



<b>AUTHORS</b> ORIGINAL VALIDATION: NISSUI PHARMACEUTICAL CO., LTD. MODIFICATION JULY 2015: Shingo Mizuochi and Maria Nelson	<b>SUBMITTING COMPANY</b> Nissui Pharmaceutical Co., Ltd. 3-23-9, Ueno Taito-ku, Tokyo Japan 110-8736	<b>CURRENT COMPANY ADDRESS</b> Shimadzu Diagnostics Corporation, formerly NISSUI Pharmaceutical Co., Ltd. 3-24-6, Ueno Taito-ku, Tokyo Japan 110-8736
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<b>METHOD NAME</b> CompactDry EC	<b>CATALOG NUMBERS</b> 06742, 06743
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<b>INDEPENDENT LABORATORY</b>	<b>July 2015 Matrix Extension</b>
Original Validation	Campden BRI
Q Laboratories, Inc.,	Station Road
1400 Harrison Ave.,	Chipping Campden
Cincinnati, OH 45214 USA	Gloucestershire, GL55 6LK UK

<b>APPLICABILITY OF METHOD</b> Target organism – <i>E. coli</i> and coliforms	<b>REFERENCE METHODS</b>
Matrixes – Original Validation AOAC OMA 966.24: raw ground pork, raw pork, raw lamb, raw veal, and raw ground beef MODIFICATION JULY 2015: ISO 16649-2:2001 cooked chicken, pre-washed bagged shredded iceberg lettuce, frozen cod fillets, instant non-fat dry milk ISO 4832:2006: pasteurized 2% milk	AOAC International, AOAC Official Method 966.24 Coliform Group and <i>Escherichia coli</i> in Tree Nut Meats. (2)  ISO 16649-2:2001, Microbiology of food and animal feeding stuffs - Horizontal method for the enumeration of Beta-glucuronidase-positive <i>Escherichia coli</i> – colony count technique at 44°C using 5-bromo-4-chloro-3-indolyl Beta-D-glucuronide (4)  ISO 4832:2006, Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of coliforms -- Colony-count technique (5)
Performance claims – The CompactDry EC kit performs at the same level as the reference method.	

<b>ORIGINAL CERTIFICATION DATE</b> November 18, 2004	<b>CERTIFICATION RENEWAL RECORD</b> Renewed annually through December 2024.
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<b>METHOD MODIFICATION RECORD</b>	<b>SUMMARY OF MODIFICATIONS</b>
1. July 2015 Level 2	1. Matrix Extension.
2. February 2019 Level 2	2. Shelf life increase to 24 months and corporate address change.
3. December 2023 Level 1	3. Corporate name change to Shimadzu Diagnostics Corporation, updated package inserts.

<b>Under this AOAC Performance Tested Methods<sup>SM</sup> License Number, 110402 this method is distributed by:</b>	<b>Under this AOAC Performance Tested Methods<sup>SM</sup> License Number, 110402 this method is distributed as:</b>
1. Hardy Diagnostics	1. CompactDry EC
2. R-Biopharm AG	2. CompactDry EC

#### PRINCIPLE OF THE METHOD (1)

The test method is a plate count unit facilitating the rapid determination of *E. coli* and coliform bacterial loads of raw meats. The plates are pre-sterilized, and contain nutrients supplemented with selective substances, two chromogenic enzyme substrates and a cold water-soluble gelling agent. The medium should be re-hydrated with 1 ml of (diluted) sample material with a diffuse automatically and can be incubated. Full medium size in the plate is 20 cm<sup>2</sup>. Gelling agent is allowed to solidify, plates are incubated, and then *E. coli* and coliforms are counted.

