



CERTIFICATE

No. J - 2623/4/2022

This is to certify that:

BioMaxima S.A.
ul. Vetterów 5, 20-277 Lublin

is in conformance with

PN-EN ISO 9001:2015-10

in the following scope of activities:

- **Design, manufacturing, sales and distribution of reagents, tests, microbiological media and systems for in-vitro diagnostics and industrial applications**
- **Distribution of products and service of in vitro diagnostic equipment and industrial applications**

The audit carried out by the Polish Centre for Testing and Certification has afforded evidence of the above.

This Certificate shall remain valid provided that above standard are respected by the Organization.

This certificate is valid:

from **16.09.2022** to **15.09.2025**

Issued under the Contract No. 3009/JM/4/2022

Date of certification decision: 09.09.2022

Certificate bears a qualified signature.

Warsaw, 09.09.2022



AC 019



POLSKIE CENTRUM AKREDYTACJI

POLISH CENTRE FOR ACCREDITATION



Sygnatariusz EA MLA
EA MLA Signatory

CERTYFIKAT AKREDYTACJI

LABORATORIUM BADAWCZEGO

ACCREDITATION CERTIFICATE OF TESTING LABORATORY

Nr AB 1863

Potwierdza się, że: / This is to confirm that:

BioMaxima S.A.
Laboratorium Kontroli Jakości Mikrobiologia
ul. Vetterów 5
20-277 Lublin

spełnia wymagania normy PN-EN ISO/IEC 17025:2018-02
meets requirements of the PN-EN ISO/IEC 17025:2018-02 standard

Akredytowana działalność jest określona w Zakresie Akredytacji Nr AB 1863
Accredited activity is defined in the Scope of Accreditation No AB 1863

Akredytacja pozostaje w mocy pod warunkiem przestrzegania
wymagań jednostki akredytującej określonych w kontrakcie Nr AB 1863
This accreditation remains in force provided the Laboratory observes
the requirements of Accreditation Body defined in the Contract No AB 1863



DYREKTOR
POLSKIEGO CENTRUM AKREDYTACJI

LUCYNA OLBORSKA

Warszawa, 16 czerwca 2023 roku



EU Declaration of Conformity

for In Vitro Diagnostic Medical Devices
according to Annex IV of Regulation (EU) 2017/746

Manufacturer: BioMaxima S.A., Vetterów 5, 20-277 Lublin, Poland

SRN: Not Available

Product Name: Chromogenic Listeria LAB-AGAR™ Base acc. to ISO 11290

Basic UDI-DI: Not Available

Classification (IVDR, Annex VIII): Class A, Rule 5

We herewith under our sole responsibility declare that the above mentioned products meet the provisions of the Regulation (EU) 2017/746

The manufacturer is exclusively responsible for the declaration of conformity.

Place and date of issue:

Lublin, 27.05.2022

Signed on behalf of BioMaxima S.A.:

Henryk Lewczuk
VicePresident

A blue ink signature of Henryk Lewczuk.

Patrycja Paniak -Sankowska
Proxy

A blue ink signature of Patrycja Paniak -Sankowska.



EU Declaration of Conformity

for In Vitro Diagnostic Medical Devices
according to Annex IV of Regulation (EU) 2017/746

Manufacturer: BioMaxima S.A., Vetterów 5, 20-277 Lublin, Poland

SRN: Not Available

Product Name: Chromogenic Listeria Set Supplement a cc. to ISO 11290

Basic UDI-DI: Not Available

Classification (IVDR, Annex VIII): Class A, Rule 5

We herewith under our sole responsibility declare that the above mentioned products meet the provisions of the Regulation (EU) 2017/746

The manufacturer is exclusively responsible for the declaration of conformity.

Place and date of issue:

Lublin, 27.05.2022

Signed on behalf of BioMaxima S.A.:

Henryk Lewczuk
VicePresident

A blue ink signature of Henryk Lewczuk.

Patrycja Paniak -Sankowska
Proxy

A blue ink signature of Patrycja Paniak -Sankowska.

Box: 5+ 5 vials / 2 vials / 500 ml

Intended use

The selective/enrichment supplement here described is used for the preparation of Chromogenic Listeria acc. to ISO 11290 LAB-AGAR™ plating medium for the isolation of Listeria spp. from food, environmental or clinical specimens and for the detection of Listeria monocytogenes. For the details of the procedure see the technical sheet of Chromogenic Listeria LAB- AGAR™Base acc. to ISO 11290 (ref. PS 165)

Selective supplement**Vial for 500 ml of medium base**

Nalidixic acid	10 mg	Amphotericin B.....	5 mg
Ceftazidime	10 mg	Polimixin B.....	38350 IU

Directions

Dissolve the contents of one vial of Selective Supplement with 5 ml of a mixture of sterile distilled water-ethanol (1:1) and add to 500 ml of Chromogenic Listeria acc.t to ISO 11290 Base (PS165) autoclaved and cooled to 50°C, together with the contents of one vial of Enrichment Supplement pre-warmed to 48-50°C. Mix well and distribute in sterile Petri dishes. Aspect of the medium: homogeneously turbid.

