



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.
050602

The AOAC Research Institute hereby certifies the method known as

Assurance[®] GDS for *Salmonella*

manufactured by

BioControl Systems, Inc. / MilliporeSigma
12822 SE 32nd Street
Bellevue, WA 98005 USA

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A handwritten signature in black ink, appearing to read "Bradley A. Stawick".

Bradley A. Stawick, AOAC Research Institute Senior Director

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METHOD NAME Assurance® GDS for <i>Salmonella</i>	CATALOG NUMBERS 71008-100, 71008-576, 71008-576ATM
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INDEPENDENT LABORATORY Original Validation Silliker Inc. Food Science Center South Holland, IL USA	2013 Modification Aegis Food Testing Laboratories North Sioux City, SD USA
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APPLICABILITY OF METHOD Target organism – <i>Salmonella</i> spp. Matrixes – (25 g) – raw beef, raw pork, ground turkey, chicken rinse, raw shrimp, nonfat dry milk, egg, stainless steel, rubber, and concrete MODIFICATION 2013 – (25 g and 375 g) – raw beef trim, raw ground beef, ready-to-eat (RTE) poultry (turkey) meat, raw leaf lettuce, raw spinach, raw mixed greens (baby lettuce and other young leafy green vegetables) (25 g) raw almonds, raw strawberries (sponge/swab, 4 x 4 in) stainless steel, rubber Performance claims – The Assurance® GDS for <i>Salmonella</i> was demonstrated to have a high level of sensitivity and was equivalent to the reference culture methods for selected foods and environmental surfaces.	REFERENCE METHODS USDA/FSIS MLG 4.03 <i>Isolation and Identification of Salmonella from Meat, Poultry, Pasteurized Egg, and Catfish Products and Carcass and Environmental Sponges.</i> (3) FDA/BAM Chapter 5 <i>Salmonella</i> reference method. (4) U.S. Department of Agriculture, Food Safety and Inspection Service. 2011. <i>Isolation and Identification of Salmonella from Meat, Poultry, Pasteurized Egg and Catfish Products</i> (6) International Organization of Standards, Anon BS ISO 6579:2002 + Cor.1:2004 + Amd.1:2007. <i>Microbiology of Food and Animal Feeding Stuffs Horizontal Method for the Detection of Salmonella sp</i> (7)
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ORIGINAL CERTIFICATION DATE May 12, 2006	CERTIFICATION RENEWAL RECORD Renewed through December 2027.
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METHOD MODIFICATION RECORD	SUMMARY OF MODIFICATION
1. October 2012 Level 2	1. Addition of polymerase enzyme in amplification tube at manufacturing.
2. September 2013 Level 3	2. Shorter incubation time, higher temperature, proprietary media (mEHEC® broth), and 375 g sampling size for raw beef trim, raw ground beef, ready-to-eat poultry (turkey) meat, raw leaf lettuce, raw spinach, raw mixed greens. (5)
3. December 2015 Level 1	3. Editorial changes for clarity.
4. October 2018 Level 1	4. Editorial changes, updated copyright, corrections.
5. January 2020 Level 2	5. mEHEC media and mEHEC+novobiocin manufacturing location change to Darmstadt, Germany and rebranding to Merck format.
6. January 2021 Level 1	6. Editorial/clerical changes and rebranding to BioControl Systems Inc. / MilliporeSigma.
7. November 2021 Level 1	7. Editorial changes and update to software.
8. January 2023 Level 1	8. Editorial changes.

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PRINCIPLE OF THE METHOD (1) GDS is an automated gene-based assay that incorporates multiple levels of specificity to ensure highly accurate results. The method utilizes proprietary probes and specific primers directed against a highly conserved DNA sequence of the target organism. GDS also utilizes a proprietary device and reagents that concentrate populations of target microorganisms and eliminate potential competitive microflora. The method is designed to be highly selective and does not detect microorganisms that are potential cross-reactors in antibody-based assays. The proof of the principle was previously demonstrated in the validations of the Assurance® GDS for <i>E. coli</i> O157:H7 Method (OMA 2005.04) and Assurance GDS for Shiga-like Toxin Genes Method (OMA 2005.05) (2).

DISCUSSION OF THE VALIDATION STUDY (1)

The results generated in these studies validated that Assurance GDS for *Salmonella* is rugged and is inclusive and specific for *Salmonella*. The results also demonstrated a high level of correlation between GDS and the reference culture methods for selected foods and environmental surfaces. Sensitivity of the method is high. In the internal method comparison study, where 514 samples and controls were analyzed, there were 13 samples across all the food types and surfaces analyzed that were negative by the GDS and confirmed positive by culture, while there were 19 samples that were negative by the reference method and confirmed positive by GDS. Some of the variances may be explained by the fact that three of the 11 sample types analyzed (liquid milk, liquid egg and raw shrimp) utilized a different primary enrichment than reference culture. Those three food types made up approximately 28% of the samples and controls analyzed but contributed to almost 70% of the discrepancies between the two methods. Similarly, GDS was demonstrated to be equivalent to the reference culture methods in the method comparison study performed by an independent laboratory. Among 90 samples and controls, there were 6 samples that were negative by the GDS and after confirmation found to be positive for *Salmonella*, while there were 3 samples that were negative by the Reference method and confirmed positive by GDS. The independent laboratory observed that the “GDS was easy to use”, “instructions were clear and easy to follow” and the “results from the GDS were easy to view”. Results of these studies validate that Assurance GDS *Salmonella* is robust, inclusive and specific for *Salmonella* species. In the internal method comparison study, Assurance GDS and the reference culture methods are statistically not different for the detection of *Salmonella* in raw beef trim, raw ground beef, RTE poultry meat, raw leaf lettuce, raw spinach, raw mixed greens, raw almonds, raw strawberries, stainless steel and rubber. The external method comparison study yielded similar results for raw beef trim, raw leaf lettuce and stainless steel. In this study, all 105 *Salmonella* tested were detected in mEHEC broth. These results demonstrate that the mEHEC broth for 8 – 24 hours at 42°C is an effective enrichment method for use with the Assurance GDS *Salmonella* for the detection of *Salmonella* in selected foods and environmental surfaces.

