



# CERTIFICATION

## AOAC Research Institute *Performance Tested Methods*<sup>SM</sup>

Certificate No.  
**012001**

The AOAC Research Institute hereby certifies the method known as:

### **CompactDry "Nissui" ETB**

manufactured by

**Nissui Pharmaceutical CO., LTD**

**3-24-6, Ueno**

**Taito-ku, Tokyo**

**110-8736, Japan**

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

A handwritten signature in black ink that reads "Scott Coates".

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Scott Coates, Senior Director  
Signature for AOAC Research Institute

Issue Date

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Expiration Date

December 31, 2023

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**SUBMITTING COMPANY**

Nissui Pharmaceutical CO., LTD  
3-24-6, Ueno  
Taito-ku, Tokyo  
110-8736, Japan

**METHOD NAME**

CompactDry "Nissui" ETB

**CATALOG NUMBERS**

54005, 54055

**INDEPENDENT LABORATORY**

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**APPLICABILITY OF METHOD**

**Target Organism – Enterobacteriaceae**

Matrixes – (2008 study) raw ground beef, cooked chicken, lettuce (pre-washed, bagged shredded iceberg), frozen fish (cod fillets), instant nonfat dry milk powder and pasteurized milk (2% fat); (2017 study) pasteurized cream, cream cheese, ready to cook fresh vegetables, vegetable juice, raw ground pork, raw bacon, fresh cooked prawns, fish paté, sandwich and cooked chilled rice

Performance claims – Performance equivalent to that of the ISO 21528-2:2004 Microbiology of food and animal feeding stuffs: Horizontal method for the detection and enumeration of Enterobacteriaceae – colony count method – part 2: colony count method (2), and to ISO/DIS 2158-2:2014 Horizontal method for the detection and enumeration of Enterobacteriaceae – Part 2: colony count method (3) for a variety of foods.

**REFERENCE METHODS**

ISO 21528-2:2004 Microbiology of food and animal feeding stuffs: Horizontal method for the detection and enumeration of Enterobacteriaceae – colony count method – part 2: colony count method (2)  
ISO/DIS 2158-2:2014 Horizontal method for the detection and enumeration of Enterobacteriaceae – Part 2: colony count method (3)  
ISO/DIS 2158-2:2017 Horizontal method for the detection and enumeration of Enterobacteriaceae – Part 2: colony count method (4)

**ORIGINAL CERTIFICATION DATE**

January 09, 2020

**CERTIFICATION RENEWAL RECORD**

Renewed annually through December 2023.

**METHOD MODIFICATION RECORD**

1. November 2020 Level 1

**SUMMARY OF MODIFICATION**

1. Editorial changes.

Under this AOAC *Performance Tested Methods*<sup>SM</sup> License Number, 012001 this method is distributed by:

1. Hardy Diagnostics
2. R-Biopharm AG

Under this AOAC *Performance Tested Methods*<sup>SM</sup> License Number, 012001 this method is distributed as:

1. Compact Dry ETB
2. Compact Dry ETB

**PRINCIPLE OF THE METHOD (1)**

The CompactDry "Nissui" ETB is a ready-to-use test method for detection and enumeration of Enterobacteriaceae in food and related products. The CompactDry "Nissui" ETB comes pre-sterilized as dry media sheets containing culture medium containing glucose and selective agents, plus a cold-soluble gelling agent which are rehydrated by adding 1 mL of prepared sample. The sample automatically and evenly diffuses throughout the plate. Enterobacteriaceae colonies appear red/purple on the medium. The total Enterobacteriaceae count can be determined in a sample after 24 ± 2 h of incubation at 37 ± 1°C.

