



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.
031209

The AOAC Research Institute hereby certifies the method known as:

iQ-Check *Campylobacter* Real-Time PCR

Corporate Location
Bio-Rad Laboratories
2000 Alfred Nobel Drive
Hercules, CA 94547 USA

Manufacturing Location
Bio-Rad Laboratories
925 Alfred Nobel Drive
Hercules, CA 94547 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.

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

Scott Coates, Senior Director
Signature for AOAC Research Institute

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<p>METHOD NAME iQ-Check <i>Campylobacter</i> Real-Time PCR</p>	<p>CATALOG NUMBER 357-8135</p>
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<p>APPLICABILITY OF METHOD Target organism – <i>Campylobacter jejuni, coli, and lari</i>.</p> <p>Matrixes – (25 g) - chicken carcass rinse, turkey carcass sponge, raw ground chicken breast</p> <p>Performance claims – The study data detected no statistical difference between the iQ-Check <i>Campylobacter</i> Real-Time PCR method and the reference methods.</p>	<p>REFERENCE METHODS U.S. Department of Agriculture, Food Safety and Inspection Service (2011) <i>Microbiology Laboratory Guidebook</i> 8.07(2)</p> <p>Standard EN ISO 10272-1. (2006) Microbiology of food and animal feeding stuffs – Horizontal method for the detection and enumeration of <i>Campylobacter</i> spp. Part 1. Detection method. (3)</p> <p>U.S. Department of Agriculture Food Safety and Inspection Service Microbiology Laboratory Manual 41.07, Isolating and Identify <i>Campylobacter jejuni/coli/lari</i> from Poultry Rinsate, Sponge, and Raw Product Samples (6)</p>
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<p>ORIGINAL CERTIFICATION DATE April 02, 2012</p>	<p>CERTIFICATION RENEWAL RECORD Renewed annually through December 2024.</p>
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<p>METHOD MODIFICATION RECORD</p> <ol style="list-style-type: none"> 1. December 2013 Level 1 2. July 2018 Level 1 3. January 2021 Level 1 4. April 2021 Level 1 5. November 2021 Level 1 6. January 2023 Level 2 7. October 2023 Level 1 8. December 2023 Level 3 	<p>SUMMARY OF MODIFICATION</p> <ol style="list-style-type: none"> 1. Software update. 2. Software update and manual edits. 3. Editorial/clerical changes. 4. Software was updated from Version 3 to Version 4 allowing compatibility with Windows 10. 5. Editorial changes and addition of user information in French, German, Spanish, Portuguese, and Italian. 6. Addition of CFX Opus Deepwell, with CFX Manager Software, Industrial Diagnostic Edition version 3.1 using Free DNA Removal Solution and Fast APF protocols. 7. Editorial/clerical changes. 8. Matrix extension to include raw ground chicken (325 g), chicken carcass rinse (30 mL) and turkey carcass sponges using Hunt broth. Also, RAPID' <i>Campylobacter</i> agar was approved as an alternative agar for confirmation of presumptive iQ-Check positive test portions.
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PRINCIPLE OF THE METHOD (1)

The iQ-Check *Campylobacter* kit is a rapid method test kit based on gene amplification and detection by real-time polymerase chain reaction, (RTI-PCR). Ready-to-use RTI-PCR reagents contain DNA primers and a DNA probe specific for *C. jejuni*, *C. coli* and *C. lari*, as well as DNA polymerase and nucleotides. PCR is a technique used to generate many copies of target DNA. During the PCR reaction, several cycles of heating and cooling performed by a thermal cycler instrument allow DNA denaturation, by heat, followed by primers binding to the target region. The DNA polymerase then uses these primers and deoxynucleotide triphosphates (dNTPs) to extend the DNA, creating copies of the target DNA. These copies, called amplicons, are detected during the amplification by hybridizing specific patented double stranded oligonucleotide fluorescent probes. These probes are linked to a fluorophore which fluoresces only when hybridized to the target sequence. In the iQ-Check *Campylobacter* kit, carboxyfluorescein (FAM) is the fluorophore linked to the probe hybridizing to the *Campylobacter* specific DNA sequence. In the absence of target DNA, no fluorescence will be detected, and the sample determined to be negative. As the amount of amplicons increases with each round of amplification, fluorescence intensity also increases. During each PCR cycle, at the annealing step, the real-time PCR instrument measures this fluorescence and the associated software plots the fluorescence intensity versus number of cycles. This method allows a simple determination of the presence of *Campylobacter* in a sample. To monitor for a successful DNA amplification in each reaction tube, a synthetic DNA "internal control" is included in the reaction mix. This control is amplified with a specific probe at the same time as the *Campylobacter* target DNA sequence and detected by a second fluorophore. The iQ-Check *Campylobacter* kit has been validated on the Bio-Rad thermal cyclers listed below.

