



CERTIFICATION

AOAC Research Institute
***Performance Tested Methods*SM**

Certificate No.
012605

The AOAC Research Institute hereby certifies the method known as

EZ-Check *Listeria monocytogenes* Kit

manufactured by

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 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 February 10, 2026

Expiration Date December 31, 2026

METHOD NAME	CATALOG NUMBER	ORIGINAL CERTIFICATION DATE
EZ-Check <i>Listeria monocytogenes</i> Kit	12018082	January 30, 2026

PRINCIPLE OF THE METHOD

The EZ-Check *Listeria monocytogenes* Kit is a simple and rapid qualitative test, allowing for the detection of specific DNA sequences unique to *L. monocytogenes* found in environmental samples and food products. Using real-time polymerase chain reaction (PCR), *L. monocytogenes*-specific DNA sequences are amplified and detected simultaneously by means of fluorescent probes. Ninety-six tests can be processed at one time, with a minimized risk of contamination and an easy-to-use procedure.

The EZ-Check *Listeria monocytogenes* Kit is based on gene amplification and detection by real time PCR. The kit’s ready-to-use lyophilized PCR reagents contain oligonucleotides (primers and probes) specific to *L. monocytogenes*, as well as DNA polymerase and nucleotides. A synthetic DNA internal control is included in the reaction mix to validate any possible negative results. This control is amplified with a specific probe at the same time as the *Listeria* target DNA sequence. Detection and data analysis are optimized for use with a Bio-Rad real-time PCR instrument, such as the CFX Opus 96, CFX Opus Deepwell, CFX96 Touch Deep Well and CFX Duet Real Time PCR Detection systems.

CERTIFIED CLAIM STATEMENT: The iQ-Check *Listeria monocytogenes* method is certified for the detection of *Listeria monocytogenes* within the scope of Tables 1 and 2.

Certified method includes:

1. Real-Time PCR Systems: CFX Opus 96, CFX Opus Deepwell and CFX DUET; with CFX Maestro Software, IDE version 4.0
2. Optional Bio-Rad iQ-Check Prep System for automated DNA extraction and PCR plate setup, version 5
3. Optional Free DNA Removal Solution
4. Alternative confirmation protocol with a direct streak from the primary enrichment to RAPID’*Listeria*, RAPID’*Listeria mono* and Agar *Listeria* according to Ottaviani and Agosti Medium Agar

Table 1. Method Performance Claims

Matrix	Test Portion	Enrichment Conditions				Reference Method ^b	Claim
		Broth	Volume	Temperature	Time		
Raw whole milk (3.5% fat)	25 mL	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
	25 mL	LSB II	225 mL	37 ± 1°C	18-26 h	ISO 11290-1	NSDD
Raw whole milk cheese	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Mexican-style pasteurized soft cheese	125 g	LSB II	1125 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Ice cream	125 g	LSB II	1125 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Pasteurized cheddar cheese	125 g	LSB II	1125 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Beef hot dogs	125 g	LSB II	1125 mL	37 ± 1°C	18-26 h	MLG 8.15	NSDD
Turkey hot dogs	125 g	LSB II	1125 mL	37 ± 1°C	18-26 h	MLG 8.15	NSDD
Raw fermented sausage	125 g	LSB II	1125 mL	37 ± 1°C	18-26 h	MLG 8.15	NSDD

Frozen breaded chicken nuggets	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	MLG 8.15	NSDD
RTE deli ham	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	MLG 8.15	NSDD
	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	ISO 11290-1	NSDD
Salami	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	MLG 8.15	NSDD
RTE deli turkey	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	MLG 8.15	NSDD
Smoked salmon	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	ISO 11290-1	NSDD
Frozen cooked shrimp	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Fresh cut cantaloupe	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	ISO 11290-1	NSDD
Bagged salad (Romaine)	125 g	LSB II	1125 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Frozen vegetable blend	125 g	LSB II	1125 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Frozen green peas (carrots, corn, green beans, green peas)	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Egg salad	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Hummus	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	ISO 11290-1	NSDD
Deli salad (RTE macaroni salad)	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
Pasteurized whole liquid egg	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
	25 g	LSB II	225 mL	37 ± 1°C	18-26 h	ISO 11290-1	NSDD
Stainless steel	4"x4", sponge ^d	BPW	60 mL	37 ± 1°C	18-24 h	BAM Ch. 10 (Apr 2022)	NSDD
Sealed concrete	4"x4", sponge ^d	BPW	60 mL	37 ± 1°C	18-24 h	BAM Ch. 10 (Apr 2022)	NSDD
Rubber	1"x1", swab ^d	BPW	10 mL	37 ± 1°C	18-24 h	BAM Ch. 10 (Apr 2022)	NSDD
Process water	25 mL	LSB II	225 mL	37 ± 1°C	18-26 h	BAM Ch. 10 (Apr 2022)	NSDD
	25 mL	LSB II	225 mL	37 ± 1°C	18-26 h	ISO 11290-1	NSDD

^a LSB = *Listeria* Special Broth (20-25°C before use)

^b BAM = Bacteriological Analytical Manual; MLG = Microbiology Laboratory Guidebook, ISO = International Organization for Standardization

^c NSDD = No statistical difference detected using SLV study design from OMA Appendix J (2012). The SLV qualitative method comparison study design from OMA Appendix J (2012) is not intended to demonstrate statistical equivalence in unpaired studies. Expert opinion is that the method is appropriate for its intended use.

^d Sponges and swabs were premoistened in 10 mL and 1 mL Hi-Cap Neutralizing Broth, respectively.

Table 2. Method Selectivity

Broth ^a	Temperature	Inclusivity Strains		Exclusivity Strains	
		No. Tested	No. Positive	No. Tested	No. Positive
LSB II	37 ± 1°C	55 ^b	55	30 ^c	0

^a LSB = *Listeria* Special Broth (20-25°C before use)

^b Comprising serovars 1, 1/2a, 1/2b, 1/2c, 2, 3, 3a, 3b, 3c, 4a, 4ab, 4b, 4c, 4d, 4e and 7

^c Comprising 30 species, including 15 non-target *Listeria* species

Table 3. Method History

No.	Date	Summary	Supporting Data
1	January 2026	Original certification	Certification Report