Biolife Italiana S.r.l

Viale Monza, 272
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Certified Quality System
ISO 13485:2016
Cert. n° D2001500012
ISO 9001:2015
Cert. n° D2001500013

DICHIARAZIONE CE DI CONFORMITA'

EC Declaration of Conformity

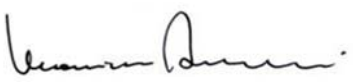
Con il presente documento, Biolife Italiana S.r.l. con sede legale in Viale Monza 272 - 20128 Milano dichiara, sotto la propria responsabilità, che i prodotti sotto elencati, classificati come Dispositivi Medici Diagnostici In Vitro (IVD) sono conformi ai requisiti essenziali della Direttiva Europea 98/79/EC sulla diagnostica in vitro e sono in accordo con l'Allegato III della Direttiva medesima.
La dichiarazione di Conformità è redatta secondo la Direttiva Europea 98/79/EC Allegato III.

Validità: questo documento è valido per 3 anni dalla data di emissione ed è revisionato su base annuale.

With this document, Biolife Italiana S.r.l. with legal address in Viale Monza 272 - 20128 Milan declares, under its own responsibility, that the products listed below, classified as In Vitro Diagnostic Medical Devices (IVD), comply with the Essential requirements of the European Directive 98/79/EC on in vitro diagnostics and are in accordance with Annex III of the Directive itself.
The declaration of conformity is drafted according to the European Directive 98/79/EC Annex III.

Validity: this document is valid for 3 years from the date of issue and is revised on an annual basis.

Biolife Italiana Srl
Dr Massimo Brunelli



Direttore Generale/*General Manager*

Milano, 30-03-2020

REV.3

Digitally signed by Ceaicovschi Tudor
Date: 2023.06.22 15:56:46 EEST
Reason: Modulgp Signature
Location: Moldova

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REF N° **Nome commerciale del prodotto /*Device Commercial Name***

