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CERTIFICATION

AOAC Research Institute
Performance Tested Methods^{SM}

Certificate No.
071302

The AOAC Research Institute hereby certifies the method known as:

MicroSnap Coliform & MicroSnap *E. coli*

manufactured by

Hygiena LLC
941 Avenida Acaso
Camarillo, CA 93012
USA

This method has been evaluated in the AOAC Research Institute *Performance Tested Methods*^{SM} 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*^{SM} 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.

Scott Coates

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Scott Coates, Senior Director
Signature for AOAC Research Institute

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SUBMITTING COMPANY
Hygiena LLC
941 Avenida Acaso
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METHOD NAME
MicroSnap Coliform & MicroSnap *E. coli*

CATALOG NUMBERS
Enrichment Device - MS1-CEC
Detection Device - MS2- CEC (COLIFORM); MS2-EC (*E. coli*)

INDEPENDENT LABORATORY
Leatherhead Food Research
Randall's Road
Leatherhead, Surrey
KT22 7RY UK

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

Matrixes – Coliforms – AOAC 966.24: raw ground beef (50 g), ready-to-eat ham (50 g*), cooked chicken (50 g), raw chicken (50 g)
Standard Methods for Examination of Dairy Products, Ch 7 – raw liquid milk (50 g)
USDA BAM Ch 4 – raw cod (50 g), raw prawns (50 g), pre-packaged lettuce leaves (50 g), sandwiches (bacon, lettuce, tomato) (50 g*), and bottled water (mineral, still)

E. coli – AOAC 966.24 raw ground beef (50 g), ready-to-eat ham (50 g*), cooked chicken (50 g), raw chicken (50 g), raw cod (50 g), raw prawns (50 g), pre-packaged lettuce leaves (50 g*), raw liquid milk (50 g), sandwich (Bacon, lettuce, tomato) (50 g)
USDA BAM Ch 4 – bottled water (mineral, still)
*Certified for enumeration only

Performance claims – The method was shown to have a good correlation with the reference methods.

REFERENCE METHODS

Official Methods of Analysis (2019), 21st Ed., 966.24, AOAC INTERNATIONAL, Rockville, MD (3)

U.S. Food and Drug Administration Bacteriological Analytical Manual (FDA-BAM), Chapter 4 (4)

The Standard Methods for the Examination of Dairy Products (SMEDP), Chapter 7, 17th edition, 2004, APHA (5)

U.S. FDA Bacteriological Analytical Manual Ch. 4 (2017), Enumeration of *Escherichia coli* and the Coliform Bacteria (10)

ORIGINAL CERTIFICATION DATE
July 12, 2013

CERTIFICATION RENEWAL RECORD
Renewed annually through December 2024.

METHOD MODIFICATION RECORD
1. December 2017 Level 1
2. May 2021 Level 2

3. December 2023 Level 1

SUMMARY OF MODIFICATION
1. Editorial/clerical changes.
2. Incorporation of handheld device, EnSURE Touch™ Luminometer.
3. Editorial/clerical changes.

PRINCIPLE OF THE METHOD (1)

The MicroSnap method consists of 2 separate devices used in sequence to achieve a result from the assay. The first device (Enrichment Device) grows the bacteria from the sample under investigation. The sample is added to this device as a 1 mL aliquot of either a liquid or a 10% food suspension. This device contains a proprietary nutrient growth media with inducers of beta-Galactosidase and beta-Glucuronidase. During the incubation at 37 ±0.5°C the beta-Galactosidase and/or beta-Glucuronidase enzymes accumulate within the bacteria. Both enzymes become proportional to the number of bacteria in the staring inoculum at specific incubation times after the lag phase of the bacteria. These incubation times have been found to be 6 hours and 8 hours at 37 ± 0.5°C. Since the bacteria do not readily export these enzymes into the media, each bacterium expresses a similar concentration of enzyme per bacterial cell; this is true for both enzymes. The concentration of enzyme expressed using the inducers are consistent across the Coliform group and *E. coli*, although exceptions do exist.

At 6 hours of incubation, the dynamic range over which the test begins to function quantitatively begins at 100 CFU and upwards this is expressed as a proportional rise in the RLU measured in each sample in each luminometer. Longer incubation times push the lower level of detection downwards.

The second device is the Detection Device. There are 2 separate specific detection devices used, one for beta-Galactosidase detection and one for beta-Glucuronidase detection. These 2 devices can be used to verify the same enrichment device for either coliforms and/or *E. coli*. Each detection device contain a lysis reagent in the tube portion with ATP, beta--Galactosidase substrate or beta-Glucuronidase substrate and luciferase reagent in the bulb portion of the device. The substrate is manufactured to have the recognition part (or sugar in these cases) for the enzyme under test, linked via a cleavable bond to luciferin. On successful cleavage of the substrate the luciferin is released, which in the presence of luciferase and other factors emits light in relation to the amount of enzyme present in the growing culture. At the specific time point of 6 hours, the concentration of enzyme is directly related to the starting concentration of bacteria. This 6-hour quantification point is true for both coliforms and *E. coli*. The time point when all bacteria, independent of starting inoculum, are detected is 8 hours, hence even levels of less than 10 coliforms will have produced enough enzyme by 8 hours to be determined as positive in the assay.

DISCUSSION OF THE VALIDATION STUDY (1)

The MicroSnap Coliform and *E. coli* detection system is primarily designed to give a rapid and semi-quantitative assessment for *E. coli* and coliforms from food samples. The product is sold as a system for quantitation and detection at low to medium levels of both *E. coli* and coliforms. The quantification is designed to be an overall indicator of levels of bacteria in the samples being tested.

The MicroSnap coliform and *E. coli* are the first of a tranche of bioluminogenic assays designed to give the investigator the possibility to determine levels of contaminating organisms in 6 hours due to the extreme sensitivity that can be gained from these forms of assay. The unique nature of the assay producing light in relation to the enzyme concentration means the system can have the ability to detect low enzyme levels from low levels of bacteria that are actively growing in the sample under investigation. The levels of quantification required can be thought of as traffic light type system for most investigators. The European Food Regulations (Commission Regulation EC No 2073/2005) of 15 November 2005 have limits set for most food for the measurement of both pathogens (Listeria and Salmonella) but also for indicator organisms, E.coli, Coliforms and Enterobacteriaceae. The regulations stipulate that certain levels need to be maintained for quality and safety. In regulation 2.1.6 governing minced meat, there are 3 levels that are mentioned <50cfu/g, 50 – 500cfu/g and greater than 500cfu/g. The numbers of replicates run and the number of each replicates that are allowed at each level tested is prescribed. If all 5 replicates are below 50cfu/g the meat is deemed excellent, if 2 of the 5 replicates are between 50 – 500cfu/g it is deemed adequate if any reps are above 500cfu/g it is deemed not fit. These levels indicate low, medium and high levels of contamination akin to a go, wait and stop. Hence, the use of MicroSnap and other systems these can be used to rapidly measure and track which level the sample best fits. The setting for these levels will be determined for each food by each investigator according to the regulations or deemed appropriate for each food by internal validation.

During the assessment of the AOAC official method, it was found that certain non-*E.coli* coliforms would not begin to grow in the first enrichment broth for the MPN (LST), which led to the conclusion that some bacteria are incapable of being picked up using the standard method. Both methods will never detect all bacteria being considered as potential targets. These exceptions could lead to both methods showing variation and non-significances.

Table 1. Inclusivity for Non-*E. coli* Coliforms at 6 and 8 hours incubation in the luminometers SS Plus and Pi102. Detection of approximately 10 – 100 CFU/mL using Coliform Detection Devices (1)						
Organism	**Source**	**Origin (if known)**	**6 hr Enrichment**		**8 hr enrichment**	
			SS +	**Pi-102**	**SS +**	**Pi-102**
Escherichia hermanii	Wild Type	Minced Beef	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Enterobacter cloacae	Surrey University E002	Water	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Enterobacter aerogenes[a]	OXOID	ATCC 10006	**NEGATIVE**	**NEGATIVE**	**POSITIVE**	**POSITIVE**
Enterobacter cloacae	Surrey University E003	Rice	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Enterobacter cloacae	Surrey University E004	Milk	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella pneumoniae	Hospital KP13	ESBL Urine	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella oxytoca[b]	Surrey University KO004	Food (unknown)	**POSITIVE**	**NEGATIVE**	**POSITIVE**	**POSITIVE**
Citrobacter diversus	Surrey University C0011	Food (unknown)	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella pneumoniae	HPA	ATCC 700603	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella pneumoniae	Hospital KP9	ESBL Faeces	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Citrobacter fruendii	Surrey University C0012	Salad	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella pneumoniae	HPA	NCTC 13438	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella pneumoniae	HPA	NCTC 13465	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella pneumoniae	HPA	NCTC 13443	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella pneumoniae	HPA	NCTC 13439	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Escherichia fergusonii	HPA	NCTC 12128	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella pneumoniae	Surrey University K0015	Food (surface)	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Escherichia hermanii	HPA	I73	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Enterococcus sakazakii	Surrey University E0023	Baby Milk	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Enterococcus aerogenes	Oxoid	ATCC 13048	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Citrobacter fruendii[c]	Oxoid	ATCC 8090	**NEGATIVE**	**NEGATIVE**	**POSITIVE**	**POSITIVE**
Enterococcus sakazakii	HPA	NCTC 8155	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
E.coli O157 (NT)	OXOID	ATCC 12900	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Klebsiella oxytoca	Surrey University KO031	Salad	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**
Enterococcus cloacae	Surrey University E0017	Salad	**POSITIVE**	**POSITIVE**	**POSITIVE**	**POSITIVE**

[a]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 1,000 CFU/mL.

[b]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 410 CFU/mL.

[c]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 720 CFU/mL.