Table 1A. Organisms Included in Validation of Inclusivity of Assurance GDS for *Salmonella* (1)

Organism	O Antigen		GDS Results
	Group	Source *	
<i>Salmonella enterica</i> ser. Abaetetuba	F	ATCC #35640	+
<i>Salmonella enterica</i> ser. Aberdeen	F	CDC isolate	+
<i>Salmonella enterica</i> ser. Abony	B	NCTC #6017	+
<i>Salmonella enterica</i> ser. Adelaide	O	ATCC #10718	+
<i>Salmonella enterica</i> ser. Agona	B	CDC isolate	+
<i>Salmonella enterica</i> ser. Alachua	O	CDC #175-87	+
<i>Salmonella enterica</i> ser. Anatum	E ₁	ATCC #9270	+
<i>Salmonella enterica</i> ser. Bere	X	CDC #315-86	+
<i>Salmonella enterica</i> ser. Berta	D ₁	CDC isolate	+
<i>Salmonella enterica</i> ser. Betioky	59	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Binza	E ₂	BioControl isolate, dry cheese	+
<i>Salmonella enterica</i> ser. Bockenheim	53	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Bovismorbificans	C ₂	CDC isolate	+
<i>Salmonella enterica</i> ser. Bredeney	B	CDC isolate	+
<i>Salmonella enterica</i> ser. California	B	BioControl isolate, bone meal	+
<i>Salmonella enterica</i> ser. Cerro	K	CDC #65-87	+
<i>Salmonella enterica</i> ser. Choleraesuis	C ₁	ATCC #10708	+
<i>Salmonella enterica</i> ser. Choleraesuis var. Kunzendorf	C ₁	ATCC #12011	+
<i>Salmonella enterica</i> ser. Crossness	67	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Cubana	G	BioControl isolate, ground beef	+
<i>Salmonella enterica</i> ser. Derby	B	BioControl isolate, chicken	+
<i>Salmonella enterica</i> ser. Dusseldorf	C ₂	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Enteritidis	D ₁	ATCC #13076	+
<i>Salmonella enterica</i> ser. Ferlac	H	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Flint	Z	CDC isolate	+
<i>Salmonella enterica</i> ser. Gallinarum	D ₁	BioControl isolate, beef	+
<i>Salmonella enterica</i> ser. Gaminara	I	CDC isolate	+
<i>Salmonella enterica</i> ser. Glostrup	C ₂	CDC isolate	+
<i>Salmonella enterica</i> ser. Grumpensis	G	CDC isolate	+
<i>Salmonella enterica</i> ser. Hadar	C ₂	ATCC #51956	+
<i>Salmonella enterica</i> ser. Havana	G	BioControl isolate, dried milk	+
<i>Salmonella enterica</i> ser. Heidelberg	B	BioControl isolate, ground pork	+
<i>Salmonella enterica</i> ser. Hilversum	N	CDC #5213-63	+
<i>Salmonella enterica</i> ser. Hittingfoss	I	CDC isolate	+
<i>Salmonella enterica</i> ser. Illinois	E ₃	ATCC #11646	+
<i>Salmonella enterica</i> ser. Infantis	C ₁	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Inverness	P	ATCC #10720	+
<i>Salmonella enterica</i> ser. Javiana	D ₁	BioControl isolate, shrimp	+
<i>Salmonella enterica</i> ser. Jerusalem	C ₁	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Johannesburg	R	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Karamoja	R	BioControl isolate, turkey	+
<i>Salmonella enterica</i> ser. Kentucky	C ₂	CDC isolate	+
<i>Salmonella enterica</i> ser. Krefeld	E ₄	CDC isolate	+
<i>Salmonella enterica</i> ser. Locarno	57	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. London	E ₁	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Luciana	F	CDC isolate	+
<i>Salmonella enterica</i> ser. Madelia	H	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Malawi	66	CDC isolate	+
<i>Salmonella enterica</i> ser. Manilla	E ₂	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Maregrosso	66	Silliker Laboratory isolate	+

Table 1A. Organisms Included in Validation of Inclusivity of Assurance GDS for *Salmonella* cont. (1)