TERRENI DI COLTURA IN POLVERE / *DEHYDRATED CULTURE MEDIA FOR MICROBIOLOGY*

EDMA CLASS. 14 01 01 01 / 14 03 01 01

4010342	AMIES TRANSPORT MEDIUM-500G
4010492	ANTIBIOGRAMMA BASE AGAR-500G
4010494	ANTIBIOGRAMMA BASE AGAR-5KG
4011002	AZIDE BLOOD AGAR BASE -500G
4011102	AZIDE VIOLET BLOOD AGAR BASE-500G
4011532	BCSA BURKHOLDERIA CEPACIA SELECTIVE AGAR BASE-500 G
4011534	BCSA BURKHOLDERIA CEPACIA SELECTIVE AGAR BASE-5KG
4011452	BIOTONE -TRYPTOSE AGAR -500G
4011464	BIOTONE -TRYPTOSE BROTH -5 KG
4011462	BIOTONE -TRYPTOSE BROTH -500G
40121022	BISMUTH SULPHITE AGAR USP-500G
4011552	BLOOD AGAR BASE -500G
4011554	BLOOD AGAR BASE -5KG
4011564	BLOOD AGAR BASE N. 2 - 5KG
4011562	BLOOD AGAR BASE N°2 -500G
4012352	BRAIN HEART INFUSION AGAR -500G
4012354	BRAIN HEART INFUSION AGAR -5KG
4012302	BRAIN HEART INFUSION BR-500G
4012304	BRAIN HEART INFUSION BR-5KG
4012752	BRUCELLA MEDIUM BASE -500G
4012832	CAMPY. BLOOD FREE MEDIUM BASE -KARMALI-500G
4012852	CAMPY..BLOOD AGAR BASE -500G
4012802	CANDIDA AGAR (NICKERSON) -500G
4012872	CARY BLAIR TRANSPORT MEDIUM
4013002	CHAPMAN-STONE MEDIUM -500G
4080001	CHROMALBICANS AGAR - 100G
4080002	CHROMALBICANS AGAR - 500G
4080102	CHROMART STREPTO B BASE
4080252	CHROMART CRE-ESBL BASE
4080052	CHROMOGENIC CANDIDA AGAR (CCA)
4055811	CHROMOGENIC E.COLI 0157 AGAR -100G
4055812	CHROMOGENIC E.COLI 0157 AGAR -500G
4053501	CHROMOGENIC SALMONELLA AG.BASE-100G
4053502	CHROMOGENIC SALMONELLA AG.BASE-500G
4098102	CHROMOGENIC URINE AGAR II -500G
409810S2	CHROMOGENIC URINE AGAR III (CLEAR)-500G
409810G1	CHROMOGENIC URINE AGAR IV -100G
409810G2	CHROMOGENIC URINE AGAR IV -500G
4013022	CIN AGAR BASE -500G
40129012	CLED MEDIUM -500G
40129014	CLED MEDIUM -5KG
4013082	CLOSTRIDIUM DIFFICILE AGAR BASE-500G
4011362	COLUMBIA AGAR BASE -500G
4011364	COLUMBIA AGAR BASE -5KG
40113614	COLUMBIA CNA AGAR BASE- 5 KG
40113612	COLUMBIA CNA AGAR BASE-500G
40133112	CPLM SELECTIVE WITH CAF-500G
4013312	CPLM TRICHOMONAS BROTH-500G
4013672	DECARBOXYLASE FALKOW BASE BROTH-500G
4013662	DECARBOXYLASE MOELLER BASE BROTH-500G
40136912	DERMATOPHYTE SELECTIVE MEDIUM -500G
4013702	DESOXYCHOLATE AGAR -500G
4013752	DESOXYCHOLATE CITRATE AGAR -500G
4013682	DESOXYRIBONUCLEASE TEST MEDIUM -500G
4013302	DRIGALSKI LACTOSE AGAR -500G
4015242	G N BROTH HAJNA -500G
4015202	GC MEDIUM BASE -500G
4015204	GC MEDIUM BASE -5KG
4015412	HEKTOEN ENTERIC AGAR -500G
4015414	HEKTOEN ENTERIC AGAR -5KG
4015432	HERELLEA AGAR -500G