DISCUSSION OF THE VALIDATION STUDY (1)

The iQ-Check *Campylobacter* kit can be used after a single 24 h primary enrichment. The culture method requires a 48 h enrichment followed by another 48 h on a selective agar plate. The culture method relies on the target bacteria's ability to grow on a plate, which can be suppressed by the cells being stressed, being out-competed for nutrients by background flora or by improper modified atmospheric conditions. The iQ-Check *Campylobacter* kit uses primers and specific DNA hybridization probes targeting a specific sequence on the *Campylobacter* genome. Detecting target DNA is possible even if the cells are stressed or in lower numbers. Previous studies have demonstrated the sensitivity of PCR methods used in the food safety industry (2). This increased sensitivity and time saving provide users with an alternative to the reference method for detection of *Campylobacter* in food samples.

Table 1 - Inclusivity Strain List (1)

Number	Strain ID	Origin
<i>Campylobacter jejuni</i>		
1	CRL 216-08	Chicken cecum
2	CRL 227-08	Chicken cecum
3	CRL 248-08	Chicken cecum
4	CRL 260-08	Chicken cecum
5	CRL 263-08	Chicken carcass
6	CRL 277-08	Chicken cecum
7	CRL 278-08	Chicken carcass
8	CRL 336-08	Chicken carcass
9	CRL 337-08	Chicken cecum
10	CRL 351-08	Chicken cecum
11	CRL 364-08	Chicken carcass
12	CRL 6-09	Chicken carcass
13	CRL 39-09	Chicken cecum
14	CRL 117-09	Chicken cecum
15	CRL 58-08	Chicken carcass
16	CRL 117-08	Chicken carcass
17	CRL 127-08	Chicken cecum
18	CRL 143-08	Chicken cecum
19	CRL 194-08	Chicken cecum
20	CCUG 11284	Reference strain
<i>Campylobacter coli</i>		
21	CRL 204-08	Chicken carcass
22	CRL 206-08	Chicken cecum
23	CRL 213-08 A	Chicken carcass
24	CRL 230-08	Chicken cecum
25	CRL 261-08	Chicken carcass
26	CRL 262-08	Chicken cecum
27	CRL 280-08	Chicken cecum
28	CRL 295-08	Chicken cecum
29	CRL 335-08	Chicken cecum
30	CRL 338-08	Chicken carcass
31	CRL 339-09	Chicken cecum
32	CRL 354-08	Chicken cecum
33	CRL 366-08	Chicken cecum
34	CRL 2-09	Chicken carcass
35	CRL 110-09	Chicken cecum
36	CRL 59-08	Chicken carcass
37	CRL 113-08	Chicken cecum
38	CRL 125-08	Chicken cecum
39	CCUG 11283	Reference strain
<i>Campylobacter lari</i>		
40	CRL 272-08	Chicken cecum
41	CRL 80-09	Chicken cecum
42	Cb 227-99	Gull, cloacae
43	Cb 221-99	Gull, cloacae
44	CB 165-98	Gull, cloacae
45	Cb 193-87 (C551)	Duck, cloacae

46	Cb 192-87 (C550)	Duck, cloacae
47	Cb 7250-04	Chicken cloacae
48	Cb 7252-04	Chicken cloacae
49	CCUG 23947	Reference strain
50	CCUG 20707	Reference strain, UPTC

Table 2 - Exclusivity Strain List (1)