#### DISCUSSION OF THE ORIGINAL VALIDATION STUDY (1)

This method validation study demonstrated that the CompactDry EC methodology and the reference conventional culture method produced comparable *E. coli* and coliform bacteria count results. Therefore, CompactDry EC plates could be a convenient alternative for routine microbiological food testing. Observations during this study have shown that the CompactDry EC plates are easy to use, with a minimal amount of analyst time needed for a single quantitative test. The time from preparation of media to setting up was 250 min per 20 samples for AOAC methodology. The time for the same procedures was 150 min per 20 samples for CompactDry EC methodology. The equipment requirement and overall cost of the assay is less than that of AOAC methodology. There is no secondary transfer into multiple tubes or additional biochemical analyses. The amount of time required to read the CompactDry EC is a bit longer than reading successive tubes and biochemicals from the AOAC methodology, but the plates are read anywhere from one to nine days prior to when the result would be completed from the AOAC methodology, allowing for faster reaction time and less down time for the producer or originator of the sample. There are economical and safety advantages to having a more rapid response time. In conclusion, the CompactDry EC, using the newly developed dry sheet medium technology, is a convenient alternative for routine microbiological food testing.

**Table 1. CompactDry EC Inclusivity Study (*E. coli* and other coliforms) (1)**

Strain	No. of tested isolates	Color reaction	No. of positive isolates
<i>Citrobacter amalonaticus</i>	1	R/Pi	1
<i>Citrobacter freundii</i>	4	R/Pi	4
<i>Citrobacter koseri</i>	2	R/Pi	2
<i>Enterobacter aerogenes</i>	4	Pi	4
<i>Enterobacter amnigenus</i>	4	R/Pi	4
<i>Enterobacter asburiae</i>	1	R/Pi	1
<i>Enterobacter cancerogenus</i>	1	R	1
<b><i>Enterobacter cloacae</i></b>	4	Pi	4
<i>Enterobacter gergoviae</i>	1	R/Pi	1
<i>Enterobacter intermedium</i>	2	R/Pi	2
<i>Enterobacter sakazakii</i>	1	R/Pi	1
<i>Escherichia blattae</i>	1	W	0
<i>Escherichia coli</i>	11	B/BPu	11
<i>Escherichia coli</i> O157:H7	2	R/Pi	0
<i>Escherichia coli</i> O111	2	B	2
<i>Escherichia fergusonii</i>	2	R/Pi	2
<i>Escherichia hermanii</i>	1	Pi	1
<i>Klebsiella oxytoca</i>	4	R/Pi	4
<i>Klebsiella ozaenae</i>	2	R/Pi	2
<i>Klebsiella pneumoniae</i>	2	R/Pi	2
<i>Klebsiella terrigena</i>	1	R/Pi	1
	53		50

B:Blue, Pi:Pink, Pu:Purple, R:Red, W:White.

**Table 2. CompactDry EC Exclusivity Study (Non-coliform) (1)**

Strain	No. of tested isolates	Color reaction	No. of negative isolates
<i>Achromobacter xylosoxidans</i> subsp. <i>denitrificans</i>	1	sW	1
<i>Achromobacter xylosoxidans</i> subsp. <i>xylosoxidans</i>	1	sW	1
<i>Acinetobacter baumannii</i>	1	W	1
<i>Acinetobacter calcoaceticus</i>	2	W /-	2
<i>Aeromonas hydrophila</i>	2	LRPi/-	1
<i>Alcaligenes faecalis</i>	1	sW	1
<i>Bacillus cereus</i>	2	-	2
<i>Edwardsiella tarda</i>	3	W	3
<i>Lactobacillus lactis</i>	1	-	1
<i>Micrococcus luteus</i>	1	-	1
<i>Micrococcus lylae</i>	1	-	1
<i>Moraxella nonliquefaciens</i>	1	-	1
<i>Moraxella ovis</i>	1	-	1
<i>Proteus mirabilis</i>	1	br	1
<i>Proteus vulgaris</i>	2	br	2
<i>Providencia alcalifaciens</i>	2	br	2
<i>Pseudomonas aeruginosa</i>	1	W	1
<i>Pseudomonas alcaligenes</i>	1	-	1
<i>Pseudomonas diminuta</i>	2	-	2
<i>Pseudomonas mendocina</i>	1	W	1
<i>Pseudomonas pseudoalcaligenes</i>	1	sW	1
<i>Pseudomonas putida</i>	1	-	1
<i>Pseudomonas stutzeri</i>	1	W	1
<i>Pseudomonas vesicularis</i>	1	-	1
<i>Salmonella</i> Choleraesuis	2	W	2
<i>Salmonella</i> Typhimurium	1	W	1
<i>Shigella flexineri</i>	2	W	2
<i>Shigella boydii</i>	1	B	0
<i>Staphylococcus aureus</i>	3	-	3
<i>Streptococcus agalactiae</i>	1	-	1
<i>Streptococcus bovis</i>	1	-	1
<i>Streptococcus canis</i>	1	-	1
<i>Streptococcus equines</i>	1	-	1
<i>Streptococcus pneumoniae</i>	1	-	1
<i>Streptococcus pyogenes</i>	1	-	1
<i>Streptococcus salivarius</i>	1	-	1
<i>Streptococcus sanguis</i>	1	-	1
<i>Streptococcus uberis</i>	1	-	1
<i>Serratia marcescens</i>	1	Rpi	0
	51		48

