



CERTIFICATION

AOAC Research Institute *Performance Tested Methods*SM

Certificate No.

052201

The AOAC Research Institute hereby certifies the method known as

RapidChek® *Campylobacter* Test System

manufactured by

Romer Labs, Inc.

130 Sandy Drive

Newark, Delaware 19713 USA

This method has been evaluated and certified according to the policies and procedures of the AOAC *Performance Tested Methods*SM Program. 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, AOAC Research Institute Senior Director

Issue Date

October 14, 2025

Expiration Date

December 31, 2026

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METHOD NAME RapidChek® <i>Campylobacter</i> Test System		CATALOG NUMBER 10005433	
INDEPENDENT LABORATORY Q Laboratories, inc. 1400 Harrison Ave. Cincinnati, OH 45214			
APPLICABILITY OF METHOD Target organisms – <i>Campylobacter jejuni</i> , <i>C. coli</i> , and <i>C. lari</i> . Matrixes – Raw ground chicken (325 g), chicken carcass rinses, and turkey carcass sponges. Performance claims – Probability of Detection (POD) analysis demonstrated no significant differences at the 5% level in the number of presumptive positives by the candidate method compared to the cultural reference method U.S. Department of Agriculture Food Safety and Inspection Service <i>Microbiology Laboratory Guidebook</i> (USDA-FSIS/MLG) 41.04: Isolation and Identification of <i>Campylobacter jejuni/coli/lari</i> from Poultry Rinse, Sponge and Raw Product Samples (2) for the detection of <i>Campylobacter jejuni/coli/lari</i> in raw ground chicken, chicken carcass rinses, and turkey carcass sponges.		REFERENCE METHOD USDA FSIS MLG 41.04, Isolation and Identification of <i>Campylobacter jejuni/coli/lari</i> from Poultry Rinse, Sponge and Raw Product Samples (2)	
ORIGINAL CERTIFICATION DATE May 10, 2022		CERTIFICATION RENEWAL RECORD Renewed annually through December 2026.	
METHOD MODIFICATION RECORD 1. November 2023 Level 1		SUMMARY OF MODIFICATIONS 1. Editorial/clerical changes.	
Under this AOAC <i>Performance Tested Methods</i> SM License Number, 052201 this method is distributed by: NONE		Under this AOAC <i>Performance Tested Methods</i> SM License Number, 052201 this method is distributed as: NONE	

PRINCIPLE OF THE METHOD (1)

The RapidChek® *Campylobacter* method utilizes a proprietary enrichment medium. After enrichment (48±1 h), an aliquot of the enriched sample is transferred to a test tube to which a test strip is added. The sample flows up the test strip through a zone containing antibody-coated colloidal gold reagents specific to *C. jejuni*, *C. coli*, *C. lari*. Any antigens in the sample will bind to the antibody-conjugate to form an antigen/antibody complex. During migration through the nitrocellulose matrix, the antigen/antibody complex passes a zone of immobilized anti- *C. jejuni*, *C. coli*, *C. lari* antibody. In the presence of antigen, the complex is captured in this zone forming an antibody-antigen “sandwich” and is visualized by the formation of a red line. A second zone on the membrane captures any unbound antibody-gold complex. As a result, when *C. jejuni*, *C. coli*, or *C. lari* antigen is present, the formation of two red lines is observed, whereas when *C. jejuni*, *C. coli*, or *C. lari* is not present, only one line forms in the second zone, named the Control Line, indicating that the test was run properly.

DISCUSSION OF THE VALIDATION STUDY (1)

The RapidChek *Campylobacter* test method provides reliable presumptive results after 48 ± 1h of enrichment under aerobic conditions. All presumptive test strip results were confirmed by Campy-Cefex agar and R&F *Campylobacter jejuni/coli* Chromogenic Plating medium, and there were no discrepancies between the confirmation agars.

For each of the matrixes, the number of samples confirmed positive by the reference method from the candidate method was compared to the number of reference method positives (Tables 3 and 4) using POD and dPOD_C. The 95% confidence interval for the dPOD_C for the number of confirmed positive samples from the RapidChek *Campylobacter* method compared to the number of positive samples from the MLG 41.04 method contained zero. Therefore, there was no significant difference between the RapidChek *Campylobacter* method and the MLG 41.04 method results at the 5% level.