**DISCUSSION OF THE VALIDATION STUDY (1)**

The CompactDry "Nissui" ETB was certified by MicroVal in 2008 and reevaluated in 2017 according to the revised (2016) ISO microbiological method validation standard. Data from matrix studies and inclusivity/exclusivity testing were examined in this report using the AOAC guidelines for AOAC PTM certification. To meet the AOAC requirements, inclusivity strains were added for a total of 50 unique Enterobacteriaceae species, and exclusivity strains were added for a total of 30 unique non-Enterobacteriaceae strains. Product consistency and stability testing was also added. Robustness was assessed as part of the multi-laboratory study. In inclusivity testing, *Serratia marcescens* (raw mince, CRA 1521), *Raoultella ornithinolytica* (ropy cream, CRA 16928), *Serratia proteamaculans* (NCTC 11544) and *Yersinia intermedia* (natural isolate, CRA 380) were not detected by the CompactDry "Nissui" ETB. However, other species of *Serratia* (*fonticola*, *liquifaciens*, *odorifera* and *rubidaea*) were positive the CompactDry "Nissui" ETB, as were *Raoultella planticola* and *Yersinia enterocolitica* and *Yersinia frederiksenii*, indicating that the CompactDry "Nissui" ETB can still detect a variety of species within these genera, but not the indicated isolates tested in this study. *Pectobacterium atrosepticum* (industrial isolate, CRA 8031) was not detected by either method (CompactDry "Nissui" ETB or reference method). Typically, this species can metabolize a variety of compounds (starch, lactose, maltose, sucrose, fructose and others) but was not able to grow on CompactDry "Nissui" ETB or VRBGA at  $37 \pm 1^\circ\text{C}$  in this case. In exclusivity testing, *Pasteurella bettyae* (NCTC 10535) gave typical colonies on both CompactDry "Nissui" ETB and VRBGA. This strain is known to ferment glucose but is oxidase-positive, which is unlike members of the Enterobacteriaceae. *Aeromonas bestiarum*, *Aeromonas eucrenophila* and *Aeromonas hydrophilia* gave typical colonies on VRBGA but were not detected by the CompactDry "Nissui" ETB. No other exclusivity strains tested were detected by the CompactDry "Nissui" ETB, indicating that this candidate method may be more selective than the reference method for certain organisms.

In the single laboratory matrix studies, there were no statistically significant differences in results seen between the CompactDry "Nissui" ETB and the ISO reference method at any contamination levels for raw ground beef, shredded iceberg lettuce, pasteurized cream, raw bacon, sandwich and cooked chilled rice. For the lowest contamination levels of cooked chicken, instant nonfat dry milk powder, cream cheese and vegetable juice, the mean differences in  $\log_{10}$  values between methods were  $<0.5$ , (0.284, 0.201, -0.185 and -0.334, respectively), however, one side of the CI was outside of the recommended (-0.5, 0.5) range. This indicates that the two methods had similar results, but because the contamination levels were so low, small differences in the number of colonies recorded had a bigger impact on the CIs. There were no statistical differences between the methods in these foods at the higher contamination levels. At the lowest contamination level of frozen fish, the mean difference between methods was -1.350, with a CI (-1.800, 0.910), both indicators well outside the acceptable range. A small number of colonies were isolated from the first dilution, 8 colonies total from 10 CompactDry "Nissui" ETB plates, while the VRBGA averaged 9 CFU/plate. The mean differences and CIs were well within the acceptance criteria at the four higher contamination levels, so the very low contamination level is not a good representation of the method performance. A difference between methods was also seen in the lowest contamination level of raw ground pork. The mean difference was  $>0.5$  (-0.530) and the CI was (-0.723, -0.337). In this case, contamination levels were not low (3.842 for CompactDry "Nissui" and 4.373 for VRBGA). However, the mean differences in the two higher contamination levels were small at -0.031 and -0.106.

For ready to cook vegetables and fresh cooked prawns, statistical differences between the methods were seen at two contamination levels. For the ready to cook vegetables, a difference was seen in the CI at the low level (-0.711, 0.054), but the mean difference was  $<0.5$  (-0.329). Because the contamination level was low, the small differences had a bigger impact on the CI. For the high level, mean differences between the methods was small, -0.032, but the upper confident limit was slightly above of the recommended acceptance parameter at -0.514. The CompactDry "Nissui" ETB method had higher variability between the replicates than the ISO method as indicated by the higher  $s_r$  (0.433 vs. 0.153). For the cooked prawns, there was a significant difference in the middle contamination level, with a mean difference of -0.801 (-1.381, -0.238). The differences in the lower and higher levels were small at 0.039 (-0.075, 0.154) and -0.161 (-0.675, 0.354), respectively. The CI for the high level could be due to the higher standard deviation for the CompactDry "Nissui" ETB in this level. Although not a statistical outlier, one of the five replicates tested in the high level gave counts well below the others.