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4015452	INDOLE NITRATE BROTH -500G
4015602	KLIGLER IRON AGAR -500G
4015822	LEGIONELLA BCYE AGAR BASE - 500 G
4015952	LEVINE EMB BLUE AGAR -500G
4015954	LEVINE EMB BLUE AGAR -5KG
4016352	LOWENSTEIN-JENSEN MEDIUM BASE-500G
4016354	LOWENSTEIN-JENSEN MEDIUM BASE-5000G
4016422	LUXURIAN AGAR (EUGONIC) -500G
4016432	LUXURIAN BROTH (EUGONIC) -500G
4016362	LYSINE IRON AGAR -500G
4017434	M. K. TETRATHIONATE BROTH -5 KG
4017432	M. K. TETRATHIONATE BROTH -500G
4016704	MAC CONKEY AGAR - 5KG
4016702	MAC CONKEY AGAR -500G
4016724	MAC CONKEY AGAR MUG - 5KG
4016722	MAC CONKEY AGAR MUG -500G
401669S2	MAC CONKEY SORBITOL AGAR -500G
4016692	MAC CONKEY SORBITOL MUG AGAR -500G
4016852	MALONATE BROTH -500G
4016652	MANNITOL SALT AGAR -500G
4016654	MANNITOL SALT AGAR -5KG
4017352	MRVP MEDIUM -500G
4017402	MULLER HINTON AGAR II -500G
4017404	MULLER HINTON AGAR II -5KG
4017412	MULLER HINTON BROTH -500G
4017602	MYCOBIOS AGAR -500G
4017612	MYCOBIOS SELECTIVE AGAR -500G
4018104	NUTRIENT AGAR - 5KG
4018102	NUTRIENT AGAR -500G
4018154	NUTRIENT BROTH - 5KG
4018152	NUTRIENT BROTH -500G
4018202	NUTRIENT GELATIN -500G
4018362	O/F HUGH LEIFSON BASE -500G
4019052	PHENOL RED AGAR BASE -500G
4019102	PHENOL RED BROTH BASE -500G
4019162	PHENYLALANINE AGAR -500G
4019612	PSEUDOMONAS AGAR F -500G
4019622	PSEUDOMONAS AGAR P -500G
4019632	PSEUDOMONAS SELECTIVE AGAR -500G
4019804	RAPPAPORT VASSILIADIS BROTH - 5KG
4019802	RAPPAPORT VASSILIADIS BROTH -500G
4019852	ROGOSA BIOS AGAR -500G
4019902	ROGOSA BIOS BROTH -500G
4020062	SABOURAUD DEX.AGAR W/CAF 50 -500G
4020072	SABOURAUD DEXT.AGAR CAF 500MG -500G
4020054	SABOURAUD DEXTROSE AGAR - 5KG
4020052	SABOURAUD DEXTROSE AGAR -500G
4020064	SABOURAUD DEXTROSE AGAR W/CAF50-5KG
4020102	SABOURAUD MALTOSE AGAR -500G
4020104	SABOURAUD MALTOSE AGAR -5KG
4020254	SELENITE BROTH - 5KG
4020252	SELENITE BROTH -500G
402025B2	SELENITE BROTH BASE -500G
4020362	SIM BIOS MEDIUM -500G
4020452	SIMMONS CITRATE AGAR -500G
4020754	SS AGAR - 5KG
4020752	SS AGAR -500G
4020852	STAPHYLOCOCCI 110 MEDIUM -500G
4020872	STREPTOCOCCUS SELECTIVE AGAR -500G
4020882	STREPTOCOCCUS SELECTIVE BROTH-500G
4020912	STUART TRANSPORT MEDIUM -500G
4021062	TCBS KOBAYASHI AGAR -500G
4021064	TCBS KOBAYASHI AGAR -5KG
4021374	THIOGLYCOLLATE MEDIUM - 5KG
4021372	THIOGLYCOLLATE MEDIUM -500G
4021342	TODD-HEWITT BROTH -500G
4021412	TRIPLE SUGAR IRON AGAR U.S.P.-500G
4021504	TRYPTIC SOY AGAR - 5KG

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4021502	TRYPTIC SOY AGAR -500G
4021514	TRYPTIC SOY BLOOD AGAR BASE - 5KG
4021512	TRYPTIC SOY BLOOD AGAR BASE -500G
4021554	TRYPTIC SOY BROTH - 5KG
4021552	TRYPTIC SOY BROTH -500G
4021752	UREA AGAR BASE-CHRISTENSEN -500G
4021802	UREA BROTH BASE-STUART -500G
4021832	VERA CTSA MEDIUM -500G
4021922	VOGEL-JOHNSON AGAR -500G
4022062	XLD AGAR -500G
4022064	XLD AGAR -5KG