Organism	Source	Origin (if known)	6 hr Enrichment		8 hr enrichment	
			SS Plus	Pi102	SS Plus	Pi102
E. coli 63	Aberdeen University	Clinical isolate	POSITIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli 64[a]	Aberdeen University	Clinical Isolate	NEGATIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 67[b]	Aberdeen University	Clinical Isolate	POSITIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli 68	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli (EC 10)	Hospital	ESBL Urine	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 50	Aberdeen University	Clinical isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 52[c]	Aberdeen University	Clinical Isolate	POSITIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli 54	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 53	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 48	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 32	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 21	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli	OXOID	ATCC 8739	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli	OXOID	ATCC 25922	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli E0018	University Surrey	Unknown	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli E0019[d]	University Surrey	Food (unknown)	NEGATIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli E0023[e]	University Surrey	Food (unknown)	NEGATIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli E0026	University Surrey	Food (unknown)	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli E0025[f]	University Surrey	Food (unknown)	NEGATIVE	NEGATIVE	NEGATIVE	POSITIVE
E. coli[g]	OXOID	ATCC 13216	NEGATIVE	NEGATIVE	NEGATIVE	POSITIVE
E. coli E0033	University Surrey	Food (unknown)	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli[h]	OXOID	ATCC 35218	NEGATIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli E0039	University Surrey	Food (unknown)	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli E0034	University Surrey	Food (unknown)	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli	OXOID	ATCC 11775	POSITIVE	POSITIVE	POSITIVE	POSITIVE

Table 2. Inclusivity for *E. coli* Coliforms at 6 and 8 hours incubation in the luminometers SS Plus and Pi102. Detection of approximately 10 – 100 CFU/mL using Coliform Detection Devices   (1)

[a]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 800 CFU/mL.
[b]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 210 CFU/mL.
[c]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 125 CFU/mL.
[d]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 1,000 CFU/mL.
[e]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 110 CFU/mL.
[f]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 770 CFU/mL.
[g]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 100 CFU/mL.
[h]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 100 CFU/mL

| Table 3. | Inclusivity for *E. coli* at 6 and 8 hours incubation in SS Plus and Pi102. Detection of approximately 10 – 100 CFU/mL using *E. coli* Detection Devices (1) | | | | | |

Organism	Source	Origin	6 hr Enrichment		8 hr enrichment	
			SS Plus	Pi102	SS Plus	Pi102
E. coli 63	Aberdeen University	Clinical isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 64[a]	Aberdeen University	Clinical Isolate	NEGATIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 67	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 68	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli (EC 10)[b]	Hospital	ESBL Urine	NEGATIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli 50	Aberdeen University	Clinical isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 52	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 54	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 53	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 48	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 32	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli 21	Aberdeen University	Clinical Isolate	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli	OXOID	ATCC 8739	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli[c]	OXOID	ATCC 25922	NEGATIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli E0018	University Surrey	Food (unknown)	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli E0019[d]	University Surrey	Food (unknown)	NEGATIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli E0023[e]	University Surrey	Food (unknown)	NEGATIVE	POSITIVE	POSITIVE	POSITIVE
E. coli E0026	University Surrey	Food (unknown)	POSITIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli E0025[f]	University Surrey	Food (unknown)	NEGATIVE	POSITIVE	POSITIVE	POSITIVE
E. coli	OXOID	ATCC 13216	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli E0033	University Surrey	Food (unknown)	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli[g]	OXOID	ATCC 35218	NEGATIVE	NEGATIVE	POSITIVE	POSITIVE
E. coli E0039	University Surrey	Food (unknown)	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli E0034	University Surrey	Food (unknown)	POSITIVE	POSITIVE	POSITIVE	POSITIVE
E. coli	OXOID	ATCC 11775	POSITIVE	POSITIVE	POSITIVE	POSITIVE

[a]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 800 CFU/mL.
[b]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 100 CFU/mL.
[c]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 100 CFU/mL.
[d]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 1,000 CFU/mL.
[e]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 110 CFU/mL.
[f]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 770 CFU/mL.
[g]Positive at CFU/mL between 100 – 1,000 at 6 h. Lowest level detected at 6 h was 100 CFU/mL.

Table 4. Exclusivity for non-Coliforms at 6 and 8 hours incubation in the luminometers SS Plus and Pi102. Detection of approximately 10^8 CFU/mL using Coliform and *E. coli* Detection Devices (1)						
Organism	**Source**	**Origin**	**Micro-Snap Coliform**		**Micro-Snap *E. coli***	
			SS+	**Pi 102**	**SS+**	**Pi 102**
MRSA 1	Surrey Hospital	Clinical	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
S. aureus 6538	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Salmonella Virchow	Campden CRA1011	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Salmonella Seftenberg	Campden CRA9281	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Salmonella Infantis	Campden CRA1038	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Salmonella Nottingham	Campden CRA1004	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Serratia flexneri	Campden CRA325	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Serratia boydii	Campden CRA324	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Serratia marcescens	Campden CRA1521	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Serratia proteomaculans	Camp CRA16483	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Serratia liquifaciens	Campden CRA1491	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Edwardsiella tarda	Campden CRA8392	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Providencia rettgeri	Campden CRA8386	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Yersinia enterocolitica	Campden CRA4103	Food (unknown)	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
E. faecalis ATCC 10100	University Surrey	Water	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Proteus vulgaris	Campden CRA1581	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Salmonella Jena NCTC 5765	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Salmonella Dublin NCTC 9676	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
S. Typhimurium 14028	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Candida albicans 10231	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
P. aeruginosa 10145	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Bacillus subtilis 6633	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
L. monocytogenes NCR 5214	University Surrey	Salad	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
L. innocua ATCC 33090	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
Bacillus cereus ATCC 11778	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
P. mirabilis ATCC 43071	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
B. cepacia ATCC 25608	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
S. Enteritidis ATCC 13076	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**
P. fluorescens ATCC 13525	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**

Listeria innocua ATCC 33090	OXOID	Unknown	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**	**NEGATIVE**

Table 5. Enumeration of Coliforms using Micro-Snap Coliform Detection Device vs. Reference Method – Pi102 Luminometer (1)

Run	Target Level[a]	FOOD	Ref. mean[b]	Ref. s_r[c]	Micro-Snap mean	Micro-Snap s_r	Mean difference	p-value[d]	95% LCL[e]	95% UCL[f]
1	10K	BEEF	4.08	0.09	4.30	0.15	-0.21	0.09	-0.48	-0.06
1	1K	*Naturally*	3.23	0.15	3.19	0.26	-0.08	0.57	-0.29	0.12
1	100	*Contaminated*	2.97	0.21	2.70	0.06	0.18	0.07	-0.02	0.38
2	10K	BEEF	4.78	0.27	4.91	0.23	0.13	0.96	-0.44	0.46
2	1K	*E. cloacae (E0002)*	3.92	0.16	4.33	0.27	-0.41	0.08	-0.89	-0.07
2	100	*E. coli ATCC 8739*	2.92	0.31	3.45	0.60	-0.44	0.10	-1.02	0.14
3	10K	BEEF[g]	5.04	0.00	5.12	0.11	-0.08	0.30	-0.25	0.10
3	1K	*Naturally*	3.66	0.00	3.73	0.10	-0.07	0.31	-0.24	0.10
3	100	*Contaminated*	2.38	0.00	2.59	0.18	-0.21	0.13	-0.49	0.09
1	10K	BLT	4.72	0.11	4.99	0.07	-0.27	0.05	0.03	0.48
1	1K	*K. pneumoniae ATCC 700603*	3.63	0.34	3.80	0.12	-0.17	0.20	-0.49	0.14
1	100	*E. coli NCTC 13216*	2.70	0.33	2.71	0.07	-0.01	0.96	-0.45	0.43
1	10K	COD	4.91	0.31	4.23	0.11	0.68	0.00	0.43	0.93
1	1K	*Naturally*	4.59	0.20	4.46	0.08	0.12	0.14	-0.06	0.31
1	100	*Contaminated*	3.37	0.22	3.87	0.40	-0.50	0.13	-1.29	0.25
2	10K	COD	3.74	0.27	3.83	0.16	-0.08	0.25	-0.26	0.09
2	1K	*Naturally*	2.82	0.34	3.20	0.34	-0.29	0.23	-0.86	0.28
2	100	*Contaminated*	1.89	0.19	2.38	0.11	-0.49	0.00	-0.71	-0.27
1	10K	COOKED CHICKEN	3.65	0.25	4.39	0.13	-0.74	0.00	-1.00	-0.48
1	1K	*E. aerogenes ATCC 10006*	3.06	0.07	3.03	0.03	0.03	0.24	-0.03	0.08
1	100	*E. coli ATCC 25922*	1.96	0.05	1.69	0.07	0.26	0.07	0.18	0.34
1	10K	LETTUCE	4.68	0.29	4.71	0.25	-0.04	0.57	-0.20	0.13
1	1K	*K. pneumoniae (ESBL 13)*	3.92	0.22	4.71	0.29	-0.79	0.06	-0.11	1.62
1	100	*E. coli (EC 64)*	3.04	0.00	2.97	0.10	0.07	0.16	-0.04	0.19
1	10k	MILK	4.82	0.03	4.88	0.07	-0.06	0.14	-0.15	0.03
1	1k	*K. oxytoca (K0005)*	3.82	0.03	4.18	0.69	-0.35	0.31	-1.19	0.49
1	100	*E. coli (EC54)*	2.82	0.03	2.98	0.19	-0.15	0.14	-0.38	0.08
2	10k	MILK	4.59	0.04	5.09	0.72	-0.49	0.00	-0.59	-0.39
2	1k	*K. oxytoca (K0005)*	3.61	0.09	5.03	0.06	-1.49	0.00	-1.60	-1.39
2	100	*E. coli (EC54)*	2.62	0.08	2.67	0.03	-0.06	0.23	-0.19	0.06
3	1k	MILK[g]	3.86	0.00	4.09	0.28	-0.23	0.14	-0.50	0.12
3	100	*K. oxytoca (K0005)*	2.90	0.00	2.20	0.05	0.70	0.00	0.63	0.78
3	10	*E. coli (EC54)*	2.06	0.00	1.77	0.21	0.29	0.05	0.01	0.47
1	10k	RAW CHICKEN	4.14	0.14	3.98	0.15	0.16	0.06	-0.01	0.33
1	1k	*Naturally*	3.04	0.00	2.94	0.12	0.09	0.14	-0.05	0.24
1	100	*Contaminated*	2.37	0.35	2.16	0.17	0.21	0.06	-0.02	0.43
2	10k	RAW CHICKEN	4.06	0.18	4.25	0.19	-0.19	0.05	-0.36	-0.02
2	1k	*Naturally*	2.97	0.17	2.82	0.38	0.15	0.24	-0.15	0.43
2	100	*Contaminated*	2.29	0.35	2.15	0.19	0.14	0.15	-0.32	0.25
1	10k	RTE HAM	4.50	0.13	4.12	0.02	0.38	0.07	0.22	0.50
1	1k	*C. diversus (C0011)*	3.34	0.07	3.31	0.07	0.03	0.50	-0.09	0.16
1	100	*E. coli (EC 67)*	2.59	0.39	2.70	0.26	-0.11	0.44	-0.46	0.24
1	10k	PRAWN	3.61	0.13	3.47	0.23	0.13	0.25	-0.14	0.40
1	1k	*Naturally*	2.61	0.13	2.57	0.27	0.05	0.79	-0.40	0.49
1	100	*Contaminated*	1.74	0.20	1.30	0.09	0.44	0.05	0.13	0.75
1	1000	MINERAL	3.29	0.14	3.33	0.35	-0.04	0.75	-0.35	0.28
1	100	*C. freundii (C0012)*	2.31	0.09	2.17	0.61	0.14	0.57	-0.50	0.78
1	10	*E. coli (EC 19)*	1.27	0.13	1.53	0.39	-0.26	0.30	-0.89	0.36

[a]Target levels in cfu/gram
[b]Mean result for the reference method relevant to each food type
[c]Repeatability standard deviation
[d]P-value for a 2-tail unmatched t-test, p-value <0.05 indicates significance at the 95% confidence level
[e]95% Lower confidence limit for difference of means
[f]95% Upper confidence limit for difference of means
[g]Test conducted at the independent laboratory

