

Thermo Scientific RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit AOAC-RI PTM Validation: Inclusivity and Exclusivity

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Summary

As part of the validation studies for AOAC Research Institute (RI) Performance Tested MethodSM certification, inclusivity and exclusivity studies were conducted as part of the performance validation of the Thermo ScientificTM RapidFinderTM Salmonella species, Typhimurium and Enteritidis PCR Kit (candidate method) for use with the Applied BiosystemsTM 7500 Fast Food Safety Real-Time PCR Instrument and associated Applied BiosystemsTM RapidFinderTM Express Software (version 2.0 or greater) and the Applied BiosystemsTM QuantStudioTM 5 Food Safety Real-Time PCR Instrument and associated Thermo Scientific RapidFinderTM Analysis Software (version 1.0 or greater) for the detection and differentiation of *Salmonella* species, *Salmonella* Typhimurium and *Salmonella* Enteritidis. Results showed that the candidate method successfully detected all *Salmonella* spp. tested and did not detect any non-*Salmonella* spp. The following is a summary of the inclusivity and exclusivity study.

Methodology

Choice of strains

A total of 200 inclusivity isolates covering all species and sub-species of *Salmonella* and 45 exclusivity isolates were analyzed during the AOAC-RI PTM validation studies. One hundred and sixty-seven isolates were selected from the culture collections at Thermo Fisher Scientific, Basingstoke, UK, and 42 isolates were selected from the culture collections at Q Laboratories Inc., Ohio, USA. The isolates chosen originated from either national culture collections or food microbiology laboratories. All testing was conducted according to AOAC-RI PTM guidelines and study protocols.

Culture enrichment

For each inclusivity isolate, one colony was inoculated into a tube containing Buffered Peptone Water (ISO) (CM1211) with 12 mg/l novobiocin and incubated for 14-18 hours at 41.5±1°C. The broth was diluted with Maximum Recovery

Diluent (MRD) to dilute the target cultures to a level of approximately 10^4 CFU/ml before analyzing with the candidate method.

For each exclusivity isolate, one colony was inoculated into a tube containing Tryptone Soya Broth (TSB) and incubated for 20-24 hours at $37\pm 2^\circ\text{C}$. Prepared cultures were analyzed with the candidate method, at the growth level achieved during the incubation time, without being diluted.

Protocol

For each of the required number of Lysis Tubes (supplied prefilled with Lysis Reagent 1), 10 μl of proteinase K reagent was added followed by 10 μl of the sample. The Lysis Tubes were transferred to the Applied Biosystems SimpliAmp™ Food Safety Thermal Cycler Instrument which heated the tubes at $37\pm 1^\circ\text{C}$ for 10 minutes, followed by $95\pm 1^\circ\text{C}$ for 5 minutes, and cooled for at least 2 minutes at room temperature. Twenty aliquots of the lysates were transferred to PCR Tubes containing RapidFinder Salmonella species, Enteritidis, and Typhimurium PCR pellets. The PCR Tubes were sealed and immediately transferred to the 7500 Fast PCR Instrument and QuantStudio 5 PCR Instrument for processing.

Results

Inclusivity and exclusivity results are summarized in tables 1 and 2 respectively. All 200 inclusivity isolates tested returned a correct PCR positive result for the target being tested, and all 45 exclusivity isolates gave negative results when analysed using the candidate method, with the QuantStudio 5 PCR Instrument with RapidFinder Analysis software and the 7500 Fast PCR Instrument with RapidFinder Express software.