ADDITIVI PER TERRENI DI COLTURA / *ADDITIVE FOR CULTURE MEDIA*

EDMA CLASS. 14 01 01 04

4240073	BCSA SELECTIVE SUPPLEMENT
4240009	BIOVITEX/RESTORING FLUID
42185011	BIOVITEX/RESTORING FLUID
4240015	BLASER WANG ANTIMICROBIC SUPPLEMENT
4240006	C.DIFFICILE ANTIMICROBIC SUPPLEMENT
4240021	CAMPYLOB.GROWTH SUPPLEMENT
4240003	CHLORAMPH.ANTIMICROBIC SUPPLEMENT
4240080	CHROMART CRE SUPPLEMENT
4240082	CHROMART ESBL SUPPLEMENT
4240053	CHROMART STREPTO B SUPPLEMENT
4240018	CNA ANTIMICROBIC SUPPLEMENT
4240024	DERMATOPHYTE ANTIMICR.SUP.
4240019	GARDNERELLA ANTIMICROBIC SUPPLEMENT
90HWH25	GLOBULI ROSSI DI MONTONE 10%
4240010	HAEMOPHILUS ANTIMICROBIC SUPPLEMENT
4240035	KARMALI ANTIMICROBIC SUPPLEMENT
423210	LEGIONELLA BCYE ALPHA GROWTH SUPPLEMENT
423212	LEGIONELLA BCYE ALPHA GROWTH SUPPLEMENT w/o CYSTEINE
423215	LEGIONELLA GVPC SELECTIVE SUPLEMENT
90HLX100	LYSED HORSE BLOOD - 100 ml
4240026	MUG SUPPLEMENT (10X50MG)
4240027	MUG TRYPTOPHAN SUPPLEMENT
4240013	SALMONELLA SELECTIVE SUPPLEMENT
90HDG25	SANGUE DEFIBRINATO DI CAVALLO
90HDG500	SANGUE DEFIBRINATO DI CAVALLO
90HDX100	SANGUE DEFIBRINATO DI CAVALLO
90HDX50	SANGUE DEFIBRINATO DI CAVALLO
90HDG1000	SANGUE DEFIBRINATO DI MONTONE
90SDG25	SANGUE DEFIBRINATO DI MONTONE
90SDX100	SANGUE DEFIBRINATO DI MONTONE
90SDX50	SANGUE DEFIBRINATO DI MONTONE
90SDX500	SANGUE DEFIBRINATO DI MONTONE
90SAX100	SANGUE DI MONTONE IN SOLUZIONE DI ALSEVER
90SAX25	SANGUE DI MONTONE IN SOLUZIONE DI ALSEVER
90SAX50	SANGUE DI MONTONE IN SOLUZIONE DI ALSEVER
90HLX100	SANGUE LISATO (LACCATO) DI CAVALLO
4240016	SKIRROW ANTIMICROBIC SUPPLEMENT
4240096	UREA, 40% SOLUTION
42211601	UREA, 40% SOLUTION
4240007	VCN ANTIMICROBIC SUPPLEMENT
4240008	VCNT ANTIMICROBIC SUPPLEMENT
4240011	YERSINIA SEL.SUPPLEMENT

TERRENI DI COLTURA PRONTI IN PROVETTA / *READY TO USE TUBES FOR MICROBIOLOGY*

EDMA CLASS. 14 01 02 01 /14 01 13 01/ 14 03 03 01

223280	TRANSFEC
551230	BRAIN HEART INFUSION BROTH
521230P	BRAIN HEART INFUSION BROTH 3 ml
554050	BRODO SIERO
553691	DERMATOPHYTE SELECTIVE MEDIUM
551524	G N BROTH HAJNA

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551634	IUT MEDIUM
551560	KLIGLER IRON AGAR
554001	LOEFFLER MEDIUM
551635W	LOWENSTEIN JENSEN MEDIUM W/O GLIGEROL
551635	LOWENSTEIN-JENSEN MEDIUM
551636	LYSINE IRON AGAR
551743	MULLER KAUFFMANN TETRATHIONATE BROTH
551810	NUTRIENT AGAR
551815	NUTRIENT BROTH
554002	PERGOLA MEDIUM
551980	RAPPARORT VASSILIADIS BROTH
552000	SABOURAUD BROTH
552005	SABOURAUD DEXTROSE AGAR
552006	SABOURAUD DEXTROSE AGAR CAF 50
552008	SABOURAUD DEXTROSEAGAR CAF-CEX
552025	SELENITE BROTH
552137	THIOGLYCOLLATE MEDIUM
552134B	TODD HEWITT CNA BROTH
552134	TODD HEWITT BROTH
5513311	TRICHOMONAS CPLM SELECTIVE BROTH
552141	TRIPLE SUGAR IRON AGAR
552150	TRYPTIC SOY AGAR
522150P	TRYPTIC SOY AGAR, 3 ml
552155	TRYPTIC SOY BROTH
551145	TRYPTOSE AGAR
551146	TRYPTOSE BROTH
552175	UREA AGAR
552180	UREA BROTH

