidis		TCC	Raw almonds	+	-	-	-	+	-	+
2450	<i>Salmonella</i> Enteritidis	1,9, 12: g,m:-	TCC	Clinical, gastroenteritis	+	-	-	-	+	-	+
2591	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	+	-	+
2668	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	+	-	+
2669	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	+	-	+
2670	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	+	-	+
3372	<i>Salmonella</i> Enteritidis		RDCC	Unknown	+	-	-	-	+	-	+
3378	<i>Salmonella</i> Enteritidis		RDCC	Unknown	+	-	-	-	+	-	+
3383	<i>Salmonella</i> Enteritidis var. Dansyz		RDCC	Clinical, gastroenteritis	+	-	-	-	+	-	+
1584	<i>Salmonella</i> Enteritidis		TCC	Unknown	+	-	-	-	+	-	+
ATCC BAA 1587	<i>Salmonella</i> Enteritidis		ATCC	Unknown	+	-	-	-	+	-	+
QL ^h 10155.1	<i>Salmonella</i> Enteritidis		Q Labs	Shell Eggs	+	-	-	-	+	-	+

QL 10170.1	<i>Salmonella</i> Enteritidis		Q Labs	Poultry Litter	+	-	+	+	-	+
QL 14255.2	<i>Salmonella</i> Enteritidis		Q Labs	Seasoning	+	-	+	+	-	+
QL 16078- 2A.40	<i>Salmonella</i> Enteritidis		Q Labs	Drag Swabs	+	-	+	+	-	+
QL 16078- 2A.80	<i>Salmonella</i> Enteritidis		Q Labs	Ground Turkey	+	-	+	+	-	+
QL 16078- 2A.121	<i>Salmonella</i> Enteritidis		Q Labs	Poultry Litter	+	-	+	+	-	+
QL 16078- 2A.184	<i>Salmonella</i> Enteritidis		Q Labs	Drag Swabs	+	-	+	+	-	+
QL 16078- 2A.185	<i>Salmonella</i> Enteritidis		Q Labs	Liquid Egg	+	-	+	+	-	+
QL 16078- 2A.186	<i>Salmonella</i> Enteritidis		Q Labs	Raw Chicken Breast	+	-	+	+	-	+
QL 16078- 2A.278	<i>Salmonella</i> Enteritidis		Q Labs	Ground Turkey	+	-	+	+	-	+
QL 16078- 2A.279	<i>Salmonella</i> Enteritidis		Q Labs	Raw Chicken Breast	+	-	+	+	-	+
QL 16078- 2A.280	<i>Salmonella</i> Enteritidis		Q Labs	Drag Swabs	+	-	+	+	-	+
QL 1698878. 3	<i>Salmonella</i> Enteritidis		Q Labs	Chicken Rinse	+	-	+	+	-	+
QL 175599.1	<i>Salmonella</i> Enteritidis		Q Labs	Chicken Rinse	+	-	+	+	-	+
QL 182282	<i>Salmonella</i> Enteritidis		Q Labs	Sausage	+	-	+	+	-	+
QL 188498.1	<i>Salmonella</i> Enteritidis		Q Labs	Raw Ham Knuckle	+	-	+	+	-	+
QL 191569.1	<i>Salmonella</i> Enteritidis		Q Labs	Env. Sample	+	-	+	+	-	+
QL 194559.3	<i>Salmonella</i> Enteritidis		Q Labs	Chicken Rinse	+	-	+	+	-	+
CCUG 9563	<i>Salmonella</i> Enteritidis		Q Labs	Guinea Pig	+	-	+	+	-	+
CCUG 21288	<i>Salmonella</i> Enteritidis		Q Labs	Human Feces	+	-	+	+	-	+
CCUG 25340	<i>Salmonella</i> Enteritidis		Q Labs	Urine	+	-	+	+	-	+
CCUG 26522	<i>Salmonella</i> Enteritidis		Q Labs	Human Feces	+	-	+	+	-	+
CCUG 27004	<i>Salmonella</i> Enteritidis		Q Labs	Rectal Swab	+	-	+	+	-	+
CCUG 27021	<i>Salmonella</i> Enteritidis		Q Labs	Feces	+	-	+	+	-	+
FSL S5- 415	<i>Salmonella</i> Enteritidis		Q Labs	Human	+	-	+	+	-	+
FSL S5- 483	<i>Salmonella</i> Enteritidis		Q Labs	Human	+	-	+	+	-	+
962	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-

1793	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
2124	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
2836	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
3380	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
3384	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
3740	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
3741	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
3897	<i>Salmonella</i> Typhimurium		RDCC	Tissue, animal	+	+	-	+	+	-
3920	<i>Salmonella</i> Typhimurium		RDCC	Dairy (Tiramisu)	+	+	-	+	+	-
3922	<i>Salmonella</i> Typhimurium		RDCC	Chocolate	+	+	-	+	+	-
3924	<i>Salmonella</i> Typhimurium		RDCC	Cocoa beans	+	+	-	+	+	-
4669	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
1585	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
1679	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
1680	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
1681	<i>Salmonella</i> Typhimurium		RDCC	Clinical, gastroenteritis	+	+	-	+	+	-
1683	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
1684	<i>Salmonella</i> Typhimurium		RDCC	Unknown	+	+	-	+	+	-
1880	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2387	<i>Salmonella</i> Typhimurium	1,4,5,12:i:-	TCC	Unknown	+	+	-	+	+	-
2390	<i>Salmonella</i> Typhimurium	1, 4, 5, 12 :- :-	TCC	Unknown	+	+	-	+	+	-
ATCC 19585	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
ATCC BAA-1603	<i>Salmonella</i> Typhimurium		TCC	Tomato	+	+	-	+	+	-
2461	<i>Salmonella</i> Typhimurium	4,5,12:i:1,2	TCC	Feces	+	+	-	+	+	-
2593	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2645	<i>Salmonella</i> Typhimurium	DT104b	TCC	Unknown	+	+	-	+	+	-

2646	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2647	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2648	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2649	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2650	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2651	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2652	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2653	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2654	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2655	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2656	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2657	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2658	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
2659	<i>Salmonella</i> Typhimurium/ DT104		TCC	Unknown	+	+	-	+	+	-
2660	<i>Salmonella</i> Typhimurium/ DT104		TCC	Unknown	+	+	-	+	+	-
2661	<i>Salmonella</i> Typhimurium/ DT104		TCC	Unknown	+	+	-	+	+	-
1586	<i>Salmonella</i> Typhimurium		TCC	Unknown	+	+	-	+	+	-
QL 11007-2	<i>Salmonella</i> Typhimurium		Q Labs	Flavouring	+	+	-	+	+	-
QL 11414-2	<i>Salmonella</i> Typhimurium		Q Labs	Animal Feed	+	+	-	+	+	-
QL 16078-2A.110	<i>Salmonella</i> Typhimurium		Q Labs	Raw Chicken Fillet	+	+	-	+	+	-
QL 16078-2A.112	<i>Salmonella</i> Typhimurium		Q Labs	Ground turkey	+	+	-	+	+	-
QL 16078-2A.1	<i>Salmonella</i> Typhimurium		Q Labs	Poultry rinse	+	+	-	+	+	-
QL 16078-2A.108	<i>Salmonella</i> Typhimurium		Q Labs	Environment al swab	+	+	-	+	+	-

^a RDCC = Research and Development culture collection – Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.^b Unknown = Origin of the strain is not listed or provided by the source.^c NCTC = National Collection of Type Cultures, Health Protection Agency, London, UK.^d TCC = Trials Culture Collection Number-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.^e ATCC = American Type Culture Collection, Manassas, Virginia, USA.^f OCC = Oxoid Culture Collection-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.^g Inclusivity isolates gave negative results due to laboratory acquired O antigen loss.^h QL = number proprietary to Q Laboratories LLC, Cincinnati, Ohio, USA.

Table 2. Exclusivity of the Thermo Scientific RapidFinder *Salmonella* species, Typhimurium and Enteritidis Multiplex PCR Kit (10)

ID number	Exclusivity strain	Source	Origin	Results - 7500 Fast			Results – QuantStudio 5		
				Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
TCC 0181	<i>Citrobacter intermedium</i>	TCC ^a	Unknown ^b	- ^c	-	-	- ^c	-	-
TCC 0401	<i>Enterobacter cloacae</i>	TCC	Unknown	-	-	-	-	-	-
TCC 0409	<i>Pantoea agglomerans</i>	TCC	Pasteurized milk	-	-	-	-	-	-
TCC 0414	<i>Serratia marcescens</i>	TCC	Clinical	- ^c	-	-	- ^c	-	-
TCC 0418	<i>Providencia stuartii</i>	TCC	Clinical	-	-	-	-	-	-
TCC 0593	<i>Klebsiella oxytoca</i>	TCC	Clinical	-	-	-	-	-	-
TCC 1388	<i>Enterobacter faecalis</i>	TCC	Unknown	-	-	-	-	-	-
TCC 1431	<i>Morganella morganii</i>	TCC	Clinical	-	-	-	-	-	-
TCC 1552	<i>Proteus vulgaris</i>	TCC	Unknown	-	-	-	- ^c	-	-
TCC 1566	<i>Proteus mirabilis</i>	TCC	Unknown	-	-	-	-	-	-
TCC 1804	<i>Klebsiella aerogenes</i>	TCC	Unknown	-	-	-	-	-	-
TCC 1809	<i>Escherichia coli</i>	TCC	Unknown	-	-	-	-	-	-
TCC 1892	<i>Klebsiella pneumoniae</i>	TCC	Unknown	-	-	-	-	-	-
TCC 1903	<i>Pseudomonas aeruginosa</i>	TCC	Unknown	-	-	-	-	-	-
TCC 2039	<i>Citrobacter koseri</i>	TCC	Clinical	-	-	-	-	-	-
TCC 2043	<i>Citrobacter youngae</i>	TCC	Unknown	-	-	-	-	-	-
TCC 2044	<i>Hafnia alvei</i>	TCC	Unknown	-	-	-	-	-	-
TCC 2047	<i>Escherichia hermanii</i>	TCC	Unknown	-	-	-	-	-	-
TCC 2048	<i>Serratia liquefaciens</i>	TCC	Milk	-	-	-	-	-	-
TCC 2053	<i>Enterobacter sakazakii</i>	TCC	Unknown	-	-	-	-	-	-
TCC 2198	<i>Enterobacter amnigenus</i> -Biogroup 1	TCC	Clinical	-	-	-	-	-	-
TCC 2200	<i>Enterobacter aerogenes</i>	TCC	Clinical	-	-	-	-	-	-
TCC 2201	<i>Providencia rettgeri</i>	TCC	Unknown	-	-	-	-	-	-
TCC 2203	<i>Enterobacter intermedium</i>	TCC	Clinical	-	-	-	-	-	-
TCC 2207	<i>Klebsiella terrigena</i>	TCC	Water isolate	-	-	-	-	-	-
TCC 2209	<i>Providencia alcalifaciens</i>	TCC	Clinical	-	-	-	-	-	-
TCC 2215	<i>Yersinia enterocolitica</i>	TCC	Frozen prawn	-	-	-	-	-	-
TCC 2216	<i>Edwardsiella tarda</i>	TCC	Unknown	-	-	-	-	-	-
TCC 2263	<i>Escherichia fergusonii</i>	TCC	Sausages	-	-	-	-	-	-
TCC 2264	<i>Escherichia vulneris</i>	TCC	Vegetables	-	-	-	-	-	-
TCC 2273	<i>Escherichia blattae</i>	TCC	Cockroach gut	-	-	-	- ^c	-	-
TCC 2050	<i>Shigella boydii</i>	TCC	Unknown	-	-	-	-	-	-
TCC 2051	<i>Shigella sonnei</i>	TCC	Clinical	-	-	-	-	-	-
TCC 2052	<i>Shigella flexneri</i>	TCC	Unknown	-	-	-	-	-	-
OCC 1872	<i>Escherichia coli</i> 0157:H7 VT neg	OCC ^d	Unknown	-	-	-	-	-	-
ATCC 13048	<i>Enterobacter aerogenes</i>	ATCC ^e	Sputum	-	-	-	-	-	-
ATCC 8739	<i>Escherichia coli</i>	ATCC	Feces	-	-	-	-	-	-
ATCC 51815	<i>Hafnia alvei</i>	ATCC	Milk	-	-	-	-	-	-
ATCC 10031	<i>Klebsiella pneumoniae</i>	ATCC	Clinical	-	-	-	-	-	-
ATCC 25829	<i>Morganella morganii</i>	ATCC	Feces	-	-	-	-	-	-
ATCC 6380	<i>Proteus vulgaris</i>	ATCC	Clinical	-	-	-	-	-	-
ATCC 35032	<i>Pseudomonas aeruginosa</i>	ATCC	Not available	-	-	-	-	-	-
ATCC 13880	<i>Serratia marcescens</i>	ATCC	Water	- ^c	-	-	- ^c	-	-
ATCC 49397	<i>Yersinia enterocolitica</i>	ATCC	Clinical	-	-	-	-	-	-
QL 100813-2A	<i>Citrobacter freundii</i>	Q Labs ^f	Sliced Deli Meat (Turkey)	-	-	-	-	-	-

^a TCC = Trials Culture Collection Number-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.^b Unknown = Origin of the strain is not listed or provided by the source.^c Result was originally positive. Isolates were re-incubated in candidate enrichment (BPW + 12 mg/L novobiocin for 14-18 hours) and were correctly excluded when reanalysed.^d OCC = Oxoid Culture Collection-Proprietary to Thermo Fisher Scientific, Microbiology Division, Basingstoke, UK.^e ATCC = American Type Culture Collection, Manassas, Virginia, USA.^f Isolate from culture collection of Q laboratories Inc., Ohio, USA.