Organism	O Antigen		GDS Results
	Group	Source *	
<i>Salmonella enterica</i> ser. Mbandaka	C ₁	BioControl isolate, bone meal	+
<i>Salmonella enterica</i> ser. Memphis	K	BioControl isolate, pork	+
<i>Salmonella enterica</i> ser. Michigan	J	CDC isolate	+
<i>Salmonella enterica</i> ser. Minnesota	L	ATCC #49284	+
<i>Salmonella enterica</i> ser. Montevideo	C ₁	CDC isolate	+
<i>Salmonella enterica</i> ser. Muenchen	C ₂	BioControl isolate, catfish	+
<i>Salmonella enterica</i> ser. Nienstedten	C ₁	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Newport	C ₂	ATCC #6962	+
<i>Salmonella enterica</i> ser. Ohio	C ₁	BioControl isolate, shrimp	+
<i>Salmonella enterica</i> ser. Oranienburg	C ₁	ATCC #9239	+
<i>Salmonella enterica</i> ser. Ouakam	D ₂	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Panama	D ₁	BioControl isolate, dried egg	+
<i>Salmonella enterica</i> ser. Paratyphi A	A	ATCC #9281	+
<i>Salmonella enterica</i> ser. Paratyphi B	C	ATCC #10719	+
<i>Salmonella enterica</i> ser. Paratyphi C	C ₁	ATCC #13428	+
<i>Salmonella enterica</i> ser. Phoenix	X	ATCC #29931	+
<i>Salmonella enterica</i> ser. Poona	G	NCTC #4840	+
<i>Salmonella enterica</i> ser. Potsdam	C ₁	CDC isolate	+
<i>Salmonella enterica</i> ser. Putten	G	CDC isolate	+
<i>Salmonella enterica</i> ser. Saintpaul	B	ATCC #9712	+
<i>Salmonella enterica</i> ser. Saphra	I	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Schwarzengrund	B	BioControl isolate, nonfat dried milk	+
<i>Salmonella enterica</i> ser. Senftenberg	E ₄	BioControl isolate, sausage	+
<i>Salmonella enterica</i> ser. Simsbury	E ₄	BioControl isolate, ground beef	+
<i>Salmonella enterica</i> ser. Sundsvall	H	BioControl isolate, ham	+
<i>Salmonella enterica</i> ser. Taksony	E ₄	BioControl isolate, river sediment	+
<i>Salmonella enterica</i> ser. Tallahassee	C ₂	ATCC #12002	+
<i>Salmonella enterica</i> ser. Thompson	C ₁	BioControl isolate, chicken	+
<i>Salmonella enterica</i> ser. Tranoroa	55	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Treforest	51	CDC #657	+
<i>Salmonella enterica</i> ser. Tulear	C ₂	BioControl isolate, egg	+
<i>Salmonella enterica</i> ser. Typhi	D ₁	CDC isolate	+
<i>Salmonella enterica</i> ser. Typhimurium	B	ATCC #13311	+
<i>Salmonella enterica</i> ser. Urbana	N	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Vellore	B	ATCC #15611	+
<i>Salmonella enterica</i> ser. Vietnam	S	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Virchow	C ₁	BioControl isolate, shrimp	+
<i>Salmonella enterica</i> ser. Vrindaban	W	Silliker Laboratory isolate	+
<i>Salmonella enterica</i> ser. Wassenaar	Z	CDC #121-87	+
<i>Salmonella enterica</i> ser. Waycross	S	BioControl isolate, turkey	+
<i>Salmonella enterica</i> ser. Weltevreden	E ₁	BioControl isolate, shrimp	+
<i>Salmonella enterica</i> ser. Weslaco	T	CDC #185-87	+
<i>Salmonella enterica</i> ser. Wichita	G	CDC isolate	+
<i>Salmonella enterica</i> ser. Worthington	G	ATCC #9607	+
<i>Salmonella enterica</i> subsp. Arizonae (40:z4,z23:-)	R	ATCC #12324	+
<i>Salmonella enterica</i> subsp. Diarizonae (47:i:z53:(z57))	X	ATCC #12325	+
<i>Salmonella enterica</i> subsp. Houtenae ser. Harmelen (51:z4,z23:-)	51	ATCC #15783	+
<i>Salmonella enterica</i> subsp. Houtenae ser. Houten (43:z4z23:-)	U	ATCC #29834	+
<i>Salmonella enterica</i> subsp. Salamae (50:z10:z6:z42)	Z	ATCC #15786	+
<i>Salmonella bongori</i>	66	ATCC #43975	+

Table 1B: Organisms Included in Validation of Exclusivity of Assurance GDS for *Salmonella* (1)

Organism	Source	GDS results
<i>Citrobacter anakibatucys</i>	BioControl isolate, ground turkey	-
<i>Citrobacter farmerii</i>	BioControl isolate, dehydrated flavor additive	-
<i>Citrobacter freundii</i>	ATCC #8090	-
<i>Citrobacter freundii</i> O157:H7	BioControl isolate, carrots	-
<i>Citrobacter youngae</i>	BioControl isolate, cake mix	-
<i>Citrobacter</i> spp.	BioControl isolate, poultry meal	-
<i>Enterobacter aerogenes</i>	ATCC #13048	-
<i>Enterobacter agglomerans</i>	BioControl isolate, raw milk	-
<i>Enterobacter cloacae</i>	ATCC #29005	-
<i>Enterobacter sakazakii</i>	ATCC #51329	-
<i>Enterobacter</i> spp.	BioControl isolate, dried egg	-
<i>E. coli</i>	ATCC #25922	-
<i>E. coli</i> O157	Silliker Laboratory isolate	-
<i>E. coli</i> O157:H7	ATCC #35150	-
<i>Hafnia alvei</i>	BioControl isolate, ground beef	-
<i>Klebsiella oxytoca</i>	ATCC #43086	-
<i>Klebsiella pneumoniae</i>	ATCC #31488	-
<i>Morganella morganii</i>	ATCC #9237	-
<i>Proteus mirabilis</i>	BioControl isolate, chicken	-
<i>Proteus penneri</i>	ATCC #33519	-
<i>Proteus vulgaris</i>	ATCC #33420	-
<i>Providencia alcalifaciens</i>	BioControl isolate, shrimp	-
<i>Providencia rettgeri</i>	ATCC #33671	-
<i>Providencia</i> spp.	BioControl isolate, apples	-
<i>Serratia liquefaciens</i>	ATCC #27592	-
<i>Serratia marcescens</i>	ATCC #13880	-
<i>Shigella boydii</i>	ATCC #49348	-
<i>Shigella dysenteriae</i> (IV)	ATCC #12021	-
<i>Shigella flexneri</i> (VI)	ATCC #15391	-
<i>Shigella sonnei</i>	ATCC #11060	-
<i>Staphylococcus aureus</i>	ATCC #49444	-
<i>Yersinia enterocolitica</i>	BioControl isolate, salmon	-
<i>Yersinia frederiksenii</i>	ATCC #33641	-
<i>Yersinia pseudotuberculosis</i>	BioControl isolate, ground beef	-
<i>Yersinia ruckeri</i>	ATCC #29473	-

Table 3. Method performance for detection of *Salmonella* spp. in foods and environmental surfaces by Assurance GDS for *Salmonella* (1)