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
1726	<i>Salmonella</i> Uphill	Positive	Negative	Negative	Positive	Negative	Negative
2355	<i>Salmonella</i> Donna	Positive	Negative	Negative	Positive	Negative	Negative
2830	<i>Salmonella</i> Locarno	Positive	Negative	Negative	Positive	Negative	Negative
NCTC™ ^a 10252	<i>Salmonella</i> Tranaroa	Positive	Negative	Negative	Positive	Negative	Negative
2599	<i>Salmonella</i> salamae	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 8297	<i>Salmonella</i> arizonae	Positive	Negative	Negative	Positive	Negative	Negative
2389	<i>Salmonella</i> arizonae	Positive	Negative	Negative	Positive	Negative	Negative
2608	<i>Salmonella</i> arizonae	Positive	Negative	Negative	Positive	Negative	Negative
2609	<i>Salmonella</i> arizonae	Positive	Negative	Negative	Positive	Negative	Negative
2610	<i>Salmonella</i> arizonae	Positive	Negative	Negative	Positive	Negative	Negative
2386	<i>Salmonella</i> diarizonae	Positive	Negative	Negative	Positive	Negative	Negative
2388	<i>Salmonella</i> diarizonae	Positive	Negative	Negative	Positive	Negative	Negative
2616	<i>Salmonella</i> diarizonae	Positive	Negative	Negative	Positive	Negative	Negative
2617	<i>Salmonella</i> diarizonae	Positive	Negative	Negative	Positive	Negative	Negative
2618	<i>Salmonella</i> diarizonae	Positive	Negative	Negative	Positive	Negative	Negative
3732	<i>Salmonella</i> houtenae	Positive	Negative	Negative	Positive	Negative	Negative
2624	<i>Salmonella</i> houtenae	Positive	Negative	Negative	Positive	Negative	Negative
2625	<i>Salmonella</i> houtenae	Positive	Negative	Negative	Positive	Negative	Negative
2626	<i>Salmonella</i> houtenae	Positive	Negative	Negative	Positive	Negative	Negative
2627	<i>Salmonella</i> houtenae	Positive	Negative	Negative	Positive	Negative	Negative
2360	<i>Salmonella</i> indica	Positive	Negative	Negative	Positive	Negative	Negative

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
2643	<i>Salmonella indica</i>	Positive	Negative	Negative	Positive	Negative	Negative
2640	<i>Salmonella indica</i>	Positive	Negative	Negative	Positive	Negative	Negative
2641	<i>Salmonella indica</i>	Positive	Negative	Negative	Positive	Negative	Negative
2642	<i>Salmonella indica</i>	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 2215	<i>Salmonella bongori</i>	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 12419	<i>Salmonella bongori</i>	Positive	Negative	Negative	Positive	Negative	Negative
3407	<i>Salmonella</i> Stanley	Positive	Negative	Negative	Positive	Negative	Negative
5096	<i>Salmonella</i> Abony	Positive	Negative	Negative	Positive	Negative	Negative
2150	<i>Salmonella</i> Saintpaul	Positive	Negative	Negative	Positive	Negative	Negative
3377	<i>Salmonella</i> Heidelberg	Positive	Negative	Negative	Positive	Negative	Negative
2358	<i>Salmonella</i> Agona	Positive	Negative	Negative	Positive	Negative	Negative
2839	<i>Salmonella</i> Brandenburg	Positive	Negative	Negative	Positive	Negative	Negative
2840	<i>Salmonella</i> Indiana	Positive	Negative	Negative	Positive	Negative	Negative
2296	<i>Salmonella</i> Abortus-equi	Positive	Negative	Negative	Positive	Negative	Negative
3016	<i>Salmonella</i> Abortusovis	Positive	Negative	Negative	Positive	Negative	Negative
3017	<i>Salmonella</i> Schwarzengrund	Positive	Negative	Negative	Positive	Negative	Negative
3018	<i>Salmonella</i> Stanleyville	Positive	Negative	Negative	Positive	Negative	Negative
3019	<i>Salmonella</i> Sandiego	Positive	Negative	Negative	Positive	Negative	Negative
3381	<i>Salmonella</i> Bredeney	Positive	Negative	Negative	Positive	Negative	Negative
30151	<i>Salmonella</i> Java	Positive	Negative	Negative	Positive	Negative	Negative
30020	<i>Salmonella</i> Paratyphi B	Positive	Negative	Negative	Positive	Negative	Negative
3399	<i>Salmonella</i> Dublin	Positive	Negative	Negative	Positive	Negative	Negative

