CERTIFICATION

AOAC® *Performance Tested*SM

Certificate No.

110402

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

Compact Dry EC

manufactured by

NISSUI Pharmaceutical Co., Ltd.
3-24-6, Ueno
Taito-ku, Tokyo
Japan 110-8736

This method has been evaluated in the AOAC® *Performance Tested Methods*SM Program and found to perform as stated by the manufacturer contingent to the comments contained in the manuscript. This certificate means that an AOAC® Certification Mark License Agreement has been executed which authorizes the manufacturer to display the AOAC *Performance Tested*SM certification mark along with the statement - "THIS METHOD'S PERFORMANCE WAS REVIEWED BY AOAC RESEARCH INSTITUTE AND WAS FOUND TO PERFORM TO THE MANUFACTURER'S SPECIFICATIONS" - on the above-mentioned method for a period of one calendar year from the date of this certificate (December 15, 2021 – December 31, 2022). Renewal may be granted at the end of one year under the rules stated in the licensing agreement.

Scott Coates

Scott Coates, Senior Director
Signature for AOAC Research Institute

December 15, 2021
Date

2275 Research Blvd., Ste. 300, Rockville, Maryland, USA Telephone: +1-301-924-7077 Fax: +1-301-924-7089
Internet e-mail: aoacri@aoac.org * World Wide Web Site: http://www.aoac.org

METHOD AUTHORS
ORIGINAL VALIDATION: NISSUI PHARMACEUTICAL CO., LTD.
MATRIX EXTENSIONS JULY 2015: Shingo Mizuochi and Maria Nelson

SUBMITTING COMPANY
Nissui Pharmaceutical Co., Ltd.
3-23-9, Ueno
Taito-ku, Tokyo
Japan 110-8736

CURRENT COMPANY ADDRESS
NISSUI Pharmaceutical Co., Ltd.
3-24-6, Ueno
Taito-ku, Tokyo
Japan 110-8736

METHOD NAME
Compact Dry EC

CATALOG NUMBERS
06742, 06743

INDEPENDENT LABORATORY
Original Validation
Q Laboratories, Inc.,
1400 Harrison Ave.,
Cincinnati, OH 45214
USA

July 2015 Matrix Extension
Campden BRI
Station Road
Chipping Campden
Gloucerstershire, GL55 6LK
UK

AOAC EXPERTS AND PEER REVIEWERS
Original Validation: Wallace Andrews[1], Joseph Odumeru[2], Yataro Kokubo[3]
July 2015 Matrix Extension: Yi Chen[4], Yvonne Salfinger[5], Maria Cristina Fernandez[6] Michael Brodsky[7]
[1] Retired USDA FDA CFSAN, College Park, MD, USA
[2] University of Guelph, Guelph, Ontario, Canada
[3] Japan Food Hygiene Association, Japan
[4] USDA FDA CFSAN, College Park, MD, USA
[5] Consultant, Association of Public Health Laboratories, Denver, CO, USA
[6] University of Buenos Aires, Buenos Aires, Argentina
[7] Brodsky Consultants, Ontario, Canada, February 2019 modification

APPLICABILITY OF METHOD
Target organism – *E. coli* and coliforms

Matrixes – Original Validation AOAC OMA 966.24: raw ground pork, raw pork, raw lamb, raw veal, and raw ground beef
July 2015 Matrix Extension: 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

Performance claims – The Compact Dry EC kit performs at the same level as the reference method.

REFERENCE METHODS
AOAC International, AOAC Official Method 966.24 Coliform Group and Escherichia coli 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 Escherichia coli – 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)

ORIGINAL CERTIFICATION DATE
November 18, 2004

CERTIFICATION RENEWAL RECORD
Renewed annually through December 2022.

METHOD MODIFICATION RECORD
1. **July 2015 Level 2**
2. **February 2019 Level 2**

SUMMARY OF MODIFICATIONS
1. **Matrix Extension.**
2. **Shelf life increase to 24 months and corporate address change.**

Under this AOAC® *Performance Tested*℠ License Number, 110402 this method is distributed by:
1. **Hardy Diagnostics**
2. **R-Biopharm AG**

Under this AOAC® *Performance Tested*℠ License Number, 110402 this method is distributed as:
1. **Compact Dry EC**
2. **Compact Dry 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^2. 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 Compact Dry EC methodology and the reference conventional culture method produced comparable *E. coli* and coliform bacteria count results. Therefore, Compact Dry EC plates could be a convenient alternative for routine microbiological food testing. Observations during this study have shown that the Compact Dry 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 Compact Dry 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 Compact Dry 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 Compact Dry EC, using the newly developed dry sheet medium technology, is a convenient alternative for routine microbiological food testing.