		Table 6. Enumeration of Coliforms using Micro-Snap Coliform Detection Device vs. Reference Method – EnSURE Luminometer (1)								
Run	Target Level[a]	FOOD	Ref. mean[b]	Ref. s$_r$[c]	Micro-Snap mean	Micro-Snap s$_r$	Mean difference	p-value[d]	95% LCL[e]	95% UCL[f]
1	10K	BEEF	4.08	0.09	4.23	0.10	-0.15	0.07	-0.31	0.02
1	1K	*Naturally*	3.23	0.15	2.97	0.31	0.30	0.11	-0.12	0.49
1	100	*Contaminated*	2.97	0.21	2.46	0.12	0.35	0.12	-0.23	0.74
2	10K	BEEF	4.78	0.27	4.56	0.18	0.26	0.13	-0.12	0.45
2	1K	*E. cloacae (E0002)*	3.92	0.16	4.23	0.23	-0.26	0.06	-0.51	0.03
2	100	*E. coli ATCC 8739*	2.92	0.31	3.45	0.26	-0.46	0.18	-0.38	0.61
3	10K	BEEF[g]	5.04	0.00	4.94	0.11	0.10	0.21	-0.09	0.30
3	1K	*Naturally*	3.66	0.00	3.32	0.12	0.34	0.01	0.13	0.54
3	100	*Contaminated*	2.38	0.00	2.08	0.21	0.20	0.11	-0.07	0.47
1	10K	BLT	4.72	0.11	4.27	0.06	0.46	0.05	-0.35	0.58
1	1K	*K. pneumoniae ATCC 700603*	3.63	0.34	3.38	0.38	0.03	0.86	-0.48	0.48
1	100	*E. coli NCTC 13216*	2.70	0.33	2.40	0.04	0.30	0.12	-0.13	0.43
1	10K	COD	4.91	0.31	4.55	0.18	0.33	0.06	0.03	0.43
1	1K	*Naturally*	4.59	0.20	4.79	0.25	-0.20	0.05	-0.37	-0.02
1	100	*Contaminated*	3.37	0.22	3.80	0.03	-0.32	0.10	-0.48	-0.15
2	10K	COD	3.74	0.27	3.94	0.25	-0.20	0.11	-0.47	0.08
2	1K	*Naturally*	2.82	0.34	3.13	0.17	-0.14	0.37	-0.51	0.25
2	100	*Contaminated*	1.89	0.19	2.11	0.26	-0.28	0.09	-0.48	-0.18
1	10K	COOKED CHICKEN	3.65	0.25	3.34	0.08	0.16	0.13	-0.07	0.38
1	1K	*E. aerogenes ATCC 10006*	3.06	0.07	3.00	0.06	-0.14	0.15	-0.65	0.15
1	100	*E. coli ATCC 25922*	1.96	0.05	1.78	0.21	0.13	0.38	-0.13	0.27
1	10K	LETTUCE	4.68	0.29	4.24	0.48	0.49	0.12	-0.78	0.20
1	1K	*K. pneumoniae (ESBL 13)*	3.92	0.22	3.95	0.34	-0.12	0.43	-0.52	0.27
1	100	*E. coli (EC 64)*	3.04	0.00	3.09	0.11	-0.13	0.18	-0.36	0.09
1	10k	MILK	4.82	0.03	4.63	0.08	0.20	0.05	0.07	0.32
1	1k	*K. oxytoca (K0005)*	3.82	0.03	3.94	0.50	-0.11	0.63	-0.50	0.49
1	100	*E. coli (EC54)*	2.82	0.03	3.11	0.24	-0.29	0.05	-0.56	0.01
2	10k	MILK	4.59	0.04	4.84	0.26	-0.24	0.24	-0.72	0.24
2	1k	*K. oxytoca (K0005)*	3.61	0.09	4.03	0.10	-0.31	0.05	-0.50	0.01
2	100	*E. coli (EC54)*	2.62	0.08	3.12	0.12	-0.51	0.00	-0.56	-0.30
3	1k	MILK[g]	3.86	0.00	2.57	0.09	1.29	0.00	1.13	1.46
3	100	*K. oxytoca (K0005)*	2.90	0.00	1.79	0.07	1.11	0.00	0.99	1.24
3	10	*E. coli (EC54)*	2.06	0.00	2.09	0.06	-0.02	0.56	-0.13	0.09
1	10k	RAW CHICKEN	4.14	0.14	4.43	0.25	-0.24	0.12	-0.50	0.10
1	1k	*Naturally*	3.04	0.00	3.98	0.25	0.78	0.03	-0.96	-0.60
1	100	*Contaminated*	2.37	0.35	2.07	0.16	0.22	0.08	-0.04	0.47
2	10k	RAW CHICKEN	4.06	0.18	4.54	0.51	-0.49	0.16	-0.28	0.30
2	1k	*Naturally*	2.97	0.17	3.40	0.55	-0.43	0.07	-0.41	0.05
2	100	*Contaminated*	2.29	0.35	2.30	0.28	-0.11	0.63	-0.68	0.47
1	10k	RTE HAM	4.50	0.13	4.78	0.13	-0.20	0.14	-0.50	0.10
1	1k	*C. diversus (C0011)*	3.34	0.07	3.67	0.26	-0.31	0.09	-0.48	0.07
1	100	*E. coli (EC 67)*	2.59	0.39	2.44	0.42	0.06	0.73	-0.41	0.50
1	10k	PRAWN	3.61	0.13	3.53	0.40	0.07	0.76	-0.50	0.60
1	1k	*Naturally*	2.61	0.13	2.95	0.34	-0.34	0.15	-0.49	0.18
1	100	*Contaminated*	1.74	0.20	1.61	0.12	0.09	0.40	-0.18	0.37
1	1000	MINERAL	3.29	0.14	3.20	0.40	0.09	0.52	-0.28	0.46
1	100	*C. freundii (C0012)*	2.31	0.09	1.90	0.47	0.35	0.21	-0.28	0.48
1	10	*E. coli (EC 19)*	1.27	0.13	0.90	0.21	0.37	0.06	-0.12	0.47

[a]Target levels in cfu/gram

[b]Mean result for the reference method relevant to each food type

[c]Repeatability standard deviation

[d]P-value for a 2-tail unmatched t-test, p-value <0.05 indicates significance at the 95% confidence level

[e]95% Lower confidence limit for difference of means

[f]95% Upper confidence limit for difference of means

[g]Test conducted at the independent laboratory

Run	Target Level[a]	FOOD	Ref. mean[b]	Ref. s_r[c]	Micro-Snap mean	Micro-Snap s_r	Mean difference	p-value[d]	95% LCL[e]	95% UCL[f]
1	10K	BEEF	4.08	0.09	4.17	0.28	-0.09	0.45	-0.47	-0.11
1	1K	*Naturally*	3.23	0.15	2.90	0.55	0.33	0.32	-0.46	0.50
1	100	*Contaminated*	2.97	0.21	2.03	0.25	0.85	0.00	0.49	1.21
2	10K	BEEF	4.78	0.27	4.71	0.20	0.12	0.53	-0.36	0.51
2	1K	*E. cloacae (E0002)*	3.92	0.16	4.13	0.33	-0.22	0.33	-0.47	0.34
2	100	*E. coli ATCC 8739*	2.92	0.31	3.61	0.32	-0.62	0.00	-0.75	-0.49
3	10K	BEEF[g]	5.04	0.00	5.07	0.18	-0.03	0.85	-0.39	0.34
3	1K	*Naturally*	3.66	0.00	3.40	0.13	0.26	0.05	0.03	0.51
3	100	*Contaminated*	2.38	0.00	2.48	0.10	-0.11	0.22	-0.32	0.10
1	10K	BLT	4.72	0.11	4.62	0.10	0.11	0.08	-0.02	0.25
1	1K	*K. pneumoniae ATCC 700603*	3.63	0.34	3.96	0.10	-0.18	0.12	-0.44	0.07
1	100	*E. coli NCTC 13216*	2.70	0.33	2.49	0.33	0.22	0.24	-0.22	0.67
1	10K	COD	4.91	0.31	4.45	0.17	0.46	0.04	0.04	0.87
1	1K	*Naturally*	4.59	0.20	4.90	0.21	-0.32	0.06	-0.65	0.02
1	100	*Contaminated*	3.37	0.22	3.90	0.20	-0.53	0.08	-1.17	0.11
2	10K	COD	3.74	0.27	4.13	0.20	-0.29	0.12	-0.50	0.11
2	1K	*Naturally*	2.82	0.34	3.48	0.41	-0.26	0.16	-0.61	0.16
2	100	*Contaminated*	1.89	0.19	2.14	0.12	-0.25	0.07	-0.48	0.39
1	10K	COOKED CHICKEN	3.65	0.25	3.17	0.07	0.42	0.04	0.17	0.86
1	1K	*E. aerogenes ATCC 10006*	3.06	0.07	2.96	0.05	0.10	0.06	-0.01	0.19
1	100	*E. coli ATCC 25922*	1.96	0.05	1.76	0.07	0.09	0.19	-0.07	0.26
1	10K	LETTUCE	4.68	0.29	4.77	0.44	-0.04	0.52	-0.49	0.47
1	1K	*K. pneumoniae (ESBL 13)*	3.92	0.22	4.27	0.59	-0.45	0.22	-0.32	0.42
1	100	*E. coli (EC 64)*	3.04	0.00	2.81	0.17	0.16	0.05	-0.01	0.32
1	10k	MILK	4.82	0.03	4.17	0.09	0.65	0.00	0.52	0.79
1	1k	*K. oxytoca (K0005)*	3.82	0.03	3.58	0.38	0.25	0.22	-0.22	0.41
1	100	*E. coli (EC54)*	2.82	0.03	2.76	0.13	0.06	0.44	-0.15	0.28
2	10k	MILK	4.59	0.04	4.53	0.16	0.06	0.50	-0.16	0.28
2	1k	*K. oxytoca (K0005)*	3.61	0.09	3.61	0.16	-0.00	0.90	-0.09	-0.09
2	100	*E. coli (EC54)*	2.62	0.08	2.36	0.36	0.26	0.17	-0.18	0.69
3	1k	MILK[g]	3.86	0.00	2.75	0.10	1.12	0.00	0.90	1.33
3	100	*K. oxytoca (K0005)*	2.90	0.00	2.50	0.04	0.40	0.05	-0.12	0.49
3	10	*E. coli (EC54)*	2.06	0.00	2.63	0.03	-0.58	0.00	-0.63	-0.52
1	10k	RAW CHICKEN	4.14	0.14	4.45	0.17	-0.31	0.09	-0.51	0.09
1	1k	*Naturally*	3.04	0.00	3.57	0.40	-0.41	0.38	-0.54	0.70
1	100	*Contaminated*	2.37	0.35	2.90	0.11	-0.62	0.05	-0.10	1.21
2	10k	RAW CHICKEN	4.06	0.18	4.14	0.36	-0.08	0.81	-0.67	0.51
2	1k	*Naturally*	2.97	0.17	2.79	0.39	0.17	0.50	-0.42	0.43
2	100	*Contaminated*	2.29	0.35	2.23	0.13	0.05	0.76	-0.43	0.50
1	10k	RTE HAM	4.50	0.13	4.24	0.16	0.32	0.09	-0.08	0.52
1	1k	*C. diversus (C0011)*	3.34	0.07	3.65	0.12	-0.33	0.06	-0.04	0.58
1	100	*E. coli (EC 67)*	2.59	0.39	2.78	0.26	-0.28	0.15	-0.42	0.16
1	10k	PRAWN	3.61	0.13	3.73	0.24	-0.13	0.69	-0.49	0.61
1	1k	*Naturally*	2.61	0.13	2.69	0.11	-0.03	0.45	-0.50	0.56
1	100	*Contaminated*	1.74	0.20	2.11	0.10	-0.27	0.21	-0.45	0.21
1	1000	MINERAL	3.29	0.14	3.27	0.32	0.01	0.90	-0.35	0.36
1	100	*C. freundii (C0012)*	2.31	0.09	1.83	0.37	0.45	0.13	-0.19	0.53
1	10	*E. coli (EC 19)*	1.27	0.13	1.21	0.10	0.06	0.51	-0.19	0.33

