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.

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

Issue Date	March 27, 2025
Expiration Date	December 31, 2025

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METHOD NAME	CATALOG NUMBER	ORIGINAL CERTIFICATION DATE
RESIST® Food *Listeria monocytogenes* Detection Kit	RF.LM.100	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 instrument. This device delivers an automatic end-point fluorescence reading, ensuring reliable and efficient results.

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.

***Certification includes**:*

1. Transilluminator at 470 nm.
2. Avenire Prime PCR with Software Version 1.0.282 (1.0.95).
3. Optional visual interpretation of results.

Table 1. Method Performance Claims

		Enrichment Conditions					
Matrix	Test Portion	Broth[a]	Volume	Temperature	Time	Reference Method[b]	Claim[c]
Fresh raw salmon	25 g	HF	225 mL	37 ± 1°C	27 ± 1 h	ISO 11290-1:2017	NSDD
Stainless steel	4”x 4”, sponge	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.

Table 2. Method Selectivity

Enrichment		Inclusivity Strains		Exclusivity Strains	
Broth[a]	Temperature	No. Tested	No. Positive	No. Tested	No. Positive
HF	37 ± 1°C	51[b]	51	34[c]	4[d]

[a] HF = Half Fraser broth.

[b] Comprising 51 strains of *Listeria monocytogenes* including 13 strains ser. 1/2a, 7 strains ser. 1/2b, 4 strains ser. 1/2c, 3 strains ser. 3a, 5 strains ser. 3b, 3 strain ser. 3c, 2 strain ser. 4a, 11 strains ser. 4b, 1 strain ser. 4c, 1 strain ser. 4d, 1 strain ser. 4e.

[c] Comprising 34 species including 9 non-listeriae strains, and 25 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.

Table 3. Method Summary

No.	Date	Summary	Supporting Data
1	March 2025	Original Certification.	Certification Report