Table 5. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results: Presumptive candidate result (PCR result) vs. confirmed candidate result (using Brilliance Agar confirmation method)
POD summary (10)

Matrix ^a	Inoculating strain(s)	MPN ^b / test portion	N ^c	RapidFinder <i>Salmonella</i> Multiplex PCR Kit presumptive			RapidFinder <i>Salmonella</i> Multiplex PCR Kit Brilliance <i>Salmonella</i> Agar confirmed ^f			dPOD _{CP} ^h	95% CI ⁱ
				x ^d	POD _{CP} ^e	95% CI	x	POD _{CC} ^g	95% CI		
Shell eggs	<i>Salmonella</i> spp. total/ (<i>S. Heidelberg</i> & <i>S. Enteritidis</i>)	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.77	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		1.78	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Heidelberg	N/A	5	NR ^l	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.53	20	NR	NR	NR	16	0.80	0.58, 0.92	NR	NR
		0.40	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
	<i>Salmonella</i> Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.18	20	16	0.80	0.58, 0.92	16	0.80	0.58, 0.92	0.00	-0.25, 0.25
		1.08	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
Ground turkey ^m (Original test)	<i>Salmonella</i> spp. total/ (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.18	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Bareilly	N/A	5	NR	NR	NR	0	0	0.00, 0.43	NR	NR
		0.65	20	NR	NR	NR	11	0.55	0.34, 0.74	NR	NR
		0.52	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	NR
	<i>Salmonella</i> Typhimurium ⁿ	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.26	20	17	0.85	0.76, 1.00	17	0.85	0.76, 1.00	0.00	-0.23, 0.23
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Ground turkey ^o (Repeat) (Applied Biosystems 7500 Fast Instrument results)	<i>Salmonella</i> spp. total/ (natural contaminant & <i>S. Typhimurium</i>)	N/A	5	1	0.20	0.00, 0.62	0 ^q	0.00	0.00, 0.43	0.20	-0.28, 0.62
		0.46	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.27, 0.27
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> natural contaminant	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	3	0.15	0.05, 0.36	NR	NR
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ground turkey ^o (Repeat) (Applied Biosystems QuantStudio 5 results)	<i>Salmonella</i> spp. total/ (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	2	0.40	0.12, 0.77	0 ^r	0.00	0.00, 0.43	0.40	-0.12, 0.77
		0.46	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.27, 0.27
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> natural contaminant	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	3	0.15	0.05, 0.36	NR	NR
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ground turkey ^p	<i>Salmonella</i> spp. total/	N/A	5	1	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.36, 0.76

(Applied Biosystems 7500 Fast Instrument results)	(S. Bareilly & S. Typhimurium)	0.89	20	15	0.75	0.53, 0.89	14	0.70	0.48, 0.85	0.05	-0.11, 0.21
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	Salmonella Bareilly	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.89	20	NR	NR	NR	14	0.70	0.48, 0.85	NR	NR
		1.97	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
	Salmonella Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.81	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Ground turkey ^p (Applied Biosystems QuantStudio 5 Instrument results)	Salmonella spp. total/ (S. Bareilly & S. Typhimurium)	N/A	5	0	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.36, 0.76
		0.89	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	Salmonella Bareilly	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.89	20	NR	NR	NR	14	0.70	0.48, 0.85	NR	NR
		1.97	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
	Salmonella Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.81	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Chicken carcass rinse	Salmonella spp. total/ (S. Bareilly & S. Typhimurium)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.85	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		2.75	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	Salmonella Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.34	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.72	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	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
		0.75	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		0.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

^a Matrix = for each matrix the data is shown combined for both Applied Biosystems 7500 Fast and Applied Biosystems QuantStudio 5 PCR instruments unless otherwise specified.^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 method presumptive positive outcomes divided by the total number of trials.^f All strains were confirmed by serotyping.^g POD_{CC} = Candidate method confirmed (via Brilliance Salmonella Agar) positive outcomes divided by the total number of trials.^h dPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via Brilliance Salmonella Agar) result POD values.ⁱ 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.^j RapidFinder presumptive PCR result for *Salmonella* species reflects all species present and therefore does not discriminate between the species.^k N/A = Not applicable.^l NR = Not reported, PCR presumptive positives cannot be achieved where there is no target.^m Ground turkey original test (failed on fractional positivity for *Salmonella* Typhimurium)ⁿ Data from the *Salmonella* Typhimurium ground turkey low spike original test represents the high level spike for the ground turkey repeat test.^o Ground turkey repeat test data.^p Matrix tested at the independent laboratory.^q A Natural contaminant PCR positive. Confirmed via the extended candidate confirmation protocol for high background matrixes (RVS broth enrichment onto Brilliance Salmonella Agar).^r A Natural contaminant PCR positive. Confirmed via the extended candidate confirmation protocol for high background matrixes (RVS broth enrichment onto Brilliance Salmonella Agar).**Table 6. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results: Presumptive candidate result (PCR result) vs. confirmed candidate result (using reference confirmation method) POD summary (10)**

Matrix ^a	Inoculating strain(s)	MPN ^b / test portion	N ^c	RapidFinder <i>Salmonella</i> Multiplex PCR Kit presumptive			RapidFinder <i>Salmonella</i> Multiplex PCR Kit reference method confirmed ^f			dPOD _{CP} ^h	95% CI ⁱ
				x ^d	POD _{CP} ^e	95% CI	x	POD _{CC} ^g	95% CI		
Shell eggs	Salmonella spp. total/ (S. Heidelberg &	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.77	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19

	<i>S. Enteritidis</i>	1.78	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
<i>Salmonella</i> Heidelberg	<i>Salmonella</i> Heidelberg	N/A	5	NR ^j	NR	NR	0	0.00	0.00, 0.43	NR	-0.43, 0.43
		0.53	20	NR	NR	NR	17	0.85	0.64, 0.95	NR	-0.29, 0.19
	<i>Salmonella</i> Enteritidis	0.40	5	NR	NR	NR	4	0.80	0.38, 1.00	NR	-0.47, 0.47
		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
Ground turkey ^m (Original test)	<i>Salmonella</i> spp. total ⁱ (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	0.18	20	16	0.80	0.58, 0.92	6	0.30	0.15, 0.52	0.50	0.19, 0.70
		1.08	5	4	0.80	0.38, 1.00	3	0.60	0.23, 0.88	0.20	-0.31, 0.62
		N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
	<i>Salmonella</i> Bareilly	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.65	20	NR	NR	NR	7	0.35	0.18, 0.57	NR	NR
		0.52	5	NR	NR	NR	2	0.40	0.12, 0.77	NR	NR
	<i>Salmonella</i> Typhimurium ⁿ	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.26	20	17	0.85	0.76, 1.00	18	0.90	0.70, 0.97	-0.05	-0.27, 0.17
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Ground turkey ^o (Repeat) (Applied Biosystems 7500 Fast Instrument results)	<i>Salmonella</i> spp. total ⁱ (natural contaminant & <i>S. Typhimurium</i>)	N/A	5	1	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.28, 0.62
		0.46	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.27, 0.27
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> natural contaminant	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	3	0.15	0.05, 0.36	NR	NR
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ground turkey ^o (Repeat) (Applied Biosystems QuantStudio 5 results)	<i>Salmonella</i> spp. total ⁱ (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	2 ^g	0.40	0.12, 0.77	0	0.00	0.00, 0.43	0.40	-0.12, 0.77
		0.46	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.27, 0.27
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> natural contaminant	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		N/A	20	NR	NR	NR	3	0.15	0.05, 0.36	NR	NR
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ground turkey ^p (Applied Biosystems 7500 Fast Instrument results)	<i>Salmonella</i> spp. total ⁱ (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	1	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.36, 0.76
		0.89	20	15	0.75	0.53, 0.89	14	0.70	0.48, 0.85	0.05	-0.11, 0.21
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	<i>Salmonella</i> Bareilly	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.89	20	NR	NR	NR	14	0.70	0.48, 0.85	NR	NR
		1.97	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.81	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Ground turkey ^p (Applied Biosystems QuantStudio 5 Instrument results)	<i>Salmonella</i> spp. total ⁱ (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	0	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.36, 0.76
		0.89	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	<i>Salmonella</i> Bareilly	N/A	5	NR	NR	NR	0	0.00	0.00, 0.43	NR	NR
		0.89	20	NR	NR	NR	14	0.70	0.48, 0.85	NR	NR
		1.97	5	NR	NR	NR	5	1.00	0.57, 1.00	NR	NR
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47

		0.81	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Chicken carcass rinse	<i>Salmonella</i> spp. total ^j (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.85	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		2.75	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.34	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.72	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.75	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		0.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

^a Matrix = for each matrix the data is shown combined for both 7500 Fast and QuantStudio 5 PCR instruments unless otherwise specified.^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 method presumptive positive outcomes divided by the total number of trials.^f All strains were confirmed by serotyping.^g POD_{CC} = Candidate method confirmed positives (via reference confirmation method) outcomes divided by the total number of trials.^h dPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via Brilliance Salmonella Agar) result POD values.ⁱ 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.^j RapidFinder presumptive PCR result for *Salmonella* species reflects all species present and therefore does not discriminate between the species.^k N/A = Not applicable.^l NR = Not reported, PCR presumptive positives cannot be achieved where there is no target.^m Ground turkey original test (failed on fractional positivity for *Salmonella* Typhimurium).ⁿ Data from the *Salmonella* Typhimurium ground turkey low spike original test represents the high level spike for the ground turkey repeat test.^o Ground turkey repeat test data.^p Matrix tested at the independent laboratory.^q A Natural contaminant PCR positive. Confirmed via the extended candidate confirmation protocol for high background matrixes (RVS broth enrichment onto Brilliance Salmonella Agar).

Table 7. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results: Confirmed candidate result (using Brilliance Agar confirmation method) vs. confirmed candidate result (using reference confirmation method) POD summary (10)

Matrix ^a	Inoculating strain(s)	MPN ^b / test portion	N ^c	RapidFinder Salmonella Multiplex PCR Kit Brilliance Salmonella Agar confirmed ^d			RapidFinder Salmonella Multiplex PCR Kit reference method confirmed ^d			dPOD _{CC} ^h	95% CI ⁱ
				x ^d	POD _{CC} ^e	95% CI	x	POD _{CC} ^g	95% CI		
Shell eggs	<i>Salmonella</i> spp. total ^j (<i>S. Heidelberg</i> & <i>S. Enteritidis</i>)	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.77	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		1.78	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Heidelberg	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.53	20	16	0.80	0.58, 0.92	17	0.85	0.64, 0.95	-0.05	-0.29, 0.19
		0.40	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
	<i>Salmonella</i> Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.18	20	16	0.80	0.58, 0.92	6	0.30	0.15, 0.52	0.50	0.19, 0.70
		1.08	5	4	0.80	0.38, 1.00	3	0.60	0.23, 0.88	0.20	-0.31, .062
Ground turkey ^l (Original test)	<i>Salmonella</i> spp. total ^j (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.18	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Bareilly	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.65	20	10	0.50	0.30, 0.70	7	0.35	0.18, 0.57	0.15	-0.15, 0.41
		0.52	5	4 ^q	0.80	0.38, 1.00	2 ^r	0.40	0.12, 0.77	0.40	-0.16, 0.75
	<i>Salmonella</i> Typhimurium ⁿ	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.26	20	17	0.85	0.76, 1.00	18	0.90	0.70, 0.97	-0.05	-0.27, 0.27
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

Ground turkey ^m (Repeat)	<i>Salmonella</i> spp. total ^l (natural contaminant & <i>S. Typhimurium</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.27, 0.27
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> natural contaminant	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	3	0.15	0.05, 0.36	3	0.15	0.05, 0.36	0.00	-0.23, 0.23
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	-0.28, 0.28
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ground turkey ^o	<i>Salmonella</i> spp. total ^l (<i>S. Bareilly</i> & <i>S.Typhimurium</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.89	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	<i>Salmonella</i> Bareilly	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.89	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
		0.81	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Chicken carcass rinse	<i>Salmonella</i> spp. total ^l (<i>S. Typhimurium</i> & <i>S.Enteritidis</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.85	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		2.75	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.34	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	-0.26, 0.26
		0.72	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.75	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		0.28	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

^a Matrix = for each matrix the data is shown combined for both 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 positives (using Brilliance Salmonella Agar method) divided by the total number of trials.^f All strains were confirmed by serotyping.^g POD_{CC2} = Candidate method confirmed positive outcomes divided by the total number of trials.^h dPOD_{CC} = Difference between the candidate method confirmed result (using Brilliance Salmonella Agar method) and candidate method confirmed result (using reference method) POD values.ⁱ 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.^j RapidFinder presumptive PCR result for *Salmonella* species reflects all species present and therefore does not discriminate between the species.^k N/A = Not applicable.^l Ground turkey original test (failed on fractional positivity for *Salmonella* Typhimurium).^m Ground turkey repeat test data.ⁿ Data from the *Salmonella* Typhimurium ground turkey low spike original test represents the high level spike for the ground turkey repeat test.^o Matrix tested at the independent laboratory.^q 1 out of 4 positives was not confirmed via O:7 latex testing. This isolate exhibited H: 1,5 antigens and therefore is reported as a *S. Bareilly* (it is likely the isolated colony had lost the O antigens).^r 1 out of 2 positives was not confirmed via O:7 latex testing. This isolated colony exhibited H:y and H:1,5 antigens and therefore is reported as *S. Bareilly* (it is likely that the isolated colony had lost the O antigen)**Table 8. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results: Confirmed candidate result (using Brilliance Agar confirmation method) vs. MLG/BAM reference method POD summary (10)**

Matrix ^a	Inoculating strain(s)	MPN ^b /test portion	N ^c	RapidFinder <i>Salmonella</i> Multiplex PCR Kit Brilliance Salmonella Agar confirmed ^d			Reference method ^f			dPOD _{CC} ^h	95% CI ⁱ
				x ^d	POD _{CC} ^e	95% CI	x	POD _R ^g	95% CI		
Shell eggs	<i>Salmonella</i> spp. total ^l (<i>S. Heidelberg</i> & <i>S. Enteritidis</i>)	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.77	20	19	0.95	0.76, 1.00	12	0.60	0.39, 0.78	0.35	0.09, 0.57
		1.78	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.28, 0.62

	<i>Salmonella</i> Heidelberg	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.53	20	16	0.80	0.58, 0.92	9	0.45	0.26, 0.66	0.35	0.05, 0.58
		0.40	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75
	<i>Salmonella</i> Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.18	20	16	0.80	0.58, 0.92	4	0.20	0.08, 0.42	0.60	0.29, 0.77
		1.08	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75
Ground turkey ^j (Original test)	<i>Salmonella</i> spp. total ^l (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.18	20	19	0.95	0.76, 1.00	20	1.00	0.84, 1.00	-0.05	-0.24, 0.12
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Bareilly	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.65	20	10	0.50	0.30, 0.70	11	0.55	0.34, 0.74	-0.05	-0.33, 0.24
		0.52	5	4 ^q	0.80	0.38, 1.00	3	0.60	0.23, 0.88	0.20	-0.31, .062
	<i>Salmonella</i> Typhimurium ⁿ	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.26	20	17	0.85	0.76, 1.00	19	0.95	0.76, 1.00	-0.10	-0.32, 0.11
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Ground turkey ^m (Repeat)	<i>Salmonella</i> spp. total ^l (natural contaminant & <i>S. Typhimurium</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	14	0.70	0.48, 0.85	6	0.30	0.15, 0.52	0.40	0.09, 0.62
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> natural contaminant	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	3	0.15	0.05, 0.36	0	0.00	0.00, 0.16	0.15	-0.04, 0.36
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	11	0.55	0.34, 0.74	6	0.30	0.15, 0.52	0.25	-0.05, 0.50
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ground turkey ^o	<i>Salmonella</i> spp. total ^l (<i>S. Bareilly</i> & <i>S. Typhimurium</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	14	0.70	0.48, 0.85	13	0.65	0.43, 0.82	0.05	-0.23, 0.32
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Bareilly	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	14	0.70	0.48, 0.85	13	0.65	0.43, 0.82	0.05	-0.23, 0.32
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Typhimurium	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	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.28, 0.28
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Chicken carcass rinse	<i>Salmonella</i> spp. total ^l (<i>S. Typhimurium</i> & <i>S. Enteritidis</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.85	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		2.75	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.28, 0.62
	<i>Salmonella</i> Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.34	20	15	0.75	0.53, 0.89	16	0.80	0.58, 0.92	-0.05	-0.30, 0.21
		0.72	5	5	1.00	0.57, 1.00	3	0.60	0.23, 0.88	0.40	-0.12, 0.77
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.75	20	20	1.00	0.84, 1.00	11	0.55	0.34, 0.74	0.45	0.20, 0.66
		0.28	5	5	1.00	0.57, 1.00	1	0.20	0.00, 0.62	0.80	0.19, 1.00

^a Matrix = for each matrix the data is shown combined for both 7500 Fast and QuantStudio 5 PCR instruments unless otherwise specified.^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 presumptive positives (confirmed via Brilliance Salmonella Agar) divided by the total number of trials.^f All strains were confirmed by serotyping.^g POD_R = Reference method positive outcomes divided by the total number of trials.^h dPOD_{CC} = Difference between the candidate method confirmed (via Brilliance Salmonella Agar) and reference method POD values.