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

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

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

Table 2. Compact Dry EC Exclusivity Study (Non-coliform) (1)

Strain	No. of tested isolates	Color reaction	No. of negative isolates
Achromobacter xylosoxidans subsp. *denitrificans*	1	sW	1
Achromobacter xylosoxidans subsp. *xylosoxidans*	1	sW	1
Acinetobacter baumanii	1	W	1
Acinetobacter calcoaceticus	2	W /-	2
Aeromonas hydrophila	2	LRPi/-	1
Alcaligenes faecalis	1	sW	1
Bacillus cereus	2	-	2
Edwardsiella tarda	3	W	3
Lactobacillus lactis	1	-	1
Micrococcus luteus	1	-	1
Micrococcus lylae	1	-	1
Moraxella nonliquefaciens	1	-	1
Moraxella ovis	1	-	1
Proteus mirabilis	1	br	1
Proteus vulgaris	2	br	2
Providencia alcalifaciens	2	br	2
Pseudomonas aeruginosa	1	W	1
Pseudomonas alcaligenes	1	-	1
Pseudomonas diminuta	2	-	2
Pseudomonas mendocina	1	W	1
Pseudomonas pseudoalcaligenes	1	sW	1
Pseudomonas putida	1	-	1
Pseudomonas stutzeri	1	W	1
Pseudomonas vesicularis	1	-	1
Salmonella Choleraesuis	2	W	2
Salmonella Typhimurium	1	W	1
Shigella flexineri	2	W	2
Shigella boydii	1	B	0
Staphylococcus aureus	3	-	3
Streptococcus agalactiae	1	-	1
Streptococcus bovis	1	-	1
Streptococcus canis	1	-	1
Streptococcus equines	1	-	1
Streptococcus pneumoniae	1	-	1
Streptococcus pyogenes	1	-	1
Streptococcus salivarius	1	-	1
Streptococcus sanguis	1	-	1
Streptococcus uberis	1	-	1
Serratia marcescens	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		Compact Dry EC				AOAC 966.24			
		E. coli		Coliform		*E. coli*		Coliform	
		cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g	cfu/g	log_{10}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		Compact Dry EC				AOAC 966.24			
		E. coli		Coliform		*E.coli*		Coliform	
		cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g	cfu/g	log_{10}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)

		CompactDryEC				AOAC 966.24			
		E. coli		Coliform		*E. coli*		Coliform	
E.coli/Coliform LEVEL		cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g	cfu/g	log_{10}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 12. AOAC Method Comparison (Raw veal) (1)

E.coli/Coliform LEVEL		Compact Dry EC				AOAC 966.24			
		E. coli		Coliform		*E. coli*		Coliform	
		cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g	cfu/g	log_{10}cfu/g
10-100 cfu/g	1	10	1.00	15	1.18	3.6	0.56	9.1	0.96
	2	10	1.00	10	1.00	9.1	0.96	23	1.36
	3	10	1.00	15	1.18	9.1	0.96	43	1.63
	4	10	1.00	45	1.65	9.1	0.96	23	1.36
	5	5	0.70	5	0.70	3.6	0.56	3.6	0.56
	Mean	9	0.94	18	1.14	6.9	0.80	20.34	1.17
	Sr	2.24	0.13	15.65	0.35	3.01	0.22	15.28	0.42
	RSDr%	24.85	14.32	86.96	30.37	43.66	27.64	75.13	35.86
100-1000 cfu/g	1	80	1.90	190	2.28	21	1.32	230	2.36
	2	65	1.81	170	2.23	28	1.45	430	2.63
	3	65	1.81	210	2.32	230	2.36	230	2.36
	4	25	1.40	140	2.15	43	1.63	150	2.18
	5	85	1.93	190	2.28	23	1.36	93	1.97
	Mean	64	1.77	180	2.25	69	1.63	226.6	2.30
	Sr	23.56	0.22	26.46	0.07	90.41	0.43	127.58	0.25
	RSDr%	36.81	12.15	14.70	2.98	131.03	26.38	56.30	10.74
1000-10000 cfu/g	1	660	2.82	2800	3.45	930	2.97	2300	3.36
	2	650	2.81	2800	3.45	210	2.32	4300	3.63
	3	720	2.86	2000	3.30	2300	3.36	4300	3.63
	4	710	2.85	2100	3.32	430	2.63	2400	3.38
	5	510	2.71	1400	3.15	430	2.63	2400	3.38
	Mean	650	2.81	2220	3.33	860	2.78	3140	3.48
	Sr	83.96	0.06	593.30	0.12	847.17	0.40	1059.72	0.14
	RSDr%	12.92	2.15	26.73	3.74	98.51	14.21	33.75	4.09
Uninoculated	1	<10	<1	<10	<1	<10	<1	<10	<1
	2	<10	<1	<10	<1	<10	<1	<10	<1
	3	<10	<1	<10	<1	<10	<1	<10	<1
	4	<10	<1	<10	<1	<10	<1	<10	<1
	5	<10	<1	<10	<1	<10	<1	<10	<1
	Mean	<10	<1	<10	<1	<10	<1	<10	<1
	Sr	-	-	-	-	-	-	-	-
	RSDr%	-	-	-	-	-	-	-	-