Number	Organism	Source	Origin
1	<i>Bacillus cereus</i>	ATCC 1778	FDA
2	<i>Bacillus mycoides</i>	ATCC 6462	Soil
3	<i>Bacillus pumilus</i>	ATCC 7061	Unknown
4	<i>Enterobacter agglomerans</i>	AFL	Wheat
5	<i>Enterobacter cloacae</i>	ATCC 23355	Stanford University
6	<i>Enterobacter amnigenus</i>	ATCC 33072	Soil
7	<i>Klebsiella oxytoca</i>	ATCC 13182	Pharyngeal tonsil
8	<i>Hafnia alvei</i>	AFL	Drinking water
9	<i>Pseudomonas aeruginosa</i>	ATCC 103457	Soil
10	<i>Pseudomonas putida</i>	ATCC 12633	Unknown
11	<i>Pseudomonas fluorescens</i>	ATCC 49642	Drinking water
12	<i>Proteus mirabilis</i>	ATCC 12453	Unknown
13	<i>Staphylococcus aureus</i>	ATCC 29213	Wound infection
14	<i>Staphylococcus epidermidis</i>	ATCC 12228	FDA
15	<i>Aeromonas hydrophila</i>	ATCC 7966	Milk
16	<i>Acinetobacter baumannii</i>	AFL	Meat
17	<i>Escherichia coli</i>	ATCC 25922	Clinical isolate
18	<i>Salmonella hadar</i>	AFL	Poultry
19	<i>Citrobacter freundii</i>	ATCC 8090	Unknown
20	<i>Shigella flexneri</i>	ATCC 12022	CDC
21	<i>Escherichia hermannii</i>	AFL	Unknown
22	<i>Yersinia enterocolitica</i>	ATCC 9610	Human issue
23	<i>Acinetobacter calcoaceticus</i>	ATCC 1966	Urine
24	<i>Arcobacter butzleri</i>	ATCC 49616	Human feces
25	<i>Streptococcus pyogenes</i>	ATCC 19615	Child with sore throat
26	<i>Listeria innocua</i>	ATCC 33091	Human feces
27	<i>Helicobacter pylori</i>	ATCC 43504	Human gastric antrum
28	<i>Morganella morganii</i>	AFL	Unknown
29	<i>Vibrio parahaemolyticus</i>	ATCC 17802	Food poisoning
30	<i>Campylobacter fetus</i>	ATCC 27374	Sheep fetus brain
31	<i>Lactobacillus plantarum</i>	ATCC 8014	Unknown
32	<i>Enterococcus faecalis</i>	ATCC 29212	Urine
33	<i>Rhodococcus equi</i>	ATCC 33701	Horse lung
34	<i>Serratia liquefaciens</i>	ATCC 27592	Milk
35	<i>Listeria monocytogenes</i>	ATCC 19115	Human

ATCC – American Type Culture Collection (Manassas, VA, USA)
Guelph (Guelph, Ontario, Canada)

AFL – Agriculture and Food Laboratory, University of

Table 3 Method Comparison Results Comparing iQ-Check vs. Reference Method for Chicken Carcass Rinses, Turkey Carcass Sponges and Raw Ground Chicken (1)

Matrix	Strain	MPN/25g	N ^a	iQ-Check <i>Campylobacter</i> Positive	Reference Method Positive -Confirmed	Chi Square ^b	Relative Sensitivity ^c
Chicken carcass rinses	Natural	N/A	20	15	15	0.00	100
Turkey carcass sponges	Natural	N/A	20	5	5	0.00	100
Raw ground chicken	<i>C. lari</i>	< 0.075	5	0	0	-	-
		0.619	20	9	9	0.00	100
		6.19	20	20	20	0.00	100

^aN = Number of test portions

^bChi Square = McNemar: $X^2 = (|a-b| - 1)^2 / (a+b)$ a = the number samples that are positive analyses by the alternative method and are negative analyses by the reference method and b = the number samples that are negative analyses by the alternative method and are positive analyses by the reference method

^cRelative sensitivity = a/c, where a = number of samples confirmed positive by the test method and c = number of samples positive by the reference method

DISCUSSION OF THE MODIFICATION STUDY APPROVED JANUARY 2023 (4)

The new CFX Opus Deepwell instrument delivers the same performance as the current CFX96 Touch Deep Well instrument but with a more modern design and cloud capabilities. The improved stability of the thermal block ensures a more uniform thermal protocol. The CFX Manager Software, IDE v 3.1 brings the same performance, algorithm, and interpretation as the current CFX Manager Software, IDE v 3.0 with the only change being compatibility to both CFX96 Touch Deep Well and CFX Opus Deepwell instruments.