ⁱ 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.^j RapidFinder presumptive PCR result for *Salmonella* species reflects all species present and therefore does not discriminate between the species.^k N/A = Not applicable.^l Ground turkey original test (failed on fractional positivity for *Salmonella* Typhimurium).^m Ground turkey repeat test data.ⁿ Data from the *Salmonella* Typhimurium ground turkey low spike original test represents the high level spike for the ground turkey repeat test.^o Matrix tested at the independent laboratory.^q 1 out of 4 positives was not confirmed via O:7 latex testing. This isolate exhibited H: 1,5 antigens and therefore is reported as a *Salmonella* Bareilly (it is likely the isolated colony had lost the O antigens)

Table 9. RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex PCR Kit Results: Confirmed candidate result (using reference confirmation method) vs. MLG/BAM reference method POD summary (10)

Matrix ^a	Inoculating strain(s)	MPN ^b /test portion	N ^c	RapidFinder <i>Salmonella</i> Multiplex PCR Kit reference method confirmed ^f			Reference method ^e			dPOD _{CCZ} ^h	95% CI ⁱ
				x ^d	POD _{CCZ} ^e	95% CI	x	POD _R ^g	95% CI		
Shell eggs	<i>Salmonella</i> spp. total ^j (<i>S.</i> Heidelberg & <i>S.</i> Enteritidis)	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.77	20	19	0.95	0.76, 1.00	12	0.60	0.39, 0.78	0.35	0.09, 0.57
		1.78	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.28, 0.62
	<i>Salmonella</i> Heidelberg	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.53	20	17	0.85	0.64, 0.95	9	0.45	0.26, 0.66	0.40	0.10, 0.62
		0.40	5	4	0.80	0.38, 1.00	2	0.40	0.12, 0.77	0.40	-0.16, 0.75
	<i>Salmonella</i> Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.18	20	6	0.30	0.15, 0.52	4	0.20	0.08, 0.42	0.10	-0.17, 0.35
		1.08	5	3	0.60	0.23, 0.88	2	0.40	0.12, 0.77	0.20	-0.32, 0.60
Ground turkey ^l (Original test)	<i>Salmonella</i> spp. total ^j (<i>S.</i> Bareilly & <i>S.</i> Typhimurium)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		3.18	20	19	0.95	0.76, 1.00	20	1.00	0.84, 1.00	-0.05	-0.24, 0.12
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Bareilly	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.65	20	7	0.35	0.18, 0.57	11	0.55	0.34, 0.74	-0.20	-0.46, 0.10
		0.52	5	2	0.40	0.12, 0.77	3	0.60	0.23, 0.88	-0.20	-0.60, 0.32
	<i>Salmonella</i> Typhimurium ⁿ	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.26	20	18	0.90	0.70, 0.97	19	0.95	0.76, 1.00	-0.05	-0.26, 0.15
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Ground turkey ^m (Repeat)	<i>Salmonella</i> spp. total ^j (natural contaminant & <i>S.</i> Typhimurium)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	14	0.70	0.48, 0.85	6	0.30	0.15, 0.52	0.40	0.09, 0.62
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> natural contaminant	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	3	0.15	0.05, 0.36	0	0.00	0.00, 0.16	0.15	-0.04, 0.36
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46	20	11	0.55	0.34, 0.74	6	0.30	0.15, 0.52	0.25	-0.05, 0.50
		N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
Ground turkey ^o	<i>Salmonella</i> spp. total ^j (<i>S.</i> Bareilly & <i>S.</i> Typhimurium)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	14	0.70	0.48, 0.85	13	0.65	0.43, 0.82	0.05	-0.23, 0.32
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Bareilly	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.89	20	14	0.70	0.48, 0.85	13	0.65	0.43, 0.82	0.05	-0.23, 0.32
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	<i>Salmonella</i> Typhimurium	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	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.28, 0.28
		1.97	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

Chicken carcass rinse	<i>Salmonella</i> spp. total ⁱ (<i>S. Typhimurium</i> & <i>S. Enteritidis</i>)	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		2.85	20	20	1.00	0.84, 1.00	20	1.00	0.84, 1.00	0.00	-0.16, 0.16
		2.75	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.28, 0.28
	<i>Salmonella</i> Enteritidis	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		1.34	20	15	0.75	0.53, 0.89	16	0.80	0.58, 0.92	-0.05	-0.30, 0.21
		0.72	5	5	1.00	0.57, 1.00	3	0.60	0.23, 0.88	0.40	-0.12, 0.77
	<i>Salmonella</i> Typhimurium	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.75	20	20	1.00	0.84, 1.00	11	0.55	0.34, 0.74	0.45	0.20, 0.66
		0.28	5	5	1.00	0.57, 1.00	1	0.20	0.00, 0.62	0.80	0.19, 1.00

^a Matrix = for each matrix the data is shown combined for both 7500 Fast and QuantStudio 5 PCR instruments unless otherwise specified.^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_{CC2} = Candidate method presumptive positives (confirmed via reference method) divided by the total number of trials.^f All strains were confirmed by serotyping.^g PODR = Reference method positive outcomes divided by the total number of trials.^h dPOD_{CC2} = Difference between the candidate method confirmed (via Brilliance Salmonella Agar) and reference method POD values.ⁱ 95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.^j RapidFinder presumptive PCR result for *Salmonella* species reflects all species present and therefore does not discriminate between the species.^k N/A = Not applicable.^l Ground turkey original test (failed on fractional positivity for *Salmonella* Typhimurium).^m Ground turkey repeat test data.ⁿ Data from the *Salmonella* Typhimurium ground turkey low spike original test represents the high level spike for the ground turkey repeat test.^o Matrix tested at the independent laboratory

DISCUSSION OF THE MODIFICATION STUDY APPROVED OCTOBER 2020 (11)

RapidFinder Salmonella Multiplex PCR assay Stage 1

RapidFinder Salmonella Multiplex PCR assay: Inclusivity/Exclusivity.—The reanalysis of the inclusivity data showed **1 change from positive to a warning call**, in the PCR result comparison between RFA 1.0 and RFA 1.1 and the relevant kit files. This change is listed in the Table 31. The warning call has been generated by the uncharacteristic shape of the PCR curve, both IPC and targets are negative with new software. The exclusivity data showed **1 change from a warning call to negative**, in the PCR result comparison between RFA 1.0 and RFA 1.1. The original warning call with RFA 1.0 was generated by a failure of the IPC which is now positive with RFA 1.1. Tables 21 and 22 detail the isolates used during the Inclusivity and Exclusivity studies.

RapidFinder Salmonella Multiplex PCR assay: Matrix testing.—The reanalysis of the matrix data showed **no change** in the PCR results between RFA 1.0 and RFA 1.1 and the relevant kit files. The details are listed in Table 29.

RapidFinder Salmonella Multiplex PCR assay Stage 2

RapidFinder Salmonella Multiplex PCR assay: Inclusivity/Exclusivity.—The reanalysis of the inclusivity data showed **1 change from a negative result to a positive for the SEN target**, in the PCR result comparison between RFA 1.0 and RFA 1.1 and the relevant kit files. This change is listed in the Table 31. The change is affecting a repeated sample and is very likely due to cross-contamination (sample showed a fluorescence peak). The original result is correct with both software versions. The exclusivity data showed 1 change from a negative to a positive result for the SPP target, in the PCR result comparison between RFA 1.0 and RFA 1.1. Tables 23 and 24 detail the isolates used during the Inclusivity and Exclusivity studies.

RapidFinder Salmonella Multiplex PCR assay: Matrix testing.—The reanalysis of the matrix data showed **2 changes in the PCR results between RFA 1.0 and RFA 1.1 and the relevant kit files**. The changes are listed in the Table 31. The 2 samples affected are part of the shell eggs and ground turkey matrix studies. The shell eggs sample has changed from a negative to a positive for the SLM and SEN targets and is very likely due to cross contamination detected by the improved baselining with RFA 1.1. The ground turkey sample (as part of the repeat test) has changed from negative to positive for the SLM target. The details are listed in Table 30. Due to the changes the POD analysis was re-done to show that the acceptability limits are still met. The details are listed in Tables 32 and 33.

Table 21. Inclusivity results for the RapidFinder Salmonella Multiplex PCR Assay using RFA v1.0 and RFA v1.1 Stage 1 (11)

ID	Isolate	Origin	Source	RFA 1.0 result			RFA 1.1 result		
				SLM	SEN	STY	SLM	SEN	STY
1726	Salmonella Uphill	Unknown	RDCC ^a	Positive	Negative	Negative	Positive	Negative	Negative
2355	Salmonella Donna	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2830	Salmonella Locarno	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 10252	Salmonella Tranaraoa	Unknown	NCTC ^b	Positive	Negative	Negative	Positive	Negative	Negative
2599	Salmonella salamae	Unknown	TCC ^c	Positive	Negative	Negative	Positive	Negative	Negative

NCTC 8297	<i>Salmonella arizoniae</i>	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
2389	<i>Salmonella arizoniae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2608	<i>Salmonella arizoniae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2609	<i>Salmonella arizoniae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2610	<i>Salmonella arizoniae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2386	<i>Salmonella diarizonae</i>	Clinical	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2388	<i>Salmonella diarizonae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2616	<i>Salmonella diarizonae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2617	<i>Salmonella diarizonae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2618	<i>Salmonella diarizonae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3732	<i>Salmonella houtenae</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2624	<i>Salmonella houtenae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2625	<i>Salmonella houtenae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2626	<i>Salmonella houtenae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2627	<i>Salmonella houtenae</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2360	<i>Salmonella indica</i>	Unknown	OCC ^d	Positive	Negative	Negative	Positive	Negative	Negative
2643	<i>Salmonella indica</i>	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2640	<i>Salmonella indica</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2641	<i>Salmonella indica</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2642	<i>Salmonella indica</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 2215	<i>Salmonella bongori</i>	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 12419	<i>Salmonella bongori</i>	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
3407	<i>Salmonella Stanley</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
5096	<i>Salmonella Abony</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2150	<i>Salmonella Saintpaul</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3377	<i>Salmonella Heidelberg</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2358	<i>Salmonella Agona</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2839	<i>Salmonella Brandenburg</i>	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2840	<i>Salmonella Indiana</i>	Turkey	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2296	<i>Salmonella Abortus-equii</i>	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
3016	<i>Salmonella Abortusovis</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3017	<i>Salmonella Schwarzengrund</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3018	<i>Salmonella Stanleyville</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3019	<i>Salmonella Sandiego</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3381	<i>Salmonella Bredeney</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30151	<i>Salmonella Java</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30020	<i>Salmonella Paratyphi B</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3399	<i>Salmonella Dublin</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 3747	<i>Salmonella Rostock</i>	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
1774	<i>Salmonella Gallinarum</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 9868	<i>Salmonella Alabama</i>	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
3024	<i>Salmonella Miami</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3025	<i>Salmonella Lomalinda</i>	Clinical	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3026	<i>Salmonella Israel</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3027	<i>Salmonella Portland</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3028	<i>Salmonella Sendai</i>	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2129	<i>Salmonella Napoli</i>	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2138	<i>Salmonella Gallinarum</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2139	<i>Salmonella Eastbourne</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2146	<i>Salmonella Javiana</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2360	<i>Salmonella Berta</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30001	<i>Salmonella Typhi</i>	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative

1654	<i>Salmonella</i> Kiel	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2135	<i>Salmonella</i> Ohio	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2359	<i>Salmonella</i> Montevideo	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2351	<i>Salmonella</i> Virchow	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3400	<i>Salmonella</i> Infantis	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3402	<i>Salmonella</i> Bovis	Unknown	RDCC	Positive	Negative	Negative	Warning ^f	Warning ^f	Warning ^f
2125	<i>Salmonella</i> Albany	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2001	<i>Salmonella</i> Bovis-Morbificans	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
3734	<i>Salmonella</i> Kentucky	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2087	<i>Salmonella</i> Newport	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2130	<i>Salmonella</i> Muenchen	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2131	<i>Salmonella</i> Hadar	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2132	<i>Salmonella</i> Shanghai	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1623	<i>Salmonella</i> Allerton	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2683	<i>Salmonella</i> Muenster	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2210	<i>Salmonella</i> Seftenburg	Faeces	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1655	<i>Salmonella</i> Krefeld	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
1612	<i>Salmonella</i> Aberdeen	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
3739	<i>Salmonella</i> Rubislaw	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3405	<i>Salmonella</i> Poona	Clinical, gastroenteritis	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2831	<i>Salmonella</i> Ibadam	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3736	<i>Salmonella</i> Madelia	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2453	<i>Salmonella</i> Schalkwijk	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2671	<i>Salmonella</i> Saphra	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2362	<i>Salmonella</i> Huttingfoss	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2673	<i>Salmonella</i> Michigan	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2127	<i>Salmonella</i> Cerro	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2679	<i>Salmonella</i> Brisbane	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2100	<i>Salmonella</i> Urbana	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2356	<i>Salmonella</i> Matopeni	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2122	<i>Salmonella</i> Adelaide	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2690	<i>Salmonella</i> Alachua	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2120	<i>Salmonella</i> Inverness	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2118	<i>Salmonella</i> Champaign	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
5372	<i>Salmonella</i> Rio Grande	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2685	<i>Salmonella</i> Johannesburg	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2675	<i>Salmonella</i> Vietnam	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2677	<i>Salmonella</i> Gera	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2937	<i>Salmonella</i> Berkeley	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2676	<i>Salmonella</i> Tornow	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
1728	<i>Salmonella</i> Teshi	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30017	<i>Salmonella</i> Paratyphi A	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30026	<i>Salmonella</i> Paratyphi C	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2207	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3379	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3729	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3900	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
723	<i>Salmonella</i> Enteritidis	Unknown	OCC	Positive	Positive	Negative	Positive	Positive	Negative
1637	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1638	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1639	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1640	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative

1986	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2424	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2425	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2426	<i>Salmonella</i> Enteritidis	Guinea pig	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2443	<i>Salmonella</i> Enteritidis	Raw almonds	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2450	<i>Salmonella</i> Enteritidis	Clinical, gastroenteritis	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2591	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2668	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2669	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2670	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
3372	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3378	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3383	<i>Salmonella</i> Enteritidis var. Dansyz	Clinical, gastroenteritis	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
1584	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
ATCC BAA 1587	<i>Salmonella</i> Enteritidis	Unknown	Q Labs ^g	Positive	Positive	Negative	Positive	Positive	Negative
QL 10155.1	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 10170.1	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 14255.2	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078- 2A.40	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078- 2A.80	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.121	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.184	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.185	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.186	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.278	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.279	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.280	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 1698878.3	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 175599.1	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 182282	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Negative ^b	Negative	Positive	Negative ^b	Negative
QL 188498.1	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 191569.1	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 194559.3	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 9563	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 21288	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 25340	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 26522	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 27004	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 27021	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
FSL S5-415	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
FSL S5-483	<i>Salmonella</i> Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
962	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1793	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
2124	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
2836	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3380	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3384	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3740	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3741	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3897	<i>Salmonella</i> Typhimurium	Tissue, animal	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3920	<i>Salmonella</i> Typhimurium	Dairy (Tiramisu)	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3922	<i>Salmonella</i> Typhimurium	Chocolate	RDCC	Positive	Negative	Positive	Positive	Negative	Positive

3924	<i>Salmonella</i> Typhimurium	Cocoa beans	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
4669	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1585	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1679	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1680	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1681	<i>Salmonella</i> Typhimurium	Clinical, gastroenteritis	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1683	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1684	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1880	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2387	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2390	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
ATCC 19585	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
ATCC BAA-1603	<i>Salmonella</i> Typhimurium	Tomato	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2461	<i>Salmonella</i> Typhimurium	Faeces	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2593	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2645	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2646	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2647	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2648	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2649	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2650	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2651	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2652	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2653	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2654	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2655	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2656	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2657	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2658	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2659	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2660	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2661	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
1586	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
QL 11007-2	<i>Salmonella</i> Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 11414-2	<i>Salmonella</i> Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 16078-2A.110	<i>Salmonella</i> Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 16078-2A.112	<i>Salmonella</i> Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 16078-2A.1	<i>Salmonella</i> Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 16078-2A.108	<i>Salmonella</i> Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive

*RDCC = R&D Culture Collection, Thermo Fisher Scientific, UK.