For the fish paté, the differences between methods were statistically significant at all contamination levels; -0.458 (-0.554, -0.63), 0.533 (0.231, 0.835) and -0.502 (-0.613, -0.391) for the low, middle and high contamination levels, respectively. However, in all cases, the differences were borderline, and the results do not trend in the same direction for all levels. The bias is low for the low and high contamination levels but high for the middle contamination level. The  $s_r$  is similar at each level for both methods, and the  $R^2$  is 0.91. Perhaps the natural flora in this matrix contributed to the difference in the bias.

The multi-laboratory study showed no differences between the methods for pasteurized liquid milk. Mean differences between the methods and CIs were within the recommended acceptable range. The  $s_r$  and  $s_R$  values were similar for the CompactDry "Nissui" ETB and VRBGA at each contamination level. The low  $s_R$  values ( $<0.2$ ) indicate robust method performance across laboratories. No differences were seen in three different manufactured lots and up to 16 months of storage.

Table 1. Inclusivity results for CompactDry "Nissui" ETB (1)

No.	Strain	CRA <sup>a</sup> code	Origin/source	CompactDry "Nissui" ETB <sup>b</sup> Result	VRBGA <sup>c</sup> Result
Inclusivity strains tested by Campden BRI in 2008					
1	<i>Citrobacter freundii</i>	40	NCTC <sup>d</sup> 9750	+	+
2	<i>Citrobacter freundii</i>	3163	Sausage	+	+
3	<i>Edwardsiella tarda</i>	8392	NCTC 10391	+	+
4	<i>Enterobacter aerogenes</i>	15736	NCTC 10006	+	+
5	<i>Enterobacter cloacae</i>	1472	Dried milk	+	+
6	<i>Enterobacter cloacae</i>	6633	DuPont <sup>e</sup> 2850	+	+
7	<i>Escherichia coli</i>	1476	Dried milk	+	+
8	<i>Escherichia coli</i>	1871	NCIMB <sup>f</sup> 10223	+	+
9	<i>Escherichia coli</i>	2003	Fish	+	+
10	<i>Escherichia coli</i>	2091	NCTC 8008	+	+
11	<i>Escherichia coli</i>	2092	NCTC 11603	+	+
12	<i>Escherichia coli</i>	11017	NCTC 12241	+	+
13	<i>Escherichia coli</i>	11626	NCTC 5933	+	+
14	<i>Escherichia coli</i>	15943	NCIMB 700555	+	+
15	<i>Escherichia coli</i>	16041	Raw ground beef	+	+
16	<i>Hafnia alvei</i>	4009	Sandwich	+	+
17	<i>Klebsiella oxytoca</i>	8387	NCTC 8167	+	+
18	<i>Klebsiella oxytoca</i>	15926	ATCC <sup>g</sup> 13182	+	+
19	<i>Pantoea agglomerans</i>	15947	NCIMB 11392	+	+
20	<i>Proteus mirabilis</i>	1588	Poultry	+	+
21	<i>Proteus vulgaris</i>	1581	Poultry	+	+
22	<i>Providencia rettgeri</i>	8386	NCTC 7475	+	+
23	<i>Salmonella</i> Dublin	1356	NCTC 9676	+	+
24	<i>Salmonella</i> Enteritidis	1004	Chicken	+	+
25	<i>Salmonella</i> Poona	725	NCTC 4840	+	+
26	<i>Salmonella</i> Typhimurium	11634	ATCC 14028	+	+
27	<i>Serratia marcescens</i>	1521	Raw mince	-	+
28	<i>Shigella boydii</i>	324	NCTC 11321	+	+
29	<i>Shigella flexneri</i>	325	NCTC 9950	+	+
30	<i>Shigella sonnei</i>	326	NCTC 10352	+	+
31	<i>Shigella sonnei</i>	4107	NCTC 9950	+	+
32	<i>Yersinia enterocolitica</i>	4103	NCTC 10352	+	+
Inclusivity strains tested by Campden BRI in 2017					
33	<i>Buttiauxella warmboldiae</i>	17112	Rainwater	+	+
34	<i>Citrobacter amalonaticus</i>	7458	Beansprouts	+	+
35	<i>Citrobacter braakii</i>	16279	Industrial isolate	+	+
36	<i>Cronobacter sakazakii</i>	16909	Dried milk	+	+
37	<i>Enterobacter agglomerans</i>	1488	Mince	+	+
38	<i>Enterobacter amnigenus</i>	7426	Mushrooms	+	+
39	<i>Enterobacter intermedium</i>	17023	Surface water	+	+
40	<i>Erwinia amylovorans</i>	8037	Industrial isolate	+	+
41	<i>Escherichia fergusonii</i>	7522	Sausages	+	+
42	<i>Escherichia hermanii</i>	7477	Sesame seeds	+	+
43	<i>Escherichia vulneris</i>	2005	Vegetables	+	+
44	<i>Klebsiella pneumoniae</i>	6650	Industrial isolate	+	+
45	<i>Morganella morganii</i>	5120	Pork	+	+
46	<i>Pectobacterium atrosepticum</i>	8031	Industrial isolate	-	-
47	<i>Providencia alcalifaciens</i>	7469	Chicken	+	+
48	<i>Rahnella aquatilis</i>	16911	NCIMB 13365	+	+
49	<i>Raoultella ornithinolytica</i>	16928	Ropy cream	-	+
50	<i>Raoultella planticola</i>	16820	ATCC 43176	+	+
51	<i>Salmonella bongori</i>	16379	Not known	+	+
52	<i>Salmonella enterica</i> subsp <i>arizonae</i>	16380	Not known	+	+
53	<i>Salmonella enterica</i> subsp <i>diarizonae</i>	16374	Not known	+	+
54	<i>Salmonella enterica</i> subsp <i>houtenae</i>	1376	NCTC 10401	+	+
55	<i>Salmonella</i> Java	1378	NCTC 5706	+	+
56	<i>Salmonella</i> Schwarzengrund	1408	NCTC 6756	+	+
57	<i>Serratia fonticola</i>	4613	Chicken	+	+
58	<i>Serratia liquifaciens</i>	1560	Mince	+	+
59	<i>Serratia proteamaculans</i>	16463	NCTC 11544	-	+
60	<i>Shigella dysenteriae</i>	4275	Industrial isolate	+	+
61	<i>Shimwellia blattae</i>	16931	Cockroach	+	+
62	<i>Yersinia intermedia</i>	380	Industrial isolate	-	+
Inclusivity strains tested by Nissui in 2018					
63	<i>Yersinia frederiksenii</i>	NA <sup>h</sup>	ATCC 33641	+	+
64	<i>Citrobacter youngae</i>	NA	Food	+	+

