

**RESULTS INTERPRETATION**

ARA	MEGLU	X-GLUPY	D-AMP	IDENTIFICATION
-	-	-	*	Not- <i>Listeria</i> sp.
-	+	+	*	Not- <i>Listeria</i> sp.
-	-	+	*	Not- <i>Listeria</i> sp.
-	+	-	*	Not- <i>Listeria</i> sp.
+	-	-	*	Not- <i>Listeria</i> sp.
+	-	+	*	Not- <i>Listeria</i> sp.
+	+	-	*	Not- <i>Listeria</i> sp.
+	+	+	+	<i>Listeria</i> sp. not- <i>monocytogenes</i>
+	+	+	-	<i>Listeria monocytogenes</i>

* When even one of the tests ARA, MEGLU, X - GLUPY is negative, do not read the AMP reaction

10 - USER QUALITY CONTROL

All manufactured lots of the product are released for sale after the Quality Control has been performed to check the compliance with the specifications. However, the end user can perform its own Quality Control in accordance with the local applicable regulations, in compliance with accreditation requirements and the experience of the Laboratory. Here below are listed the test strains useful for the quality control.

Positive control: *L. monocytogenes* ATCC 13932 or ATCC 19111

Negative control: *L. innocua* ATCC 33090

ATCC is a trademark of American Type Culture Collection

11 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of Mono Confirm Test is tested with positive and negative strains.

Pure cultures of the strains shown below are inoculated in the wells and colour development is recorded after 18-24 hours of incubation

L. monocytogenes strains: ATCC 19111, ATCC 13932, ATCC 7644, CB 001, CB002,

Listeria non-monocytogenes strains: *L. innocua* ATCC 33090, *L. gray* CB007, *L. ivanovii* ATCC 19119, *L. murray* CB 008, *L. seeligeri* ATCC 35967, *L. welshimeri* CB 006.

Non-*Listeria* strains: *S. aureus* ATCC 25923, *E. faecalis* ATCC 19433, *P. aeruginosa* ATCC 27853

All tested bacterial strains develop coloration in the wells in accordance with specifications.

CB: Biolife microbial collection

12 - LIMITATIONS OF THE METHOD

- According to ISO 11290, isolates which are considered to be *L. monocytogenes* may be sent for further characterization to a recognized national or regional *Listeria* Reference Laboratory.¹

13 - PRECAUTIONS AND WARNINGS

- This product is for laboratory use and for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is classified as dangerous according to the current European legislation. Consult the Safety Data Sheet before the use.
- Apply good laboratory practice guidelines when performing the test.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as the reagents, the culture media or the microbial strains.
- Sterilize all biohazard waste before disposal. Dispose the used and unused strips and the plates inoculated with samples or microbial strains in accordance with current local legislation.
- The Certificates of Analysis and the Safety Data Sheet are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

14 - STORAGE CONDITIONS AND SHELF LIFE

Upon receipt, store the product in the original pack with the cap tightly closed, at +2/+8°C away from direct light. If properly stored, the product may be used up to the expiration date. Do not use the product beyond this date.

15 - REFERENCES

- ISO 11290-1:2017. Microbiology of the food chain - Horizontal method for the detection and enumeration of *Listeria monocytogenes* and of *Listeria* spp. - Part 1: Detection method.

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	Manufacturer	This side up	Fragile, handle with care
Temperature limitation	Content sufficient for <n> tests	Consult Instructions for Use	Use by	Keep away from direct light

REVISION HISTORY

Version	Description of changes	Date
Revision 3	Updated layout and content	2023/03

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.