Table 7. Enumeration of Coliforms using Micro-Snap Coliform Detection Device vs. Reference Method – SS Plus Luminometer (1)

[a]Target levels in cfu/gram
[b]Mean result for the reference method relevant to each food type
[c]Repeatability standard deviation
[d]P-value for a 2-tail unmatched t-test, p-value <0.05 indicates significance at the 95% confidence level
[e]95% Lower confidence limit for difference of means
[f]95% Upper confidence limit for difference of means
[g]Test conducted at the independent laboratory

Run	Target Level[a]	FOOD	Ref. mean[b]	Ref. s_r[c]	Micro-Snap mean	Micro-Snap s_r	Mean difference	p-value[d]	95% LCL[e]	95% UCL[f]
		Table 8. Enumeration of *E. coli* using Micro-Snap *E. coli* Detection Device vs. Reference Method – Pi 102 Luminometer (1)								
1	10K	BEEF	3.71	0.24	3.90	0.32	-0.19	0.45	-0.50	0.44
1	1K	*Naturally*	2.78	0.15	3.10	0.14	-0.32	0.05	-0.01	0.64
1	100	*Contaminated*	2.61	0.25	2.33	0.55	0.28	0.22	-0.26	0.48
2	10K	BEEF	4.90	0.15	5.05	0.14	-0.15	0.35	-0.54	0.25
2	1K	*E. cloacae (E0002)*	3.62	0.42	3.85	0.24	-0.23	0.40	-0.41	0.44
2	100	*E. coli ATCC 8739*	2.63	0.27	2.83	0.12	-0.21	0.26	-0.53	0.21
3	10K	BEEF[g]	4.66	0.00	4.64	0.11	0.03	0.71	-0.15	0.20
3	1K	*Naturally*	3.58	0.00	3.12	0.24	0.46	0.12	-0.60	0.28
3	100	*Contaminated*	0.79	0.00	0.87	0.48	-0.07	0.80	-0.46	0.49
1	10K	BLT	4.18	0.14	3.97	0.10	0.20	0.06	-0.02	0.42
1	1K	*K. pneumoniae ATCC 700603*	3.51	0.42	3.13	0.10	0.37	0.14	-0.20	0.94
1	100	*E. coli NCTC 13216*	2.11	0.20	2.31	0.19	-0.19	0.33	-0.66	0.28
1	10K	COD	4.50	0.31	4.47	0.05	0.02	0.87	-0.32	0.36
1	1K	*Naturally*	3.85	0.19	3.79	0.19	0.06	0.70	-0.32	0.43
1	100	*Contaminated*	2.70	0.25	2.67	0.16	0.02	0.81	-0.18	0.22
2	10K	COD	3.42	0.31	3.58	0.06	-0.16	0.38	-0.60	0.29
2	1K	*Naturally*	2.84	0.47	2.70	0.28	0.14	0.34	-0.23	0.51
2	100	*Contaminated*	1.94	0.22	2.42	0.39	-0.48	0.07	-0.07	0.61
1	10K	COOKED CHICKEN	3.66	0.26	4.25	0.33	-0.58	0.04	-1.13	-0.04
1	1K	*E. aerogenes ATCC 10006*	3.04	0.49	2.93	0.35	0.11	0.61	-0.46	0.69
1	100	*E. coli ATCC 25922*	2.04	0.09	1.69	0.36	0.35	0.18	-0.24	0.52
1	10K	LETTUCE	4.03	0.24	4.11	0.07	-0.08	0.48	-0.36	0.20
1	1K	*K. pneumoniae (ESBL 13)*	2.93	0.09	3.15	0.34	-0.22	0.35	-0.78	0.35
1	100	*E. coli (EC 64)*	2.13	0.55	2.10	0.52	-0.50	0.01	-0.77	-0.24
1	10k	MILK	4.47	0.31	4.97	0.04	-0.50	0.02	-0.82	-0.14
1	1k	*K. oxytoca (K0005)*	3.85	0.19	3.80	0.19	0.06	0.70	-0.32	0.43
1	100	*E. coli (EC54)*	2.70	0.25	2.68	0.16	0.02	0.81	-0.18	0.22
2	10k	MILK	4.40	0.18	4.28	0.15	0.11	0.42	-0.24	0.47
2	1k	*K. oxytoca (K0005)*	3.31	0.13	3.17	0.16	0.15	0.18	-0.11	0.42
2	100	*E. coli (EC54)*	2.34	0.20	2.29	0.19	0.05	0.65	-0.21	0.30
3	1k	MILK[g]	4.04	0.00	4.21	0.31	-0.08	0.70	-0.60	0.44
3	100	*K. oxytoca (K0005)*	1.46	0.00	1.78	0.14	-0.29	0.01	-0.47	-0.12
3	10	*E. coli (EC54)*	1.63	0.00	1.60	0.17	-0.05	0.57	-0.26	0.16
1	10k	RAW CHICKEN	3.69	0.31	3.47	0.05	0.21	0.20	-0.17	0.59
1	1k	*Naturally*	2.43	0.16	2.30	0.19	0.14	0.38	-0.24	0.51
1	100	*Contaminated*	1.66	0.14	1.12	0.16	0.54	0.03	0.10	0.86
2	10k	RAW CHICKEN	3.07	0.13	2.87	0.32	0.20	0.37	-0.34	0.51
2	1k	*Naturally*	2.44	0.01	2.16	0.10	0.28	0.01	0.11	0.44
2	100	*Contaminated*	1.45	0.10	1.57	0.09	-0.12	0.16	-0.32	0.07
1	10k	RTE HAM	3.61	0.33	3.61	0.10	0.01	0.98	-0.47	0.48
1	1k	*C. diversus (C0011)*	3.22	0.33	3.51	0.40	-0.29	0.27	-0.50	0.33
1	100	*E. coli (EC 67)*	2.06	0.20	1.60	0.09	0.20	0.05	-0.48	0.41
1	10k	PRAWN	3.09	0.24	2.97	0.69	0.12	0.77	-0.48	0.51
1	1k	*Naturally*	1.98	0.23	1.21	0.64	0.77	0.05	-0.03	1.52
1	100	*Contaminated*	1.05	0.23	1.10	0.32	-0.04	0.92	-0.53	0.54
1	1000	MINERAL	3.71	0.24	3.90	0.32	-0.19	0.45	-0.50	0.44
1	100	*C. freundii (C0012)*	2.78	0.15	3.10	0.14	-0.32	0.05	-0.01	0.64
1	10	*E. coli (EC 19)*	2.61	0.25	2.33	0.55	0.28	0.22	-0.26	0.48

[a]Target levels in cfu/gram

[b]Mean result for the reference method relevant to each food type

[c]Repeatability standard deviation

[d]P-value for a 2-tail unmatched t-test, p-value <0.05 indicates significance at the 95% confidence level

[e]95% Lower confidence limit for difference of means

[f]95% Upper confidence limit for difference of means

[g]Test conducted at the independent laboratory

Table 9. Enumeration of *E. coli* using Micro-Snap *E. coli* Detection Device vs. Reference Method – EnSURE Luminometer (1)									
Run	Target Level[a]	FOOD	Ref. mean[b]	Ref. s[c]	Micro-Snap mean	Micro-Snap s$_r$	Mean difference	p-value[d]	95% LCL[e]	95% UCL[f]
1	10K	BEEF	3.71	0.24	3.89	0.34	-0.17	0.58	-0.44	0.43
1	1K	*Naturally*	2.78	0.15	2.76	0.17	-0.06	0.72	-0.51	0.39
1	100	*Contaminated*	2.61	0.25	2.22	0.13	0.39	0.09	-0.68	0.11
2	10K	BEEF	4.90	0.15	4.55	0.30	0.35	0.18	-0.25	0.95
2	1K	*E. cloacae (E0002)*	3.62	0.42	4.04	0.20	-0.42	0.05	-0.57	0.08
2	100	*E. coli ATCC 8739*	2.63	0.27	3.25	0.10	-0.62	0.00	-0.86	-0.38
3	10K	BEEF[g]	4.66	0.00	4.24	0.07	0.42	0.05	-0.09	0.54
3	1K	*Naturally*	3.58	0.00	2.80	0.24	0.78	0.00	0.42	1.14
3	100	*Contaminated*	0.79	0.00	2.34	0.07	-1.55	0.00	-1.66	-1.43
1	10K	BLT	4.18	0.14	3.83	0.31	0.34	0.09	-0.07	0.77
1	1K	*K. pneumoniae ATCC 700603*	3.51	0.42	3.06	0.30	0.45	0.17	-0.30	0.68
1	100	*E. coli NCTC 13216*	2.11	0.20	1.99	0.09	0.12	0.37	-0.21	0.45
1	10K	COD	4.50	0.31	4.34	0.08	0.16	0.26	-0.17	0.49
1	1K	*Naturally*	3.85	0.19	4.19	0.21	-0.33	0.09	-0.73	0.08
1	100	*Contaminated*	2.70	0.25	2.94	0.19	-0.24	0.04	-0.48	-0.01
2	10K	COD	3.42	0.31	3.51	0.05	-0.09	0.61	-0.54	0.36
2	1K	*Naturally*	2.84	0.47	2.55	0.20	0.29	0.11	-0.11	0.60
2	100	*Contaminated*	1.94	0.22	2.34	0.19	-0.40	0.07	-0.05	0.61
1	10K	COOKED CHICKEN	3.66	0.26	3.32	0.08	0.28	0.13	-0.13	0.69
1	1K	*E. aerogenes ATCC 10006*	3.04	0.49	2.33	0.06	0.07	0.74	-0.45	0.58
1	100	*E. coli ATCC 25922*	2.04	0.09	1.60	0.21	0.07	0.38	-0.13	0.27
1	10K	LETTUCE	4.03	0.24	4.35	0.44	-0.39	0.06	-0.51	0.03
1	1K	*K. pneumoniae (ESBL 13)*	2.93	0.09	3.01	0.23	-0.06	0.67	-0.45	0.32
1	100	*E. coli (EC 64)*	2.13	0.55	2.54	0.28	-0.41	0.30	-0.68	0.48
1	10k	MILK	4.47	0.31	4.34	0.11	0.16	0.26	-0.17	0.49
1	1k	*K. oxytoca (K0005)*	3.85	0.19	4.19	0.30	-0.33	0.09	-0.73	0.08
1	100	*E. coli (EC54)*	2.70	0.25	2.94	0.27	-0.23	0.05	-0.48	0.01
2	10k	MILK	4.40	0.18	4.06	0.18	0.32	0.07	-0.04	0.52
2	1k	*K. oxytoca (K0005)*	3.31	0.13	3.47	0.17	-0.15	0.05	-0.29	0.02
2	100	*E. coli (EC54)*	2.34	0.20	2.48	0.32	-0.14	0.44	-0.32	0.61
3	1k	MILK[g]	4.04	0.00	3.00	0.35	1.04	0.00	0.54	2.91
3	100	*K. oxytoca (K0005)*	1.46	0.00	1.74	0.14	-0.28	0.02	0.02	028
3	10	*E. coli (EC54)*	1.63	0.00	1.20	0.13	0.43	0.29	-0.53	0.41
1	10k	RAW CHICKEN	3.69	0.31	3.34	0.08	0.35	0.06	-0.02	0.51
1	1k	*Naturally*	2.43	0.16	3.07	0.21	-0.64	0.01	-0.96	-0.31
1	100	*Contaminated*	1.66	0.14	1.94	0.19	-0.29	0.15	-0.46	0.16
2	10k	RAW CHICKEN	3.07	0.13	2.97	0.38	0.07	0.75	-0.50	0.64
2	1k	*Naturally*	2.44	0.01	3.10	0.20	-0.66	0.01	-0.61	-0.30
2	100	*Contaminated*	1.45	0.10	1.33	0.20	-0.09	0.71	-0.43	0.55
1	10k	RTE HAM	3.61	0.33	3.78	0.44	-0.11	0.79	-0.53	0.49
1	1k	*C. diversus (C0011)*	3.22	0.33	3.69	0.23	-0.45	0.07	-0.59	0.06
1	100	*E. coli (EC 67)*	2.06	0.20	2.67	0.13	-0.55	0.05	-0.56	0.01
1	10k	PRAWN	3.09	0.24	3.00	0.35	0.04	0.90	-0.44	0.52
1	1k	*Naturally*	1.98	0.23	2.07	0.04	-0.02	0.86	-0.25	0.22
1	100	*Contaminated*	1.05	0.23	2.04	0.04	-0.99	0.00	-1.26	-0.73
1	1000	MINERAL	3.71	0.24	3.89	0.34	-0.17	0.58	-0.44	0.43
1	100	*C. freundii (C0012)*	2.78	0.15	2.76	0.17	-0.06	0.72	-0.51	0.39
1	10	*E. coli (EC 19)*	2.61	0.25	2.22	0.13	0.39	0.09	-0.68	0.11