Additionally, the number of presumptive positives from the candidate method was compared to the number of confirmed positives by the candidate method cultural confirmation (Tables 3 and 4) using POD and dPOD_{CP}. The 95% confidence interval for the dPOD_{CP} for the number of presumptive samples from the RapidChek *Campylobacter* method compared to the confirmed positive contained zero. Therefore, there was no significant difference in the results at the 5% level. The RapidChek *Campylobacter* test system was able to detect 50 *C. jejuni*, *C. coli*, *C. lari* strains. Additionally, of the 30 exclusivity strains tested, including non-target *Campylobacter spp.*, none was detected by the test strip. The candidate method also showed a robust performance when subjected to small variations commonly encountered in food testing laboratories. The test strip showed consistency between lots and stable under recommended storage conditions.

Table 1. Results from RapidChek *Campylobacter* Method Inclusivity Evaluation (1)

No.	Bacterium ^a	Serotype	Source	Origin	Designation	Test Reactivity
1	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:26	ATCC ^b	Porcine feces	43477	+ ^e
2	<i>Campylobacter jejuni</i>	O:30	ATCC	Human feces	43479	+
3	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Bovine feces	33560	+
4	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Aborted ovine fetus	35918	+
5	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Human male infant	35919	+
6	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:10	ATCC	Pigeon	35925	+
7	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Animal feces	43430	+
8	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Human feces	43431	+
9	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:10	ATCC	Human feces	43438	+
10	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:21	ATCC	Human feces	43447	+
11	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Human feces	43449	+
12	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:31	ATCC	Human feces	43452	+
13	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:32	ATCC	Human feces	43453	+
14	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:50	ATCC	Human feces	43465	+
15	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:58	ATCC	Human feces	43470	+
16	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:60	ATCC	Human feces	43471	+
17	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>	O:62	ATCC	Human feces	49300	+
18	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Human feces	49349	+
19	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Human gastric biopsy	49350	+
20	<i>Campylobacter jejuni</i> subsp. <i>jejuni</i>		ATCC	Human feces	49351	+
21	<i>Campylobacter coli</i>		ATCC	Pig feces	33559	+
22	<i>Campylobacter coli</i>		ATCC	Swine	43133	+
23	<i>Campylobacter coli</i>	O:14	ATCC	Human feces	43473	+
24	<i>Campylobacter coli</i>	O:28	ATCC	Marmoset feces	43478	+
25	<i>Campylobacter coli</i>	O:39	ATCC	Turkey feces	43481	+
26	<i>Campylobacter coli</i>	O:46	ATCC	Human feces	43482	+
27	<i>Campylobacter coli</i>	O:47	ATCC	Ileum of pig	43483	+
28	<i>Campylobacter coli</i>	O:48	ATCC	N/A ^f	43484	+
29	<i>Campylobacter coli</i>	O:49	ATCC	Human feces	43485	+
30	<i>Campylobacter coli</i>		ATCC	Human feces	43488	+
31	<i>Campylobacter coli</i>		ATCC	N/A	49941	+
32	<i>Campylobacter coli</i>		ATCC	Ileum of pig	51729	+
33	<i>Campylobacter coli</i>		ATCC	Ileum of pig	51798	+
34	<i>Campylobacter lari</i>		ATCC	Herring gull cloaca	35221	+
35	<i>Campylobacter lari</i>		ATCC	Human	35223	+
36	<i>Campylobacter coli</i>		QL ^c	Poultry	31016.8	+
37	<i>Campylobacter coli</i>		ATCC	Chicken carcass	BAA-1061	+
38	<i>Campylobacter lari</i> subsp. <i>lari</i>		CCUG ^d	Human	15031	+
39	<i>Campylobacter lari</i> subsp. <i>lari</i>		CCUG	Sea Gull	15035	+
40	<i>Campylobacter lari</i>		CCUG	Human	19528	+
41	<i>Campylobacter lari</i>		CCUG	Human	20581	+
42	<i>Campylobacter lari</i>		CCUG	Human	19512	+
43	<i>Campylobacter lari</i>		CCUG	Human	19528	+
44	<i>Campylobacter lari</i>		CCUG	Sea Gull	20707	+
45	<i>Campylobacter lari</i>		CCUG	Human Stool	22395	+
46	<i>Campylobacter lari</i>		CCUG	Human Appendicitis	22396	+
47	<i>Campylobacter lari</i>		CCUG	Water	29405	+
48	<i>Campylobacter lari</i>		CCUG	Human	29406	+
49	<i>Campylobacter lari</i> subsp. <i>concheu</i>		CCUG	Human Feces	55788	+
50	<i>Campylobacter lari</i> subsp. <i>concheu</i>		CCUG	Human Infection	55789	+

^aCultures 1-35 tested by Romer Labs; cultures 36-50 tested by Q Laboratories.

