

## **CERTIFICATION**

# AOAC Research Institute Performance Tested Methods<sup>SM</sup>

Certificate No.

052401

The AOAC Research Institute hereby certifies the method known as:

## Microlab Salmonella

manufactured by

Zeulab S.L. Calle Bari 25 dpdo Zaragoza, Spain 50197

This method has been evaluated in the AOAC Research Institute *Performance Tested Methods*<sup>SM</sup> Program and certified for its intended use. 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
Expiration Date

May 26, 2024 December 31, 2024 METHOD NAME Microlab Salmonella **CATALOG NUMBER** ZE/MISAL6

ORIGINAL CERTIFICATION DATE May 20, 2024

#### PRINCIPLE OF THE METHOD

Microlab Salmonella integrates all the necessary components to carry out the steps of enrichment, specific detection, and bacterial inactivation in a single disposable device. In the enrichment step, Salmonella O antigens for Groups A-E grow up to detectable levels in a ready-to-use culture medium. In the following step, a lateral-flow immunoassay detects Salmonella O antigens for Groups A-E, which react on the test strip with a specific antibody bound to red particles. In this way, the appearance of a red line on the test strip corresponds to a positive result. A blue control line indicates the correct development of the test. The final inactivation step consists of a solution that inactivates any microorganism that may have grown in the culture medium.

INTENDED USE: The Zeulab S.L. Microlab Salmonella method is certified for the detection of Salmonella O antigens for Groups A-E within the scope of Table 1 and Table 2.

**Table 1. Method Performance Claims** 

		Enrichment Conditions				
Matrix	<b>Test Portion</b>	Brotha	Temperature	Time	Reference Method <sup>b</sup>	Claim <sup>c</sup>
Raw ground beef	25 g	pwBPW	37 ± 1 °C	24 h ± 1 h	ISO 6579:2020	NSDD
Raw turkey (thermal processed, marinated)	25 g	pwBPW	37 ± 1 °C	24 h ± 1 h	ISO 6579:2020	NSDD
Fresh cheese (queso fresco)	25 g	pwBPW	37 ± 1 °C	24 h ± 1 h	ISO 6579:2020	NSDD
Pasteurized liquid egg	25 mL	pwBPW	37 ± 1 °C	24 h ± 1 h	ISO 6579:2020	NSDD
Deli ham <sup>d</sup>	25 g	pwBPW	37 ± 1 °C	24 h ± 1 h	ISO 6579:2020	NSDD

<sup>&</sup>lt;sup>a</sup> Buffered Peptone Water contained within device; device is prewarmed to 37 ± 1 °C.

<sup>&</sup>lt;sup>b</sup> International Organization for Standarization.

<sup>&</sup>lt;sup>c</sup> NSDD = No statistical difference detected using SLV 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.

<sup>&</sup>lt;sup>d</sup> Matrix analyzed by Zeulab and the Independent Laboratory.

**Table 2. Method Selectivity** 

Enrichment		Inclusivit	:y Strains <sup>b</sup>	Exclusivity Strains <sup>c</sup>	
Broth <sup>a</sup>	Temp., °C	No. Tested	No. Positive	No. Tested	No. Positive
pwBPW	37 ± 1 °C	100	99	40	0

 $<sup>^{\</sup>circ}$  Buffered Peptone Water contained within device; device is prewarmed to 37 ± 1  $^{\circ}$ C.

### **REFERENCES CITED**

1. Alonso, R., Razgiun, P., Carrascón, V., & Mata, L. (2024) Validation of the Microlab Salmonella for Detection of Salmonella O Group A-E in selected foods.

<sup>&</sup>lt;sup>b</sup> Inclusivity study: Zeulab analyzed 38 *Salmonella* O Group A-E strains comprised of 38 serovars. The Independent Laboratory analyzed 62 *Salmonella* O Group A-E strains comprised of 62 serovars.

<sup>&</sup>lt;sup>c</sup> Exclusivity study: Zeulab analyzed 30 non-Salmonella species comprised of 21 species. The Independent Laboratory analyzed 10 non-Salmonella species, of which 5 were the same species as tested by Zeulab. All exclusivity organisms were cultured under optimal conditions for growth.