Sample	Level	MPN/g	Total Samples	Positive samples		Culture Method	Chi square	Sensitivity rate ^c		Specificity rate ^a
				Pres. ^d	Conf. ^d			GDS	Culture	
Raw pork	Low	0.0919	20	13	13	13	_f	100	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100
	High	0.0933	20	20	20	20	_f	100	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100
Raw beef	Low	0.0074	20	6	6	6	_f	100	100	-
	High	0.092	20	16	16	16	_f	100	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100
Raw ground turkey	Lot 1	0.042	20	15	15	15	_f	100	100	-
	Lot 2	<0.003	20	16	16	16	_f	100	100	-
Shrimp	Low	0.003	20	3	3	3	0.25	60	60	-
	High	0.045	20	19	19	17	0.25	95	85	-
	Control	<0.003	5	0	0	0	_f	-	-	100
Liquid milk	Low	0.074	20	13	13	10	0.80	93	71	-
	Control	<0.003	5	0	0	0	_f	-	-	100
	High	0.147	20	20	20	20	_f	100	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100
Nonfat dry milk	Low	0.0231	20	2	2	2	_f	100	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100
	High	0.0427	20	8	9	9	0.0	89	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100
Liquid egg	Low	0.042	20	15	14	13	0.0	78	72	-
	High	0.933	20	20	20	20	_f	100	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100
Chicken rinse	Low	0.092	20	18	18	18	_f	100	100	100
	Control	<0.003	4	0	0	0	_f	-	-	-
	High	0.385	20	19	20	20	0.0	95	100	-
	Control	<0.003	5	0	0	0	_f	-	-	-
Stainless Steel	Low	-	20	18	18	19	0.0	90	95	-
	High	-	20	20	20	19	0.0	100	95	-
	Control	<0.003	5	0	0	0	_f	-	-	100
Rubber	Low	-	20	19	20	19	0.5	95	95	-
	High	-	20	20	20	20	_f	100	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100
Concrete	Low	-	20	6	6	4	0.5	100	67	-
	Control	<0.003	5	0	0	0	_f	-	-	100
	High	-	20	19	19	19	_f	100	100	-
	Control	<0.003	5	0	0	0	_f	-	-	100

a Pres. = presumptive data. Conf. = culturally

b Chi square, as defined by McNemar is $(|a - b| - 1)^2 / (a + b)$ where a = samples positive by GDS and b = samples negative by GDS and positive by Reference. A chi square value > 3.84

c Sensitivity rate is defined as: No. of analyzed positive results divided by total no. of samples confirmed

d Specificity rate is defined as: No. of analyzed negative results divided by total no. of samples confirmed negative by the reference method and negative controls total number of "known" negative defined as samples confirmed negative by the reference method and negative controls

e Rate reflects number of confirmed determinations that were equivalent between GDS and

f Statistical analysis

Table 4. Method performance for detection of *Salmonella* spp. in raw pork and stainless steel surface by Assurance GDS for *Salmonella* (1)

Sample	Level	MPN/g	Total Samples	Positive samples		Culture Method	Chi square	Sensitivity rate ^c		Specificity rate ^a
				Pres. ^d	Conf. ^d			GDS	Culture	GDS
Raw pork	Low	0.023	20	7	7	10	1.33	70	100	-
	High	0.460	20	20	20	20	- ^f	100	100	-
	Control	na	5	0	0	0	- ^f	-	-	100
Stainless Steel	Low	na	20	9	8	8	0.17	73	73	-
	High	na	20	20	20	20	- ^f	100	100	-
	Control	na	5	0	0	0	- ^f	-	-	100

a Pres. = presumptive data. Conf. = culturally

b Chi square, as defined by McNemar is $(|a - b| - 1)^2 / (a + b)$ where a = samples positive by GDS and b = samples negative by GDS and positive by Reference. A chi square value > 3.84

c Sensitivity rate is defined as: No. of analyzed positive results divided by total no. of samples confirmed

d Specificity rate is defined as: No. of analyzed negative results divided by total no. of samples confirmed negative by the total number of "known" negative defined as samples confirmed negative by the reference and negative

e Rate reflects number of confirmed determinations that were equivalent

f Statistical analysis not applicable. Methods gave

DISCUSSION MODIFICATION APPROVED OCTOBER 2012 (7)

The modified Assurance GDS detected 100% of the isolates of *Salmonella* demonstrating 100% inclusivity. Assurance GDS correctly identified the 30 non-*Salmonella* organisms as negative, demonstrating 100% exclusivity among the organisms tested (Table 2). Inclusivity and exclusivity strains are detailed in Tables 3 and 4.

Three food types were analyzed by the modified Assurance GDS method. Fractional recovery was achieved for all food types tested. In total, there were valid results from 90 samples and controls. There were 47 samples that were positive by both the Assurance GDS (assay positive and subsequently confirmed) method and by reference culture. There were 43 samples that were negative by both Assurance GDS and reference culture. POD statistical analyses of the matched samples indicated that for all foods analyzed, there was no statistical difference between the GDS presumptive compared to the Assurance GDS confirmed. Furthermore, Assurance GDS method results were statistically not different than the reference culture method for the detection of *Salmonella*. POD results are summarized in Tables 5 and 6.

Chi square statistical analyses of the unmatched samples indicated that for all foods analyzed, Assurance GDS results were statistically not different than the reference culture method for the detection of *Salmonella*. Chi square results are summarized in Table 7.

Table 2. Inclusivity and Exclusivity of Assurance GDS *Salmonella* (7)

	Total number of serovars tested	Total number of Assurance GDS positive results	Inclusivity/exclusivity (%)
<i>Salmonella</i>	100	100	100
Non- <i>Salmonella</i>	30	0	100

Table 3 (7)

Table 3. Organisms Included in Validation of Inclusivity of Assurance GDS *Salmonella*

Organisms	Serotype	Source	Test Method Test Result
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Abaetetuba	F	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Abony	B	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Adelaide	O	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Agona	B	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Alabama	D1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Amsterdam	E1	NZRCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Anatum	E1	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Artis	56	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Basel	58	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Bere	X	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Betioky	59	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Bockenheim	53	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Braenderup	C1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Cerro	K	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Chandans	F	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Choleraesuis	C1	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Crossness	67	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Cubana	G2	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Derby	B	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Dublin	D1	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Enteritidis	D1	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Gallinarum	D1	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Give var. 15+	E2	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Godesberg	N	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Grumpensis	G2	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Hadar	C2	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Havana	G2	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Heidelberg	B	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Hofit	Q	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Houten	U	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Ibadan	G1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Indiana	B	NCTC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Infantis	C1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Inverness	P	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Javiana	D1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Johannesburg	R	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Lexington var. 15+	E2	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Lexington var. 15+,34+	E3	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Locarno	57	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. London	E1	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Matadi	J	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Mbandaka	C1	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Memphis	K	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Minnesota	L	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Mississippi	G2	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Montevideo	C1	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Muenchen	C2	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Muenster var. 15+,34+	E3	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Newport	C2	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Niarenbe	V	ATCC	+