^bATCC – American Type Culture Collection

^cQL – Q Laboratories Culture Collection

^dCCUG – Culture Collection University of Gothenburg

^e+ – Positive strip test result

^fN/A – Information non-available

Table 2. Results from RapidChek *Campylobacter* Method Exclusivity Evaluation (1)

No.	Bacterium ^a	Source	Designation	Origin	Test Reactivity
1	<i>Campylobacter fetus</i> subsp. <i>fetus</i>	ATCC ^b	33249	Human blood	- ^d
2	<i>Campylobacter fetus</i> subsp. <i>intestinalis</i>	ATCC	33293	Human feces	-
3	<i>Campylobacter helveticus</i>	ATCC	51209	Cat	-
4	<i>Campylobacter upsaliensis</i>	ATCC	43954	Dog feces	-
5	<i>Campylobacter hyointestinalis</i>	ATCC	35217	Intestine of swine	-
6	<i>Campylobacter sputorum</i> subsp. <i>BV. sputorum</i>	ATCC	49916	Bull semen	-
7	<i>Salmonella enterica</i> subsp. <i>enterica</i> ser. Kentucky	ATCC	9263	N/A ^e	-
8	<i>Acinetobacter baumannii</i>	ATCC	19606	N/A	-
9	<i>Arcobacter skirrowii</i>	ATCC	51399	Animal feces	-
10	<i>Aeromonas veronii</i>	ATCC	51106	Infected fish	-
11	<i>Enterococcus gallinarum</i>	ATCC	49573	Chicken intestine	-
12	<i>Listeria monocytogenes</i>	ATCC	19115	Human	-
13	<i>Macrococcus caseolyticus</i>	ATCC	13548	Cow's milk	-
14	<i>Serratia liquefaciens</i>	ATCC	27592	Milk	-
15	<i>Staphylococcus aureus</i>	ATCC	25923	Clinical isolate	-
16	<i>Vibrio parahaemolyticus</i>	ATCC	17802	Food poisoning isolate	-
17	<i>Providencia stuartii</i>	ATCC	49809	Clinical isolate	-
18	<i>Shigella</i> spp.	ATCC	23354	N/A	-
19	<i>Yersinia enterocolitica</i>	ATCC	23715	Human blood	-
20	<i>Citrobacter freundii</i>	QL ^c	11007.1	Clinical Isolate	-
21	<i>Klebsiella pneumoniae</i>	ATCC	10031	Clinical Isolate	-
22	<i>Pseudomonas aeruginosa</i>	ATCC	35032	Not Available	-
23	<i>Pseudomonas fluorescens</i>	QL	17041.3	Raw milk	-
24	<i>Enterobacter cloacae</i>	ATCC	23355	Spinal Fluid	-
25	<i>Escherichia coli</i> O157:H7	ATCC	43895	Raw Hamburger	-
26	<i>Hafnia alvei</i>	ATCC	51815	Milk	-
27	<i>Proteus mirabilis</i>	QL	11007.6	Veterinary	-
28	<i>Proteus vulgaris</i>	ATCC	6380	Clinical Isolate	-
29	<i>Serratia marcescens</i>	QL	11007.1	Bottled Water	-
30	<i>Streptococcus pneumoniae</i>	ATCC	19615	Pharynx of Child	-

^aCultures 1-19 tested by Romer Labs; cultures 20-30 tested by Q Laboratories.

^bATCC – American Type Culture Collection

^cQL – Q Laboratories Culture Collection

^d- – Negative strip test result

^eN/A – Information non-available

Table 3. Matrix Study – RapidChek Presumptive vs. Confirmed Results (3)