[a]Target levels in cfu/gram

[b]Mean result for the reference method relevant to each food type

[c]Repeatability standard deviation

[d]P-value for a 2-tail unmatched t-test, p-value <0.05 indicates significance at the 95% confidence level

[e]95% Lower confidence limit for difference of means

[f]95% Upper confidence limit for difference of means

[g]Test conducted at the independent laboratory

Run	Target Level[a]	FOOD	Ref. mean[b]	Ref. s_r[c]	Micro-Snap mean	Micro-Snap s_r	Mean difference	p-value[d]	95% LCL[e]	95% UCL[f]
		Table 10. Enumeration of *E. coli* using Micro-Snap *E. coli* Detection Device vs. Reference Method – SS Plus Luminometer (1)								
1	10K	BEEF	3.71	0.24	3.46	0.18	0.25	0.55	-0.38	0.50
1	1K	*Naturally*	2.78	0.15	2.56	0.23	0.13	0.53	-0.42	0.49
1	100	*Contaminated*	2.61	0.25	2.18	0.11	0.43	0.00	0.19	0.67
2	10K	BEEF	4.90	0.15	4.47	0.25	0.43	0.01	0.35	0.51
2	1K	*E. cloacae (E0002)*	3.62	0.42	4.15	0.21	-0.47	0.13	-0.43	0.23
2	100	*E. coli ATCC 8739*	2.63	0.27	2.87	0.18	-0.25	0.13	-0.60	0.11
3	10K	BEEF[g]	4.66	0.00	4.38	0.11	0.28	0.17	-0.18	0.44
3	1K	*Naturally*	3.58	0.00	2.80	NA	1.78	NA	NA	NA
3	100	*Contaminated*	0.79	0.00	0.88	0.15	-0.08	0.49	-0.39	0.23
1	10K	BLT	4.18	0.14	4.00	0.36	0.15	0.48	-0.38	0.67
1	1K	*K. pneumoniae ATCC 700603*	3.51	0.42	3.33	0.20	0.06	0.73	-0.43	0.46
1	100	*E. coli NCTC 13216*	2.11	0.20	2.33	0.23	-0.18	0.17	-0.48	0.12
1	10K	COD	4.50	0.31	4.30	0.10	0.19	0.26	-0.22	0.61
1	1K	*Naturally*	3.85	0.19	4.15	0.20	-0.30	0.14	-0.75	0.16
1	100	*Contaminated*	2.70	0.25	2.73	0.18	-0.04	0.60	-0.24	0.16
2	10K	COD	3.42	0.31	3.69	0.19	-0.27	0.23	-0.40	0.26
2	1K	*Naturally*	2.84	0.47	2.73	0.15	0.11	0.53	-0.34	0.55
2	100	*Contaminated*	1.94	0.22	2.53	0.17	-0.59	0.01	-0.97	-0.22
1	10K	COOKED CHICKEN	3.66	0.26	3.66	0.48	-0.01	0.98	-0.50	0.61
1	1K	*E. aerogenes ATCC 10006*	3.04	0.49	3.18	0.18	-0.12	0.64	-0.48	0.59
1	100	*E. coli ATCC 25922*	2.04	0.09	1.94	0.22	0.10	0.36	-0.17	0.38
1	10K	LETTUCE	4.03	0.24	3.80	0.21	0.23	0.25	-0.25	0.51
1	1K	*K. pneumoniae (ESBL 13)*	2.93	0.09	2.96	0.44	-0.03	0.91	-0.41	0.35
1	100	*E. coli (EC 64)*	2.13	0.55	1.94	0.16	0.18	0.30	-0.25	0.41
1	10k	MILK	4.47	0.31	4.30	0.10	0.19	0.26	-0.22	0.61
1	1k	*K. oxytoca (K0005)*	3.85	0.19	4.15	0.20	-0.30	0.14	-0.75	0.16
1	100	*E. coli (EC54)*	2.70	0.25	2.73	0.18	-0.04	0.60	-0.24	0.16
2	10k	MILK	4.40	0.18	3.79	0.18	0.60	0.03	0.09	1.13
2	1k	*K. oxytoca (K0005)*	3.31	0.13	3.28	0.26	0.03	0.78	-0.27	0.33
2	100	*E. coli (EC54)*	2.34	0.20	2.55	0.31	-0.35	0.03	-0.64	-0.05
3	1k	MILK[g]	4.04	0.00	3.42	0.09	0.62	0.03	0.04	0.80
3	100	*K. oxytoca (K0005)*	1.46	0.00	1.60	0.15	-0.14	0.25	-0.43	0.15
3	10	*E. coli (EC54)*	1.63	0.00	1.78	0.11	-0.14	0.05	-0.25	0.03
1	10k	RAW CHICKEN	3.69	0.31	3.80	0.11	-0.11	0.46	-0.51	0.28
1	1k	*Naturally*	2.43	0.16	2.94	0.25	-0.45	0.05	-0.92	0.01
1	100	*Contaminated*	1.66	0.14	2.14	0.19	-0.48	0.02	-0.71	-0.11
2	10k	RAW CHICKEN	3.07	0.13	3.20	0.17	-0.13	0.38	-0.50	0.23
2	1k	*Naturally*	2.44	0.01	2.69	0.24	-0.26	0.11	-0.60	0.09
2	100	*Contaminated*	1.45	0.10	2.51	0.21	-1.07	0.00	-1.57	-0.58
1	10k	RTE HAM	3.61	0.33	3.66	0.25	-0.05	0.86	-0.53	0.46
1	1k	*C. diversus (C0011)*	3.22	0.33	3.36	0.38	-0.11	0.66	-0.47	0.36
1	100	*E. coli (EC 67)*	2.06	0.20	2.35	0.12	-0.29	0.14	-0.42	0.15
1	10k	PRAWN	3.09	0.24	2.70	0.37	0.35	0.21	-0.32	0.62
1	1k	*Naturally*	1.98	0.23	1.82	0.04	0.23	0.06	-0.01	0.46
1	100	*Contaminated*	1.05	0.23	1.63	0.14	-0.51	0.04	-0.61	0.01
1	1000	MINERAL	3.71	0.24	3.46	0.18	0.25	0.55	-0.38	0.50
1	100	*C. freundii (C0012)*	2.78	0.15	2.56	0.23	0.13	0.53	-0.42	0.49
1	10	*E. coli (EC 19)*	2.61	0.25	2.18	0.11	0.43	0.00	0.19	0.67

[a]Target levels in cfu/gram

[b]Mean result for the reference method relevant to each food type

[c]Repeatability standard deviation

[d]P-value for a 2-tail unmatched t-test, p-value <0.05 indicates significance at the 95% confidence level