†NCTC = National Collection of Type Cultures, Health Protection Agency, London, UK.

‡TCC = Trials Culture Collection, Thermo Fisher Scientific, UK.

§OCC = Oxoid Culture Collection, Thermo Fisher Scientific, UK.

^RFA v1.1 with kit file 2.1.

^Warning result with RFA 1.1 and kit file 2.1.

^Q Labs = Q Laboratories Culture Collection, Ohio, US.

^original result remained negative with RFA 1.1.

Table 22. Exclusivity results for the RapidFinder Salmonella Multiplex PCR Assay using RFA v1.0 and RFA v1.1 Stage 1 (11)

^aTCC = Trials Culture Collection, Thermo Fisher Scientific, UK.^bOCC = Oxoid Culture Collection, Thermo Fisher Scientific, UK.^cQ Labs = Q Laboratories Culture Collection, Ohio, US.**Table 23. Inclusivity results for the RapidFinder Salmonella Multiplex PCR Assay using RFA v1.0 and RFA v1.1 Stage 2 (11)**

ID	Isolate	Origin	Source	RFA 1.0 result			RFA 1.1 result		
				SLM	SEN	STY	SLM	SEN	STY
1726	Salmonella Uphill+B259:BB259:B362	Unknown ^a	RDCC ^b	Positive	Negative	Negative	Positive	Negative	Negative
2355	Salmonella Donna	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2830	Salmonella Locarno	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 10252	Salmonella Tranaroa	Unknown	NCTC ^c	Positive	Negative	Negative	Positive	Negative	Negative
2599	Salmonella salamae	Unknown	TCC ^d	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 8297	Salmonella arizoniae	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
2389	Salmonella arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2608	Salmonella arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2609	Salmonella arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2610	Salmonella arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2386	Salmonella diarizonae	Clinical	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2388	Salmonella diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2616	Salmonella diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2617	Salmonella diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2618	Salmonella diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3732	Salmonella houtenae	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2624	Salmonella houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2625	Salmonella houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2626	Salmonella houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2627	Salmonella houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2360	Salmonella indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2643	Salmonella indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2640	Salmonella indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2641	Salmonella indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2642	Salmonella indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 2215	Salmonella bongori	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 12419	Salmonella bongori	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
3407	Salmonella Stanley	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
5096	Salmonella Abony	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2150	Salmonella Saintpaul	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3377	Salmonella Heidelberg	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2358	Salmonella Agona	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2839	Salmonella Brandenburg	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2840	Salmonella Indiana	Turkey	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2296	Salmonella Abortus-equii	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3016	Salmonella Abortusovis	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3017	Salmonella Schwarzengrund	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3018	Salmonella Stanleyville	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3019	Salmonella Sandiego	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3381	Salmonella Bredeney	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3399	Salmonella Dublin	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 3747	Salmonella Rostock	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
1774	Salmonella Gallinarum	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative

NCTC 9868	<i>Salmonella</i> Alabama	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
3024	<i>Salmonella</i> Miami	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3025	<i>Salmonella</i> Lomalinda	Clinical	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3026	<i>Salmonella</i> Israel	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3027	<i>Salmonella</i> Portland	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3028	<i>Salmonella</i> Sendai	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2129	<i>Salmonella</i> Napoli	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2138	<i>Salmonella</i> Gallinarum	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2139	<i>Salmonella</i> Eastbourne	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2146	<i>Salmonella</i> Javiana	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2360	<i>Salmonella</i> Berta	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1654	<i>Salmonella</i> Kiel	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2135	<i>Salmonella</i> Ohio	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2359	<i>Salmonella</i> Montevideo	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2351	<i>Salmonella</i> Virchow	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3400	<i>Salmonella</i> Infantis	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3402	<i>Salmonella</i> Bovis	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2125	<i>Salmonella</i> Albany	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2001	<i>Salmonella</i> Bovis-Morbificans	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3734	<i>Salmonella</i> Kentucky	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2087	<i>Salmonella</i> Newport	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2130	<i>Salmonella</i> Muenchen	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2131	<i>Salmonella</i> Hadar	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2132	<i>Salmonella</i> Shanghai	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1623	<i>Salmonella</i> Allerton	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2683	<i>Salmonella</i> Muenster	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2210	<i>Salmonella</i> Seftenburg	Feces	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1655	<i>Salmonella</i> Krefeld	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
1612	<i>Salmonella</i> Aberdeen	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3739	<i>Salmonella</i> Rubislaw	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3405	<i>Salmonella</i> Poona	Clinical, gastroenteritis	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2831	<i>Salmonella</i> Ibidam	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3736	<i>Salmonella</i> Madelia	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2453	<i>Salmonella</i> Schalkwijk	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2671	<i>Salmonella</i> Saphra	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2362	<i>Salmonella</i> Huttingfoss	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2673	<i>Salmonella</i> Michigan	Unknown	TCC	Positive	Negative	Negative	Positive	Positive	Negative
2127	<i>Salmonella</i> Cerro	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2679	<i>Salmonella</i> Brisbane	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2100	<i>Salmonella</i> Urbana	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2356	<i>Salmonella</i> Matopeni	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2122	<i>Salmonella</i> Adelaide	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2690	<i>Salmonella</i> Alachua	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2120	<i>Salmonella</i> Inverness	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2118	<i>Salmonella</i> Champaign	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
5372	<i>Salmonella</i> Rio grande	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2685	<i>Salmonella</i> Johannesburg	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2675	<i>Salmonella</i> Vietnam	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2677	<i>Salmonella</i> Gera	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2937	<i>Salmonella</i> Berkeley	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2676	<i>Salmonella</i> Tornow	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
1728	<i>Salmonella</i> Teshi	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative

5767	Salmonella Rostock	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
2207	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3379	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3729	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3900	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
723	Salmonella Enteritidis	Unknown	OCC ^e	Positive	Positive	Negative	Positive	Positive	Negative
1637	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1638	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1639	Salmonella Enteritidis	Unknown	TCC	Positive	Negative ^g	Negative	Positive	Negative ^g	Negative
1640	Salmonella Enteritidis	Unknown	TCC	Negative ^g	Negative ^g	Negative	Negative ^g	Negative ^g	Negative
1986	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2424	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2425	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2426	Salmonella Enteritidis	Guinea pig	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2443	Salmonella Enteritidis	Raw almonds	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2450	Salmonella Enteritidis	Clinical, gastroenteritis	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2591	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2668	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2669	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2670	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
3372	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3378	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3383	Salmonella Enteritidis var. Dansyz	Clinical, gastroenteritis	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
1584	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
962	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1793	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
2124	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
2836	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3380	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3384	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3740	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3741	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3897	Salmonella Typhimurium	Tissue, animal	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3920	Salmonella Typhimurium	Dairy (Tiramisu)	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3922	Salmonella Typhimurium	Chocolate	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3924	Salmonella Typhimurium	Cocoa beans	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
4669	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1585	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1679	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1680	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1681	Salmonella Typhimurium	Clinical, gastroenteritis	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1683	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1684	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1880	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2387	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2390	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
ATCC 19585	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
ATCC BAA-1603	Salmonella Typhimurium	Tomato	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2461	Salmonella Typhimurium	Faeces	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2593	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2645	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2646	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive

2647	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2648	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2649	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2650	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2651	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2652	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2653	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2654	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2655	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2656	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2657	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2658	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2659	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2660	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2661	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
1586	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive

^aUnknown = Origin of the strain is not listed or provided by the source

^bRDCC = R&D Culture Collection, Thermo Fisher Scientific, UK

^cNCTC = National Collection of Type Cultures, Health Protection Agency, London, UK

^dTCC = Trials Culture Collection, Thermo Fisher Scientific, UK

^eOCC = Oxoid Culture Collection, Thermo Fisher Scientific, UK

^fResult positive with RFA 1.1 and 2.1 kit file.

^gInclusivity isolates gave negative results due to laboratory acquired O antigen loss

Table 24. Exclusivity results for the RapidFinder Salmonella Multiplex PCR Assay using RFA v1.0 and RFA v1.1 Stage 2 (11)

TCC 2203	<i>Enterobacter intermedium</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2207	<i>Klebsiella terrigena</i>	Water isolate	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2209	<i>Providencia alcalifaciens</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2215	<i>Yersinia enterocolitica</i>	Frozen prawn	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2216	<i>Edwardsiella tarda</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2263	<i>Escherichia fergusonii</i>	Sausages	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2264	<i>Escherichia vulneris</i>	Vegetables	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2273	<i>Escherichia blattae</i>	Cockroach gut	TCC	Negative ^b	Negative	Negative	Negative ^b	Negative	Negative
TCC 2050	<i>Shigella boydii</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2051	<i>Shigella sonnei</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2052	<i>Shigella flexneri</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
OCC 1872	<i>Escherichia coli</i> 0157:H7 VT neg	Unknown	OCC ^d	Negative	Negative	Negative	Negative	Negative	Negative

^aTCC = Trials Culture Collection, Thermo Fisher Scientific, UK.^bResult was originally positive. Isolates were r-incubated in candidate enrichment (BPW+novobiocin for 14-18h) and were correctly excluded when reanalysed.^cResult positive with RFA 1.1 and kit file 2.1.^dOCC = Oxoid Culture Collection, Thermo Fisher Scientific, UK.

Table 29. Thermo Scientific RapidFinder Salmonella Multiplex PCR Assay Stage 1 result comparison for RFA v1.0 and RFA v1.1 (11)

Matrix	Inoculating Strain(s)	MPN ^a / Test Portion	N ^b	Candidate Method ^c		
				RFA 1.0 x ^d	RFA 1.0 -! ^e	RFA 1.1 x ^f
Raw chicken thighs w/ skin	<i>Salmonella</i> spp. total (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A ^g	5	0	N/A	0
		1.8	20	19	N/A	19
		1.8	5	5	N/A	5
	S. Enteritidis D ₁	N/A	5	0	N/A	0
		0.3	20	15	N/A	15
		0.2	5	4	N/A	4
	S. Kentucky C ₃	N/A	5	NR ^h	NR	NR
		1.0	20	NR	NR	NR
		1.5	5	NR	NR	NR
Raw chicken thighs w/ skin (independent lab) ⁱ	<i>Salmonella</i> spp. total (S. Kentucky C ₃ & S. Enteritidis D ₁)	N/A	5	0	N/A	0
		1.9	20	16	N/A	16
		3.6	5	5	N/A	5
	S. Enteritidis D ₁	N/A	5	0	N/A	0
		0.9	20	12	N/A	12
		2.3	5	5	N/A	5
	S. Kentucky C ₃	N/A	5	NR	NR	NR
		0.8	20	NR	NR	NR
		2.4	5	NR	NR	NR
Raw chicken wings w/ skin	S. Typhimurium B	N/A	5	0	N/A	0
		1.0	20	15	N/A	15
		3.1	5	4	N/A	4
Chicken nuggets	S. Montevideo C ₁	N/A ^m	5	NR	NR	NR
		0.5	20	NR	NR	NR
		1.3	5	NR	NR	NR
Chicken nuggets	S. Typhimurium B	N/A	5	0	N/A	0
		1.5	20	15	N/A	15
		3.0	5	3	N/A	3
Raw Pork Sausage	<i>Salmonella</i> spp. total (S. Ohio C ₁ & S. Typhimurium B & S. Enteritidis D ₁)	N/A	5	0	N/A	0
		3.8	20	20	N/A	20
		> 4.4	5	5	N/A	5
	S. Typhimurium B	N/A	5	0	N/A	0
		0.6	20	11	N/A	11
		0.8	5	4	N/A	4
	S. Enteritidis D ₁	N/A	5	0	N/A	0
		0.4	20	15	N/A	15
		0.3	5	5	N/A	5
	S. Ohio C ₁	N/A	5	NR	NR	NR
		1.3	20	NR	NR	NR
		4.4	5	NR	NR	NR
Stainless Steel Environmental Surface Sponges	<i>Salmonella</i> spp. total (S. Poona G ₁ & S. Typhimurium B)	N/A	5	0	N/A	0
		N/A	20	17	N/A	17
		N/A	5	5	N/A	5
	S. Typhimurium B	N/A	5	0	N/A	0
		N/A	20	13	N/A	13
		N/A	5	5	N/A	5
	S. Poona G ₁	N/A	5	NR	NR	NR
		N/A	20	NR	NR	NR
		N/A	5	NR	NR	NR
Stainless Steel Environmental Surface Sponges (independent lab)	<i>Salmonella</i> spp. total (S. Poona G ₁ & S. Typhimurium B)	N/A	5	0	N/A	0
		N/A	20	15	N/A	15
		N/A	5	5	N/A	5
	S. Typhimurium B	N/A	5	0	N/A	0
		N/A	20	10	N/A	10
		N/A	5	5	N/A	5
	S. Poona G ₁	N/A	5	NR	N/A	NR
		N/A	20	NR	N/A	NR
		N/A	5	NR	N/A	NR

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

^bN = Number of test portions, 5 unspiked, 20 low spike, 5 high spike.

^cCandidate method presumptive result (PCR only).

^dRFA 1.0 x = Number of positive test portions gained originally with RFA 1.0 and original kit file.

^eRFA 1.0 - ! = Number of positive test portions gained originally with RFA 1.0 and original kit file (excluding samples with warning calls seen on RFA 1.1).

^fRFA 1.1 x = Number of positive test portions gained originally with RFA 1.0 and original kit file.

^gN/A = Not applicable.

^hNR = Not reported. *Salmonella* strains that are not a specific PCR target cannot generate a presumptive PCR result for the specific strain.

ⁱMatrix tested by the independent laboratory.

Table 30. Thermo Scientific RapidFinder Salmonella Multiplex PCR Assay Stage 2 result comparison for RFA v1.0 and RFA v1.1 (11)

Matrix	Inoculating Strain(s)	MPN ^a / Test Portion	N ^b	Candidate Method ^c		
				RFA 1.0 x ^d	RFA 1.0 -!e	RFA 1.1 x ^f
Shell eggs	Salmonella spp. total (S. Heidelberg & S. Enteritidis)	N/A ^g	5	0	N/A	1
		0.8	20	19	N/A	19
		1.8	5	5	N/A	5
	S. Heidelberg	N/A	5	NR ^h	NR	NR
		0.5	20	NR	NR	NR
		0.4	5	NR	NR	NR
	S. Enteritidis	N/A	5	0	N/A	1
		0.2	20	16	N/A	16
		1.1	5	4	N/A	4
Ground Turkey ⁱ (Original test)	Salmonella spp. total (S. Bareilly & S. Typhimurium)	N/A	5	0	N/A	0
		3.2	20	19	N/A	19
		N/A	5	5	N/A	5
	S. Bareilly	N/A	5	NR	NR	NR
		0.7	20	NR	NR	NR
		0.5	5	NR	NR	NR
	S. Typhimurium ^j	N/A	5	0	N/A	0
		2.3	20	17	N/A	17
		N/A	5	5	N/A	5
Ground Turkey ^k (Repeat)	Salmonella spp. total (natural contaminant & S. Typhimurium)	N/A	5	2 ^l	N/A	2 ^l
		0.5	20	14	N/A	15
		N/A	N/A	N/A	N/A	N/A
	Salmonella natural contaminant	N/A	5	NR	NR	NR
		N/A	20	NR	NR	NR
		N/A	N/A	N/A	N/A	N/A
	S. Typhimurium	N/A	5	0	N/A	0
		0.5	20	11	N/A	11
		N/A	N/A	N/A	N/A	N/A
Chicken carcass rinse	Salmonella spp. total (S. Typhimurium & S. Enteritidis)	N/A	5	0	N/A	0
		2.9	20	20	N/A	20
		2.8	5	5	N/A	5
	S. Enteritidis	N/A	5	0	N/A	0
		1.3	20	15	N/A	15
		0.7	5	5	N/A	5
	S. Typhimurium	N/A	5	0	N/A	0
		0.8	20	20	N/A	20
		0.3	5	5	N/A	5

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

^bN = Number of test portions, 5 unspiked, 20 low spike, 5 high spike.