B: Blue, br: Brown, L: Light, Pi: Pink, Pu: Purple, R: Red, W: White, s: small, -: non growth.

Table3. AOAC Method Comparison (Raw ground pork) (1)

E. coli/ Coliform LEVEL		CompactDry EC				AOAC 966.24			
		E. coli		Coliform		E. coli		Coliform	
		cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g
10-100 cfu/g	1	10	1.00	10	1.00	23	1.36	23	1.36
	2	10	1.00	10	1.00	9.1	0.96	9.1	0.96
	3	5	0.70	15	1.18	9.1	0.96	9.1	0.96
	4	10	1.00	10	1.00	43	1.63	43	1.63
	5	10	1.00	10	1.00	23	1.36	39	1.59
	Mean	9	0.94	11	1.04	21.44	1.26	24.64	1.30
	Sr	2.24	0.13	2.24	0.08	13.91	0.29	16.04	0.33
RSDr%	24.85	14.32	20.33	7.61	64.89	23.27	65.09	25.27	
100-1000 cfu/g	1	510	2.71	580	2.76	640	2.81	640	2.81
	2	460	2.66	500	2.70	390	2.59	530	2.72
	3	350	2.54	420	2.62	460	2.66	460	2.66
	4	350	2.54	390	2.59	360	2.56	360	2.56
	5	370	2.57	460	2.66	280	2.45	350	2.54
	Mean	408	2.61	470	2.67	426	2.61	468	2.66
	Sr	72.94	0.08	74.16	0.07	135.94	0.13	121.53	0.11
RSDr%	17.88	2.89	15.78	2.52	31.91	5.10	25.97	4.19	
1000-10000 cfu/g	1	7600	3.88	8000	3.90	4600	3.66	4600	3.66
	2	6100	3.79	6900	3.84	1100	3.04	4600	3.66
	3	1300	3.11	1200	3.08	930	2.97	2400	3.38
	4	8900	3.95	9600	3.98	2400	3.38	4600	3.66
	5	5900	3.77	6900	3.84	2400	3.38	4600	3.66
	Mean	5960	3.70	6520	3.73	2286	3.29	4160	3.61
	Sr	2875.41	0.34	3172.85	0.37	1468.50	0.28	983.87	0.13
RSDr%	48.25	9.07	48.66	9.86	64.24	8.61	23.65	3.50	
Uninoculated	1	<10	<1	NT	NT	<10	<1	NT	NT
	2	<10	<1	NT	NT	<10	<1	NT	NT
	3	<10	<1	NT	NT	<10	<1	NT	NT
	4	<10	<1	NT	NT	<10	<1	NT	NT
	5	<10	<1	NT	NT	<10	<1	NT	NT
	Mean	<10	<1	-	-	<10	<1	-	-
	Sr	-	-	-	-	-	-	-	-
RSDr%	-	-	-	-	-	-	-	-	

NT: Not tested. Coliform bacterial counts were tested using naturally contaminated raw ground pork.