[e]95% Lower confidence limit for difference of means

[f]95% Upper confidence limit for difference of means

[g]Test conducted at the independent laboratory

Table 11. Detection of Coliforms using Micro-Snap Coliform Detection Device vs. Reference Method (1)											
Matrix	**Inoculating Strains**	**MPN[a]/Portion**	**Instrument**	**N[b]**	**Hygiena Micro-Snap Coliform Detection Device**				**Reference Method[g]**		**dPOD_C[i]**
					Presumptive		**Confirmed**		**dPOD_CP[f]**		
					X[c]	**POD_CP[d]**	**x**	**POD_CC[e]**		**x**	**POD_R[h]**	
Raw ground beef - 1	Naturally Contaminated	201 (124,281)	SS Plus	5	5	1.00 (0.84, 1.00)	5	1.00 (0.84, 1.00)	0.00 (-0.26, 0.26)	5	1.00 (0.84, 1.00)	0.00 (-0.26, 0.26)
			EnSURE	5	5	1.00 (0.84, 1.00)	5	1.00 (0.84, 1.00)	0.00 (-0.26, 0.26)	5	1.00 (0.84, 1.00)	0.00 (-0.26, 0.26)
			Pi102	5	5	1.00 (0.84, 1.00)	5	1.00 (0.84, 1.00)	0.00 (-0.26, 0.26)	5	1.00 (0.84, 1.00)	0.00 (-0.26, 0.26)
		254 (185,320)	SS Plus	20	19	0.95 (0.76, 1.00)	19	0.95 (0.76, 1.00)	0.00 (-0.19, 0.19)	20	1.00 (0.84, 1.00)	-0.05 (-0.24, 0.12)
			EnSURE	20	19	0.95 (0.76, 1.00)	19	0.95 (0.76, 1.00)	0.00 (-0.19, 0.19)	20	1.00 (0.84, 1.00)	-0.05 (-0.24, 0.12)
			Pi102	20	19	0.95 (0.76, 1.00)	19	0.95 (0.76, 1.00)	0.00 (-0.19, 0.19)	20	1.00 (0.84, 1.00)	-0.05 (-0.24, 0.12)
Raw ground beef - 2	*E. cloacae* (E0002) *E. coli* (ATCC 8739)	<3.0	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
		5.02 (3.39, 6.65)	SS Plus	20	10	0.50 (0.30, 0.70)	12	0.60 (0.39, 0.78)	-0.10 (-0.37, 0.19)	11	0.55 (0.34, 0.74)	0.05 (-0.24, 0.33)
			EnSURE	20	12	0.60 (0.39, 0.78)	12	0.60 (0.39, 0.78)	0.00 (-0.28, 0.28)	11	0.55 (0.34, 0.74)	0.05 (-0.24, 0.33)
			Pi102	20	11	0.55 (0.34, 0.74)	12	0.60 (0.39, 0.78)	-0.05 (-0.33, 0.24)	11	0.55 (0.34, 0.74)	0.00 (-0.28, 0.28)
Raw ground beef[j]	Naturally contaminated	9.76 (5.98, 13.50)	SS Plus	20	12	0.60 (0.39, 0.78)	15	0.75 (0.53, 0.89)	-0.15 (-0.40, 0.13)	17	0.85 (0.64, 0.95)	-0.25 (-0.48, 0.03)
			EnSURE	20	12	0.60 (0.39, 0.78)	15	0.75 (0.53, 0.89)	-0.15 (-0.40, 0.13)	17	0.85 (0.64, 0.95)	-0.25 (-0.48, 0.03)
			Pi102	20	14	0.70 (0.48, 0.85)	15	0.75 (0.53, 0.89)	-0.05 (-0.31, 0.22)	17	0.85 (0.64, 0.95)	-0.15 (-0.39, 0.11)
Raw cod - 1	Naturally contaminated	3.1	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
		8.61 (3.21-12.82)	SS Plus	20	16	0.80 (0.58, 0.92)	16	0.80 (0.58, 0.92)	0.00 (-0.44, 0.44)	17	0.85 (0.64, 0.95)	-0.05 (-0.29, 0.19)
			EnSURE	20	19	0.95 (0.76, 1.00)	16	0.80 (0.58, 0.92)	0.15 (-0.07, 0.37)	17	0.85 (0.64, 0.95)	-0.05 (-0.29, 0.19)
			Pi102	20	19	0.95 (0.76, 1.00)	16	0.80 (0.58, 0.92)	0.15 (-0.07, 0.37)	17	0.85 (0.64, 0.95)	-0.05 (-0.29, 0.19)
Raw cod - 2	Naturally contaminated	<3.0	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
		3.36 (1.42, 4.78)	SS Plus	20	15	0.75 (0.53, 0.89)	14	0.70 (0.48, 0.85)	0.05 (-0.22, 0.31)	11	0.55 (0.34, 0.74)	0.15 (-0.14, 0.41)
			EnSURE	20	16	0.80 (0.58, 0.92)	14	0.70 (0.48, 0.85)	0.10 (-0.17, 0.35)	11	0.55 (0.34, 0.74)	0.15 (-0.14, 0.41)
			Pi102	20	14	0.70 (0.48, 0.85)	14	0.70 (0.48, 0.85)	0.00 (-0.27, 0.27)	11	0.55 (0.34, 0.74)	0.15 (-0.14, 0.41)
Cooked	*E. aerogenes* (ATCC 10006) *E. coli*	<3.0	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			Pi102	5	0	0	0	0	0	0	0	0

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Matrix	Organism	Level	Method	N	n	Prop (CI)	n	Prop (CI)	Diff (CI)	n	Prop (CI)	Diff (CI)
chicken	(ATCC 25922)					(0.00, 0.44)		(0.00, 0.44)	(-0.44, 0.44)		(0.00, 0.44)	(-0.44, 0.44)
		6.72 (5.31, 8.1)	SS Plus	20	14	0.70 (0.48, 0.85)	16	0.80 (0.58, 0.92)	-0.10 (-0.35, 0.17)	14	0.70 (0.48, 0.85)	0.00 (-0.27, 0.27)
			EnSURE	20	17	0.85 (0.64, 0.95)	16	0.80 (0.58, 0.92)	0.05 (-0.19, 0.29)	14	0.70 (0.48, 0.85)	0.10 (-0.17, 0.35)
			Pi102	20	17	0.85 (0.64, 0.95)	16	0.80 (0.58, 0.92)	0.05 (-0.19, 0.29)	14	0.70 (0.48, 0.85)	0.10 (-0.17, 0.35)
Milk - 2	*K. oxytoca* (K0005) *E. coli* (EC 54)	<3.0	SS Plus	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			EnSURE	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			Pi102	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
		5.7 (2.4, 7.7)	SS Plus	20	15	0.75 (0.53, 0.89)	15	0.75 (0.53, 0.89)	0.00 (-0.26, 0.26)	17	0.85 (0.64, 0.95)	-0.10 (-0.34, 0.15)
			EnSURE	20	15	0.75 (0.53, 0.89)	15	0.75 (0.53, 0.89)	0.00 (-0.26, 0.26)	17	0.85 (0.64, 0.95)	-0.10 (-0.34, 0.15)
			Pi102	20	16	0.80 (0.58, 0.92)	15	0.75 (0.53, 0.89)	0.05 (-0.21, 0.30)	17	0.85 (0.64, 0.95)	-0.10 (-0.34, 0.15)
Milk[j]	*K. oxytoca* (K0005) *E. coli* (EC 54)	<10	SS Plus	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			EnSURE	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			Pi102	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
		13.8 (6.12, 20.3)	SS Plus	20	19	0.95 (0.76, 1.00)	15	0.75 (0.53, 0.89)	0.20 (-0.03, 0.42)	17	0.85 (0.64, 0.95)	-0.10 (-0.34, 0.15)
			EnSURE	20	16	0.80 (0.58, 0.92)	15	0.75 (0.53, 0.89)	0.05 (-0.21, 0.30)	17	0.85 (0.64, 0.95)	-0.10 (-0.34, 0.15)
			Pi102	20	16	0.80 (0.58, 0.92)	15	0.75 (0.53, 0.89)	0.05 (-0.21, 0.30)	17	0.85 (0.64, 0.95)	-0.10 (-0.34, 0.15)
Raw chicken - 1	Naturally contaminated	<3.0	SS Plus	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			EnSURE	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			Pi102	5	1	0.20 (0.08, 0.42)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
		4.43 (3.15, 5.71)	SS Plus	20	15	0.75 (0.53, 0.89)	16	0.80 (0.58, 0.89)	-0.05 (-0.30, 0.21)	18	0.90 (0.76, 1.00)	-0.15 (-0.38, 0.09)
			EnSURE	20	17	0.85 (0.64, 0.95)	16	0.80 (0.58, 0.89)	0.05 (-0.19, 0.29)	18	0.90 (0.76, 1.00)	-0.10 (-0.33, 0.13)
			Pi102	20	16	0.80 (0.58, 0.89)	16	0.80 (0.58, 0.89)	0.00 (-0.25, 0.25)	18	0.90 (0.76, 1.00)	-0.10 (-0.33, 0.13)
Raw chicken - 2	Naturally contaminated	<3.0	SS Plus	5	0	0.00 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
			EnSURE	5	0	0.00 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
			Pi102	5	1	0.20 (0.08, 0.42)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
		1.35 (0.22, 2.48)	SS Plus	20	9	0.45 (0.26, 0.66)	8	0.40 (0.22, 0.61)	0.05 (-0.24, 0.33)	6	0.30 (0.15, 0.52)	0.10 (-0.18, 0.36)
			EnSURE	20	9	0.45 (0.26, 0.66)	8	0.40 (0.22, 0.61)	0.05 (-0.24, 0.33)	6	0.30 (0.15, 0.52)	0.10 (-0.18, 0.36)
			Pi102	20	9	0.45 (0.26, 0.66)	8	0.40 (0.22, 0.61)	0.05 (-0.24, 0.33)	6	0.30 (0.15, 0.52)	0.10 (-0.18, 0.36)
Raw prawn	Naturally contaminated	<3.0	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
		5.46 (0.73, 9.19)	SS Plus	20	19	0.95 (0.76, 1.00)	17	0.85 (0.64, 0.95)	0.10 (-0.11, 0.32)	15	0.75 (0.53, 0.89)	0.10 (-0.15, 0.34)
			EnSURE	20	19	0.95 (0.76, 1.00)	17	0.85 (0.64, 0.95)	0.10 (-0.11, 0.32)	15	0.75 (0.53, 0.89)	0.10 (-0.15, 0.34)
			Pi102	20	17	0.95 (0.76, 1.00)	17	0.85 (0.64, 0.95)	0.00 (-0.44, 0.44)	15	0.75 (0.53, 0.89)	0.10 (-0.15, 0.34)
Mineral water	*C. fruendii* (C0012) *E. coli*	<1.00	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0	0	0	0	0	0	0

						(0.00, 0.44)		(0.00, 0.44)	(-0.44, 0.44)		(0.00, 0.44)	(-0.44, 0.44)
(EC 67)		Pi102	5	0	0	(0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
	1.77 (0.77, 2.77)	SS Plus	20	5	0.25 (0.11, 0.47)	9	0.45 (0.26, 0.66)	-0.20 (-0.45, 0.09)	9	0.45 (0.26, 0.66)	-0.20 (-0.45, 0.09)
		EnSURE	20	5	0.25 (0.11, 0.47)	9	0.45 (0.26, 0.66)	-0.20 (-0.45, 0.09)	9	0.45 (0.26, 0.66)	-0.20 (-0.45, 0.09)
		Pi102	20	9	0.45 (0.26, 0.66)	9	0.45 (0.26, 0.66)	0.00 (-0.28, 0.28)	9	0.45 (0.26, 0.66)	0.00 (-0.28, 0.28)

[a]MPN = Most Probable Number is based on the POD of reference method
[b]N = Number of test potions
[c]x = Number of positive test portions
[d]POD_CP = Candidate method presumptive positive outcomes divided by the total number of trials
[e]POD_CC = Candidate method confirmed positive outcomes divided by the total number of trials
[f]dPOD_CP = Difference between the candidate method presumptive result and candidate method confirmed result POD values. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[g]Reference Method used was appropriate to the food type
[h]POD_R = Reference method positive outcomes divided by the total number of trials
[i]dPOD_C = Difference between the candidate method confirmed result and the reference method result POD values. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level
[j]Study conducted at the independent laboratory