Organisms	Serotype	Source	Test Method Test Result
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Nima	M	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Nottingham	I	NCTC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Ohio	C1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Oranienburg	C1	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Orion var. 15+	E1	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Ouakam	D2	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Paratyphi A	A	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Paratyphi B	B	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Pheonix	X	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Pomona	M	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Poona	G1	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Quentin	D2	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Saintpaul	B	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Salford	I	IMVS	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Schwarzengrund	B	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Senftenberg	E4	natural isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Setubal	60	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Stockholm	E1	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Stuivenberg	E1	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Sundsvall	H	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Tallahassee	C2	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Tennessee	C1	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Thompson	C2	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Typhi	D1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Typhimurium	B	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Uccle	54	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Umbilo	M	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Urbana	N	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Utrecht	52	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Vellore	B	ATCC	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Vrindaban	W	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Wandsworth	Q	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Wassenaar	Z	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Waycross	S	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Weltevreden	E1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Weslaco	T	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Westhampton	E1	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Wichita	G2	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Worthington	G2	Government testing lab isolate	+
<i>Salmonella enterica</i> subsp. <i>salamae</i> ser. Hooggraven	Z	ATCC	+
<i>Salmonella enterica</i> subsp. <i>salamae</i> ser. Tranoroa	C1	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>arizonae</i>	61	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>arizonae</i>	62	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>arizonae</i>	63	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>arizonae</i>	65	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>arizonae</i>	Y	Reference lab isolate	+
<i>Salmonella enterica</i> subsp. <i>diazona</i>	X	ATCC	+
<i>Salmonella enterica</i> subsp. <i>houtenae</i> ser. Harmelen	51	ATCC	+
<i>Salmonella enterica</i> subsp. <i>indica</i> ser. Ferlac	H	ATCC	+
<i>Salmonella bongori</i>	66	ATCC	+

Table 4 (7)

Table 4. Organisms Included in Validation of Exclusivity of Assurance GDS *Salmonella*

Organisms	Source	Test Method Test Result
<i>Citrobacter amalonaticus</i>	ATCC	-
<i>Citrobacter farmerii</i>	Natural isolate	-
<i>Citrobacter freundii</i>	ATCC	-
<i>Citrobacter youngae</i>	Natural isolate	-
<i>Cronobacter sakazakii</i>	ATCC	-
<i>Enterobacter aerogenes</i>	ATCC	-
<i>Enterobacter asburiae</i>	ATCC	-
<i>Enterobacter cloacae</i>	ATCC	-
<i>Enterobacter gergoviae</i>	ATCC	-
<i>Escherichia coli</i>	ATCC	-
<i>Escherichia coli</i> O157:H7	ATCC	-
<i>Hafnia alvei</i>	ATCC	-
<i>Klebsiella oxytoca</i>	ATCC	-
<i>Klebsiella pneumoniae</i>	ATCC	-
<i>Morganella morganii</i>	ATCC	-
<i>Pantoea agglomerans</i>	ATCC	-
<i>Proteus mirabilis</i>	ATCC	-
<i>Proteus penneri</i>	ATCC	-
<i>Proteus vulgaris</i>	ATCC	-
<i>Providencia rettgeri</i>	ATCC	-
<i>Serratia liquefaciens</i>	ATCC	-
<i>Serratia marcescens</i>	ATCC	-
<i>Shigella boydii</i>	ATCC	-
<i>Shigella dysenteriae</i>	ATCC	-
<i>Shigella flexneri</i>	ATCC	-
<i>Shigella sonnei</i>	ATCC	-
<i>Yersinia enterocolitica</i>	Natural isolate	-
<i>Yersinia frederiksenii</i>	Reference lab isolate	-
<i>Yersinia pseudotuberculosis</i>	Natural isolate	-
<i>Yersinia ruckeri</i>	ATCC	-
		0/30

Table 5. Comparison Assurance GDS *Salmonella* to Reference: Assurance GDS Presumptive vs. Confirmed – POD (7)

Matrix	MPN ^{a,b} /25g	N ^c	Assurance GDS Presumptive			Assurance GDS Confirmed			dPOD _{CP} ^g	95% CI ^h
			x ^d	POD _{CP} ^e	95% CI	x	POD _{CC} ^f	95% CI		
Raw ground beef	0.00	5	0	0.00	0.00 – 0.43 ⁱ	0	0.00	0.00 – 0.43	0.00	(-0.43) – 0.43
	1.49	20	16	0.80	0.58 – 0.92	16	0.80	0.58 – 0.92	0.00	(-0.25) – 0.25
	12.20	5	5	1.00	0.57 – 1.00	5	1.00	0.57 – 1.00	0.00	(-0.43) – 0.43
Raw ground turkey	0.00	5	0	0.00	0.00 – 0.43	0	0.00	0.00 – 0.43	0.00	(-0.43) – 0.43
	0.33	20	7	0.35	0.18 – 0.57	7	0.35	0.18 – 0.57	0.00	(-0.28) – 0.28
	0.83	5	3	0.60	0.23 – 0.88	3	0.60	0.23 – 0.88	0.00	(-0.46) – 0.46
Stainless steel	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	11	0.55	0.34 – 0.74	11	0.55	0.34 – 0.74	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

^aMPN = Most Probable Number is based on the POD of reference method test portions across labs using the AOAC MPN calculator, with 95% confidence interval

^bN/A = Not applicable

^cN = Number of test portions

^dx = Number of positive test portions

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

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

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

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

ⁱ – = This indicates the range of lowest to highest values, with a dash (–) between the two values

Table 6. Comparison Assurance GDS *Salmonella* to Reference: Method Comparison Results – POD (7)