65	<i>Citrobacter farmeri</i>	NA	Human	+	+
66	<i>Enterobacter gergoviae</i>	NA	ATCC 33028	+	+
67	<i>Serratia rubidaea</i>	NA	ATCC 27593	+	+
68	<i>Serratia odorifera</i>	NA	Unknown	+	+
69	<i>Citrobacter koseri</i>	NA	ATCC 25408	+	+
70	<i>Escherichia blattae</i>	NA	JCM <sup>f</sup> 1650	+	+
71	<i>Kluyvera ascorbata</i>	NA	ATCC 33433	+	+
72	<i>Kluyvera cryocrescens</i>	NA	ATCC 33435	+	+
73	<i>Morganella morganii</i>	NA	ATCC 25830	+	+
74	<i>Rahnella aquatilis</i>	NA	JCM 1683	+	+
75	<i>Salmonella Choleraesuis</i>	NA	ATCC 13312	+	+
76	<i>Serratia marcescens</i>	NA	ATCC 13880	+	+

<sup>a</sup>CRA code = Cambden BRI Laboratories, Chipping Campden, Gloucestershire, UK.

<sup>b</sup>CompactDry "Nissui" ETB results: "+" = typical growth, "-" = no growth.

<sup>c</sup>VRBGA = Violet red bile glucose agar, per ISO 21528-2:2004 and ISO/DIS 21528-2:2014.

<sup>d</sup>NCTC = National Collection of Type Cultures, Porton Down, Salisbury, UK.

<sup>e</sup>DuPont = Wilmington, DE.

<sup>f</sup>NCIMB = National Collection of Industrial Food and Marine Bacteria, Aberdeen, Scotland.

<sup>g</sup>ATCC = American Type Culture Collection, Manassas, VA.

<sup>h</sup>NA = Not applicable.

<sup>i</sup>JCM = Japan Collection of Microorganisms, Ibaraki, Japan.