Table 12. Detection of *E. coli* using Micro-Snap *E. coli* Detection Device vs. Reference Method (1)											
					Hygiena Micro-Snap *E. coli* Detection Device					Reference Method[g]		dPOD_C[i]
Matrix	Inoculating Strains	MPN[a]/Portion	Instrument	N[b]	Presumptive		Confirmed		dPOD_CP[f]			
					X[c]	POD_CP[d]	x	POD_CC[e]		x	POD_R[h]	
Raw ground beef - 1	Naturally contaminated	1.1 (0.2, 2.3)	SS Plus	5	2	0.10 (0.03, 0.30)	1	0.05 (0.00, 0.24)	0.05 (-0.15, 0.26)	2	0.10 (0.03, 0.30)	-0.05 (-0.26, 0.15)
			EnSURE	5	2	0.10 (0.03, 0.30)	1	0.05 (0.00, 0.24)	0.05 (-0.15, 0.26)	2	0.10 (0.03, 0.30)	-0.05 (-0.26, 0.15)
			Pi102	5	2	0.10 (0.03, 0.30))	1	0.05 (0.00, 0.24)	0.05 (-0.15, 0.26)	2	0.10 (0.03, 0.30))	-0.05 (-0.26, 0.15)
		49.5 (22.1, 67.2)	SS Plus	20	13	0.65 (0.43, 0.82)	9	0.45 (0.26, 0.66)	0.20 (-0.10, 0.46)	5	0.25 (0.11, 0.47)	0.20 (-0.09, 0.45)
			EnSURE	20	13	0.65 (0.43, 0.82)	9	0.45 (0.26, 0.66)	0.20 (-0.10, 0.46)	5	0.25 (0.11, 0.47)	0.20 (-0.09, 0.45)
			Pi102	20	13	0.65 (0.43, 0.82)	9	0.45 (0.26, 0.66)	0.20 (-0.10, 0.46)	5	0.25 (0.11, 0.47)	0.20 (-0.09, 0.45)
Raw ground beef[j]	Naturally Contaminated	5.2 (3.6, 6.8)	SS Plus	20	12	0.60 (0.39, 0.78)	13	0.65 (0.43, 0.82)	-0.05 (-0.32, 0.23)	14	0.70 (0.48, 0.85)	-0.10 (-0.36, 0.18)
			EnSURE	20	11	0.55 (0.34, 0.74)	13	0.65 (0.43, 0.82)	-0.10 (-0.37, 0.19)	14	0.70 (0.48, 0.85)	-0.15 (-0.41, 0.14)
			Pi102	20	14	0.70 (0.48, 0.85)	13	0.65 (0.43, 0.82)	0.05 (-0.23, 0.32)	14	0.70 (0.48, 0.85)	-0.05 (-0.32, 0.23)
BLT sandwich	*K. pneumoniae* (ATCC 700603) *E. coli* (NCTC 13216)	<3.0	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
		19.6 (13.9, 26.1)	SS Plus	20	15	0.75 (0.53, 0.89)	15	0.75 (0.53, 0.89)	0.00 (-0.44, 0.44)	19	0.95 (0.76, 1.00)	-0.20 (-0.42, 0.03)
			EnSURE	20	15	0.75 (0.53, 0.89)	15	0.75 (0.53, 0.89)	0.00 (-0.44, 0.44)	19	0.95 (0.76, 1.00)	-0.20 (-0.42, 0.03)
			Pi102	20	15	0.75 (0.53, 0.89)	15	0.75 (0.53, 0.89)	0.00 (-0.44, 0.44)	19	0.95 (0.76, 1.00)	-0.20 (-0.42, 0.03)
Raw cod - 1	Naturally contaminated	<10	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
		18.6 (9.9, 29.1)	SS Plus	20	17	0.85 (0.64, 0.95)	17	0.85 (0.64, 0.95)	0.00 (-0.23, 0.23)	20	1.00 (0.84, 1.00)	-0.15 (-0.36, 0.04)
			EnSURE	20	17	0.85 (0.64, 0.95)	17	0.85 (0.64, 0.95)	0.00 (-0.23, 0.23)	20	1.00 (0.84, 1.00)	-0.15 (-0.36, 0.04)
			Pi102	20	17	0.85 (0.64, 0.95)	17	0.85 (0.64, 0.95)	0.00 (-0.23, 0.23))	20	1.00 (0.84, 1.00)	-0.15 (-0.36, 0.04)
Raw cod - 2	Naturally contaminated	<3.0	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0	0	0	0	0	0	0

Food type	Organism	MPN	Device	N	x	POD_CP	x	POD_CC	dPOD_CP	x	POD_CP	dPOD_CP
						(0.00, 0.44)		(0.00, 0.44)	(-0.44, 0.44)		(0.00, 0.44)	(-0.44, 0.44)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
		3.3 (1.4, 5.2)	SS Plus	20	8	0.40 (0.22, 0.61)	8	0.40 (0.22, 0.61)	0.00 (-0.28, 0.28)	7	0.35 (0.18, 0.57)	0.05 (-0.23, 0.32)
			EnSURE	20	7	0.35 (0.18, 0.57)	8	0.40 (0.22, 0.61)	-0.05 (-0.32, 0.23)	7	0.35 (0.18, 0.57)	0.00 (-0.26, 0.26)
			Pi102	20	12	0.60 (0.39, 0.78)	8	0.40 (0.22, 0.61)	0.20 (-0.10, 0.46)	7	0.35 (0.18, 0.57)	0.05 (-0.23, 0.32)
Cooked chicken	E. aerogenes (ATCC 10006) E. coli (ATCC 25922)	<3.0	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
		4.5 (3.4, 5.6)	SS Plus	20	15	0.75 (0.53, 0.89)	14	0.70 (0.48, 0.85)	0.05 (-0.22, 0.31)	18	0.90 (0.48, 0.85)	-0.20 (-0.43, 0.05)
			EnSURE	20	15	0.75 (0.53, 0.89)	14	0.70 (0.48, 0.85)	0.05 (-0.22, 0.31)	18	0.90 (0.48, 0.85)	-0.20 (-0.43, 0.05)
			Pi102	20	16	0.80 (0.58, 0.92)	14	0.70 (0.48, 0.85)	0.10 (-0.17, 0.35)	18	0.90 (0.48, 0.85)	-0.20 (-0.43, 0.05)
Milk - 2	K. oxytoca (K0005) E. coli (EC 54)	<10	SS Plus	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			EnSURE	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			Pi102	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
		11.2 (5.5, 16.2)	SS Plus	20	16	0.80 (0.58, 0.92)	15	0.75 (0.53, 0.89)	0.05 (-0.21, 0.30)	13	0.65 (0.43, 0.82)	0.10 (-0.18, 0.36)
			EnSURE	20	16	0.80 (0.58, 0.92)	15	0.75 (0.53, 0.89)	0.00 (-0.26, 0.26)	13	0.65 (0.43, 0.82)	0.10 (-0.18, 0.36)
			Pi102	20	13	0.65 (0.43, 0.82)	15	0.75 (0.53, 0.89)	0.05 (-0.21, 0.30)	13	0.65 (0.43, 0.82)	0.00 (-0.28, 0.28)
Milk[j]	K. oxytoca (K0005) E. coli (EC 54)	<10	SS Plus	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			EnSURE	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			Pi102	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
		28.9 (13.1, 42.3)	SS Plus	20	17	0.85 (0.64, 0.95)	14	0.70 (0.48, 0.85)	0.15 (-0.11, 0.39)	19	0.85 (0.64, 0.95)	-0.25 (-0.47, -0.01)
			EnSURE	20	17	0.85 (0.64, 0.95)	14	0.70 (0.48, 0.85)	0.15 (-0.11, 0.39)	19	0.85 (0.64, 0.95)	-0.25 (-0.47, -0.01)
			Pi102	20	18	0.90 (0.70, 0.97)	14	0.70 (0.48, 0.85)	0.20 (-0.05, 0.43)	19	0.85 (0.64, 0.95)	-0.25 (-0.47, -0.01)
Raw chicken - 1	Naturally contaminated	<3.0	SS Plus	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			EnSURE	5	0	0.00 (0.00, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)
			Pi102	5	1	0.20 (0.08,0.42)	0	0.00 (0.00, 0.44)	0.00 (-0.44, 0.44)	1	0.05 (0.00, 0.24)	-0.05 (-0.24, 0.12)
		4.1 (3.4, 4.6)	SS Plus	20	13	0.65 (0.43, 0.82)	14	0.70 (0.48, 0.85)	-0.05 (-0.32, 0.23)	15	0.75 (0.53, 0.89)	-0.10 (-0.36, 0.18)
			EnSURE	20	14	0.70 (0.48, 0.85)	14	0.70 (0.48, 0.85)	0.00 (-0.27, 0.27)	15	0.75 (0.53, 0.89)	-0.05 (-0.31, 0.22)
			Pi102	20	16	0.80 (0.58, 0.92)	14	0.70 (0.48, 0.85))	0.10 (-0.17, 0.35)	15	0.75 (0.53, 0.89)	-0.05 (-0.31, 0.22)
Raw prawn	Naturally contaminated	<3.0	SS Plus	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			EnSURE	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
			Pi102	5	0	0 (0.00, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)	0	0 (0.00, 0.44)	0 (-0.44, 0.44)
		6.2 (4.1, 8.7)	SS Plus	20	17	0.85 (0.64, 0.95)	15	0.75 (0.53, 0.89)	0.10 (-0.15, 0.34)	18	0.90 (0.70, 0.97)	-0.15 (-0.38, 0.09)
			EnSURE	20	17	0.85 (0.64, 0.95)	15	0.75 (0.53, 0.89)	0.10 (-0.15, 0.34)	18	0.90 (0.70, 0.97)	-0.15 (-0.38, 0.09)
			Pi102	20	17	0.85 (0.64, 0.95)	15	0.75 (0.53, 0.89)	0.10 (-0.15, 0.34)	18	0.90 (0.70, 0.97)	-0.15 (-0.38, 0.09)

[a]MPN = Most Probable Number is based on the POD of reference method
[b]N = Number of test potions
[c]x = Number of positive test portions
[d]POD_CP = Candidate method presumptive positive outcomes divided by the total number of trials
[e]POD_CC = Candidate method confirmed positive outcomes divided by the total number of trials
[f]dPOD_CP = Difference between the candidate method presumptive result and candidate method confirmed result POD values. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[g]Reference Method used was appropriate to the food type.

[h]POD_R = Reference method positive outcomes divided by the total number of trials
[i]$dPOD_C$ = Difference between the candidate method confirmed result and the reference method result POD values. If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level.
[j]Study conducted at the independent laboratory.

DISCUSSION OF MODIFICATION APPROVED MAY 2021 (10)

The mean $\log_{10}$ differences for the ground beef for all comparisons (coliforms and *E. coli* measured by both the EnSURE and EnSURE Touch, each compared to the reference method results, and instruments compared to each other) were well below 0.5 for all samples tested. The 90% CIs on the mean differences between any comparison was within (-0.5, 0.5) except for a few cases. For the coliform comparisons, there were four cases that were just outside of the acceptance criterion for equivalence at the lower confidence limit, and for *E. coli*, there was one case that were just outside of the acceptance criterion for equivalence at the higher confidence limit. In general, the MicroSnap method showed good correlation to the reference method with either luminometer (EnSURE Touch and EnSURE). The three comparable MicroSnap Coliform R^2 values were as follows; EnSURE to MLG 3.02/BAM Ch.4 R^2=0.985, for EnSURE Touch to MLG 3.02/BAM Ch.4 R^2=0.989 and EnSURE to the EnSURE Touch directly R^2= 0.979. The three comparable MicroSnap *E. coli* R^2 values were as follows; EnSURE to MLG 3.02/BAM Ch.4 R^2=0.976, for EnSURE Touch to MLG 3.02/BAM Ch.4 R^2=0.984 and EnSURE to the EnSURE Touch directly R^2= 0.995. Both the luminometers successfully measured the same Log levels within the samples of ground beef tested.

Overall, the MicroSnap Coliform and MicroSnap *E. coli* method is capable of detecting Coliform bacteria and *E. coli* specifically at more than 3 Log range from the ground beef using both the current EnSURE Luminometer and the newly developed EnSURE Touch to a similar extent and accuracy.