Matrix	MPN ^{a,b} /25g	N ^c	Assurance GDS Presumptive			USDA Reference			dPOD _C ^g	95% CI ^h
			x ^d	POD _{CP} ^e	95% CI	x	POD _R ^f	95% CI		
Raw ground beef	0.00	5	0	0.00	0.00 – 0.43 ⁱ	0	0.00	0.00 – 0.43	0.00	(-0.43) – 0.43
	1.49	20	16	0.80	0.58 – 0.92	16	0.80	0.58 – 0.92	0.00	(-0.25) – 0.25
	12.20	5	5	1.00	0.57 – 1.00	5	1.00	0.57 – 1.00	0.00	(-0.43) – 0.43
Raw ground turkey	0.00	5	0	0.00	0.00 – 0.43	0	0.00	0.00 – 0.43	0.00	(-0.43) – 0.43
	0.33	20	7	0.35	0.18 – 0.57	7	0.35	0.18 – 0.57	0.00	(-0.28) – 0.28
	0.83	5	3	0.60	0.23 – 0.88	3	0.60	0.23 – 0.88	0.00	(-0.46) – 0.46
Stainless steel	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	11	0.55	0.34 – 0.74	11	0.55	0.34 – 0.74	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

^aMPN = Most Probable Number is based on the POD of reference method test portions across labs using the AOAC MPN calculator, with 95% confidence interval

^bN/A = Not applicable

^cN = Number of test portions

^dx = Number of positive test portions

^ePOD_C = Confirmed candidate method positive outcomes divided by the total number of trials

^fPOD_R = Confirmed reference method positive outcomes divided by the total number of trials

^gdPOD_C = Difference between the candidate method and reference method POD values

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

ⁱ – = This indicates the range of lowest to highest values, with a dash (–) between the two values

Table 7. Comparison Assurance GDS *Salmonella* to Reference: Method Comparison Results – Chi Square (7)

Matrix	MPN ^{a,b} /25g	N ^c	GDS Method		USDA Reference	Chi Square ^d	Relative Sensitivity ^f
			Presumptive Pos.	Confirmed Pos.	Positive		
Raw ground beef	0.00	5	0	0	0	– ^e	–
	1.49	20	16	16	16	–	–
	12.20	5	5	5	5	–	–
Raw ground turkey	0.00	5	0	0	0	–	–
	0.33	20	7	7	7	–	–
	0.83	5	3	3	3	–	–
Stainless steel	N/A	5	0	0	0	–	–
	N/A	20	11	11	11	–	–
	N/A	5	5	5	5	–	–

^aMPN = Most Probable Number is based on the POD of reference method test portions across labs using the AOAC MPN calculator, with 95% confidence interval

^bN/A = Not applicable

^cN = Number of test portions

^dChi Square = McNemar's: $\chi^2 = (|a-b|)^2/(a+b)$, where a = number of samples positive by the test method and negative by reference method and b = number of samples negative by the test method and positive by reference method

^eWhere the methods give equivalent results, the statistic is not applicable, and is noted as a dash (–)

^fRelative sensitivity = a/c, where a = number of samples confirmed positive by the test method and c = number of samples positive by the reference method. Not calculated when the number of test positive results is higher than the number of reference positive results. Also not calculated when the denominator is zero

DISCUSSION MODIFICATION APPROVED SEPTEMBER 2013 (8)

Results of these studies validate that Assurance GDS *Salmonella* is robust, inclusive and specific for *Salmonella* species. In the internal method comparison study, Assurance GDS and the reference culture methods are statistically not different for the detection of *Salmonella* in raw beef trim, raw ground beef, RTE poultry meat, raw leaf lettuce, raw spinach, raw mixed greens, raw almonds, raw strawberries, stainless steel and rubber. The external method comparison study yielded similar results for raw beef trim, raw leaf lettuce and stainless steel. In this study, all 105 *Salmonella* tested were detected in mEHEC broth. These results demonstrate that the mEHEC broth for 8 – 24 hours at 42°C is an effective enrichment method for use with the Assurance GDS *Salmonella* for the detection of *Salmonella* in selected foods and environmental surfaces.

Table 1. Organisms Included in Validation of Inclusivity of Assurance GDS *Salmonella* (8)

	Organism	Serotype	Source	Assurance GDS <i>Salmonella</i>
1	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Abaetetuba	F	ATCC	+
2	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Abony	B	ATCC	+
3	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Adelaide	O	ATCC	+
4	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Agona	B	ATCC	+
5	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Alabama	D1	CDC isolate	+
6	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Amsterdam var. 15+	E2	NZRCC	+
7	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Anatum	E1	ATCC	+
8	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Artis	56	commercial establishment isolate	+
9	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Basel	58	ATCC	+
10	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Bere	X	CDC isolate	+
11	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Betioky	59	commercial establishment isolate	+
12	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Bockenheimer	53	commercial establishment isolate	+
13	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Braenderup	C1	CDC isolate	+
14	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Cerro	K	CDC isolate	+
15	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Chandans	F	commercial establishment isolate	+
16	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Choleraesuis	C1	ATCC	+
17	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Crossness	67	commercial establishment isolate	+
18	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Cubana	G2	commercial establishment isolate	+
19	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Derby	B	USDA isolate	+
20	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Dublin	D1	commercial establishment isolate	+
21	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Enteritidis	D1	ATCC	+
22	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Gallinarum	D1	commercial establishment isolate	+
23	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Give var. 15+	E2	CDC isolate	+
24	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Godesberg	N	CDC isolate	+
25	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Goldcoast	C2	NCTC	+
26	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Grumpensis	G2	commercial establishment isolate	+
27	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Hadar	C2	ATCC	+
28	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Havana	G2	commercial establishment isolate	+
29	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Heidelberg	B	ATCC	+
30	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Hofit	Q	commercial establishment isolate	+
31	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Houten	U	ATCC	+
32	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Ibadan	G1	CDC isolate	+
33	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Indiana	B	NCTC	+
34	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Infantis	C1	CDC isolate	+
35	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Inverness	P	ATCC	+
36	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Javiana	D1	FDA isolate	+
37	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Johannesburg	R	commercial establishment isolate	+
38	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Lexington var. 15+	E2	commercial establishment isolate	+
39	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Lexington var. 15+,34	E3	ATCC	+
40	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Locarno	57	commercial establishment isolate	+
41	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. London	E1	commercial establishment isolate	+
42	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Matadi	J	CDC isolate	+
43	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Mbandaka	C1	commercial establishment isolate	+
44	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Memphis	K	commercial establishment isolate	+
45	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Miami	D1	CDC isolate	+
46	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Minnesota	L	ATCC	+
47	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Mississippi	G2	commercial establishment isolate	+
48	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Montevideo	C1	ATCC	+
49	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Muenchen	C2	FDA isolate	+
50	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Muenster var. 15+,34	E3	CDC isolate	+
51	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. New port	C2	ATCC	+
52	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Niarenbe	V	ATCC	+