Table 6. AOAC Method Comparison(Raw pork) (1)

E.coli/Coliform LEVEL		CompactDry EC				AOAC 966.24			
		E. coli		Coliform		E.coli		Coliform	
		cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g
10-100 cfu/g	1	10	1.00	100	2.00	3.6	0.56	43	1.63
	2	5	0.70	77	1.89	9.1	0.96	75	1.88
	3	15	1.18	90	1.95	15	1.18	39	1.59
	4	10	1.00	45	1.65	3.6	0.56	93	1.97
	5	10	1.00	92	1.96	3	0.48	46	1.66
	Mean	10	0.98	80.8	1.89	6.86	0.74	59.2	1.75
	Sr	3.54	0.17	21.65	0.14	5.18	0.31	23.65	0.17
RSDr%	35.36	17.65	26.79	7.37	75.55	41.08	39.94	9.49	
100-1000 cfu/g	1	45	1.65	730	2.86	43	1.63	460	2.66
	2	25	1.40	920	2.96	23	1.36	460	2.66
	3	75	1.88	955	2.98	43	1.63	750	2.88
	4	20	1.30	770	2.89	43	1.63	750	2.88
	5	55	1.74	655	2.82	43	1.63	650	2.81
	Mean	44	1.59	806	2.90	39	1.58	614	2.78
	Sr	22.47	0.24	127.54	0.07	8.94	0.12	146.39	0.11
RSDr%	51.07	14.99	15.82	2.37	22.93	7.70	23.84	3.89	
1000-10000 cfu/g	1	3030	3.48	4950	3.69	4300	3.63	4300	3.63
	2	3340	3.52	6600	3.82	2400	3.38	2400	3.38
	3	3900	3.59	10000	4.00	11000	4.04	11000	4.04
	4	2900	3.46	14000	4.15	11000	4.04	4600	3.66
	5	2680	3.43	3100	3.49	4600	3.66	4300	3.63
	Mean	3170	3.50	7730	3.83	6660	3.75	5320	3.67
	Sr	472.86	0.06	4327.47	0.26	4050.68	0.29	3293.48	0.24
RSDr%	14.92	1.79	55.98	6.68	60.82	7.63	61.91	6.46	
Uninoculated	1	<10	<1	NT	NT	<10	<1	NT	NT
	2	<10	<1	NT	NT	<10	<1	NT	NT
	3	<10	<1	NT	NT	<10	<1	NT	NT
	4	<10	<1	NT	NT	<10	<1	NT	NT
	5	<10	<1	NT	NT	<10	<1	NT	NT
	Mean	<10	<1	-	-	<10	<1	-	-
	Sr	-	-	-	-	-	-	-	-
RSDr%	-	-	-	-	-	-	-	-	

NT: Not tested. Coliform bacterial counts were tested using naturally contaminated raw pork.