**Table 2: Exclusivity results for CompactDry "Nissui" ETB (1)**

No.	Strain	CRA <sup>a</sup> code	Origin/source	CompactDry "Nissui" ETB <sup>b</sup> Result	VRBGA <sup>c</sup> Result
Exclusivity strains tested by Campden BRI in 2008					
1	<i>Aeromonas hydrophilia</i>	4111	NCTC <sup>d</sup> 8049	-	+
2	<i>Avibacterium avium</i>	8389	NCTC 11297	-	-
3	<i>Bacillus cereus</i>	1761	Dairy product	-	-
4	<i>Bacillus cereus</i>	4110	NCTC 7464	-	-
5	<i>Bacillus subtilis</i>	4112	NCTC 10400	-	-
6	<i>Bronchothrix thermospacta</i>	16019	NCTC 10822	-	-
7	<i>Enterococcus faecalis</i>	4113	NCTC 775	-	-
8	<i>Enterococcus faecalis</i>	16049	NCIMB <sup>e</sup> 12280	-	-
9	<i>Lactobacillus gasseri</i>	6804	NCIMB 13081	-	-
10	<i>Pasteurella bettyae</i>	8391	NCTC 10535	+	+
11	<i>Pediococcus pentosaceus</i>	16030	Brine	-	-
12	<i>Pseudomonas aeruginosa</i>	8299	NCIMB 10753	-	-
13	<i>Pseudomonas fluorescens</i>	15937	NCIMB 10586	-	-
14	<i>Pseudomonas fragi</i>	16050	NCTC 10689	-	-
15	<i>Staphylococcus aureus</i>	1216	NCTC 10655	-	-
16	<i>Staphylococcus aureus</i>	1224	Margarine	-	-
17	<i>Staphylococcus aureus</i>	1227	Frozen cooked prawns	-	-
18	<i>Staphylococcus aureus</i>	4105	NCIMB 12702	-	-
19	<i>Vibrio mimicus</i>	6351	NCTC 11435	-	-
20	<i>Vibrio parahaemolyticus</i>	15737	NCTC 11344	+ <sup>f</sup>	+
Exclusivity strains tested by Campden BRI in 2017					
21	<i>Aeromonas bestiarum</i>	17068	Stream water	-	+
22	<i>Aeromonas eucrenophila</i>	17121	Wet land water	-	+
23	<i>Aeromonas salmonicida</i>	8388	NCTC 10402	-	-
24	<i>Bacillus circulans</i>	16584	Pasteurized cream	-	-
25	<i>Bacillus coagulans</i>	16586	Sterilized milk	-	-
26	<i>Flavobacterium indologenes</i>	4088	Bamboo shoots	-	-
27	<i>Lactobacillus acidophilus</i>	7675	Dairy product	-	-
28	<i>Lactobacillus brevis</i>	16628	NCTC 13386	-	-
29	<i>Listeria innocua</i>	6602	NCTC 11288	-	-
30	<i>Listeria monocytogenes</i>	1104	Soft cheese	-	-
31	<i>Staphylococcus delphinii</i>	16900	NCIMB 8709	-	-
32	<i>Staphylococcus haemolyticus</i>	7818	Sandwich	-	-
33	<i>Streptococcus agalactiae</i>	7115	ATCC <sup>g</sup> 13813	-	-
34	<i>Streptococcus pyogenes</i>	16892	NCIMB 13285	-	-
35	<i>Streptococcus thermophilus</i>	16045	NCIMB 8510	-	-

<sup>a</sup>CRA code = Cambden BRI Laboratories, Chipping Campden, Gloucestershire, UK.

<sup>b</sup>CompactDry "Nissui" ETB results: "+" = typical growth, "-" = no growth.

<sup>c</sup>VRBGA = Violet red bile glucose agar, per ISO 21528-2:2004 and ISO/DIS 21528-2:2014.

<sup>d</sup>NCTC = National Collection of Type Cultures, Porton Down, Salisbury, UK.

<sup>e</sup>NCIMB = National Collection of Industrial Food and Marine Bacteria, Aberdeen, Scotland.

<sup>f</sup>Growth was atypical on CompactDry "Nissui" ETB.

<sup>g</sup>ATCC = American Type Culture Collection, Manassas, VA.