^cCandidate method presumptive result (PCR only).

^dRFA 1.0 x = Number of positive test portions gained originally with RFA 1.0 and original kit file.

^eRFA 1.0 - ! = Number of positive test portions gained originally with RFA 1.0 and original kit file (excluding samples with warning calls seen on RFA 1.1).

^fRFA 1.1 x = Number of positive test portions gained originally with RFA 1.0 and original kit file.

^gN/A = Not applicable.

^hNR = Not reported. *Salmonella* strains that are not a specific PCR target cannot generate a presumptive PCR result for the specific strain.

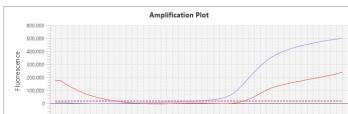
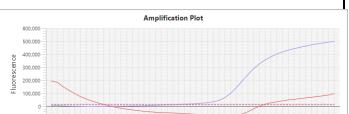
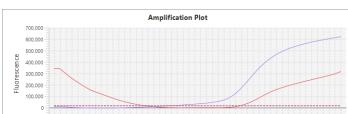
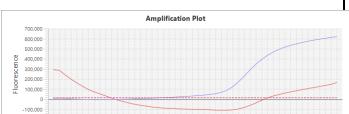
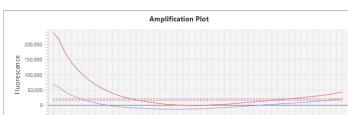
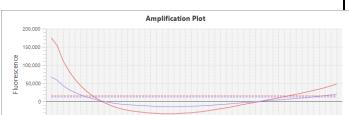
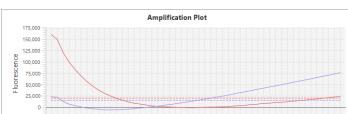
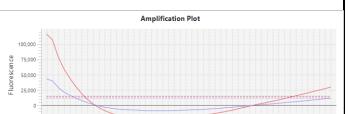
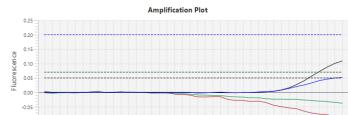
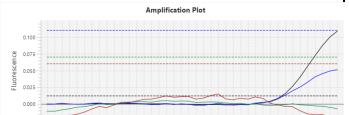
ⁱGround turkey original test (failed on fractional positivity for *Salmonella* Typhimurium).

^jData from the *Salmonella* Typhimurium ground turkey low spike original test represents the high level spike for the ground turkey repeat test.

^kGround turkey repeat test data.

^lA natural contaminant PCR positive. Confirmed via the extended candidate confirmation protocol for high background matrixes (RVS onto Brilliance Salmonella Agar).

Table 31. Thermo Scientific SureTect and RapidFinder PCR range warning call/changes summary using RFA 1.0 and RFA 1.1 (11)

Assay	Sample	Strain	Sample ID	RFA 1.0	RFA 1.1	Description	RFA 1.0	RFA 1.1																																																																						
SureTect Listeria monocytogenes	Inclusivity	TCC 1195 L. monocytogenes	27	Positive	Warning	No IPC amplification; Positive for target	 <table border="1"> <thead> <tr> <th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>C_r</th><th>ΔR_n</th></tr> </thead> <tbody> <tr> <td>A1</td><td>27</td><td>Unknown</td><td>IPC LMO ST</td><td>Positive</td><td>33.37</td><td>239.849... 6...</td></tr> <tr> <td>A1</td><td>27</td><td>Unknown</td><td>LMO ST</td><td>Positive</td><td>23.40</td><td>499.897... 8...</td></tr> </tbody> </table>	Well	Sample	Type	Target	Call	C _r	ΔR _n	A1	27	Unknown	IPC LMO ST	Positive	33.37	239.849... 6...	A1	27	Unknown	LMO ST	Positive	23.40	499.897... 8...	 <table border="1"> <thead> <tr> <th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>C_r</th><th>ΔR_n</th></tr> </thead> <tbody> <tr> <td>A1</td><td>27</td><td>Unknown</td><td>IPC LMO ST</td><td>Positive</td><td>37.92</td><td>98.003.963</td></tr> <tr> <td>A1</td><td>27</td><td>Unknown</td><td>LMO ST</td><td>Positive</td><td>21.89</td><td>499.897... 8...</td></tr> </tbody> </table>	Well	Sample	Type	Target	Call	C _r	ΔR _n	A1	27	Unknown	IPC LMO ST	Positive	37.92	98.003.963	A1	27	Unknown	LMO ST	Positive	21.89	499.897... 8...																												
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SureTect Listeria monocytogenes	Inclusivity	TCC 1208 L. monocytogenes	35	Positive	Warning	No IPC amplification; Positive for Target	 <table border="1"> <thead> <tr> <th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>C_r</th><th>ΔR_n</th></tr> </thead> <tbody> <tr> <td>C1</td><td>35</td><td>Unknown</td><td>IPC LMO ST</td><td>Positive</td><td>33.03</td><td>315.987... 4...</td></tr> <tr> <td>C1</td><td>35</td><td>Unknown</td><td>LMO ST</td><td>Positive</td><td>20.12</td><td>620.823... 1...</td></tr> </tbody> </table>	Well	Sample	Type	Target	Call	C _r	ΔR _n	C1	35	Unknown	IPC LMO ST	Positive	33.03	315.987... 4...	C1	35	Unknown	LMO ST	Positive	20.12	620.823... 1...	 <table border="1"> <thead> <tr> <th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>C_r</th><th>ΔR_n</th></tr> </thead> <tbody> <tr> <td>C1</td><td>35</td><td>Unknown</td><td>IPC LMO ST</td><td>Negative</td><td>38.21</td><td>165.025... 3...</td></tr> <tr> <td>C1</td><td>35</td><td>Unknown</td><td>LMO ST</td><td>Positive</td><td>19.04</td><td>620.823... 1...</td></tr> </tbody> </table>	Well	Sample	Type	Target	Call	C _r	ΔR _n	C1	35	Unknown	IPC LMO ST	Negative	38.21	165.025... 3...	C1	35	Unknown	LMO ST	Positive	19.04	620.823... 1...																												
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SureTect Listeria monocytogenes	Inclusivity	TCC 1215 L. monocytogenes	38	Positive	Warning	NC graph; Negative for IPC and target Correct call	 <table border="1"> <thead> <tr> <th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>C_r</th><th>ΔR_n</th></tr> </thead> <tbody> <tr> <td>G1</td><td>38</td><td>Unknown</td><td>IPC LMO ST</td><td>Negative</td><td>40.93</td><td>42.178.99</td></tr> <tr> <td>G1</td><td>38</td><td>Unknown</td><td>LMO ST</td><td>Positive</td><td>47.48</td><td>19.931.367</td></tr> </tbody> </table>	Well	Sample	Type	Target	Call	C _r	ΔR _n	G1	38	Unknown	IPC LMO ST	Negative	40.93	42.178.99	G1	38	Unknown	LMO ST	Positive	47.48	19.931.367	 <table border="1"> <thead> <tr> <th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>C_r</th><th>ΔR_n</th></tr> </thead> <tbody> <tr> <td>G1</td><td>38</td><td>Unknown</td><td>IPC LMO ST</td><td>Negative</td><td>41.64</td><td>47.643.075</td></tr> <tr> <td>G1</td><td>38</td><td>Unknown</td><td>LMO ST</td><td>Negative</td><td>45.78</td><td>19.931.367</td></tr> </tbody> </table>	Well	Sample	Type	Target	Call	C _r	ΔR _n	G1	38	Unknown	IPC LMO ST	Negative	41.64	47.643.075	G1	38	Unknown	LMO ST	Negative	45.78	19.931.367																												
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RapidFinder Salmonella Multiplex (Stage 1)	Inclusivity	RDCC 3402 S. Bovis	ENT 06	Positive (For SLM target only)	Warning	NC graph; Negative for IPC and all targets Correct call	 <table border="1"><thead><tr><th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>Ct</th><th>Cr</th><th>ΔRn</th></tr></thead><tbody><tr><td>G3</td><td>ENT 06</td><td>Unknown</td><td>IPC SLM</td><td>Negative</td><td>0.000</td><td></td><td></td></tr><tr><td>G3</td><td>ENT 06</td><td>Unknown</td><td>Salmonella Ent.</td><td>Negative</td><td>0.007</td><td></td><td></td></tr><tr><td>G3</td><td>ENT 06</td><td>Unknown</td><td>Salmonella Typ.</td><td>Negative</td><td>0.038</td><td></td><td></td></tr><tr><td>G3</td><td>ENT 06</td><td>Unknown</td><td>Salmonella spe.</td><td>Positive</td><td>23.64</td><td>0.176</td><td></td></tr></tbody></table>	Well	Sample	Type	Target	Call	Ct	Cr	ΔRn	G3	ENT 06	Unknown	IPC SLM	Negative	0.000			G3	ENT 06	Unknown	Salmonella Ent.	Negative	0.007			G3	ENT 06	Unknown	Salmonella Typ.	Negative	0.038			G3	ENT 06	Unknown	Salmonella spe.	Positive	23.64	0.176		 <table border="1"><thead><tr><th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>Ct</th><th>Cr</th><th>ΔRn</th></tr></thead><tbody><tr><td>G3</td><td>ENT 06</td><td>Unknown</td><td>IPC SLM</td><td>Negative</td><td>0.000</td><td></td><td></td></tr><tr><td>G3</td><td>ENT 06</td><td>Unknown</td><td>Salmonella Ent.</td><td>Negative</td><td>0.009</td><td></td><td></td></tr><tr><td>G3</td><td>ENT 06</td><td>Unknown</td><td>Salmonella Typ.</td><td>Negative</td><td>-0.001</td><td></td><td></td></tr><tr><td>G3</td><td>ENT 06</td><td>Unknown</td><td>Salmonella spe.</td><td>Negative</td><td>0.007</td><td></td><td></td></tr></tbody></table>	Well	Sample	Type	Target	Call	Ct	Cr	ΔRn	G3	ENT 06	Unknown	IPC SLM	Negative	0.000			G3	ENT 06	Unknown	Salmonella Ent.	Negative	0.009			G3	ENT 06	Unknown	Salmonella Typ.	Negative	-0.001			G3	ENT 06	Unknown	Salmonella spe.	Negative	0.007		
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RapidFinder Salmonella Multiplex (Stage 2)	Inclusivity	TCC 2673 S. Michigan	145 (ENT 26)	Positive (For SLM target only)	Positive (SLM and SEN)	Repeat (originally correct result by both software) Fluorescence peak (cross-contamination?)	 <table border="1"><thead><tr><th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>Ct</th><th>Cr</th><th>ΔRn</th></tr></thead><tbody><tr><td>A2</td><td>TCC 2673</td><td>Unknown</td><td>IPC SLM</td><td>Positive</td><td>0.001</td><td>0.116</td><td></td></tr><tr><td>A2</td><td>TCC 2673</td><td>Unknown</td><td>Salmonella Ent.</td><td>Negative</td><td>0.179</td><td></td><td></td></tr><tr><td>A2</td><td>TCC 2673</td><td>Unknown</td><td>Salmonella Typ.</td><td>Negative</td><td>0.007</td><td></td><td></td></tr><tr><td>A2</td><td>TCC 2673</td><td>Unknown</td><td>Salmonella spe.</td><td>Positive</td><td>26.81</td><td>0.187</td><td></td></tr></tbody></table>	Well	Sample	Type	Target	Call	Ct	Cr	ΔRn	A2	TCC 2673	Unknown	IPC SLM	Positive	0.001	0.116		A2	TCC 2673	Unknown	Salmonella Ent.	Negative	0.179			A2	TCC 2673	Unknown	Salmonella Typ.	Negative	0.007			A2	TCC 2673	Unknown	Salmonella spe.	Positive	26.81	0.187		 <table border="1"><thead><tr><th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>Ct</th><th>Cr</th><th>ΔRn</th></tr></thead><tbody><tr><td>A2</td><td>TCC 2673</td><td>Unknown</td><td>IPC SLM</td><td>Positive</td><td>30.33</td><td>0.116</td><td></td></tr><tr><td>A2</td><td>TCC 2673</td><td>Unknown</td><td>Salmonella Ent.</td><td>Negative</td><td>38.05</td><td>0.164</td><td></td></tr><tr><td>A2</td><td>TCC 2673</td><td>Unknown</td><td>Salmonella Typ.</td><td>Negative</td><td>38.03</td><td></td><td></td></tr><tr><td>A2</td><td>TCC 2673</td><td>Unknown</td><td>Salmonella spe.</td><td>Positive</td><td>25.87</td><td>0.180</td><td></td></tr></tbody></table>	Well	Sample	Type	Target	Call	Ct	Cr	ΔRn	A2	TCC 2673	Unknown	IPC SLM	Positive	30.33	0.116		A2	TCC 2673	Unknown	Salmonella Ent.	Negative	38.05	0.164		A2	TCC 2673	Unknown	Salmonella Typ.	Negative	38.03			A2	TCC 2673	Unknown	Salmonella spe.	Positive	25.87	0.180	
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RapidFinder Salmonella Multiplex (Stage 2)	Exclusivity	TCC 2200 Enterobacter aerogenes	125 (EXC 23)	Negative (for all targets)	Positive (for SLM)	Repeat (originally positive by both software) Better baseline with RFA 1.1	 <table border="1"><thead><tr><th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>Ct</th><th>Cr</th><th>ΔRn</th></tr></thead><tbody><tr><td>B1</td><td>EXC 23</td><td>Unknown</td><td>IPC SLM</td><td>Positive</td><td>35.05</td><td>0.206</td><td></td></tr><tr><td>B1</td><td>EXC 23</td><td>Unknown</td><td>Salmonella Ent.</td><td>Negative</td><td>0.017</td><td></td><td></td></tr><tr><td>B1</td><td>EXC 23</td><td>Unknown</td><td>Salmonella Typ.</td><td>Negative</td><td>-0.008</td><td></td><td></td></tr><tr><td>B1</td><td>EXC 23</td><td>Unknown</td><td>Salmonella spe.</td><td>Positive</td><td>35.00</td><td></td><td></td></tr></tbody></table>	Well	Sample	Type	Target	Call	Ct	Cr	ΔRn	B1	EXC 23	Unknown	IPC SLM	Positive	35.05	0.206		B1	EXC 23	Unknown	Salmonella Ent.	Negative	0.017			B1	EXC 23	Unknown	Salmonella Typ.	Negative	-0.008			B1	EXC 23	Unknown	Salmonella spe.	Positive	35.00			 <table border="1"><thead><tr><th>Well</th><th>Sample</th><th>Type</th><th>Target</th><th>Call</th><th>Ct</th><th>Cr</th><th>ΔRn</th></tr></thead><tbody><tr><td>B1</td><td>EXC 23</td><td>Unknown</td><td>IPC SLM</td><td>Positive</td><td>35.77</td><td>0.206</td><td></td></tr><tr><td>B1</td><td>EXC 23</td><td>Unknown</td><td>Salmonella Ent.</td><td>Negative</td><td>0.014</td><td></td><td></td></tr><tr><td>B1</td><td>EXC 23</td><td>Unknown</td><td>Salmonella Typ.</td><td>Negative</td><td>-0.012</td><td></td><td></td></tr><tr><td>B1</td><td>EXC 23</td><td>Unknown</td><td>Salmonella spe.</td><td>Positive</td><td>38.88</td><td>0.006</td><td></td></tr></tbody></table>	Well	Sample	Type	Target	Call	Ct	Cr	ΔRn	B1	EXC 23	Unknown	IPC SLM	Positive	35.77	0.206		B1	EXC 23	Unknown	Salmonella Ent.	Negative	0.014			B1	EXC 23	Unknown	Salmonella Typ.	Negative	-0.012			B1	EXC 23	Unknown	Salmonella spe.	Positive	38.88	0.006	
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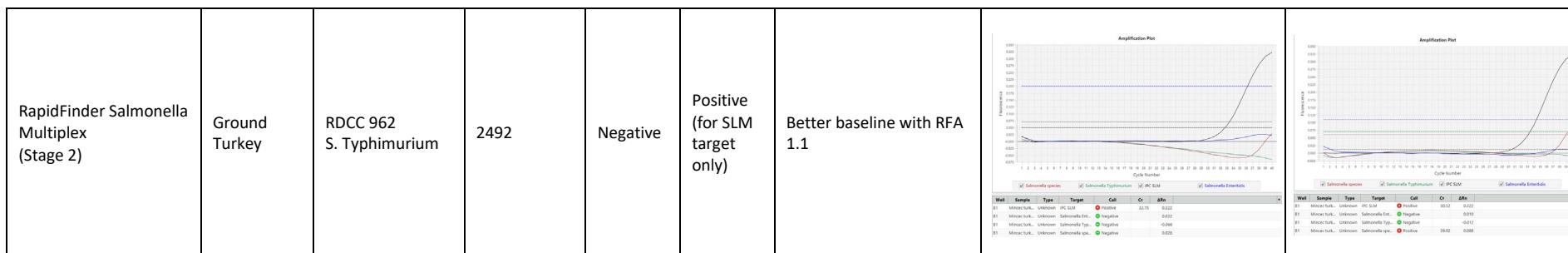


