



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.
122303

The AOAC Research Institute hereby certifies the method known as:

RAPID'Campylobacter

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, appearing to read 'Bradley A. Stawick'.

Bradley A. Stawick, Senior Director
Signature for AOAC Research Institute

Issue Date

January 2, 2024

Expiration Date

December 31, 2024

AUTHORS Michael Clark ¹ , Kateland Lanzit ² , Wesley Thompson ² , M. Joseph Benzinger Jr. ² , Benjamin Bastin ² , and Erin Crowley ²	SUBMITTING COMPANY Bio-Rad Laboratories 925 Alfred Nobel Drive Hercules, CA 94547 USA
METHOD NAME RAPID' <i>Campylobacter</i>	CATALOG NUMBER 12012036
INDEPENDENT LABORATORY Q Laboratories 1930 Radcliff Drive Cincinnati, OH 45204, USA	APPLICABILITY OF METHOD Target organisms – <i>C. coli</i> , <i>C. jejuni</i> , <i>C. lari</i> . Matrixes – Raw ground chicken (325 g), chicken carcass rinse (30 mL), and turkey carcass sponge (30 mL). Performance claims – There was no statistical difference detected between the RAPID' <i>Campylobacter</i> agar method and the U.S. Department of Agriculture Food Safety and Inspection Service Microbiology Laboratory Guidebook 41.07 <i>Isolating and identifying Campylobacter jejuni/coli/lari from Poultry Rinsate, Sponge, and Raw Product Samples</i> (USDA-FSIS MLG 41.07) for the detection of <i>Campylobacter</i> species in raw ground chicken, chicken carcass rinse, and turkey carcass sponge (2).
ORIGINAL CERTIFICATION DATE December 27, 2023	CERTIFICATION RENEWAL RECORD New approval 2023.
METHOD MODIFICATION RECORD NONE	SUMMARY OF MODIFICATION NONE
Under this AOAC Performance Tested MethodsSM License Number, 122303 this method is distributed by: NONE	Under this AOAC Performance Tested MethodsSM License Number, 122303 this method is distributed as: NONE

PRINCIPLE OF THE METHOD (1)

RAPID' *Campylobacter* is a selective chromogenic agar which can be used for the detection and enumeration of thermophilic *Campylobacter* spp. in select foods and environmental samples. The agar contains a selective nutritive mixture, reducing agent, and chromogenic substrate. The selective nutritive mixture inhibits other bacterial and fungal species. The reducing agent allows for rapid growth of thermophilic *Campylobacter* spp. Finally, thermophilic *Campylobacter* spp. produce brick-red colonies on the agar as the chromogenic substrate is utilized by enzymatic activity (3).

DISCUSSION OF THE VALIDATION STUDY (1)

The RAPID' *Campylobacter* detected *Campylobacter* spp. in raw ground chicken, chicken carcass rinsate, and turkey carcass sponge. Using POD analysis, no statistically significant differences were observed between the number of positive samples detected by the candidate method and the reference methods for all samples tested. The results of the product consistency and stability study and robustness study demonstrate that the RAPID' *Campylobacter* is robust and performed as expected with no differences in results observed regardless of the variation. The RAPID' *Campylobacter* Method is easy to use and plates are easily interpreted.

Table 1. Summary of inclusivity results for RAPID[®]Campylobacter (2)

Sample No.	Genus	Species	Source	Origin	RAPID [®] Campylobacter Agar Result ^a
1	<i>Campylobacter</i>	<i>coli</i>	ATCC 33559 ^b	Pig feces	Positive
2	<i>Campylobacter</i>	<i>coli</i>	QL 071412-1 ^c	Meat	Positive
3	<i>Campylobacter</i>	<i>coli</i>	CCUG 10772 ^d	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 Strains tested in Hunt Broth

^b American Type Culture collection, Manassas, VA

^c Q Laboratories Culture Collection, Cincinnati, OH

^d Culture Collection University of Gothenburg, Göteborg, Sweden

Table 2. Summary of exclusivity results for RAPID[®] Campylobacter Agar (2)

Sample No.	Genus	Species	Source	Origin	RAPID [®] Campylobacter Agar 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>	monocytogenes	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>	Typhimurium	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 3. RAPID[®] Campylobacter POD Results, Presumptive vs. Confirmed – Traditional Plating Method After Enrichment (2)

Matrix	MPN ^a / Test Portion	N ^b	x ^c	Presumptive		X	Confirmed		dPOD _{CP} ^f	95% CI ^g
				POD _{CP} ^d	95% CI		POD _{CC} ^e	95% CI		
Raw Ground	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Chicken	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	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Rinse	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	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Sponge	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_{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

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

^g95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level

Table 4. RAPID/Campylobacter POD Results, Candidate vs. Reference – Traditional Plating Method After Enrichment (2)

Matrix	MPN ^a / Test Portion	N ^b	x ^c	Candidate		X	Reference		dPOD ^f	95% CI ^g
				POD _c ^d	95% CI		POD _R ^e	95% CI		
Raw Ground	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Chicken (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
	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	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Rinse (30 mL)	6	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
	50	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Turkey Carcass	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Sponge	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

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

^g95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level

Table 5. RAPID/Campylobacter POD Results, Presumptive vs. Confirmed – Alternative Plating Method Before and After Enrichment^h (2)

Matrix	MPN ^a / Test Portion	N ^b	x ^c	Presumptive		X	Confirmed		dPOD _{CP} ^f	95% CI ^g
				POD _{CP} ^d	95% CI		POD _{CC} ^e	95% CI		
Raw Ground	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Chicken (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
	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	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Rinse (30 mL)	6	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
	50	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Turkey Carcass	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Sponge	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_{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

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

^g95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level

^hIdentical results produced from sample analysis before and after enrichment

Table 6. RAPID/Campylobacter POD Results, Candidate vs. Reference – Alternative Plating Method Before and After Enrichment^h (2)

Matrix	MPN ^a / Test Portion	N ^b	x ^c	Candidate		X	Reference		dPOD ^f	95% CI ^g
				POD _c ^d	95% CI		POD _R ^e	95% CI		
Raw Ground	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Chicken (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
	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	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Rinse (30 mL)	6	20	12	0.60	0.39, 0.78	12	0.60	0.39, 0.78	0.00	-0.13, 0.13
	50	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.47, 0.47
Turkey Carcass	-	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.47, 0.47
Sponge	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

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

^g95% CI = If the confidence interval of a dPOD does not contain zero, then the difference is statistically significant at the 5% level

^hIdentical results produced from sample analysis before and after enrichment

REFERENCES CITED

1. Clark, M., Lanzit, K., Thomson, W., Benzinger, Jr., M.J., Bastin, B., and Crowley, E., Validation of the RAPID' *Campylobacter* Agar Method for the Determination of *Campylobacter* Species in Raw Ground Chicken, Chicken Carcass Rinse, and Turkey Carcass Sponge, AOAC *Performance Tested Methods*SM certification number 122303.
2. U.S. Department of Agriculture Food Safety and Inspection Service Microbiology Laboratory Manual 41.07, Isolating and Identify *Campylobacter jejuni/coli/lari* from Poultry Rinsate, Sponge, and Raw Product Samples (03/07/2022) <https://www.fsis.usda.gov/news-events/publications/microbiology-laboratory-guidebook> [Accessed October 2023].
3. RAPID' *Campylobacter* User Guide – Chromogenic media for the detection and enumeration of the main thermophilic *Campylobacter* (*C. jejuni*, *C. coli*, and *C. lari*) in food products and environmental samples. Version B, November 2021.