



CERTIFICATION

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

Certificate No.

032503

The AOAC Research Institute hereby certifies the method known as

RESIST[®] Food *Listeria monocytogenes* Detection Kit

manufactured by

Kura Biotech

Avenida Gramado Interior 1410

Parcela 20

Puerto Varas, Chile

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

April 21, 2026

Expiration Date

December 31, 2026

METHOD NAMERESIST® Food *Listeria monocytogenes* Detection Kit**CATALOG NUMBER**

RF.LM.100

ORIGINAL CERTIFICATION DATE

March 27, 2025

PRINCIPLE OF THE METHOD

The RESIST Food *Listeria monocytogenes* Detection Kit is based on the rapid extraction of DNA from unknown samples followed by isothermal amplification of the target genetic material. The qualitative result can be obtained by fluorometric visualization, using a blue light transilluminator with excitation at 470 nm. To facilitate interpretation and traceability of the results, the fluorometric reaction can also be read using the Avenire Prime PCR equipment. This device delivers an automatic end-point fluorescence reading, ensuring a reliable and efficient result.

CERTIFIED CLAIM STATEMENT: The RESIST Food *Listeria monocytogenes* Detection Kit method is certified for the detection of *Listeria monocytogenes* within the scope of Tables 1 and 2 and the modification indicated in Table 3.

Certified method includes:

1. Transilluminator at 470 nm
2. Avenire Prime PCR, 16, 48, and 96 well platforms
3. Optional visual interpretation of results

Table 1. Method performance claims

Matrix	Test portion	Enrichment conditions				Reference method ^b	Claim ^c
		Broth ^a	Volume	Temperature	Time		
Fresh raw salmon	25 g	HF	225 mL	37 ± 1°C	27 ± 1 h	ISO 11290-1:2017	NSDD
Frozen cooked shrimp	25 g	HF	225 mL	37 ± 1°C	27 ± 1 h	ISO 11290-1:2017	NSDD
Smoked salmon	25 g	HF	225 mL	37 ± 1°C	27 ± 1 h	ISO 11290-1:2017	NSDD
Hot dog	25 g	HF	225 mL	37 ± 1°C	27 ± 1 h	ISO 11290-1:2017	NSDD
Turkey ham	25 g	HF	225 mL	37 ± 1°C	27 ± 1 h	ISO 11290-1:2017	NSDD
Stainless steel	4"x 4", sponge ^d	HF	90 mL	37 ± 1°C	27 ± 1 h	ISO 11290-1:2017	NSDD

^a HF = Half Fraser broth^b 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. Expert opinion is that the method is appropriate for its intended use.^d Sponge premoistened in 10 mL Dey/Engley neutralizing broth

Table 2. Method selectivity

Broth ^a	Temperature	Inclusivity strains		Exclusivity strains	
		No. tested	No. positive	No. tested	No. positive
HF	37 ± 1°C	51 ^b	51	34 ^c	4 ^d
HF	37 ± 1°C	25 ^b	25	15 ^e	1 ^f

^a HF = Half Fraser broth

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

^c Comprising 34 species including non-listeriae strains, and non-*monocytogenes* *Listeria* species, including *sensu stricto* strains *L. cossartiae* subsp. *cossartiae*, *L. immobilis*, *L. innocua*, *L. ivanovii*, *L. marthii*, *L. seeligeri*, *L. swaminathanii*, *L. welshimeri*, and *sensu lato* strains *L. aquatica*, *L. booriae*, *L. cornellensis*, *L. costaricensis*, *L. fleischmannii* subsp. *fleischmannii*, *L. floridensis*, *L. grandensis*, *L. grayii*, *L. newyorkensis*, *L. portnoyi*, *L. riparia*, *L. rocourtiae*, *L. rustica*, *L. thailandensis*, *L. valentina*, *L. weihenstephanensis*.

^d *L. marthii*, *L. cossartiae* subsp. *cossartiae*, *L. immobilis*, and *L. swaminathanii* were detected.

^e Comprising 15 species including *sensu stricto* strains *L. cossartiae* subsp. *cossartiae*, *L. immobilis*, *L. innocua*, *L. ivanovii*, *L. marthii*, *L. seeligeri*, *L. swaminathanii*, *L. welshimeri*, and *sensu lato* strains *L. cornellensis*, *L. costaricensis*, *L. fleischmannii* subsp. *fleischmannii*, *L. grayii*, *L. newyorkensis*, *L. rustica*.

^f *L. marthii* was detected.

Table 3. Method history

No.	Date	Summary	Supporting data
1	March 2025	Original Certification	Certification Report
2	March 2026	Level 2 Modification: Addition of frozen cooked shrimp, hot dog, turkey ham, and smoked salmon; addition of Avenire Prime 96 instrument	Modification 1 Report