				Assurance GDS Salmonella
Organism	Serotype	Source		
53 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Nima	M	commercial establishment isolate		+
54 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Nottingham	I	NCTC		+
55 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Ohio	C1	USDA isolate		+
56 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Oranienburg	C1	ATCC		+
57 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Orion var. 15+	E1	commercial establishment isolate		+
58 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Ouakam	D2	commercial establishment isolate		+
59 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Paratyphi A	A	ATCC		+
60 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Paratyphi B	B	ATCC		+
61 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Phoenix	X	ATCC		+
62 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Pomona	M	commercial establishment isolate		+
63 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Poona	G1	ATCC		+
64 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Quentin	D2	commercial establishment isolate		+
65 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Reading	B	CDC isolate		+
66 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Saintpaul	B	ATCC		+
67 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Salford	I	IMVS		+
68 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Schw arzengrund	B	commercial establishment isolate		+
69 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Senftenberg	E4	Natural food isolate, soy		+
70 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Setubal	60	commercial establishment isolate		+
71 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Stockholm	E1	commercial establishment isolate		+
72 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Stui venberg	E1	commercial establishment isolate		+
73 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Sundsvall	H	commercial establishment isolate		+
74 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Tallahassee	C2	ATCC		+
75 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Tennessee	C1	ATCC		+
76 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Thompson	C2	USDA isolate		+
77 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Typhi	D1	CDC isolate		+
78 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Typhimurium	B	ATCC		+
79 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Uccle	54	ATCC		+
80 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Umbilo	M	commercial establishment isolate		+
81 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Urbana	N	commercial establishment isolate		+
82 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Utrecht	52	ATCC		+
83 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Vellore	B	ATCC		+
84 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Vrindaban	W	CDC isolate		+
85 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Wandsw orth	Q	commercial establishment isolate		+
86 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Wassenaar	Z	commercial establishment isolate		+
87 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Waycross	S	commercial establishment isolate		+
88 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Weltevreden	E1	FDA isolate		+
89 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Weslaco	T	commercial establishment isolate		+
90 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Westhampton	E1	CDC isolate		+
91 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Wichita	G2	commercial establishment isolate		+
92 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Worthington	G2	USDA isolate		+
93 <i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Zanzibar	E1	commercial establishment isolate		+
94 <i>Salmonella enterica</i> subsp. <i>salamae</i> ser. Hooggraven	Z	ATCC		+
95 <i>Salmonella enterica</i> subsp. <i>salamae</i> ser. Tranoroa	55	commercial establishment isolate		+
96 <i>Salmonella enterica</i> subsp. <i>arizonae</i>	61	commercial establishment isolate		+
97 <i>Salmonella enterica</i> subsp. <i>arizonae</i>	62	commercial establishment isolate		+
98 <i>Salmonella enterica</i> subsp. <i>arizonae</i>	63	commercial establishment isolate		+
99 <i>Salmonella enterica</i> subsp. <i>arizonae</i>	65	commercial establishment isolate		+
100 <i>Salmonella enterica</i> subsp. <i>arizonae</i>	D1	ATCC		+
101 <i>Salmonella enterica</i> subsp. <i>arizonae</i>	Y	commercial establishment isolate		+
102 <i>Salmonella enterica</i> subsp. <i>diarizonae</i>	X	ATCC		+
103 <i>Salmonella enterica</i> subsp. <i>houtenae</i> ser. Harmelen	51	ATCC		+
104 <i>Salmonella enterica</i> subsp. <i>indica</i> ser. Ferlac	H	ATCC		+
105 <i>Salmonella bongori</i>	66	ATCC		+

^aCDC = Center for Disease Control; ATCC = American Type Culture Collection; NZRCC = New Zealand Reference Culture Collection; IMVS = Institute of Medical and Veterinary Science; NCTC = National Collection of Type Cultures; FDA = Food and Drug Administration; USDA = United States Department of Agriculture

Table 3. Comparison of Assurance GDS *Salmonella* to Reference: Assurance GDS Presumptive vs. Confirmed – POD (8)

Matrix	Concentration		N ^b	Assurance GDS Presumptive			Assurance GDS Confirmed			dPOD _{CP} ^f	95% CI ^g
	MPN ^a /25g	LCL, UCL		X ^c	POD _{CP} ^d	95% CI	x	POD _{CC} ^e	95% CI		
Raw ground beef	0.00		5	0	0.00	0.00, 0.43 ^h	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	1.18	0.70, 2.17	20	17	0.85	0.64, 0.95	17	0.85	0.64, 0.95	0.00	(-0.23), 0.23
	5.09	1.90, 13.6	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Raw beef trim	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	1.07	0.24, 4.66	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	(-0.28), 0.28
	5.09	1.90, 13.6	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
	0.00 ⁱ		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.52 ⁱ	0.26, 0.87	20	10	0.50	0.30, 0.70	10	0.50	0.30, 0.70	0.00	(-0.28), 0.28
	2.29 ⁱ	1.05, 5.02	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
RTE poultry meat	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	1.11	0.68, 1.81	20	13	0.65	0.43, 0.82	12	0.60	0.37, 0.78	0.05	(-0.23), 0.32
	9.57	3.99, 22.95	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Raw leaf Lettuce	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.86	0.51, 1.43	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	(-0.26), 0.26
	8.0	4.47, 13.86	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
	0.00 ⁱ		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.75 ⁱ	0.43, 1.25	20	6	0.30	0.15, 0.52	6	0.30	0.15, 0.52	0.00	(-0.27), 0.27
	0.92 ⁱ	0.46, 1.86	5	3	0.60	0.24, 0.88	3	0.60	0.24, 0.88	0.00	(-0.47), 0.47
Raw spinach	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.65	0.36, 1.11	20	11	0.55	0.34, 0.74	12	0.60	0.39, 0.78	-0.05	(-0.33), 0.24
	5.09	1.90, 13.6	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Raw mixed Greens	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.63	0.35, 1.03	20	7	0.35	0.18, 0.58	8	0.40	0.22, 0.61	-0.05	(-0.32), 0.23
	1.33	0.60, 2.96	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Raw strawberries	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.77	0.44, 1.38	20	7	0.35	0.18, 0.58	7	0.35	0.18, 0.58	0.00	(-0.28), 0.28
	1.33	0.60, 2.96	5	4	0.80	0.38, 0.96	4	0.80	0.38, 0.96	0.00	(-0.45), 0.45
Raw almonds	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.72	0.41, 1.24	20	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	(-0.28), 0.28
	14.3	5.46, 37.4	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Stainless steel	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	16	0.80	0.58, 0.92	-0.05	(-0.30), 0.20
	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 ⁱ		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	N/A ⁱ		20	14	0.70	0.48, 0.86	14	0.70	0.48, 0.86	0.00	(-0.27), 0.27
	N/A ⁱ		5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Rubber	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	11	0.55	0.34, 0.74	7	0.35	0.18, 0.57	0.20	(-0.10), 0.46
	N/A		5	4	0.80	0.37, 0.96	5	1.00	0.57, 1.00	-0.20	(-0.62), 0.26