Table 5. Single laboratory matrix study - 2008: CompactDry "Nissui" ETB vs ISO 21528-2:2004 (1)

Matrix	Cont. level	ETB			ISO 21528-2:2004			Mean diff. <sup>d</sup>	95% CI <sup>e</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>
Raw ground beef	1	3.415	0.092	2.69	3.596	0.105	2.92	-0.181	-0.265	-0.097
	2	4.301	0.065	1.51	4.430	0.092	2.08	-0.129	-0.209	-0.048
	3	5.104	0.217	4.25	5.077	0.190	3.74	0.027	-0.016	0.071
	4	5.457	0.200	3.67	5.628	0.156	2.77	-0.171	-0.339	-0.003
	5	6.464	0.318	4.92	6.547	0.293	4.48	-0.083	-0.149	-0.018
Cooked chicken	1	0.000	0.000	NA <sup>h</sup>	0.000	0.000	NA	0.000	0.000	0.000
	2	0.653	0.568	87.0	0.369	0.598	162	0.284	-0.301	0.869
	3	2.291	0.172	7.51	2.456	0.175	7.13	-0.165	-0.250	-0.080
	4	3.434	0.125	3.64	3.407	0.194	5.69	0.028	-0.105	0.160
	5	4.412	0.095	2.15	4.368	0.092	2.11	0.043	-0.032	0.118
Pre-washed bagged shredded iceberg lettuce	1	0.000	0.000	NA	0.000	0.000	NA	0.000	0.000	0.000
	2	2.583	0.367	14.2	2.502	0.520	20.8	0.081	-0.200	0.361
	3	3.935	0.190	4.83	4.161	0.158	3.80	-0.226	-0.296	-0.155
	4	4.733	0.317	6.69	4.566	0.356	7.80	0.167	0.060	0.274
	5	5.054	0.068	1.35	4.952	0.176	3.55	0.102	0.009	0.195
Frozen fish (cod fillet)	1	0.518	0.677	131	1.868	0.285	15.3	-1.350	-1.800	-0.901
	2	2.039	0.208	10.2	2.203	0.217	9.85	-0.164	-0.240	-0.088
	3	2.850	0.134	4.70	3.088	0.108	3.50	-0.238	-0.300	-0.176
	4	3.957	0.144	3.64	4.086	0.147	3.60	-0.129	-0.166	-0.092
	5	4.922	0.245	4.98	5.114	0.184	3.60	-0.192	-0.244	-0.139
Instant nonfat dry milk powder	1	0.000	0.000	NA	0.000	0.000	NA	0.000	0.000	0.000
	2	1.862	0.892	47.9	1.661	1.290	77.7	0.201	-0.242	0.644
	3	2.804	0.257	9.17	2.921	0.283	9.69	-0.117	-0.202	-0.033
	4	3.642	0.446	12.2	3.767	0.464	12.3	-0.124	-0.240	-0.009
	5	4.917	0.162	3.29	4.853	0.190	3.92	0.064	-0.008	0.136

<sup>a</sup>Mean of five replicate portions, plated in duplicate, after logarithmic transformation.<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>Not applicable.

Table 6. Single laboratory matrix study - 2017: CompactDry "Nissui" ETB vs ISO/DIS 21528-2:2014 (1)