DISCUSSION OF THE MODIFICATION STUDY APPROVED DECEMBER 2023 (5)

The iQ-Check *Campylobacter* Method successfully detected *Campylobacter* spp. in raw ground chicken, chicken carcass rinsate, and turkey carcass sponge using Hunt broth. After POD analysis, no statistical differences were detected between the number of positive iQ-Check results and the reference methods for all test portions tested. There were no differences in the confirmed results when using RAPID' *Campylobacter* as an alternative confirmation agar to Campy-Cefex agar. The iQ-Check *Campylobacter* Method and RAPID' *Campylobacter* agar as an alternative confirmation agar are easy to use. All test results are easily interpreted, and for iQ-Check *Campylobacter* results are displayed automatically at the end of the run without manipulation by the end user.

Table 2. Summary of inclusivity results for iQ-Check *Campylobacter* (5)

Sample No.	Genus	Species	Source	Origin	iQ-Check <i>Campylobacter</i> Method Result
1	<i>Campylobacter</i>	<i>coli</i>	ATCC 33559 ^a	Pig feces	Positive
2	<i>Campylobacter</i>	<i>coli</i>	QL 071412-1 ^b	Meat	Positive
3	<i>Campylobacter</i>	<i>coli</i>	CCUG 10772 ^c	Pig placenta	Positive
4	<i>Campylobacter</i>	<i>coli</i>	ATCC 43481	Turkey feces	Positive
5	<i>Campylobacter</i>	<i>coli</i>	CCUG 15360	Human feces	Positive
6	<i>Campylobacter</i>	<i>coli</i>	ATCC BAA-1061	Chicken carcass	Positive
7	<i>Campylobacter</i>	<i>coli</i>	QL 071412-2	Meat	Positive
8	<i>Campylobacter</i>	<i>coli</i>	CCUG 8320	Porcine feces	Positive
9	<i>Campylobacter</i>	<i>coli</i>	QL 071412-3	Meat, poultry	Positive
10	<i>Campylobacter</i>	<i>coli</i>	CCUG 10955	Porcine feces	Positive
11	<i>Campylobacter</i>	<i>coli</i>	QL 071412-4	Meat, poultry	Positive
12	<i>Campylobacter</i>	<i>coli</i>	CCUG 10960	Human feces	Positive
13	<i>Campylobacter</i>	<i>coli</i>	QL 071412-5	Meat, poultry	Positive
14	<i>Campylobacter</i>	<i>coli</i>	CCUG 15362	Human feces	Positive
15	<i>Campylobacter</i>	<i>coli</i>	QL 071412-6	Meat	Positive
16	<i>Campylobacter</i>	<i>coli</i>	CCUG 14537	Human feces	Positive
17	<i>Campylobacter</i>	<i>coli</i>	QL 071412-7	Meat	Positive
18	<i>Campylobacter</i>	<i>jejuni</i>	ATCC BAA-1062	Chicken carcass	Positive
19	<i>Campylobacter</i>	<i>jejuni</i>	QL 022117.1	Chicken carcass	Positive
20	<i>Campylobacter</i>	<i>jejuni</i>	QL 022117.2	Chicken carcass	Positive
21	<i>Campylobacter</i>	<i>jejuni</i>	QL 012516.11	Poultry	Positive
22	<i>Campylobacter</i>	<i>jejuni</i>	QL 012516.12	Poultry	Positive
23	<i>Campylobacter</i>	<i>jejuni</i>	QL 040798	Poultry plant	Positive
24	<i>Campylobacter</i>	<i>jejuni</i>	QL 012599	Poultry plant	Positive
25	<i>Campylobacter</i>	<i>jejuni</i>	QL 021599	Poultry plant	Positive
26	<i>Campylobacter</i>	<i>jejuni</i>	QL 030599	Poultry plant	Positive
27	<i>Campylobacter</i>	<i>jejuni</i>	QL 061498	Poultry plant	Positive
28	<i>Campylobacter</i>	<i>jejuni</i>	QL 081998	Poultry plant	Positive
29	<i>Campylobacter</i>	<i>jejuni</i>	QL 112010	Poultry plant	Positive
30	<i>Campylobacter</i>	<i>jejuni</i>	QL 062011	Poultry plant	Positive
31	<i>Campylobacter</i>	<i>jejuni</i>	QL 112010	Poultry plant	Positive
32	<i>Campylobacter</i>	<i>jejuni</i>	QL 062298	Poultry plant	Positive
33	<i>Campylobacter</i>	<i>jejuni</i>	QL 062298	Poultry plant	Positive
34	<i>Campylobacter</i>	<i>jejuni</i>	QL 062298	Poultry plant	Positive
35	<i>Campylobacter</i>	<i>lari</i>	CCUG 19512	Human	Positive
36	<i>Campylobacter</i>	<i>lari</i>	CCUG 12774	Human child feces	Positive
37	<i>Campylobacter</i>	<i>lari</i>	CCUG 19528	Human	Positive
38	<i>Campylobacter</i>	<i>lari</i>	CCUG 15031	Human	Positive
39	<i>Campylobacter</i>	<i>lari</i>	CCUG 20707	Seagull	Positive
40	<i>Campylobacter</i>	<i>lari</i>	CCUG 22396	Human	Positive
41	<i>Campylobacter</i>	<i>lari</i>	CCUG 20581	Human	Positive
42	<i>Campylobacter</i>	<i>lari</i>	CCUG 29405	Water	Positive
43	<i>Campylobacter</i>	<i>lari</i>	CCUG 22395	Human	Positive
44	<i>Campylobacter</i>	<i>lari</i>	CCUG 29406	Human	Positive
45	<i>Campylobacter</i>	<i>lari</i>	ATCC 35221	Herring gull	Positive
46	<i>Campylobacter</i>	<i>lari</i>	CCUG 55788	Human feces	Positive
47	<i>Campylobacter</i>	<i>lari</i>	CCUG 55789	Human	Positive
48	<i>Campylobacter</i>	<i>lari</i>	CCUG 12773	Unknown	Positive
49	<i>Campylobacter</i>	<i>lari</i>	CCUG 15035	Sea gull	Positive
50	<i>Campylobacter</i>	<i>lari</i>	ATCC BAA-1060	Human feces	Positive