Table 9. AOAC Method Comparison (Raw lamb) (1)									
E.coli/Coliform LEVEL		CompactDryEC				AOAC 966.24			
		E. coli		Coliform		E. coli		Coliform	
		cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g	cfu/g	log <sub>10</sub> cfu/g
10-100 cfu/g	1	5	0.70	5	0.70	7.2	0.86	43	1.63
	2	10	1.00	15	1.18	9.1	0.96	23	1.36
	3	10	1.00	15	1.18	9.1	0.96	9.1	0.96
	4	10	1.00	10	1.00	9.1	0.96	9.1	0.96
	5	10	1.00	20	1.30	9.1	0.96	23	1.36
	Mean	9	0.94	13	1.07	8.72	0.94	21.44	1.26
	Sr	2.24	0.13	5.70	0.23	0.85	0.05	13.91	0.29
	RSDr%	24.85	14.32	43.85	21.83	9.74	4.85	64.89	23.27
100-1000 cfu/g	1	90	1.95	360	2.56	95	1.98	430	2.63
	2	120	2.08	255	2.41	120	2.08	240	2.38
	3	100	2.00	195	2.29	120	2.08	240	2.38
	4	80	1.90	130	2.11	95	1.98	430	2.63
	5	145	2.16	255	2.41	160	2.20	150	2.18
	Mean	107	2.02	239	2.35	118	2.06	298	2.44
	Sr	25.88	0.10	85.10	0.16	26.60	0.09	125.98	0.19
	RSDr%	24.19	5.07	35.61	6.98	22.54	4.53	42.27	7.98
1000-10000 cfu/g	1	8500	3.93	8500	3.93	9300	3.97	9300	3.97
	2	3100	3.49	8450	3.93	9300	3.97	9300	3.97
	3	2890	3.46	5040	3.70	2400	3.38	4300	3.63
	4	2660	3.42	5500	3.74	4600	3.66	4600	3.66
	5	3150	3.50	4950	3.69	4600	3.66	4600	3.66
	Mean	4060	3.56	6488	3.80	6040	3.73	6420	3.78
	Sr	2489.59	0.21	1825.92	0.12	3108.54	0.25	2631.92	0.17
	RSDr%	61.32	5.84	28.14	3.14	51.47	6.64	41.00	4.58
Uninoculated	1	<10	<1	NT	NT	<10	<1	NT	NT
	2	<10	<1	NT	NT	<10	<1	NT	NT
	3	<10	<1	NT	NT	<10	<1	NT	NT
	4	<10	<1	NT	NT	<10	<1	NT	NT
	5	<10	<1	NT	NT	<10	<1	NT	NT
	Mean	<10	<1	-	-	<10	<1	-	-
	Sr	-	-	-	-	-	-	-	-
	RSDr%	-	-	-	-	-	-	-	-

NT: Not tested. Coliform bacterial counts were tested using naturally contaminated raw lamb.



**Table 39 (Number shown is mean log of actual counts of coliform samples out of a total of 5 replicates for each category, sdev and p values from paired t-test) (1)**

	Nissui	AOAC	sdev	p
High	3.72	3.61	0.103	0.128
Int.	2.78	2.66	0.041	0.002
Low	1.92	1.88	0.133	0.662

**Table 40 (Number shown is mean log of actual counts of *E. coli* samples out of a total of 5 replicates for each category, sdev and p values from paired t-test) (1)**

	Nissui	AOAC	sdev	p
<b>High</b>	<b>3.65</b>	<b>3.55</b>	<b>0.110</b>	<b>0.120</b>
Int.	2.66	2.66	0.147	0.039
Low	1.87	1.75	0.125	0.138

**DISCUSSION OF THE MATRIX EXTENSION STUDY APPROVED JULY 2015 (3)**

For this matrix extension study, the CompactDry EC was evaluated against ISO 16649-2 and ISO 4832 for enumeration of *E. coli* and total coliforms, respectively. In the single laboratory matrix studies, CIs were outside the acceptance criterion, (-0.5, 0.5), and thus statistical differences were indicated for *E. coli* enumeration in one level of cooked chicken and two levels of lettuce (Table 2). For the cooked chicken and the low level of lettuce, the differences were seen in the lowest levels where only a few colonies were recovered in each of these matrixes at each of these levels, so the significance is not considered to be relevant. For the high level of lettuce, the mean difference between the methods was less than 0.5, even though the CI was slightly out of the acceptance criterion. For all other *E. coli* results, mean differences between methods were <0.5 and CIs were within (-0.5, 0.5). The sr and RSDr were sometimes smaller for the CompactDry method and sometimes smaller for ISO 16649-2, but in general were similar. The r2 values were ≥0.94 for all matrixes.