Enrichment supplement – ready to use**Vial for 500 ml of medium base**

L- fosphatidylinositol.....	1,0 g	Distilled water.....	20 ml
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Precautions:

- ★ For Laboratory use only
- ★ The supplement should be used only by adequately trained personnel with knowledge of microbiological techniques in the laboratory.
- ★ Consult the material safety data sheet before the use.
- ★ Do not use beyond stated expiry date

Storage / Shelf life

- ★ Store at 2-8°C - When stored as directed the supplement remains stable until the expiry date shown on the label
- ★ The expiration date is indicated on the label



Box: 10 vials / 1 vial / 500 ml

Intended use

Supplement for the detection of *Listeria* spp. from food and other samples.

Vials for 500 ml of medium base

Ammonium iron (III) citrate 250,0 mg
Nalidixic acid sodium salt 10,0 mg
Acryflavine HCl 12,5 mg

Directions

Aseptically reconstitute 1 vial with 4 ml of 1:1 solution ethanol / sterile distilled water.

Mix gently until complete dissolution. Aseptically add vial to 500 ml Fraser Listeria Enrichment Broth Base (ref. PS 99), autoclaved and cooled to 50 °C. Mix well and distribute into sterile containers.

Precautions:

- ★ For Laboratory use only
- ★ The supplement should be used only by adequately trained personnel with knowledge of microbiological techniques in the laboratory.
- ★ Consult the material safety data sheet before the use.
- ★ Do not use beyond stated expiry date

Storage / Shelf life

- ★ Store at 2-8°C - When stored as directed the supplement remains stable until the expiry date shown on the label
- ★ The expiration date is indicated on the label



Box: 10 vials / 1 vial / 225 ml

Intended useSupplement for the detection of *Listeria* spp.**Vials for 225 ml of medium base**

Ferric ammonium citrate..... 112,50 mg
Nalidixic acid 2,25 mg
Acryflavine HCl 2,8125 mg

Directions

Aseptically reconstitute 1 vial with 2 ml of 1:1 solution ethanol / sterile distilled water.
Mix gently until complete dissolution. Aseptically add vial to 225 ml Fraser Listeria Enrichment Broth Base (ref. PS 99), autoclaved and cooled to 50 °C. Mix well and distribute into sterile containers.

Precautions:

- ★ For Laboratory use only
- ★ The supplement should be used only by adequately trained personnel with knowledge of microbiological techniques in the laboratory.
- ★ Consult the material safety data sheet before the use.
- ★ Do not use beyond stated expiry date

Storage / Shelf life

- ★ Store at 2-8°C - When stored as directed the supplement remains stable until the expiry date shown on the label
- ★ The expiration date is indicated on the label



Enrichment medium for the detection of *Listeria* in food and environmental samples acc. to ISO 11290-1 standard.

Formula in g/L

Sodium chloride	20,00	Disodium hydrogen phosphate 2-hydrate....	12,00
Enzymatic digest of animal tissues.....	5,00	Tryptone (enzymatic digest of casein).....	5,00
Yeast extract.....	5,00	Beef extract	5,00
Lithium chloride	3,00	Dipotassium hydrogen phosphate	1,35
Esculin	1,00		

Final pH at 25°C: 7,2 ± 0,2

Principle:

Fraser Listeria Enrichment Broth Base is an appropriate medium for the selective enrichment of *Listeria* in the two-step method according to ISO 11290-1, for the preparation of Fraser or Half Fraser Broth by adding the respective supplements.

It is recommended for the detection of *Listeria* spp. in food products and in sample from the environment. All *Listeria* species hydrolyse the esculin to esculentin, which reacts with iron ions producing blackening of the medium. Another advantage of this medium is that the addition of ferric ammonium citrate improves the growth of *Listeria monocytogenes*. Lithium chloride included in the medium, along with nalidixic acid and acryflavine from the supplement, inhibit the growth of the accompanying flora, which can hydrolyze the esculin. The high amount of sodium chloride inhibits the growth of enterococci. Tryptone, proteose peptone and beef extract provide nitrogen, vitamins, minerals and amino acids essential for growth. Yeast extract is the source of vitamins, particularly of the B-group. Phosphate salts act as a buffer.