^a American Type Culture collection, Manassas, VA^b Q Laboratories Culture Collection, Cincinnati, OH^c Culture Collection University of Gothenburg (CCUG).— Göteborg, Sweden

Table 3 Summary of exclusivity results for iQ-Check *Campylobacter* (5)

Sample No.	Genus	Species	Source	Origin	iQ-Check <i>Campylobacter</i> Result
1	<i>Pseudomonas</i>	<i>aeruginosa</i>	ATCC 35032 ^a	Not available	Negative
2	<i>Escherichia</i>	<i>vulneris</i>	ATCC 29943	Human wound	Negative
3	<i>Proteus</i>	<i>mirabilis</i>	QL 11007.6 ^b	Veterinary	Negative
4	<i>Listeria</i>	<i>monocytogenes</i>	ATCC 13932	Spinal fluid	Negative
5	<i>Morganella</i>	<i>morganii</i>	ATCC 25829	Human	Negative
6	<i>Enterococcus</i>	<i>faecalis</i>	ATCC 51299	Peritoneal fluid	Negative
7	<i>Enterococcus</i>	<i>faecium</i>	ATCC 8459	Dairy product	Negative
8	<i>Salmonella</i>	<i>Typhimurium</i>	ATCC 14028	Animal tissue	Negative
9	<i>Klebsiella</i>	<i>pneumoniae</i>	ATCC 10031	Clinical isolate	Negative
10	<i>Klebsiella</i>	<i>oxytoca</i>	ATCC 43165	Clinical isolate	Negative
11	<i>Hafnia</i>	<i>alvei</i>	ATCC 51815	Milk	Negative
12	<i>Franconibacter</i>	<i>pulveris</i>	ATCC 19144	Not available	Negative
13	<i>Salmonella</i>	<i>Agona</i>	ATCC 51957	Not available	Negative
14	<i>Cronobacter</i>	<i>sakazakii</i>	ATCC 51329	Rice flour	Negative
15	<i>Escherichia</i>	<i>coli O157:H7</i>	ATCC 43895	Raw hamburger	Negative
16	<i>Escherichia</i>	<i>coli</i>	QL 11010.2	Bottled water	Negative
17	<i>Escherichia</i>	<i>fergusonii</i>	ATCC 35470	Not available	Negative
18	<i>Enterobacter</i>	<i>cloacae</i>	ATCC 23355	Spinal fluid	Negative
19	<i>Escherichia</i>	<i>hermannii</i>	ATCC 33651	Human arm wound	Negative
20	<i>Enterobacter</i>	<i>cancerogenus</i>	QL11010-1	Bottled water	Negative
21	<i>Cronobacter</i>	<i>malonaticus</i>	QL 123015-1A	Rice flour	Negative
22	<i>Citrobacter</i>	<i>amalonaticus</i>	ATCC 25407	Feces	Negative
23	<i>Citrobacter</i>	<i>braakii</i>	ATCC 43162	Clinical isolate	Negative
24	<i>Citrobacter</i>	<i>farmeri</i>	ATCC 51633	Human feces	Negative
25	<i>Citrobacter</i>	<i>youngae</i>	ATCC 11102	Not available	Negative
26	<i>Citrobacter</i>	<i>freundii</i>	QL 11007.10	Clinical isolate	Negative
27	<i>Enterobacter</i>	<i>aerogenes</i>	ATCC 35029	Not available	Negative
28	<i>Enterobacter</i>	<i>amnigenus</i>	ATCC 51816	Milk	Negative
29	<i>Edwardsiella</i>	<i>tarda</i>	QL 11007.11	Clinical isolate	Negative
30	<i>Salmonella</i>	Enteritidis	ATCC 13076	Not available	Negative