Table 32. Thermo Scientific RapidFinder Salmonella Multiplex PCR Assay: POD re-analysis comparison for RFA 1.0 and RFA 1.1 vs. confirmed candidate result (using Brilliance Agar confirmation method) for the matrixes which showed a change to the number of positive results between software versions (11)

Assay	Matrix	Inoculating strain(s)	Software ^a	MPN ^b /test portion	N ^c	SureTect PCR Presumptive			Brilliance Salmonella Agar Confirmed ^f			dPOD	
						x ^d	POD _{CP} ^e	95% CI	x	POD _{CC} ^g	95% CI	dPOD _{CP} ^h	95% CI ⁱ
RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex (Stage 2)	Shell eggs	Salmonella spp. total ^j (S. Heidelberg & S. Enteritidis)	RFA 1.0	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
				0.8	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
				1.8	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		S. Enteritidis	RFA 1.1	N/A	5	1 ^l	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.28, 0.62
				0.8	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
				1.8	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
	Ground turkey (repeat) ^m	Salmonella spp. total ^j (natural contaminant & S. Typhimurium)	RFA 1.0	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
				0.2	20	16	0.80	0.58, 0.92	16	0.80	0.58, 0.92	0.00	-0.25, 0.25
				1.1	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
		S. Enteritidis	RFA 1.1	N/A	5	1 ^l	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.28, 0.62
				0.2	20	16	0.80	0.58, 0.92	16	0.80	0.58, 0.92	0.00	-0.25, 0.25
				1.1	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47

^aRapidFinder Analysis (RFA) software v1.0 (kit file 1.1) and v1.1 (kit file 2.0).

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

^cN = Number of test portions, 5 unspiked, 20 low spike, 5 high spike.

^dNumber of positive test portions.

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

^fAll strains were confirmed by serotyping.

^gPOD_{CC} = Candidate method confirmed (via Brilliance Salmonella Agar) positive outcomes divided by the total number of trials.

^hdPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via Brilliance Salmonella Agar) result POD values.

ⁱ95% CI = If the confidence interval of a dPOD does not straddle zero, then the difference is statistically significant at the 5% level.

^jRapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between species.

^kN/A = Not applicable.

^lExtra positive result generated with RFA v1.1.

^mGround turkey repeat test data.

ⁿA natural contaminant PCR positive. Confirmed via the extended candidate confirmation protocol for high background matrixes (RVS onto Brilliance Salmonella Agar).

Table 33. Thermo Scientific RapidFinder Salmonella Multiplex PCR Assay: POD re-analysis comparison for RFA 1.0 and RFA 1.1 vs. confirmed candidate result (using reference confirmation method) for the matrixes which showed a change to the number of positive results between software versions (11)

Assay	Matrix	Inoculating strain(s)	Software ^a	MPN ^b /test portion	N ^c	SureTect PCR Presumptive			Brilliance Salmonella Agar Confirmed ^f			dPOD	
						x ^d	POD _{CP} ^e	95% CI	x	POD _{CC2} ^g	95% CI	dPOD _{CP} ^h	95% CI ⁱ
RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex (Stage 2)	Shell eggs	Salmonella spp. total ^j (<i>S. Heidelberg</i> & <i>S. Enteritidis</i>)	RFA 1.0	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
				0.8	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
				1.8	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		<i>S. Enteritidis</i>	RFA 1.1	N/A	5	1 ^l	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.28, 0.62
				0.8	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19, 0.19
				1.8	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
		Salmonella spp. total ^j (natural contaminant & <i>S. Typhimurium</i>)	RFA 1.0	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
				0.2	20	16	0.80	0.58, 0.92	16	0.80	0.58, 0.92	0.00	-0.25, 0.25
				1.1	5	4	0.80	0.38, 1.00	4	0.80	0.38, 1.00	0.00	-0.47, 0.47
		Ground turkey (repeat) ^m	RFA 1.0	N/A	5	1 ^l	0.20	0.00, 0.62	0	0.00	0.00, 0.43	0.20	-0.28, 0.62
				0.5	20	14	0.70	0.48, 0.85	14	0.70	0.48, 0.85	0.00	-0.27, 0.27
				N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
		RFA 1.1	RFA 1.1	N/A	5	2	0.40	0.12, 0.77	0 ⁿ	0.00	0.00, 0.43	0.40	-0.12, 0.77
				0.5	20	15 ^l	0.75	0.53, 0.89	14	0.70	0.48, 0.85	0.05	-0.22, 0.31
				N/A	N/A	N/A	N/ ^k	N/A	N/A	N/A	N/A	N/A	N/A

^aRapidFinder Analysis (RFA) software v1.0 (kit file 1.1) and v1.1 (kit file 2.0).^bMPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.^cN = Number of test portions, 5 unspiked, 20 low spike, 5 high spike.^dNumber of positive test portions.^ePOD_{CP} = Candidate method presumptive positive outcomes divided by total number of trials.^fAll strains were confirmed by serotyping.^gPOD_{CC2} = Candidate method confirmed (via reference method) positive outcomes divided by the total number of trials.^hdPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via reference method) result POD values.ⁱ95% CI = If the confidence interval of a dPOD does not straddle zero, then the difference is statistically significant at the 5% level.^jRapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between species.^kN/A = Not applicable.^lExtra positive result generated with RFA v1.1.^mGround turkey repeat test data.ⁿA natural contaminant PCR positive. Confirmed via the extended candidate confirmation protocol for high background matrixes (RVS onto Brilliance Salmonella Agar).

DISCUSSION OF MODIFICATION APPROVED OCTOBER 2020 (12)

RapidFinder Salmonella Multiplex PCR assay: Inclusivity Exclusivity.—The reanalysis of the inclusivity data for Stage 1 showed one change for one sample in the Stage 1 inclusivity data that changed from a **positive to a warning**, as detailed in Table Table 33. This sample had a failed amplification of the internal amplification control. Since RFE kit file v2.0 requires a positive result of the internal amplification control (IPC) for a positive sample result, the interpretation for this sample changes to ‘Warning’ with the new kit file. The reanalysis of the inclusivity data for Stage 2 showed no change in the PCR results after reanalysis between the RFE kit file v1.0 and RFE kit file v2.0.

The reanalysis of the exclusivity data for Stage 1 showed no change in the PCR results after reanalysis between the RFE kit file v1.0 and RFE kit file v2.0. The reanalysis of the exclusivity data for Stage 2 showed changes in the PCR results for one sample from a **negative to a positive** and for another sample it changed from a **negative to a warning** after reanalysis between the RFE kit file v1.0 and RFE kit file v2.0, as detailed in Table 33. The reasons for these results were the change in baselining of amplification curves in RFE kit file v2.0 and respectively no amplification of the IPC.

RapidFinder Salmonella Multiplex PCR assay: Matrix testing.—The reanalysis of the matrix data for Stage 1 showed no change in the PCR results after reanalysis between the RFE kit file v1.0 and RFE kit file v2.0. The reanalysis of the matrix data for Stage 2 showed one change for one sample in the Ground turkey data changed from a **positive to a warning**, as detailed in Table Table 33. This sample had a failed amplification of the internal amplification control. Since RFE kit file v2.0 requires a positive result of the internal amplification control (IPC) for a positive sample result, the interpretation for this sample changes to ‘Warning’ with the new kit file.

Table 23. Inclusivity results for the RapidFinder Salmonella Multiplex PCR Assay Stage 1 using the original and upgraded kit files with RFE v2.0 (12)

ID	Isolate	Origin	Source	RFE kit file v.1.0			RFE kit file v.2.0		
				SLM	SEN	STY	SLM	SEN	STY
1726	Salmonella Uphill	Unknown ^a	RDCC ^b	Positive	Negative	Negative	Positive	Negative	Negative
2355	Salmonella Donna	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2830	Salmonella Locarno	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 10252	Salmonella Tranaraoa	Unknown	NCTC ^c	Positive	Negative	Negative	Positive	Negative	Negative
2599	Salmonella salamae	Unknown	TCC ^d	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 8297	Salmonella arizoniae	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
2389	Salmonella arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2608	Salmonella arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2609	Salmonella arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2610	Salmonella arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2386	Salmonella diarizonae	Clinical	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2388	Salmonella diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2616	Salmonella diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2617	Salmonella diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2618	Salmonella diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3732	Salmonella houtenae	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2624	Salmonella houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2625	Salmonella houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2626	Salmonella houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2627	Salmonella houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2360	Salmonella indica	Unknown	OCC ^e	Positive	Negative	Negative	Positive	Negative	Negative
2643	Salmonella indica	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2640	Salmonella indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2641	Salmonella indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2642	Salmonella indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 2215	Salmonella bongori	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 12419	Salmonella bongori	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
3407	Salmonella Stanley	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
5096	Salmonella Abony	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2150	Salmonella Saintpaul	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3377	Salmonella Heidelberg	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2358	Salmonella Agona	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2839	Salmonella Brandenburg	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2840	Salmonella Indiana	Turkey	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2296	Salmonella Abortus-equii	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
3016	Salmonella Abortusovis	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3017	Salmonella Schwarzengrund	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3018	Salmonella Stanleyville	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3019	Salmonella Sandiego	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3381	Salmonella Bredeney	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30151	Salmonella Java	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30020	Salmonella Paratyphi B	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3399	Salmonella Dublin	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 3747	Salmonella Rostock	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
1774	Salmonella Gallinarum	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 9868	Salmonella Alabama	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
3024	Salmonella Miami	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3025	Salmonella Lomalinda	Clinical	TCC	Positive	Negative	Negative	Positive	Negative	Negative

3026	Salmonella Israel	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3027	Salmonella Portland	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3028	Salmonella Sendai	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2129	Salmonella Napoli	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2138	Salmonella Gallinarum	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2139	Salmonella Eastbourne	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2146	Salmonella Javiana	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2360	Salmonella Berta	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30001	Salmonella Typhi	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1654	Salmonella Kiel	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2135	Salmonella Ohio	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2359	Salmonella Montevideo	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2351	Salmonella Virchow	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3400	Salmonella Infantis	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3402	Salmonella Bovis	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2125	Salmonella Albany	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
	Salmonella Bovis-Morbificans	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2001	Salmonella Kentucky	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3734	Salmonella Newport	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2087	Salmonella Muenchen	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2130	Salmonella Hadar	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2132	Salmonella Shanghai	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1623	Salmonella Allerton	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2683	Salmonella Muenster	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2210	Salmonella Senftenburg	Faeces	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2831	Salmonella Ibidam	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3736	Salmonella Madelia	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2453	Salmonella Schalkwijk	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2671	Salmonella Saphra	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2362	Salmonella Huttingfoss	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2673	Salmonella Michigan	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2127	Salmonella Cerro	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2679	Salmonella Brisbane	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2100	Salmonella Urbana	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2356	Salmonella Matopeni	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2122	Salmonella Adelaide	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2690	Salmonella Alachua	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2120	Salmonella Inverness	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2118	Salmonella Champaign	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
5372	Salmonella Riogrande	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2685	Salmonella Johannesburg	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2675	Salmonella Vietnam	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2677	Salmonella Gera	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
2937	Salmonella Berkeley	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2676	Salmonella Tornow	Unknown	OCC	Positive	Negative	Negative	Positive	Negative	Negative
1728	Salmonella Teshi	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30017	Salmonella Paratyphi A	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
30026	Salmonella Paratyphi C	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2207	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3379	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3729	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative

3900	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
723	Salmonella Enteritidis	Unknown	OCC	Positive	Positive	Negative	Positive	Positive	Negative
1637	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1638	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1639	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1640	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1986	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2424	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2425	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2426	Salmonella Enteritidis	Guinea pig	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2443	Salmonella Enteritidis	Raw almonds	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2450	Salmonella Enteritidis	Clinical, gastroenteritis	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2591	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2668	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2669	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
3372	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3378	Salmonella Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3383	Salmonella Enteritidis var. Dansyz	Clinical, gastroenteritis	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
1584	Salmonella Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
ATCC BAA 1587	Salmonella Enteritidis	Unknown	ATCC ^f	Positive	Positive	Negative	Positive	Positive	Negative
QL 10155.1	Salmonella Enteritidis	Unknown	Q Labs ^g	Positive	Positive	Negative	Positive	Positive	Negative
QL 10170.1	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 14255.2	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.40	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.80	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.121	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.184	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.185	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.186	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.278	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.279	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.280	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 1698878.3	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 175599.1	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 182282	Salmonella Enteritidis	Unknown	Q Labs	Positive	Negative	Negative	Positive	Negative	Negative
QL 182282 ^h	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 188498.1	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 191569.1	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
QL 194559.3	Salmonella Enteritidis	Unknown	Q Labs	Negative	Negative	Negative	Negative	Negative	Negative
QL 194559.3 ^h	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Positive	Positive	Positive	Positive
CCUG 9563	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 21288	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 25340	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 26522	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 27004	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 27021	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Positive	Warning ⁱ	Warning ⁱ	Warning ⁱ
FSL S5-415	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
FSL S5-483	Salmonella Enteritidis	Unknown	Q Labs	Positive	Positive	Negative	Positive	Positive	Negative
962	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1793	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
2124	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive

2836	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3380	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3384	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3740	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3741	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3897	Salmonella Typhimurium	Tissue, animal	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3920	Salmonella Typhimurium	Dairy (Tiramisu)	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3922	Salmonella Typhimurium	Chocolate	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3924	Salmonella Typhimurium	Cocoa beans	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
4669	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1585	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1679	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1680	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1681	Salmonella Typhimurium	Clinical, gastroenteritis	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1683	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1684	Salmonella Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1880	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2387	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2390	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
ATCC 19585	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
ATCC BAA-1603	Salmonella Typhimurium	Tomato	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2593	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2645	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2646	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2647	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2648	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2649	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2650	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2651	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2652	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2653	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2654	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2655	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2656	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2657	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2658	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2659	Salmonella Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2660	Salmonella Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2661	Salmonella Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
1586	Salmonella Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
QL 11007-2	Salmonella Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 11414-2	Salmonella Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 16078-2A.110	Salmonella Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 16078-2A.112	Salmonella Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 16078-2A.1	Salmonella Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive
QL 16078-2A.108	Salmonella Typhimurium	Unknown	Q Labs	Positive	Negative	Positive	Positive	Negative	Positive

^aUnknown = Origin of strain is not listed or provided by the sources.