Table 1. Matrix Study: MicroSnap Coliform read in the EnSURE Touch Luminometer vs. MLG 3.02/BAM Ch.4 method (10)

Matrix	Cont. level[a]	EnSURE Touch Luminometer			MLG 3.02/BAM Ch.4 method			Mean diff[e]	90% CI[f]		95% CI	
		Mean[b]	s_r[c]	RSD%[d]	Mean	s_r	RSD%		LCL[g]	UCL[h]	LCL	UCL
	Low	1.68	0.16	9.3	2.02	0.10	4.80	-0.35	-0.59	-0.04	-0.66	0.03
	Low	2.26	0.17	7.40	2.52	0.06	2.40	-0.26	-0.46	-0.06	-0.52	0.00
Fresh raw ground beef (naturally contaminated)	Low	2.71	0.14	5.30	2.66	0.06	2.10	0.05	-0.07	0.17	-0.10	0.21
	Med	3.22	0.01	0.40	3.11	0.22	7.10	0.11	-0.08	0.25	-0.17	0.39
	Med	3.78	0.18	4.70	3.96	0.23	5.92	-0.18	-0.25	0.00	-0.37	0.02
	Med	4.03	0.05	1.40	4.04	0.10	2.40	-0.01	-0.07	0.06	-0.09	0.08
	Med	4.06	0.03	0.81	4.06	0.04	0.90	0.00	-0.03	0.02	-0.04	0.00
	High	5.49	0.40	7.20	5.57	0.06	1.07	-0.08	-0.18	0.01	-0.21	0.03
	High	5.93	0.05	0.80	6.09	0.23	3.80	-0.17	-0.41	0.04	-0.47	0.10

[a]Contamination level for each lot of fresh raw ground beef material tested.
[b]Mean of five replicate portions, after logarithmic transformation: $\log_{10}$[CFU/g + (0.1)f].
[c]Repeatability standard deviation.
[d]Relative standard deviation for repeatability. Reported as a percentage.
[e]Mean difference between the candidate and reference methods.
[f]Confidence interval.
[g]95% Lower confidence limit for difference of means.
[h]95% Upper confidence limit for difference of means.

Table 2. Matrix Study: MicroSnap Coliform read in the EnSURE Luminometer vs. MLG 3.02/BAM Ch.4 method (10)

Matrix	Cont. level[a]	EnSURE Luminometer			MLG 3.02/BAM Ch.4 method			Mean diff[e]	90% CI[f]		95% CI	
		Mean[b]	s_r[c]	RSD%[d]	Mean	s_r	RSD%		LCL[g]	UCL[h]	LCL	UCL
	Low	2.03	0.23	11.10	2.02	0.10	4.80	0.01	-0.20	0.21	-0.26	0.28
	Low	2.40	0.12	5.10	2.52	0.06	2.40	0.12	-0.01	0.24	-0.04	0.28
Fresh raw ground beef (naturally contaminated)	Low	2.71	0.10	3.80	2.66	0.06	2.10	0.05	-0.07	0.17	-0.10	0.20
	Low	2.95	0.04	1.30	3.11	0.22	7.10	-0.17	-0.34	0.04	-0.44	0.11
	Med	4.13	0.13	3.20	3.96	0.23	5.90	0.17	-0.12	0.41	-0.21	0.54
	Med	4.14	0.02	0.40	4.04	0.10	2.40	0.10	0.04	0.18	-0.01	0.21
	Med	4.26	0.02	0.50	4.06	0.04	0.90	0.20	0.16	0.25	0.15	0.27
	High	5.48	0.04	0.80	5.57	0.06	1.07	-0.09	-0.15	0.00	-0.02	0.18
	High	5.76	0.02	0.30	6.09	0.23	3.80	-0.33	-0.56	-0.03	-0.63	0.07

[a]Contamination level for each lot of fresh raw ground beef material tested.
[b]Mean of five replicate portions, after logarithmic transformation: $\log_{10}$[CFU/g + (0.1)f].
[c]Repeatability standard deviation.
[d]Relative standard deviation for repeatability. Reported as a percentage.
[e]Mean difference between the candidate and reference methods.
[f]Confidence interval.
[g]95% Lower confidence limit for difference of means.
[h]95% Upper confidence limit for difference of means.

Table 3. Matrix Study: MicroSnap Coliform read in the EnSURE Touch Luminometer vs. EnSURE Luminometer (10)

| Matrix | Cont. level[a] | EnSURE Touch Luminometer | | | EnSURE Luminometer | | | Mean diff[e] | 90% CI[f] | | 95% CI | |
		Mean[b]	s_r[c]	RSD%[d]	Mean	s_r	RSD%		LCL[g]	UCL[h]	LCL	UCL
	Low	1.68	0.16	9.30	2.03	0.23	11.1	-0.35	-0.65	-0.05	-0.75	0.04
	Low	2.26	0.17	7.40	2.40	0.12	5.10	-0.14	-0.39	0.10	-0.46	0.18
Fresh raw	Low	2.71	0.14	5.30	2.71	0.10	3.80	0.00	-0.21	0.22	-0.28	0.28
ground beef	Med	3.22	0.01	0.40	2.95	0.04	1.30	0.28	0.15	0.21	0.23	0.32
(naturally	Med	3.78	0.18	4.70	4.13	0.13	3.20	-0.35	-0.51	0.02	-0.63	0.06
contaminated)	Med	4.03	0.05	1.40	4.14	0.02	0.40	-0.11	-0.14	-0.07	-0.15	-0.06
	Med	4.06	0.03	0.81	4.26	0.02	0.50	-0.20	-0.25	-0.15	-0.26	-0.14
	High	5.49	0.40	7.20	5.48	0.04	0.80	0.01	-0.06	0.04	-0.08	0.06
	High	5.93	0.05	0.80	5.76	0.02	0.30	0.16	0.06	0.21	0.09	0.23

[a]Contamination level for each lot of fresh raw ground beef material tested.
[b]Mean of five replicate portions, after logarithmic transformation: Log_{10}[CFU/g + (0.1)f].
[c]Repeatability standard deviation.
[d]Relative standard deviation for repeatability. Reported as a percentage.
[e]Mean difference between the candidate and reference methods.
[f]Confidence interval.
[g]95% Lower confidence limit for difference of means.
[h]95% Upper confidence limit for difference of means.

Table 4. Matrix Study: MicroSnap *E. coli* read in the EnSURE Touch Luminometer vs. MLG 3.02/BAM Ch.4 method (10)

| Matrix | Cont. level[a] | EnSURE Touch Luminometer | | | MLG 3.02/BAM Ch.4 method | | | Mean diff[e] | 90% CI[f] | | 95% CI | |
		Mean[b]	s_r[c]	RSD%[d]	Mean	s_r	RSD%		LCL[g]	UCL[h]	LCL	UCL
	Low	2.05	0.16	8.04	1.97	0.39	20.0	0.08	-0.42	0.61	-0.57	0.73
	Low	2.60	0.30	11.5	2.66	0.06	2.14	-0.06	-0.25	0.03	-0.49	0.38
Fresh raw	Med	3.05	0.19	6.20	2.65	0.19	7.20	0.40	0.00	0.71	-0.05	0.83
ground beef	High	3.74	0.03	0.73	3.84	0.11	2.86	-0.10	-0.18	-0.02	-0.23	0.03
(naturally	High	3.91	0.12	2.96	3.69	0.21	5.60	0.22	-0.02	0.31	-0.05	0.45
contaminated)	High	4.32	0.07	1.73	4.18	0.13	3.14	0.14	-0.02	0.24	-0.06	0.33
	High	5.35	0.08	1.40	5.42	0.14	2.60	-0.07	-0.15	0.05	-0.22	0.10

[a]Contamination level for each lot of fresh raw ground beef material tested.
[b]Mean of five replicate portions, after logarithmic transformation: Log_{10}[CFU/g + (0.1)f].
[c]Repeatability standard deviation.
[d]Relative standard deviation for repeatability. Reported as a percentage.
[e]Mean difference between the candidate and reference methods.
[f]Confidence interval.
[g]95% Lower confidence limit for difference of means.
[h]95% Upper confidence limit for difference of mean.

Table 5. Matrix Study: MicroSnap *E. coli* read in the EnSURE Luminometer vs. MLG 3.02/BAM Ch.4 method (10)

| Matrix | Cont. level[a] | EnSURE Luminometer | | | MLG 3.02/BAM Ch.4 method | | | Mean diff[e] | 90% CI[f] | | 95% CI | |
		Mean[b]	s_r[c]	RSD%[d]	Mean	s_r	RSD%		LCL[g]	UCL[h]	LCL	UCL
	Low	2.02	0.16	8.15	1.97	0.39	20.00	0.06	-0.38	0.41	-0.54	0.65
	Low	2.62	0.16	6.24	2.66	0.06	2.14	-0.04	-0.12	0.09	-0.25	0.17
Fresh raw ground	Med	2.87	0.18	6.30	2.65	0.19	7.16	0.22	-0.03	0.45	-0.11	0.55
beef	High	3.68	0.03	0.73	3.84	0.11	2.86	-0.16	-0.25	-0.04	-0.36	0.05
(naturally	High	3.81	0.07	1.82	3.69	0.21	5.60	0.13	-0.02	0.21	-0.10	0.36
contaminated)	High	4.36	0.16	3.56	4.18	0.13	3.14	0.18	0.04	0.21	-0.01	0.37
	High	5.29	0.04	0.70	5.42	0.14	2.60	-0.12	-0.18	0.01	-0.28	0.04

[a]Contamination level for each lot of fresh raw ground beef material tested.
[b]Mean of five replicate portions, after logarithmic transformation: Log_{10}[CFU/g + (0.1)f].
[c]Repeatability standard deviation.
[d]Relative standard deviation for repeatability. Reported as a percentage.

[e]Mean difference between the candidate and reference methods.
[f]Confidence interval.
[g]95% Lower confidence limit for difference of means.
[h]95% Upper confidence limit for difference of means.

Matrix	Cont. level[a]	EnSURE Touch Luminometer			EnSURE Luminometer			Mean diff[e]	90% CI[f]		95% CI	
		Mean[b]	s_r[c]	RSD%[d]	Mean	s_r	RSD%		LCL[g]	UCL[h]	LCL	UCL
Fresh raw ground beef (naturally contaminated)	Low	2.05	0.16	8.04	2.02	0.16	8.15	0.03	-0.15	0.18	-0.24	0.29
	Low	2.60	0.30	11.5	2.62	0.16	6.24	-0.02	-0.34	0.35	-0.48	0.46
	Med	3.05	0.19	6.20	2.87	0.18	6.30	0.18	0.00	0.25	-0.04	0.39
	High	3.74	0.03	0.73	3.68	0.09	2.58	0.06	-0.02	0.12	-0.09	0.21
	High	3.91	0.12	2.96	3.81	0.07	1.82	0.10	-0.03	0.12	-0.05	0.24
	High	4.32	0.07	1.73	4.36	0.16	3.56	-0.04	-0.19	0.15	-0.31	0.23
	High	5.35	0.08	1.40	5.29	0.04	0.70	0.06	-0.01	0.09	-0.05	0.17

Table 6. Matrix Study: MicroSnap *E. coli* read in the EnSURE Touch Luminometer vs. EnSURE Luminometer (10)

[a]Contamination level for each lot of fresh raw ground beef material tested.
[b]Mean of five replicate portions, after logarithmic transformation: Log_{10}[CFU/g + (0.1)f].
[c]Repeatability standard deviation.
[d]Relative standard deviation for repeatability. Reported as a percentage.
[e]Mean difference between the candidate and reference methods.
[f]Confidence interval.
[g]95% Lower confidence limit for difference of means.
[h]95% Upper confidence limit for difference of means.

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