Preparation: suspend 28,68 grams of the medium in 500 ml of distilled water. Mix well and dissolve by heating with frequent agitation until complete dissolution. Sterilize in autoclave at 121°C for 15 minutes. Cool to 45-50°C and add one vial of Half Fraser Listeria Selective Supplement (ref. SL 0014) or Fraser Listeria Selective Supplement (ref. SL 0012). Mix well.

The prepared medium should be stored at 2-8°C.

Procedure:

Detection of *Listeria monocytogenes* according to standard method: Refer to standards ISO 11290-1

Storage / Shelf life

- ★ Once opened keep powdered medium closed to avoid hydration at 2 - 30°C
- ★ The expiration date is indicated on the label.

Microbiological test

The following results were obtained in the performance of the medium from type cultures after incubation at a temperature of 30±1°C and observed 24 ± 3 hours – Half Fraser Broth and after incubation at a temperature of 37±1°C and observed 28 ± 3 hours – Fraser Broth

Microorganisms	Growth	Esculin reactions
<i>Listeria monocytogenes</i> ATCC 19111	Good	+
<i>Enterococcus faecalis</i> ATCC 29212	Null	-

Packaging: 500 g

Supplements: Half Fraser Listeria Selective Supplement 10 vials. 1 vial / 500 ml (ref. SL 0014)
Fraser Listeria Selective Supplement 10 vials. 1 vial / 500 ml (ref. SL 0012)



Selective medium for the detection and enumeration of *Listeria monocytogenes*. Medium is recommendations of the norm: ISO 11290-1 and ISO 11290-2.

Formula in g/L

Enzymatic digest of animal tissues	18,00	Enzymatic digest of casein.....	6,00
Yeast extract.....	10,00	Sodium pyruvate	2,00
Glucose.....	2,00	Lithium chloride.....	10,00
Magnesium glycerophosphate.....	1,00	Magnesium sulphate anh.	0,50
Sodium chloride	5,00	Disodium hydrogen phosphate anh.	2,50
5-bromo-4-chloro-3-indolyl- β -D-glucopyranoside	0,05	Agar	13,50

Final pH at 25°C: 7,2 \pm 0,2

Principle:

Chromogenic medium for the presumptive isolation, enumeration and identification of *Listeria monocytogenes* and *Listeria* spp. in food and clinical samples. It is used for confirmation after using *Listeria* Enrichment Broth Base (PS 99). The differential activity of the medium is due to two factors. On one hand, the presence of the chromogenic component X-glucoside, a substrate for the detection of the enzyme β -glucosidase, common to all *Listeria* species giving the colonies their blue colour. Other organisms that possess this enzyme, for example enterococci, are inhibited by the selective agents within the medium and by the selective supplement. On the other hand, the differential activity is also obtained by the lipase substrate, upon which the specific enzyme for *L. monocytogenes* acts. The lipase is responsible for the opaque white halo which surrounds *L. monocytogenes*. The combination of both substrates allows us to differentiate the colonies of *Listeria monocytogenes* from the rest of *Listeria* spp. since, although all are blue in colour, *L. monocytogenes* present an opaque white halo surrounding them. It has been observed that some strains of *Listeria ivanovii*, mostly pathogenic to animals although some of which have caused infections in humans, also lipase activity.

Preparation: suspend 35,25 grams of the medium in 500 ml of distilled water. Mix well and dissolve by heating with frequent agitation until complete dissolution. Sterilize in autoclave at 121°C for 15 minutes. Cool to 45-50°C add 2 vials of Chromogenic *Listeria* Set Supplement acc. to ISO 11290 (ref. SL 0001). Mix well and pour into sterile Petri dishes .

Procedure:

Detection and enumeration of *Listeria monocytogenes* according to standard method: Refer to standards ISO 11290-1 and ISO 11290-2

Morphology colony:

***Listeria* species:** blue to blue –green colonies, round regular, without any opaque halo, diameter from 1 to 2 mm;

***Listeria monocytogenes* :** colonies with *Listeria* spp. Characteristics and surrounded by an opaque halo. *L. monocytogenes* strains grow as typical colonies in 24 hours

Storage / Shelf life

- ★ Once opened keep powdered medium closed to avoid hydration at 2 - 25°C
- ★ The expiration date is indicated on the label.

Packaging: 500 g

Supplement: Chromogenic *Listeria* Set Supplement acc. to ISO 11290 2 x 5 vials 1+1/500 ml Ref. SL 0001