^bRDCC = R&D Culture Collection, Thermo Fisher Scientific, UK.

^cNTCT = National Collection of Type Cultures, Health Protection Agency, London, UK.

^dTCC = Trials Culture Collection, Thermo Fisher Scientific, UK.

^eOCC = Oxoid Culture Collection, Thermo Fisher Scientific, UK.

^fATCC = American Type Culture Collection, Manassas, VA

^gQ Labs = Q Laboratories Culture Collection, Ohio, US

^hA retest result of the isolate.

'Warning result with RFE 2.0.

Table 24. Exclusivity results for the RapidFinder Salmonella Multiplex PCR Assay Stage 1 using the original and upgraded kit files with RFE v2.0 (12)

ATCC 51815	<i>Hafnia alvei</i>	Milk	Q Labs	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 4352	<i>Klebsiella pneumoniae</i>	Cow's milk	Q Labs	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 25829	<i>Morganella morganii</i>	Feces	Q Labs	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 6380	<i>Proteus vulgaris</i>	Unknown	Q Labs	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 9027	<i>Pseudomonas aeruginosa</i>	Clinical	Q Labs	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 13880	<i>Serratia marcescens</i>	Water	Q Labs	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 49397	<i>Yersinia enterocolitica</i>	Clinical	Q Labs	Negative	Negative	Negative	Negative	Negative	Negative

^aTCC = Trials Culture Collection, Thermo Fisher Scientific, UK.^bOCC = Oxoid Culture Collection, Thermo Fisher Scientific, UK.^cQ Labs = Q Laboratories Culture Collection, Ohio, US.

Table 25. Inclusivity results for the RapidFinder Salmonella Multiplex PCR Assay Stage 2 using the original and upgraded kit files with RFE v2.0 (12)

ID	Isolate	Origin	Source	RFE kit file v.1.0			RFE kit file v.2.0		
				SLM	SEN	STY	SLM	SEN	STY
1726	<i>Salmonella</i> Uphill+B259:BB259:B362	Unknown ^a	RDCC ^b	Positive	Negative	Negative	Positive	Negative	Negative
2355	<i>Salmonella</i> Donna	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2830	<i>Salmonella</i> Locarno	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 10252	<i>Salmonella</i> Tranaroa	Unknown	NCTC ^c	Positive	Negative	Negative	Positive	Negative	Negative
2599	<i>Salmonella</i> salamae	Unknown	TCC ^d	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 8297	<i>Salmonella</i> arizoniae	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
2389	<i>Salmonella</i> arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2608	<i>Salmonella</i> arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2609	<i>Salmonella</i> arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2610	<i>Salmonella</i> arizoniae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2386	<i>Salmonella</i> diarizonae	Clinical	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2388	<i>Salmonella</i> diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2616	<i>Salmonella</i> diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2617	<i>Salmonella</i> diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2618	<i>Salmonella</i> diarizonae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3732	<i>Salmonella</i> houtenae	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2624	<i>Salmonella</i> houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2625	<i>Salmonella</i> houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2626	<i>Salmonella</i> houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2627	<i>Salmonella</i> houtenae	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2360	<i>Salmonella</i> indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2643	<i>Salmonella</i> indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2640	<i>Salmonella</i> indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2641	<i>Salmonella</i> indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2642	<i>Salmonella</i> indica	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 2215	<i>Salmonella</i> bongori	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 12419	<i>Salmonella</i> bongori	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
3407	<i>Salmonella</i> Stanley	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
5096	<i>Salmonella</i> Abony	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2150	<i>Salmonella</i> Saintpaul	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3377	<i>Salmonella</i> Heidelberg	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2358	<i>Salmonella</i> Agona	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2839	<i>Salmonella</i> Brandenburg	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2840	<i>Salmonella</i> Indiana	Turkey	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2296	<i>Salmonella</i> Abortus-equus	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3016	<i>Salmonella</i> Abortusovis	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative

3017	<i>Salmonella</i> Schwarzengrund	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3018	<i>Salmonella</i> Stanleyville	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3019	<i>Salmonella</i> Sandiego	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3381	<i>Salmonella</i> Bredeney	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3399	<i>Salmonella</i> Dublin	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 3747	<i>Salmonella</i> Rostock	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
1774	<i>Salmonella</i> Gallinarum	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 9868	<i>Salmonella</i> Alabama	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
3024	<i>Salmonella</i> Miami	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3025	<i>Salmonella</i> Lomalinda	Clinical	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3026	<i>Salmonella</i> Israel	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3027	<i>Salmonella</i> Portland	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3028	<i>Salmonella</i> Sendai	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2129	<i>Salmonella</i> Napoli	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2138	<i>Salmonella</i> Gallinarum	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2139	<i>Salmonella</i> Eastbourne	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2146	<i>Salmonella</i> Javiana	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2360	<i>Salmonella</i> Berta	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1654	<i>Salmonella</i> Kiel	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2135	<i>Salmonella</i> Ohio	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2359	<i>Salmonella</i> Montevideo	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2351	<i>Salmonella</i> Virchow	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3400	<i>Salmonella</i> Infantis	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3402	<i>Salmonella</i> Bovis	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2125	<i>Salmonella</i> Albany	Clinical	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2001	<i>Salmonella</i> Bovis-Morbificans	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3734	<i>Salmonella</i> Kentucky	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2087	<i>Salmonella</i> Newport	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2130	<i>Salmonella</i> Muenchen	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2131	<i>Salmonella</i> Hadar	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2132	<i>Salmonella</i> Shanghai	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1623	<i>Salmonella</i> Allerton	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2683	<i>Salmonella</i> Muenster	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2210	<i>Salmonella</i> Senftenburg	Feces	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
1655	<i>Salmonella</i> Krefeld	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
1612	<i>Salmonella</i> Aberdeen	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
3739	<i>Salmonella</i> Rubislaw	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3405	<i>Salmonella</i> Poona	Clinical, gastroenteritis	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2831	<i>Salmonella</i> Ibidam	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
3736	<i>Salmonella</i> Madelia	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2453	<i>Salmonella</i> Schalkwijk	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2671	<i>Salmonella</i> Saphra	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2362	<i>Salmonella</i> Huttingfoss	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2673	<i>Salmonella</i> Michigan	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2127	<i>Salmonella</i> Cerro	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2679	<i>Salmonella</i> Brisbane	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2100	<i>Salmonella</i> Urbana	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2356	<i>Salmonella</i> Matopeni	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2122	<i>Salmonella</i> Adelaide	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2690	<i>Salmonella</i> Alachua	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2120	<i>Salmonella</i> Inverness	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2118	<i>Salmonella</i> Champaign	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative

5372	<i>Salmonella</i> Rio grande	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2685	<i>Salmonella</i> Johannesburg	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2675	<i>Salmonella</i> Vietnam	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2677	<i>Salmonella</i> Gera	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
2937	<i>Salmonella</i> Berkeley	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
2676	<i>Salmonella</i> Tornow	Unknown	TCC	Positive	Negative	Negative	Positive	Negative	Negative
1728	<i>Salmonella</i> Teshi	Unknown	RDCC	Positive	Negative	Negative	Positive	Negative	Negative
5767	<i>Salmonella</i> Rostock	Unknown	NCTC	Positive	Negative	Negative	Positive	Negative	Negative
2207	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3379	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3729	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3900	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
723	<i>Salmonella</i> Enteritidis	Unknown	OCC ^e	Positive	Positive	Negative	Positive	Positive	Negative
1637	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1638	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1639	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Negative ^f	Negative	Positive	Negative ^f	Negative
1640	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
1986	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2424	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2425	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2426	<i>Salmonella</i> Enteritidis	Guinea pig	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2443	<i>Salmonella</i> Enteritidis	Raw almonds	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2450	<i>Salmonella</i> Enteritidis	Clinical, gastroenteritis	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2591	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2668	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2669	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
2670	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
3372	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3378	<i>Salmonella</i> Enteritidis	Unknown	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
3383	<i>Salmonella</i> Enteritidis var. Dansyz	Clinical, gastroenteritis	RDCC	Positive	Positive	Negative	Positive	Positive	Negative
1584	<i>Salmonella</i> Enteritidis	Unknown	TCC	Positive	Positive	Negative	Positive	Positive	Negative
962	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1793	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
2124	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
2836	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3380	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3384	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3740	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3741	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3897	<i>Salmonella</i> Typhimurium	Tissue, animal	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3920	<i>Salmonella</i> Typhimurium	Dairy (Tiramisu)	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3922	<i>Salmonella</i> Typhimurium	Chocolate	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
3924	<i>Salmonella</i> Typhimurium	Cocoa beans	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
4669	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1585	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1679	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1680	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1681	<i>Salmonella</i> Typhimurium	Clinical, gastroenteritis	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1683	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1684	<i>Salmonella</i> Typhimurium	Unknown	RDCC	Positive	Negative	Positive	Positive	Negative	Positive
1880	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2387	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive

2390	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
ATCC 19585	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
ATCC BAA-1603	<i>Salmonella</i> Typhimurium	Tomato	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2461	<i>Salmonella</i> Typhimurium	Faeces	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2593	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2645	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2646	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2647	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2648	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2649	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2650	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2651	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2652	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2653	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2654	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2655	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2656	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2657	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2658	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2659	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2660	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
2661	<i>Salmonella</i> Typhimurium/ DT104	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
1586	<i>Salmonella</i> Typhimurium	Unknown	TCC	Positive	Negative	Positive	Positive	Negative	Positive
6539	<i>S.</i> Typhi	Unknown	ATCC ^g	Positive	Negative	Negative	Positive	Negative	Negative
9150	<i>S.</i> Paratyphi A	Unknown	ATCC	Positive	Negative	Negative	Positive	Negative	Negative
10719	<i>S.</i> Paratyphi B	Unknown	ATCC	Positive	Negative	Negative	Positive	Negative	Negative
13428	<i>S.</i> Paratyphi C	Unknown	ATCC	Positive	Negative	Negative	Positive	Negative	Negative
ATCC BAA 1587	<i>Salmonella</i> Enteritidis	Unknown	ATCC	Positive	Positive	Negative	Positive	Positive	Negative

*Unknown = Origin of the strain is not listed or provided by the source.

^bRDCC = R&D Culture Collection, Thermo Fisher Scientific, UK.

^cNCTC = National Collection of Type Cultures, Porton Down, Salisbury, UK.

^dTCC = Trials Culture Collection, Thermo Fisher Scientific, UK.

^eOCC = Oxoid Culture Collection, Thermo Fisher Scientific, UK.

^fInclusivity isolates gave negative results due to laboratory acquired O antigen loss.

^gATCC = American type Culture Collection, Manassas, VA.

Table 26. Exclusivity results for the RapidFinder Salmonella Multiplex PCR Assay Stage 2 using the original and upgraded kit files with RFE v2.0 (12)

ID	Isolate	Origin	Source	RFE kit file v.1.0			RFE kit file v.2.0		
				SLM	SEN	STY	SLM	SEN	STY
TCC 0181	<i>Citrobacter intermedius</i>	Unknown	TCC ^a	Negative ^b	Negative	Negative	Warning ^c	Warning ^c	Warning ^c
TCC 0401	<i>Enterobacter cloacae</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 0409	<i>Pantoea agglomerans</i>	Pasteurized milk	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 0414	<i>Serratia marcescens</i>	Clinical	TCC	Negative ^b	Negative	Negative	Negative ^b	Negative	Negative
TCC 0418	<i>Providencia stuartii</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 0593	<i>Klebsiella oxytoca</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 1388	<i>Enterobacter faecalis</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 1431	<i>Morganella morganii</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 1552	<i>Proteus vulgaris</i>	Unknown	TCC	Negative ^b	Negative	Negative	Negative ^b	Negative	Negative
TCC 1566	<i>Proteus mirabilis</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 1804	<i>Klebsiella aerogenes</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 1809	<i>Escherichia coli</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 1892	<i>Klebsiella pneumoniae</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
	<i>Pseudomonas aeruginosa</i>								
TCC 1903	<i>Citrobacter koseri</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2039	<i>Citrobacter youngae</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2043	<i>Hafnia alvei</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2044	<i>Escherichia hermanii</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2048	<i>Serratia liquefaciens</i>	Milk	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2053	<i>Enterobacter sakazakii</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
	<i>Enterobacter amnigenus</i> -Biogroup 1	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2198	<i>Enterobacter aerogenes</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2200	<i>Providencia rettgeri</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
	<i>Enterobacter intermedius</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2203	<i>Klebsiella terrigena</i>	Water isolate	TCC	Negative	Negative	Negative	Negative	Negative	Negative
	<i>Providencia alcalifaciens</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2209	<i>Yersinia enterocolitica</i>	Frozen prawn	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2215	<i>Edwardsiella tarda</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2216	<i>Escherichia fergusonii</i>	Sausages	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2263	<i>Escherichia vulneris</i>	Vegetables	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2264	<i>Escherichia blattae</i>	Cockroach gut	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2273	<i>Shigella boydii</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2050	<i>Shigella sonnei</i>	Clinical	TCC	Negative	Negative	Negative	Negative	Negative	Negative
TCC 2051	<i>Shigella flexneri</i>	Unknown	TCC	Negative	Negative	Negative	Negative	Negative	Negative
	<i>Escherichia coli</i> O157:H7 VT neg	Unknown	OCC ^d	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 13048	<i>Enterobacter aerogenes</i>	Sputum	ATCC ^e	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 8739	<i>Escherichia coli</i>	Feces	ATCC	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 51815	<i>Hafnia alvei</i>	Milk	ATCC	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 10031	<i>Klebsiella pneumoniae</i>	Clinical	ATCC	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 25829	<i>Morganella morganii</i>	Feces	ATCC	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 6380	<i>Proteus vulgaris</i>	Clinical	ATCC	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 35032	<i>Pseudomonas aeruginosa</i>	Not available	ATCC	Negative	Negative	Negative	Negative	Negative	Negative
ATCC 13880	<i>Serratia marcescens</i>	Water	ATCC	Negative ^b	Negative	Negative	Negative	Negative	Negative
ATCC 49397	<i>Yersinia enterocolitica</i>	Clinical	ATCC	Negative	Negative	Negative	Positive ^f	Negative	Negative

^aTCC = Trials Culture Collection, Thermo Fisher Scientific, UK.

^bResult was originally positive. Isolates were r-incubated in candidate enrichment (BPW+novobiocin for 14-18h) and were correctly excluded when reanalysed.

^cWarning positive with RFE v2.0.

^dOCC = Oxoid Culture Collection, Thermo Fisher Scientific, UK.

^eATCC = American type Culture Collection, Manassas, VA.

^f/Result positive with RFE v2.0.