^a American Type Culture collection, Manassas, VA

^b Q Laboratories Culture Collection, Cincinnati, OH

Table 4. iQ-Check *Campylobacter* POD Results, Presumptive vs. Confirmed (5)

Matrix/Strain	MPN ^a / Test Portion	N ^b	x ^c	Presumptive			Confirmed ^f			dPOD _{CP} ^g	95% CI ^h
				POD _{CP} ^d	95% CI	X	POD _{CC} ^e	95% CI			
Raw Ground Chicken	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47	
<i>C. coli</i> ATCC ⁱ BAA-1061 (325 g)	0.56 (0.29, 0.94)	20	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.13, 0.13	
Chicken Carcass Rinse	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47	
<i>C. jejuni</i> ATCC BAA-1062 (30 mL)	6	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13	
Turkey Carcass Sponge	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47	
<i>C. lari</i> ATCC 35221 (Sponge)	100	20	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13	
	1300	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47	

^aMPN = Most Probable Number is calculated using the LCF MPN calculator ver. 2.0 provided by AOAC RI, with 95% confidence interval

^bN = Number of test portions

^cx = Number of positive test portions

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

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

^fIdentical results between Campy-Cefex agar and RAPID[®] *Campylobacter* agar

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

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

ⁱATCC = American Type Culture collection, Manassas, VA

Table 5. iQ-Check *Campylobacter* POD Results, Candidate vs. Reference (5)

Matrix/Strain	MPN ^a / Test Portion	N ^b	x ^c	Candidate			Reference ^f		dPOD ^e	95% CI ^h
				POD _c ^d	95% CI	X	POD _R ^e	95% CI		
Raw Ground Chicken	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
<i>C. coli</i> ATCC ⁱ BAA-1061	0.56 (0.29, 0.94)	20	9	0.45	0.26, 0.66	9	0.45	0.26, 0.66	0.00	-0.13, 0.13
(325 g)	1.97 (1.27, 3.70)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Chicken Carcass Rinse	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
<i>C. jejuni</i> ATCC BAA-1062	6	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
(30 mL)	50	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Turkey Carcass Sponge	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
<i>C. lari</i> ATCC 35221	100	20	7	0.35	0.18, 0.57	7	0.35	0.18, 0.57	0.00	-0.13, 0.13
(Sponge)	1300	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47

^aMPN = Most Probable Number is calculated using the LCF MPN calculator ver. 2.0 provided by AOAC RI, with 95% confidence interval

^bN = Number of test portions

^cx = Number of positive test portions

^dPOD_c = Candidate method confirmed positive outcomes divided by the total number of trials

^ePOD_R = Reference method confirmed positive outcomes divided by the total number of trials

^fIdentical results between Campy-Cefex agar and RAPID[®] *Campylobacter* agar

^gdPOD_c = Difference between the confirmed candidate method result and reference method confirmed result POD values

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

ⁱATCC = American Type Culture collection, Manassas, VA

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