For total coliform enumeration, CIs were outside the acceptance criterion, (-0.5, 0.5), and thus statistical differences were indicated in two levels of lettuce, one level of frozen fish and two levels of milk powder (Table 3). For the lowest contamination levels of frozen fish and milk powder, only a few colonies were recovered in each of these matrixes at each of these levels, so the significance is not considered to be relevant. For lettuce, the ISO 4832 recorded higher results than the CompactDry EC in the lower contamination level, and the CompactDry EC recorded higher results in the higher contamination level. For the other three levels, mean differences were small (<0.5) and CIs were within (-0.5, 0.5). For the low level of milk powder, the mean difference between methods was <0.5, with the CI outside of the acceptance criterion. For the milk powder and lettuce contamination levels with significant differences, a 10-fold range in counts between the five replicates for each method was seen, which may have had an effect on the CIs. For all other total coliform results, mean differences between the CompactDry and ISO methods were small (<0.5 log<sub>10</sub>) with CIs well within the acceptance criterion (-0.5, 0.5). The sr and RSDr were sometimes smaller for the CompactDry method and sometimes smaller for ISO 4832, but in general were similar. The r2 values were ≥0.92 for all matrixes.

In the multi-laboratory study on pasteurized milk, no statistical differences were found in *E. coli* and total coliform enumeration between the CompactDry EC and the ISO methods. Due to shipping and scheduling issues, three laboratories initiated testing one day later than the other 11 laboratories. Because the organizing laboratory discovered a potential for die-off during sample storage, data from the laboratories (Laboratories 12–14) starting one day late were not included in the statistical analysis. Across 11 data sets, the mean differences between the CompactDry EC and ISO 4832 were less than 0.10 log<sub>10</sub> at each contamination level, and the CIs were less than (-0.2, 0.2), well within the (-0.5, 0.5) acceptance criterion. The sr, RSDr, sR, and RSDR were slightly smaller for the CompactDry EC compared to ISO 4832. The r2 value was 0.99. In addition to excluding data from the 3 laboratories initiating testing one day later, 2 laboratories did not submit data for *E. coli* enumeration. Thus, data from 9 laboratories were analyzed to compare the CompactDry EC to ISO 16649-2. Across the 9 data sets, the mean differences between methods were less than 0.20 log<sub>10</sub> at each contamination level and the CIs were less than (-0.30, 0.30), meeting the acceptance criteria. The sr, RSDr, sR, and RSDR were comparable or smaller for the CompactDry EC compared to ISO 16649-2. The r2 value was 0.97. The results from both the single laboratory and multi-laboratory studies indicate that the CompactDry EC gives consistent results, comparable to the reference method, within and across laboratories.



Table 2. Single laboratory matrix study: CompactDry EC vs ISO 16649-2 – *E. coli* (3)