MPN^a = Most Probable Number is based on the POD of reference method test portions using the “Least Cost Formulations” MPN calculator (5), with 95% confidence interval

N^b = Number of test portions

x^c = Number of positive test portions

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

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

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

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

–^h = This indicates the range of lowest to highest values, with a comma between the two values =ⁱ analysis by Independent Laboratory LCL = lower confidence limit; UCL = upper confidence limit; N/A = not analyzed

Table 4. Comparison of Assurance GDS *Salmonella* to Reference: Method Comparison Results – POD (8)

Matrix	Concentration		N ^b	Assurance GDS Presumptive			FDA/USDA Reference			dPOD _{CP} ^f	95% CI ^g
	MPN ^a /25g	LCL, UCL		X ^c	POD _{CP} ^d	95% CI	x	POD _R ^e	95% CI		
Raw ground beef	0.00		5	0	0.00	0.00, 0.43 ^h	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	1.18	0.70, 2.17	20	17	0.85	0.64, 0.95	16	0.80	0.58, 0.92	0.05	(-0.19), 0.29
	5.09	1.90, 13.6	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Raw beef trim	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	1.07	0.24, 4.66	20	12	0.60	0.39, 0.78	15	0.75	0.53, 0.89	-0.15	(-0.40), 0.13
	5.09	1.90, 13.6	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
	0.00 ⁱ		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.52 ⁱ	0.26, 0.87	20	10	0.50	0.30, 0.70	9	0.45	0.26, 0.66	0.05	(-0.24), 0.33
	2.29 ⁱ	1.05, 5.02	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
RTE poultry meat	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	1.11	0.68, 1.81	20	12	0.60	0.37, 0.78	12	0.60	0.37, 0.78	0.00	(-0.28), 0.28
	9.57	3.99, 22.95	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Raw leaf lettuce	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.86	0.51, 1.43	20	15	0.75	0.53, 0.89	15	0.75	0.53, 0.89	0.00	(-0.26), 0.26
	8.0	4.47, 13.86	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
	0.00 ⁱ		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.75 ⁱ	0.43, 1.25	20	6	0.30	0.15, 0.52	12	0.60	0.39, 0.78	-0.30	(-0.54), 0.01
	0.92 ⁱ	0.46, 1.86	5	3	0.60	0.15, 0.52	4	0.80	0.38, 1.0	-0.20	(-0.62), 0.31
Raw spinach	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.65	0.36, 1.11	20	11	0.55	0.34, 0.74	10	0.50	0.30, 0.70	0.05	(-0.24), 0.33
	5.09	1.90, 13.6	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Raw mixed Greens	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.63	0.35, 1.03	20	7	0.35	0.18, 0.58	8	0.40	0.22, 0.61	-0.05	(-0.32), 0.23
	1.33	0.60, 2.96	5	5	1.00	0.57, 1.00	4	0.80	0.36, 0.96	0.20	(-0.26), 0.62
Raw strawberries	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.77	0.44, 1.38	20	7	0.35	0.18, 0.58	11	0.55	0.34, 0.74	-0.20	(-0.46), 0.10
	1.33	0.60, 2.96	5	4	0.80	0.38, 0.96	4	0.80	0.38, 0.96	0.00	(-0.45), 0.45
Raw almonds	0.00		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	0.72	0.41, 1.24	20	9	0.45	0.26, 0.66	11	0.55	0.34, 0.74	-0.10	(-0.37), 0.19
	14.3	5.46, 37.4	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Stainless steel	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	13	0.65	0.43, 0.82	-0.10	(-0.18), 0.36
	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 ⁱ		5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	(-0.43), 0.43
	N/A ⁱ		20	14	0.70	0.48, 0.86	11	0.55	0.34, 0.74	0.15	(-0.14), 0.41
	N/A ⁱ		5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	(-0.43), 0.43
Rubber	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	11	0.55	0.34, 0.74	11	0.55	0.34, 0.74	0.00	(-0.28), 0.28
	N/A		5	4	0.80	0.37, 0.96	5	1.00	0.57, 1.00	-0.20	(-0.62), 0.26

MPN^a = Most Probable Number is based on the POD of reference method test portions using the "Least Cost Formulations" MPN calculator (5), with 95% confidence intervalN^b = Number of test portionsX^c = Number of positive test portionsPOD_{CP}^d = Confirmed candidate method positive outcomes divided by the total number of trialsPOD_R^e = Confirmed reference method positive outcomes divided by the total number of trialsdPOD_{CP}^f = Difference between the candidate method and reference method POD values95% CI^g = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level—^h = This indicates the range of lowest to highest values, with a comma between the two values=ⁱ analysis by Independent Laboratory

LCL = lower confidence limit; UCL = upper confidence limit; N/A = not analyzed

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