TERRENI DI COLTURA PRONTI IN FLACONE / *READY TO USE FLASKS FOR MICROBIOLOGY*

EDMA CLASS. 14 01 03 01 / 14 03 03 03

5115412	HEKTOEN ENTERIC AGAR (6X100ML)
5115413	HEKTOEN ENTERIC AGAR (6X200ML)
5115822	LEGIONELLA BCYE AGAR BASE (6X 90 ML)
5115824	LEGIONELLA BCYE AGAR BASE (6X180ML)
5115823	LEGIONELLA BCYE AGAR BASE (6X225ML)
5116702	MAC CONKEY AGAR (6X100ML)
5116703	MAC CONKEY AGAR (6X200ML)
5116652	MANNITOL SALT AGAR -6X100ML
5116653	MANNITOL SALT AGAR -6X200ML
5117432	MULLER KAUFFMAN TET.BROTH (6X100ML)
5118102	NUTRIENT AGAR (6X100ML)
5119632	PSEUDOMONAS SELECTIVE AGAR (6X100ML)
5119802	RAPPAPORT VASSILIADIS BROTH (6X100ML)
5120002	SABOURAUD BROTH (6X100ML)
5120052	SABOURAUD DEXTROSE AG.-6X100ML
5120053	SABOURAUD DEXTROSE AG.-6X200ML
5120062	SABOURAUD DEXTROSE AGAR+CAF 6X100ML
5120063	SABOURAUD DEXTROSE AGAR+CAF 6X200ML
5120252	SELENITE BROTH (6X100ML)
5120752	SS AGAR (6X100ML)
5121062	TCBS AGAR -6X100ML
5121372	THIOGLYCOLLATE MEDIUM (6X100ML)
5121373	THIOGLYCOLLATE MEDIUM (6X200ML)
5121502	TRYPTIC SOY AGAR (6X100ML)
5121503	TRYPTIC SOY AGAR (6X200ML)
5121552	TRYPTIC SOY BROTH -6X100ML
5121553	TRYPTIC SOY BROTH -6X200ML

TERRENI DI COLTURA PRONTI IN PIASTRA / *READY TO USE PLATES FOR MICROBIOLOGY*

EDMA CLASS. 14 01 04/ 14 03 02

541100	AZIDE BLOOD AGAR
541153	BCSA BURKHOLDERIA CEPACIA SELECTIVE AGAR
549988	BACTEROIDES BILE AESCULIN AGAR
541014VR	BEEA-VAN (BILE ESCULIN AZIDE AGAR-VANCOMYCIN)