Matrix	Cont. level	CompactDry EC			ISO 16649-2			Mean diff. <sup>d</sup>	95% CI <sup>e</sup>		r <sup>2h</sup>
		Mean <sup>a</sup>	s <sub>r</sub> <sup>b</sup>	RSD <sub>r</sub> <sup>c</sup>	Mean	s <sub>r</sub>	RSD <sub>r</sub>		LCL <sup>f</sup>	UCL <sup>g</sup>	
Cooked chicken	1	0.000	0.000	NA <sup>i</sup>	0.000	0.000	NA	0.000	0.000	0.000	0.95
	2	0.577	0.617	107	0.341	0.554	162	0.236	-0.336	0.809	
	3	2.470	0.126	5.10	2.312	0.184	7.96	0.158	-0.015	0.300	
	4	3.511	0.111	3.16	3.340	0.283	8.47	0.172	-0.025	0.318	
	5	4.473	0.147	3.29	4.310	0.207	4.80	0.163	0.020	0.305	
Lettuce	1	0.000	0.000	NA	0.000	0.000	NA	0.000	0.000	0.000	0.94
	2	0.754	0.663	87.9	0.521	0.549	105	0.233	-0.374	0.841	
	3	2.676	0.303	11.3	2.558	0.167	6.53	0.118	-0.067	0.304	
	4	3.737	0.404	10.8	3.559	0.300	8.43	0.178	0.034	0.322	
	5	4.635	0.429	9.26	4.273	0.275	6.44	0.362	-0.124	0.600	
Frozen fish	1	0.000	0.000	NA	0.000	0.000	NA	0.000	0.000	0.000	0.99
	2	1.833	0.260	14.2	1.821	0.332	18.2	0.012	-0.271	0.294	
	3	2.832	0.135	4.77	2.827	0.101	3.57	0.005	-0.085	0.095	
	4	3.796	0.215	5.66	3.859	0.143	3.71	-0.063	-0.133	0.006	
	5	4.845	0.189	3.90	4.749	0.222	4.67	0.095	0.005	0.185	
Milk powder	1	0.000	0.000	NA	0.000	0.000	NA	0.000	0.000	0.000	0.99
	2	2.837	0.307	10.8	2.838	0.218	7.68	-0.001	-0.146	0.144	
	3	3.520	0.139	3.95	3.551	0.182	5.13	-0.030	-0.111	0.050	
	4	4.201	0.028	0.67	4.564	0.217	4.75	-0.363	-0.519	-0.207	
	5	5.561	0.267	4.80	5.521	0.252	4.56	0.040	-0.069	0.149	

<sup>a</sup>Mean of five replicate portions, plated in duplicate, after logarithmic transformation:  $\text{Log}_{10}[\text{CFU/g} + (0.1)\text{f}]$ .

<sup>b</sup>Repeatability standard deviation.

<sup>c</sup>Relative standard deviation for repeatability.

<sup>d</sup>Mean difference between the candidate and reference methods.

<sup>e</sup>Confidence interval.

<sup>f</sup>95% Lower confidence limit for difference of means.

<sup>g</sup>95% Upper confidence limit for difference of means.

<sup>h</sup>Square of correlation coefficient.

<sup>i</sup>Not applicable.

Table 3. Single laboratory matrix study: CompactDry EC vs ISO 4832 – Coliforms (3)

Matrix	Cont. level	CompactDry EC			ISO 4832			Mean diff. <sup>d</sup>	95% CI <sup>e</sup>		r <sup>2h</sup>
		Mean <sup>a</sup>	s <sub>r</sub> <sup>b</sup>	RSD <sub>r</sub> <sup>c</sup>	Mean	s <sub>r</sub>	RSD <sub>r</sub>		LCL <sup>f</sup>	UCL <sup>g</sup>	
Cooked chicken	1	0.000	0.000	NA <sup>i</sup>	0.000	0.000	NA	0.000	0.000	0.000	0.98
	2	0.577	0.617	107	0.774	0.552	71.3	-0.197	-0.525	0.131	
	3	2.473	0.123	4.97	2.448	0.134	5.47	0.026	-0.017	0.068	
	4	3.514	0.112	3.19	3.428	0.248	7.23	0.085	-0.038	0.209	
	5	4.473	0.147	3.29	4.353	0.133	3.06	0.120	0.013	0.253	
Lettuce	1	0.000	0.000	NA	0.000	0.000	NA	0.000	0.000	0.000	0.94
	2	1.700	0.829	48.8	2.216	0.531	24.0	-0.756	-1.057	0.025	
	3	3.813	0.197	5.17	4.026	0.153	3.80	-0.212	-0.287	-0.138	
	4	4.635	0.429	9.26	4.241	0.202	4.76	0.394	0.058	0.730	
	5	5.053	0.111	2.20	4.955	0.126	2.54	0.098	-0.019	0.177	
Frozen fish	1	0.945	0.516	54.6	1.748	0.296	16.9	-0.802	-1.078	-0.527	0.96
	2	2.042	0.233	11.4	2.169	0.180	8.3	-0.127	-0.262	0.008	
	3	3.030	0.130	4.29	3.098	0.116	3.74	-0.068	-0.176	0.039	
	4	4.010	0.193	4.81	4.090	0.135	3.30	-0.080	-0.150	-0.010	
	5	5.091	0.146	2.87	5.097	0.179	3.51	-0.006	-0.056	0.045	
Milk powder	1	0.653	0.568	87.0	0.000	0.000	NA	0.653	-0.246	1.060	0.92
	2	1.797	1.058	58.9	2.041	0.735	36.0	-0.244	-0.690	0.202	
	3	2.661	0.119	4.47	2.719	0.236	8.68	-0.058	-0.190	0.074	
	4	3.960	0.072	1.82	3.972	0.079	1.99	-0.012	-0.057	0.033	
	5	4.648	0.225	4.84	4.951	0.177	3.58	-0.303	-0.389	-0.218	