Table 31. Thermo Scientific RapidFinder Salmonella Multiplex PCR Assay Stage 1 result comparison for the original and upgraded kit files with RFE v2.0 (12)

Matrix	Inoculating Strain(s)	MPN ^a / Test Portion	N ^b	Candidate Method ^c		
				Kit file 1.0 x ^d	Kit file v1.0 -! ^e	Kit file v2.0 x ^f
Raw chicken thighs w/ skin	<i>Salmonella</i> spp. total (<i>S.Kentucky C₃</i> & <i>S.Enteritidis D₁</i>)	N/A ^g	5	0	N/A	0
		1.84	20	19	N/A	19
		1.77	5	5	N/A	5
	<i>S.Enteritidis D₁</i>	N/A	5	0	N/A	0
		0.34	20	15	N/A	15
		0.2	5	4	N/A	4
	<i>S.Kentucky C₃</i>	N/A	5	NR ^h	NR	NR
		1.01	20	NR	NR	NR
		1.51	5	NR	NR	NR
Raw chicken thighs w/ skin (independent lab) ⁱ	<i>Salmonella</i> spp. total (<i>S.Kentucky C₃</i> & <i>S.Enteritidis D₁</i>)	N/A	5	0	N/A	0
		1.87	20	16	N/A	16
		3.63	5	5	N/A	5
	<i>S.Enteritidis D₁</i>	N/A	5	0	N/A	0
		0.89	20	12	N/A	12
		2.28	5	5	N/A	5
	<i>S.Kentucky C₃</i>	N/A	5	NR	NR	NR
		0.81	20	NR	NR	NR
		2.37	5	NR	NR	NR
Raw chicken wings w/ skin	S.Typhimurium B	N/A	5	0	N/A	0
		0.99	20	15	N/A	15
		3.14	5	4	N/A	4
Chicken nuggets	S.Montevideo C ₁	N/A	5	NR	NR	NR
		0.52	20	NR	NR	NR
		1.32	5	NR	NR	NR
Chicken nuggets	S.Typhimurium B	N/A	5	0	N/A	0
		1.5	20	15	N/A	15
		3.01	5	3	N/A	3
Raw pork sausage	<i>Salmonella</i> spp. total (<i>S.Ohio C₁</i> , <i>S.Typhimurium B</i> , <i>S.Enteritidis D₁</i>)	N/A	5	0	N/A	0
		3.8	20	20	N/A	20
		>4.38	5	5	N/A	5
	S.Typhimurium B	N/A	5	0	N/A	0
		0.63	20	11	N/A	11
		0.8	5	4	N/A	4
	<i>S.Enteritidis D₁</i>	N/A	5	0	N/A	0
		0.36	20	15	N/A	15
		0.27	5	5	N/A	5
	S.Ohio C ₁	N/A	5	NR	NR	NR
		1.25	20	NR	NR	NR
		4.38	5	NR	NR	NR
Stainless steel environmental surface sponges	<i>Salmonella</i> spp. total (<i>S.Poona G₁</i> & S.Typhimurium B)	N/A	5	0	N/A	0
		N/A	20	17	N/A	17
		N/A	5	5	N/A	5
	S.Typhimurium B	N/A	5	0	N/A	0
		N/A	20	13	N/A	13
		N/A	5	5	N/A	5
	S.Poona G ₁	N/A	5	NR	NR	NR
		N/A	20	NR	NR	NR
		N/A	5	NR	NR	NR
Stainless steel environmental surface sponges (independent lab) ^j	<i>Salmonella</i> spp. total (<i>S.Poona G₁</i> & S.Typhimurium B)	N/A	5	0	N/A	0
		N/A	20	15	N/A	15
		N/A	5	5	N/A	5
	S.Typhimurium B	N/A	5	0	N/A	0
		N/A	20	10	N/A	10
		N/A	5	5	N/A	5
	S.Poona G ₁	N/A	5	NR	NR	NR
		N/A	20	NR	NR	NR
		N/A	5	NR	NR	NR

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

^bPN = Number of test portions, 5 unspiked, 20 low spike, 5 high spike.

^cCandidate method presumptive result (PCR only).

^dRFE 1.0 x = Number of positive test portions gained originally with RFA 1.0 and original kit file.

^eRFE 1.0 - ! = Number of positive test portions gained originally with RFA 1.0 and original kit file (excluding samples with warning calls seen on RFA 1.1).

^fRFE 2.0 x = Number of positive test portions gained originally with RFA 1.0 and original kit file.

^gN/A = Not applicable.

^hNR = Not reported. *Salmonella* strains that are not specific PCR targets cannot have presumptive PCR results for the specific strain.

ⁱMatrix tested by the independent lab.

Table 32. Thermo Scientific RapidFinder Salmonella Multiplex PCR Assay Stage 2 result comparison for the original and upgraded kit files with RFE v2.0 (12)

Matrix	Inoculating Strain(s)	MPN ^a / Test Portion	N ^b	Candidate Method ^c		
				Kit file 1.0 x ^d	Kit file v1.0-! ^e	Kit file v2.0 x ^f
Shell eggs	<i>Salmonella</i> spp. total (<i>S</i> .Heidelberg & <i>S</i> .Enteritidis)	N/A ^g	5	0	N/A	0
		0.77	20	19	N/A	19
		1.78	5	5	N/A	5
	<i>S</i> .Heidelberg	N/A	5	NR ^h	NR	NR
		0.53	20	NR	NR	NR
		0.4	5	NR	NR	NR
	<i>S</i> .Enteritidis	N/A	5	0	N/A	0
		0.18	20	16	N/A	16
		1.08	5	4	N/A	4
Ground turkey (original test) ⁱ	<i>Salmonella</i> spp. total (<i>S</i> .Bareilly & <i>S</i> .Typhimurium)	N/A	5	0	N/A	0
		3.18	20	19	18	18
		N/A	5	5	N/A	5
	<i>S</i> .Bareilly	N/A	5	NR	NR	NR
		0.65	20	NR	NR	NR
		0.52	5	NR	NR	NR
	<i>S</i> .Typhimuriumr	N/A	5	0	N/A	0
		2.26	20	17	16	16
		N/A	5	5	N/A	5
Ground turkey (repeat) ^j	<i>Salmonella</i> spp. total (<i>Salmonella</i> natural contaminant & <i>S</i> .Typhimurium)	N/A	5	2 ^k	N/A	2 ^k
		0.46	20	14	N/A	14
		N/A	N/A	N/A	N/A	N/A
	<i>Salmonella</i> natural contaminant	N/A	5	NR	NR	NR
		N/A	20	NR	NR	NR
		N/A	N/A	N/A	N/A	N/A
	<i>S</i> .Typhimurium	N/A	5	0	N/A	0
		0.46	20	11	N/A	11
		N/A	N/A	N/A	N/A	N/A
Chicken carcass rinse	<i>Salmonella</i> spp. total (<i>S</i> .Typhimurium & <i>S</i> .Enteritidis)	N/A	5	0	N/A	0
		2.85	20	20	N/A	20
		2.75	5	5	N/A	5
	<i>S</i> .Enteritidis	N/A	5	0	N/A	0
		1.34	20	15	N/A	15
		0.72	5	5	N/A	5
	<i>S</i> .Typhimurium	N/A	5	0	N/A	0
		0.75	20	20	N/A	20
		0.28	5	5	N/A	5

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

^bN = Number of test portions, 5 unspiked, 20 low spike, 5 high spike.

^cCandidate method presumptive result (PCR only).

^dRFE 1.0 x = Number of positive test portions gained originally with RFA 1.0 and original kit file.

^eRFE 1.0 - ! = Number of positive test portions gained originally with RFA 1.0 and original kit file (excluding samples with warning calls seen on RFA 1.1).

^fRFE 2.0 x = Number of positive test portions gained originally with RFA 1.0 and original kit file.

^gN/A = Not applicable.

^hNR = Not reported. *Salmonella* strains that are not specific PCR targets cannot have presumptive PCR results for the specific strain.

ⁱGround turkey original test (failed on fractional positivity for *Salmonella* Typhimurium).

^jGround turkey repeat test data.

^kNatural contaminant PCR positive. Confirmed via extended candidate confirmation protocol for high background matrixes (RVS broth enrichment onto *Brilliance* *Salmonella* Agar).

Table 33. Thermo Scientific SureTect and RapidFinder PCR range warning call summary for the original and upgraded kit files with RFE v2.0 (12)

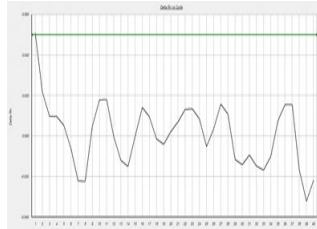
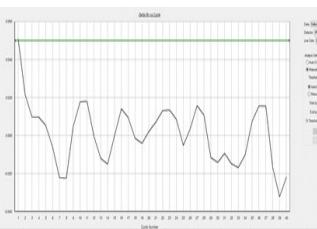
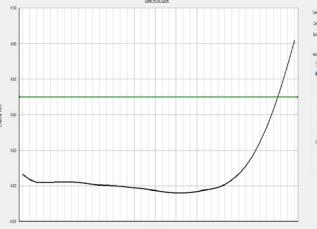
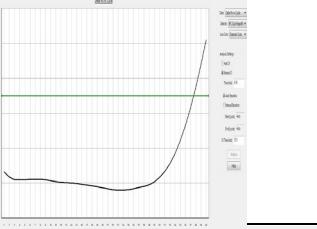
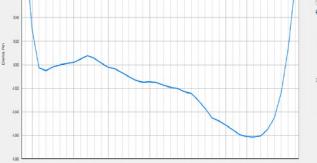
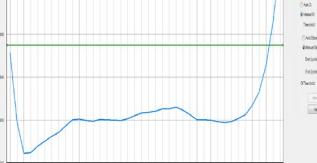
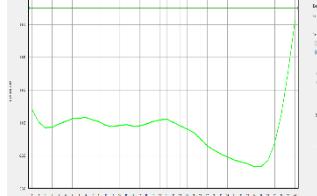
Assay	Sample	Strain	Sample ID	RFA 1.0	RFA 1.1	Description	RFE 1.0	RFE 2.0
RapidFinder Salmonella Multiplex (Stage 1)	Inclusivity	<i>Salmonella</i> Enteritidis	CCUG 27021	Positive	Warning	No IPC amplification: Positive for all targets with kit file 1.0, but <i>Salmonella</i> Typhimurium target call changed to negative with kit file 2.0, resulting in warning well call.		
RapidFinder Salmonella Multiplex (Stage 2)	Ground turkey (original test)	RDCC 962 <i>Salmonella</i> Typhimurium RDCC 3388 <i>Salmonella</i> Bareilly	2424	Positive	Warning	No IPC amplification;		
RapidFinder Salmonella Multiplex (Stage 2)	Exclusivity	<i>Yersinia enterocolitica</i> TCC 2215	EXC 28	Negative	Positive	Target call change for <i>Salmonella</i> species Baseline parameters updated		
RapidFinder Salmonella Multiplex (Stage 2)	Exclusivity	<i>Citrobacter intermedium</i> TCC 181	EXC 2	Negative	Warning	Target call change for <i>Salmonella</i> Typhimurium Baseline parameters updated		

Table 34. Thermo Scientific RapidFinder Salmonella Multiplex PCR Assay Stage 2: POD re-analysis comparison for RFE kit files v1.0 and kit files v2.0, vs confirmed candidate result (using Brilliance Agar confirmation method) for the matrixes which showed a change to the number of positive results between software versions (12)

Assay	Matrix	Inoculating strain(s)	RFE kit file ^a	MPN ^b / test portion	N ^c	RapidFinder PCR Presumptive			Brilliance Salmonella Agar Confirmed ^f			dPOD	
						x ^d	POD _{CP} ^e	95% CI	x	POD _{CC} ^g	95% CI	dPOD _{CP} ^h	95% CI ⁱ
RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex (Stage 2)	Ground turkey (original test)	Salmonella spp. total ^j (S. Bareilly & S. Typhimurium)	v 1.0	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43; 0.43
				3.18	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19; 0.19
				N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43; 0.43
		S. Typhimurium	v 2.0	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43; 0.43
				3.18	20	18 ^l	0.90	0.70, 0.97	19	0.95	0.76, 1.00	-0.05	-0.26; 0.15
				N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43; 0.43
		S. Typhimurium	v 1.0	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43; 0.43
				2.26	20	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23; 0.23
				N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43; 0.43
		S. Typhimurium	v 2.0	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43; 0.43
				2.26	20	16 ^l	0.80	0.58, 0.92	17	0.85	0.64, 0.95	-0.05	-0.29; 0.19
				N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43; 0.43

^aRapidFinder Express (RFE) software v1.0 (kit file 1.1) and v1.1 (kit file 2.0).^bMPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.^cN = Number of test portions, 5 unspiked, 20 low spike, 5 high spike.^dNumber of positive test portions.^ePOD_{CP} = Candidate method presumptive positive outcomes divided by total number of trials.^fAll strains were confirmed by serotyping.^gPOD_{CC} = Candidate method confirmed (via Brilliance Salmonella Agar) positive outcomes divided by the total number of trials.^hdPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via Brilliance Salmonella Agar) result POD values.ⁱ95% CI = If the confidence interval of a dPOD does not straddle zero, then the difference is statistically significant at the 5% level.^jRapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between species.^kN/A = Not applicable.^lPositive results excluding the warning call.**Table 35. Thermo Scientific RapidFinder Salmonella Multiplex PCR Assay Stage 2: POD re-analysis comparison for RFE kit files v1.0 and kit files v2.0, vs confirmed candidate result (using reference method) for the matrixes which showed a change to the number of positive results between software versions (12)**

Assay	Matrix	Inoculating strain(s)	RFE kit file ^a	MPN ^b / test portion	N ^c	RapidFinder PCR Presumptive			Reference method Confirmed ^f			dPOD	
						x ^d	POD _{CP} ^e	95% CI	x	POD _{CC2} ^g	95% CI	dPOD _{CP} ^h	95% CI ⁱ
RapidFinder Salmonella species, Typhimurium and Enteritidis Multiplex (Stage 2)	Ground turkey (original test)	Salmonella spp. total ^j (S. Bareilly & S. Typhimurium)	v 1.0	N/A ^k	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43; 0.43
				3.18	20	19	0.95	0.76, 1.00	19	0.95	0.76, 1.00	0.00	-0.19; 0.19
				N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43; 0.43
		S. Typhimurium	v 2.0	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43; 0.43
				3.18	20	18 ^l	0.90	0.70, 0.97	19	0.95	0.76, 1.00	-0.05	-0.26; 0.15
				N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43; 0.43
		S. Typhimurium	v 1.0	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43; 0.43
				2.26	20	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	-0.23; 0.23
				N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43; 0.43
		S. Typhimurium	v 2.0	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43; 0.43
				2.26	20	16 ^l	0.80	0.58, 0.92	17	0.85	0.64, 0.95	-0.05	-0.29; 0.19
				N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43; 0.43

^aRapidFinder Express (RFE) software v1.0 (kit file 1.1) and v1.1 (kit file 2.0).^bMPN = Most Probable Number is based on the POD of reference method test portions using the Least Cost Formulations MPN calculator, with 95% confidence interval.^cN = Number of test portions, 5 unspiked, 20 low spike, 5 high spike.^dNumber of positive test portions.^ePOD_{CP} = Candidate method presumptive positive outcomes divided by total number of trials.^fAll strains were confirmed by serotyping.^gPOD_{CC2} = Candidate method confirmed (via reference method) positive outcomes divided by the total number of trials.^hdPOD_{CP} = Difference between the candidate method presumptive result and candidate method confirmed (via reference method) result POD values.ⁱ95% CI = If the confidence interval of a dPOD does not straddle zero, then the difference is statistically significant at the 5% level.^jRapidFinder presumptive PCR result for Salmonella species reflects all species present and therefore does not discriminate between species.^kN/A = Not applicable.^lPositive results excluding the warning call.

DISCUSSION OF THE MODIFICATION STUDY APPROVED JANUARY 2024 (13)

The comparison study was selected to evaluate the automated procedure as it allowed for an accurate and precise comparison of the performance between the manual and automated lysis and PCR setup procedures without interference from other parts of the method, such as the enrichment. The study followed a paired study design with a post enrichment spike to assess the performance of the lysis and PCR setup procedures specifically.

Comparison studies above the LOD of the PCR assays showed that the difference in average C_t values were always ±1.5 cycles when comparing the automated and manual procedures. At the LOD, the numbers of positives per dilution for each assay-matrix combination was statistically comparable when comparing the automated procedure to the manual.

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