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
NCTC 3747	Salmonella Rostock	Positive	Negative	Negative	Positive	Negative	Negative
1774	Salmonella Gallinarum	Positive	Negative	Negative	Positive	Negative	Negative
NCTC 9868	Salmonella Alabama	Positive	Negative	Negative	Positive	Negative	Negative
3024	Salmonella Miami	Positive	Negative	Negative	Positive	Negative	Negative
3025	Salmonella Lomalinda	Positive	Negative	Negative	Positive	Negative	Negative
3026	Salmonella Israel	Positive	Negative	Negative	Positive	Negative	Negative
3027	Salmonella Portland	Positive	Negative	Negative	Positive	Negative	Negative
3028	Salmonella Sendai	Positive	Negative	Negative	Positive	Negative	Negative
2129	Salmonella Napoli	Positive	Negative	Negative	Positive	Negative	Negative
2138	Salmonella Gallinarum	Positive	Negative	Negative	Positive	Negative	Negative
2139	Salmonella Eastbourne	Positive	Negative	Negative	Positive	Negative	Negative
2146	Salmonella Javiana	Positive	Negative	Negative	Positive	Negative	Negative
2360	Salmonella Berta	Positive	Negative	Negative	Positive	Negative	Negative
30001	Salmonella Typhi	Positive	Negative	Negative	Positive	Negative	Negative
1654	Salmonella Kiel	Positive	Negative	Negative	Positive	Negative	Negative
2135	Salmonella Ohio	Positive	Negative	Negative	Positive	Negative	Negative
2359	Salmonella Montevideo	Positive	Negative	Negative	Positive	Negative	Negative
2351	Salmonella Virchow	Positive	Negative	Negative	Positive	Negative	Negative
3400	Salmonella Infantis	Positive	Negative	Negative	Positive	Negative	Negative
3402	Salmonella Bovis	Positive	Negative	Negative	Positive	Negative	Negative
2125	Salmonella Albany	Positive	Negative	Negative	Positive	Negative	Negative
2001	Salmonella Bovis-Morbificans	Positive	Negative	Negative	Positive	Negative	Negative
3734	Salmonella Kentucky	Positive	Negative	Negative	Positive	Negative	Negative

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
2087	Salmonella Newport	Positive	Negative	Negative	Positive	Negative	Negative
2130	Salmonella Muenchen	Positive	Negative	Negative	Positive	Negative	Negative
2131	Salmonella Hadar	Positive	Negative	Negative	Positive	Negative	Negative
2132	Salmonella Shanghai	Positive	Negative	Negative	Positive	Negative	Negative
1623	Salmonella Allerton	Positive	Negative	Negative	Positive	Negative	Negative
2683	Salmonella Muenster	Positive	Negative	Negative	Positive	Negative	Negative
2210	Salmonella Seftenburg	Positive	Negative	Negative	Positive	Negative	Negative
1655	Salmonella Krefeld	Positive	Negative	Negative	Positive	Negative	Negative
1612	Salmonella Aberdeen	Positive	Negative	Negative	Positive	Negative	Negative
3739	Salmonella Rubislaw	Positive	Negative	Negative	Positive	Negative	Negative
3405	Salmonella Poona	Positive	Negative	Negative	Positive	Negative	Negative
2831	Salmonella Ibidam	Positive	Negative	Negative	Positive	Negative	Negative
3736	Salmonella Madelia	Positive	Negative	Negative	Positive	Negative	Negative
2453	Salmonella Schalkwijk	Positive	Negative	Negative	Positive	Negative	Negative
2671	Salmonella Saphra	Positive	Negative	Negative	Positive	Negative	Negative
2362	Salmonella Huttingfoss	Positive	Negative	Negative	Positive	Negative	Negative
2673	Salmonella Michigan	Positive	Negative	Negative	Positive	Negative	Negative
2127	Salmonella Cerro	Positive	Negative	Negative	Positive	Negative	Negative
2679	Salmonella Brisbane	Positive	Negative	Negative	Positive	Negative	Negative
2100	Salmonella Urbana	Positive	Negative	Negative	Positive	Negative	Negative
2356	Salmonella Matopeni	Positive	Negative	Negative	Positive	Negative	Negative
2122	Salmonella Adelaide	Positive	Negative	Negative	Positive	Negative	Negative