<sup>a</sup>Mean of five replicate portions, plated in duplicate, after logarithmic transformation:  $\text{Log}_{10}[\text{CFU/g} + (0.1)]$ .

<sup>b</sup>Repeatability standard deviation.

<sup>c</sup>Relative standard deviation for repeatability.

<sup>d</sup>Mean difference between the candidate and reference methods.

<sup>e</sup>Confidence interval.

<sup>f</sup>95% Lower confidence limit for difference of means.

<sup>g</sup>95% Upper confidence limit for difference of means.

<sup>h</sup>Square of correlation coefficient.

<sup>i</sup>Not applicable.

**Table 6. Multi-laboratory study: Method comparison of pasteurized milk results for each contamination level across 9 data sets<sup>a</sup> – *E. coli* (3)**

Contam. level	CompactDry EC vs ISO 16649-2					
	Mean <sup>b</sup> CD EC	Mean ISO 16649-2	Mean diff. <sup>c</sup>	LCL <sup>d</sup>	UCL <sup>e</sup>	r <sup>2f</sup>
Uncont.	0.000	0.000	0.000	0.000	0.000	
Low	2.437	2.436	0.001	-0.059	0.053	0.97
Mid	3.458	3.484	-0.026	-0.050	0.109	
High	4.553	4.382	0.171	-0.261	-0.055	

<sup>a</sup>Data from Laboratories 12, 13 and 14 excluded, due to initiation of samples one day later than intended start date. Laboratories 5 and 8 did not submit data for *E. coli*.

<sup>b</sup>Overall mean across nine laboratories for each method, after logarithmic transformation:  $\text{Log}_{10}[\text{CFU/g} + (0.1)\text{f}]$ .

<sup>c</sup>Mean difference between methods.

<sup>d</sup>95% Lower confidence limit for difference of means.

<sup>e</sup>95% Upper confidence limit for difference of means.

<sup>f</sup>Square of correlation coefficient.

**Table 9. Multi-laboratory study: Method comparison of pasteurized milk results for each contamination level across 11 data sets<sup>a</sup> – Coliforms (3)**

Contam. level	CompactDry EC vs ISO 4832					
	Mean <sup>b</sup> CD EC	Mean ISO 4832	Mean diff. <sup>c</sup>	LCL <sup>d</sup>	UCL <sup>e</sup>	r <sup>2f</sup>
Uncont.	0.000	0.000	0.000	0.000	0.000	
Low	2.553	2.542	0.011	-0.058	0.036	0.99
Mid	3.566	3.591	-0.025	-0.012	0.068	
High	4.570	4.468	0.102	-0.183	0.019	

<sup>a</sup>Data from Laboratories 12, 13 and 14 excluded, due to initiation of samples one day later than Laboratories 1–11.

<sup>b</sup>Overall mean across Laboratories 1–11 for each method, after logarithmic transformation:  $\text{Log}_{10}[\text{CFU/g} + (0.1)\text{f}]$ .

<sup>c</sup>Mean difference between methods.

<sup>d</sup>95% Lower confidence limit for difference of means.

<sup>e</sup>95% Upper confidence limit for difference of means.

<sup>f</sup>Square of correlation coefficient.

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