Matrix	Cont. level	ETB			ISO/DIS 21528-2:2014			Mean diff. <sup>d</sup>	95% CI <sup>e</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>
Pasteurized cream	1	2.298	0.117	5.09	2.316	0.100	4.32	-0.019	-0.085	0.048
	2	4.064	0.044	1.08	3.953	0.105	2.66	0.111	-0.020	0.242
	3	5.932	0.054	0.91	5.651	0.095	1.68	0.281	-0.194	0.368
Cream cheese	1	1.643	0.235	14.3	1.828	0.209	11.4	-0.185	-0.712	0.342
	2	3.682	0.048	1.30	3.834	0.038	0.99	-0.153	-0.207	-0.098
	3	5.495	0.095	1.73	5.666	0.072	1.27	-0.171	-0.346	0.004
Ready to cook fresh vegetables	1	1.778	0.166	9.34	2.106	0.195	9.26	-0.329	-0.711	0.054
	2	3.292	0.076	2.31	3.408	0.189	5.55	-0.117	-0.271	0.038
	3	5.643	0.433	7.67	5.610	0.153	2.73	0.032	-0.451	0.514
Vegetable juice	1	1.597	0.202	12.7	1.942	0.145	7.47	-0.344	-0.583	-0.106
	2	3.633	0.079	2.17	3.838	0.067	1.75	-0.205	-0.356	-0.054
	3	5.559	0.094	1.69	5.804	0.044	0.76	-0.245	-0.353	-0.136
Raw ground pork	1	3.842	0.061	1.59	4.373	0.110	2.52	-0.530	-0.723	-0.337
	2	4.744	0.097	2.04	4.775	0.076	1.59	-0.031	-0.110	0.047
	3	6.749	0.017	0.25	6.855	0.048	0.70	-0.106	-0.181	-0.031
Raw bacon	1	2.744	0.277	10.1	2.637	0.409	15.5	0.107	-0.192	0.406
	2	4.449	0.246	5.53	4.344	0.216	4.97	0.104	-0.086	0.295
	3	6.308	0.197	3.12	6.356	0.216	3.40	-0.048	-0.349	0.254
Fresh cooked prawns	1	2.361	0.184	7.79	2.322	0.133	5.73	0.039	-0.075	0.154
	2	4.352	0.324	7.44	5.161	0.748	14.5	-0.810	-1.381	-0.238
	3	5.783	0.394	6.81	5.944	0.083	1.40	-0.161	-0.675	0.354
Fish paté	1	2.464	0.075	3.04	2.923	0.078	2.67	-0.458	-0.554	-0.363
	2	4.434	0.137	3.09	3.901	0.174	4.46	0.533	0.231	0.835
	3	6.240	0.187	3.00	6.741	0.122	1.81	-0.502	-0.613	-0.391
Sandwich	1	2.415	0.061	2.53	2.618	0.109	4.16	-0.203	-0.326	-0.080
	2	4.422	0.070	1.58	4.383	0.142	3.24	0.039	-0.133	0.211
	3	6.525	0.059	0.90	6.635	0.099	1.49	-0.110	-0.229	0.008
Cooked chilled rice	1	1.365	0.201	14.7	1.701	0.125	7.35	-0.336	-0.579	-0.092
	2	3.526	0.008	0.23	3.716	0.091	2.45	-0.191	-0.375	-0.006
	3	5.442	0.170	3.12	5.650	0.113	2.00	-0.207	-0.523	0.109

<sup>a</sup>Mean of five replicate portions, after logarithmic transformation.<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.

Table 7. Multi-laboratory study - 2008: Summary of pasteurized milk results by laboratory for each contamination level for CompactDry "Nissui" ETB and ISO 21528-2:2004 (1)

Laboratory	Non-contaminated		Low Level		Medium Level		High Level	
	CD ETB <sup>a</sup>	ISO 21528-2	CD ETB	ISO 21528-2	CD ETB	ISO 21528-2	CD ETB	ISO 21528-2
1	0.000 <sup>b</sup>	0.000	2.241	2.714	3.343	3.747	4.406	4.588
2	0.000	0.000	2.443	2.655	3.713	3.772	4.823	4.841
3	0.000	0.000	2.279	2.492	3.634	3.648	4.525	4.625
4	0.000	0.000	2.247	2.496	3.343	3.544	4.467	4.578
5	0.000	0.000	2.123	2.483	3.347	3.575	4.370	4.488
6	0.000	0.000	2.344	2.575	3.542	3.622	4.602	4.625
7	0.000	0.000	2.147	2.667	3.554	3.680	4.497	4.656
8	0.000	0.000	2.312	2.479	3.514	3.572	4.577	4.659
9	0.000	0.000	2.072	2.560	3.317	3.603	4.469	4.467
10	0.000	0.000	2.511	2.681	3.504	3.697	4.486	4.472
11 <sup>c</sup>	0.000	0.000	2.160	2.405	3.379	3.342	4.317	4.204

<sup>a</sup>CompactDry "Nissui" ETB.

<sup>b</sup>Results are reported for each laboratory as a mean of two replicate portions, plated in duplicate, after logarithmic transformation.

<sup>c</sup>Organizing Laboratory.

#### REFERENCES CITED

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2. ISO 21528-2:2004 Microbiology of food and animal feeding stuffs: Horizontal method for the detection and enumeration of Enterobacteriaceae – colony count method – part 2: colony count method
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