Matrix	Strain	MPN ^a /test portion (95% CI)	N ^b	RapidChek <i>Campylobacter</i> Presumptive Results				RapidChek <i>Campylobacter</i> Confirmed Results			
				x ^c	POD _{CP} ^d	95% CI		x	POD _{CC} ^e	95% CI	dPOD _{CP} ^f
Raw ground chicken	<i>C. jejuni</i> , ATCC 33560	N/A ^h	5	0	0.00	0.00, 0.43		0	0.00	0.00, 0.43	0.00
		0.46 (0.25, 0.81)	20	10	0.50	0.30, 0.70		10	0.50	0.30, 0.70	0.00
		2.02 (0.98, 4.23)	5	5	1.00	0.57, 1.00		5	1.00	0.57, 1.00	0.00
Raw ground chicken ⁱ	<i>C. jejuni</i> , ATCC 33560	N/A	5	0	0.00	0.00, 0.43		0	0.00	0.00, 0.43	0.00
		0.62 (0.36, 0.92)	20	8	0.40	0.22, 0.61		8	0.40	0.22, 0.61	0.00
		2.16 (0.92, 4.26)	5	5	1.00	0.57, 1.00		5	1.00	0.57, 1.00	0.00
Chicken carcass rinsate	<i>C. lari</i> , ATCC 35221	N/A	5	0	0.00	0.00, 0.43		0	0.00	0.00, 0.43	0.00
		N/A	20	17	0.85	0.64, 0.95		17	0.85	0.64, 0.95	0.00
		N/A	5	5	1.00	0.57, 1.00		5	1.00	0.57, 1.00	0.00
Turkey carcass sponges	<i>C. coli</i> , ATCC 43478	N/A	5	0	0.00	0.00, 0.43		0	0.00	0.00, 0.43	0.00
		N/A	20	14	0.70	0.48, 0.85		14	0.70	0.48, 0.85	0.00
		N/A	5	5	1.00	0.57, 1.00		5	1.00	0.57, 1.00	0.00

^aMPN = Most Probable Number

^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.

^hN/A = Not applicable.

ⁱMatrix tested in the independent laboratory.

Table 4. Matrix Study – RapidChek *Campylobacter* vs. MLG 41.04 (1)

Matrix	Strain	MPN ^a /test portion (95% CI)	N ^b	RapidChek <i>Campylobacter</i> Results			MLG 41.04 Results			dPOD _c ^f	95% CI ^g
				x ^c	POD _c ^d	95% CI	x	POD _R ^e	95% CI		
Raw ground chicken	<i>C. jejuni</i> , ATCC 33560	N/A ^h	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.46 (0.25, 0.81)	20	10	0.50	0.30, 0.70	5	0.25	0.11, 0.47	0.25	-0.03, 0.53
		2.02 (0.98, 4.23)	5	5	1.00	0.57, 1.00	4	0.80	0.38, 1.00	0.20	-0.23, 0.63
Raw ground chicken ⁱ	<i>C. jejuni</i> , ATCC 33560	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		0.62 (0.36, 0.92)	20	8	0.40	0.22, 0.61	6	0.30	0.15, 0.52	0.10	-0.18, 0.38
		2.16 (0.92, 4.26)	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Chicken carcass rinsate	<i>C. lari</i> , ATCC 35221	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		N/A	20	17	0.85	0.64, 0.95	15	0.75	0.53, 0.89	0.10	-0.13, 0.33
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43
Turkey carcass sponges	<i>C. coli</i> , ATCC 43478	N/A	5	0	0.00	0.00, 0.43	0	0.00	0.00, 0.43	0.00	-0.43, 0.43
		N/A	20	14	0.70	0.48, 0.85	15	0.75	0.53, 0.89	-0.05	-0.32, 0.22
		N/A	5	5	1.00	0.57, 1.00	5	1.00	0.57, 1.00	0.00	-0.43, 0.43

^aMPN = Most Probable Number is based on the POD of reference method test portions using the Least cost Formulations MPN calculator, with 95% confidence interval.

^bN = Number of test portions.

^cx = Number of positive test portions.

^dPOD_c = Candidate method presumptive positive outcomes confirmed positive.

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

^fdPOD_c = Difference between the candidate method and reference method 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.

^hN/A = Not applicable.

ⁱMatrix tested in the independent laboratory.

REFERENCES CITED

- Gonzalez, V., Juck, G., Sutzko, M., and Muldoon, M.T., Romer Labs RapidChek® *Campylobacter* Test System for the Detection of *C. jejuni*, *C. coli*, and *C. lari* in Poultry Samples, AOAC Performance Tested MethodsSM certification number 052201.
- U. S. Department of Agriculture-Food Safety and Inspection Service Microbiology Laboratory Guidebook (MLG), 41.04, Isolation and Identification of *Campylobacter jejuni/coli/lari* from Poultry Rinse, Sponge and Raw Product Samples (2016).
https://www.fsis.usda.gov/sites/default/files/media_file/2021-03/MLG-41.pdf [accessed January 2020]