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
High	***3.65***	***3.55***	***0.110***	***0.120***
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 Compact Dry 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 Compact Dry 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 Compact Dry EC in the lower contamination level, and the Compact Dry 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 Compact Dry and ISO methods were small (<0.5 log10) with CIs well within the acceptance criterion (-0.5, 0.5). The sr and RSDr were sometimes smaller for the Compact Dry 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 Compact Dry 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 Compact Dry EC and ISO 4832 were less than 0.10 log10 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 Compact Dry 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 Compact Dry EC to ISO 16649-2. Across the 9 data sets, the mean differences between methods were less than 0.20 log10 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 Compact Dry 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 Compact Dry EC gives consistent results, comparable to the reference method, within and across laboratories.

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

Matrix	Cont. level	Compact Dry EC			ISO 16649-2			Mean diff.[d]	95% CI[e]		r^{2h}
		Mean[a]	s_r[b]	RSD_r[c]	Mean	s_r	RSD_r		LCL[f]	UCL[g]	
Cooked chicken	1	0.000	0.000	NA[i]	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	

[a]Mean of five replicate portions, plated in duplicate, after logarithmic transformation: Log_{10}[CFU/g + (0.1)f].
[b]Repeatability standard deviation.
[c]Relative standard deviation for repeatability.
[d]Mean difference between the candidate and reference methods.
[e]Confidence interval.
[f]95% Lower confidence limit for difference of means.
[g]95% Upper confidence limit for difference of means.
[h]Square of correlation coefficient.
[i]Not applicable.

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

Matrix	Cont. level	Compact Dry EC			ISO 4832			Mean diff.[d]	95% CI[e]		r^{2h}
		Mean[a]	s_r[b]	RSD_r[c]	Mean	s_r	RSD_r		LCL[f]	UCL[g]	
Cooked chicken	1	0.000	0.000	NA[i]	0.000	0.000	NA	0.000	0.000	0.000	
	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	0.98
	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	
	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	0.94
	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	
	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	0.96
	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	
	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	0.92
	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	

[a]Mean of five replicate portions, plated in duplicate, after logarithmic transformation: Log_{10}[CFU/g + (0.1)f].
[b]Repeatability standard deviation.
[c]Relative standard deviation for repeatability.
[d]Mean difference between the candidate and reference methods.
[e]Confidence interval.
[f]95% Lower confidence limit for difference of means.
[g]95% Upper confidence limit for difference of means.
[h]Square of correlation coefficient.
[i]Not applicable.

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

Contam. level	Compact Dry EC vs ISO 16649-2					
	Mean[b] CD EC	Mean ISO 16649-2	Mean diff.[c]	LCL[d]	UCL[e]	r^{2f}
Uncont.	0.000	0.000	0.000	0.000	0.000	0.97
Low	2.437	2.436	0.001	-0.059	0.053	
Mid	3.458	3.484	-0.026	-0.050	0.109	
High	4.553	4.382	0.171	-0.261	-0.055	

[a]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*.
[b]Overall mean across nine laboratories for each method, after logarithmic transformation: Log_{10}[CFU/g + (0.1)f].
[c]Mean difference between methods.
[d]95% Lower confidence limit for difference of means.
[e]95% Upper confidence limit for difference of means.
[f]Square of correlation coefficient.

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

Contam. level	Compact Dry EC vs ISO 4832					
	Mean[b] CD EC	Mean ISO 4832	Mean diff.[c]	LCL[d]	UCL[e]	r^{2f}
Uncont.	0.000	0.000	0.000	0.000	0.000	0.99
Low	2.553	2.542	0.011	-0.058	0.036	
Mid	3.566	3.591	-0.025	-0.012	0.068	
High	4.570	4.468	0.102	-0.183	0.019	

[a]Data from Laboratories 12, 13 and 14 excluded, due to initiation of samples one day later than Laboratories 1–11.
[b]Overall mean across Laboratories 1–11 for each method, after logarithmic transformation: Log_{10}[CFU/g + (0.1)f].
[c]Mean difference between methods.
[d]95% Lower confidence limit for difference of means.
[e]95% Upper confidence limit for difference of means.
[f]Square of correlation coefficient.

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