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
2690	Salmonella Alachua	Positive	Negative	Negative	Positive	Negative	Negative
2120	Salmonella Inverness	Positive	Negative	Negative	Positive	Negative	Negative
2118	Salmonella Champaign	Positive	Negative	Negative	Positive	Negative	Negative
5372	Salmonella Riogrande	Positive	Negative	Negative	Positive	Negative	Negative
2685	Salmonella Johannesburg	Positive	Negative	Negative	Positive	Negative	Negative
2675	Salmonella Vietnam	Positive	Negative	Negative	Positive	Negative	Negative
2677	Salmonella Gera	Positive	Negative	Negative	Positive	Negative	Negative
2937	Salmonella Berkeley	Positive	Negative	Negative	Positive	Negative	Negative
2676	Salmonella Tornow	Positive	Negative	Negative	Positive	Negative	Negative
1728	Salmonella Teshi	Positive	Negative	Negative	Positive	Negative	Negative
30017	Salmonella Paratyphi A	Positive	Negative	Negative	Positive	Negative	Negative
30026	Salmonella Paratyphi C	Positive	Negative	Negative	Positive	Negative	Negative
2207	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
3379	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
3729	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
3900	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
723	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
1637	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
1638	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
1639	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
1640	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
1986	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2424	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2425	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2426	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2443	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2450	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2591	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2668	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2669	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
2670	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
3372	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
3378	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
3383	Salmonella Enteritidis var. Dansyz	Positive	Positive	Negative	Positive	Positive	Negative
1584	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
ATCC ^{®b} BAA 1587	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL ^c 10155.1	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 10170.1	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 14255.2	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.40	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.80	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
QL 16078-2A.121	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.184	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.185	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.186	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.278	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.279	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 16078-2A.280	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 1698878.3	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 175599.1	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 182282	Salmonella Enteritidis	Positive	Negative	Negative	Positive	Negative	Negative
QL 182282 (retest) ^d	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 188498.1	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 191569.1	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
QL 194559.3 (IPC failed run) ^e	Salmonella Enteritidis	Negative	Positive	Negative	Positive	Positive	Negative
QL 194559.3 (retest) ^f	Salmonella Enteritidis	Positive	Positive	Positive	Positive	Positive	Negative
CCUG 9563	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 21288	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 25340	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 26522	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
CCUG 27004	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
CCUG 27021	Salmonella Enteritidis	Positive	Positive	Positive	Positive	Positive	Negative
CCUG 27021 (retest) ^k	Salmonella Enteritidis	Positive	Positive	Negative	n/a	n/a	n/a
FSL S5-415	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
FSL S5-483	Salmonella Enteritidis	Positive	Positive	Negative	Positive	Positive	Negative
962	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
1793	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2124	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2836	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
3380	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
3384	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
3740	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
3741	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
3897	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
3920	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
3922	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
3924	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
4669	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
1585	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
1679	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
1680	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
1681	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
1683	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
1684	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
1880	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2387	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2390	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
ATCC® 19585	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
ATCC® BAA-1603	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2461	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2593	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2645	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2646	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2647	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2648	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2649	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2650	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2651	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2652	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2653	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2654	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive

Table 1: Inclusivity results for the RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit using the 7500 Fast PCR Instrument and the QuantStudio 5 PCR Instrument (Continued)

ID number	Salmonella serotype	7500 Fast PCR Instrument results			QuantStudio 5 PCR Instrument results		
		Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result	Salmonella spp. result	Salmonella Enteritidis result	Salmonella Typhimurium result
2655	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2656	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2657	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2658	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
2659	Salmonella Typhimurium/ DT104	Positive	Negative	Positive	Positive	Negative	Positive
2660	Salmonella Typhimurium/ DT104	Positive	Negative	Positive	Positive	Negative	Positive
2661	Salmonella Typhimurium/ DT104	Positive	Negative	Positive	Positive	Negative	Positive
1586	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
11007-2	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
11414-2	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
16078-2A.110	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
16078-2A.112	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
16078-2A.1	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive
16078-2A.108	Salmonella Typhimurium	Positive	Negative	Positive	Positive	Negative	Positive

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

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

^c QL = number proprietary to Q Laboratories LLC, Cincinnati, Ohio, USA.

^d Retest results for isolate QL 182282.

^e First results for isolate QL 194559.3 which had an IPC failure.

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

^g Results for isolate CCUG 27021, retested only on the 7500 Fast Real-Time PCR Instrument

Conclusion

The inclusivity and exclusivity studies conducted as part of the AOAC-RI PTM validation studies demonstrated that the Thermo Scientific RapidFinder Salmonella species, Typhimurium and Enteritidis PCR Kit (candidate method) showed 100% inclusivity and 100% exclusivity with all isolates analyzed using the candidate method when using the QuantStudio 5 PCR Instrument and the 7500 Fast PCR Instrument. The AOAC-RI PTM report is available for download via <https://doi.org/10.5740/jaoacint.17-0344>. The AOAC-RI PTM validation certificate (License number: 081707) is available from either www.thermofisher.com or the AOAC Research Institute at www.aoac.org.

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