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541180	BLOOD AGAR HORSE
541151	BLOOD AGAR SHEEP
549905	BORDETELLA SELECTIVE AGAR
541235	BRAIN HEART INFUSION AGAR
(58) 501808	BRAIN HEART INFUSION AGAR
541274	BRUCELLA AGAR HORSE
(58) 501823	BRUCELLA BLOOD AGAR +5% SANGUE DI CAVALLO
541111	CAMPYLOBACTER AGAR BLASER WANG
541111B	CAMPYLOBACTER SELECTIVE AG. SKIRROW
541283	CAMPYLOBACTER BLOOD FREE MEDIUM (KARMALI)
541519	CHOCOLATE AGAR BACITRACINE
541521	CHOCOLATE AGAR ENRICHED
548000	CHROMALBICANS AGAR
548015	CHROMART CRE
548020	CHROMART ESBL
548010	CHROMART STREPTO B
548005	CHROMOGENIC CANDIDA AGAR (CCA)
545350	CHROMOGENIC SALMONELLA AGAR
545350S	CHROMOGENIC SALMONELLA AGAR CLEAR
549810S	CHROMOGENIC URINE AGAR III
549810G	CHROMOGENIC URINE AGAR IV
541901	CLED AGAR
541308	CLOSTRIDIUM DIFFICILE SELECTIVE MEDIUM
541136	COLUMBIA BLOOD AGAR
541361	COLUMBIA CNA BLOOD AGAR
541363	COLUMBIA CNA-CV BLOOD AGAR
541369	DERMATOPHYTE SELECTIVE MEDIUM (DTM)
541370	DESOXYCHOLATE AGAR
549993	GARDNERELLA SELECTIVE AGAR
549901	HAEMOPHILUS TEST MEDIUM
541541	HEKTOEN ENTERIC AGAR
549994	HERELLEA AGAR
(58) 501815	HERELLEA AGAR
549945	LEGIONELLA AGAR
549943	LEGIONELLA AGAR w/o CYSTEINE
549995	LEGIONELLA SELECTIVE AGAR (GVPC)
541595	LEVINE EMB BLUE AGAR
(58) 501813	E.M.B. (LEVINE) AGAR
541670	MAC CONKEY AGAR
541672	MAC CONKEY AGAR MUG
(58) 501817	MAC CONKEY MUG
541669S	MAC CONKEY SORBITOL AGAR
541669	MAC CONKEY SORBITOL MUG AGAR
541665	MANNITOL SALT AGAR
541522	MODIFIED THAYER MARTIN (MTM) AGAR
501740P	MUELLER HINTON AGAR II
(58) 501817	MUELLER HINTON AGAR Ø 150
549860	MUELLER HINTON AGAR + 2% NACL
541743	MUELLER HINTON AGAR BLOOD SHEEP
541740F	MHA- F
541740	MUELLER HINTON AGAR II
501743P	MUELLER HINTON AGAR BLOOD SHEEP
541742	MUELLER HINTON CHOCOLATE AGAR
541810	NUTRIENT AGAR
549510	OXACILLIN SCREEN AGAR
541963	PSEUDOMONAS SELECTIVE AGAR
541971	PURPLE LACTOSE AGAR
501971P	PURPLE LACTOSE AGAR
541985	ROGOSA BIOS AGAR
(58) 501820	ROGOSA AGAR
54RPMI90	RPMI AGAR 90 mm
54RPMI15	RPMI AGAR 150 mm
542005	SABOURAUD DEXTROSE AGAR
542006	SABOURAUD DEXTROSE AGAR + CAF
542008	SABOURAUD DEXTROSE AGAR + CAF + CEX

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542009	SABOURAUD DEXTROSE AGAR + CAF + GENTAMICIN
549989	SCHAEDLER BLOOD AGAR
549990	SCHAEDLER SELECTIVE BLOOD AGAR
549907	SCHAEDLER SELECTIVE CNA BLOOD AGAR
549998	SERUM TELLURITE AGAR
542075	SS AGAR
546550	STRONGYLOIDES STERCORALIS AGAR
549850	SUPPLEMENTED BRUCELLA AGAR
542106	TCBS KOBAYASHI AGAR
(58) 501825	TCBS CHOLERA AGAR
542150	TRYPTIC SOY AGAR
542181	UREAPLASMA DIFFERENTIAL AGAR A7
549520	VANCOMYCIN SCREEN AGAR
542200	WURTZ AGAR
(58) 501826	WURTZ AGAR
542206	XLD AGAR
549997	YERSINIA SELECTIVE AGAR
491001	BIOSECTOR 1 HEKTOEN ENTERIC AGAR / SS AGAR
(48) 501830	HEKTOEN ENTERIC AGAR / SS AGAR
491003	BIOSECTOR 3 BLOOD AGAR SHEEP / MAC CONKEY AGAR MUG
(48) 502247	BLOOD AGAR (5% SANGUE MONTONE) / MAC CONKEY AGAR + MUG
491004	BIOSECTOR 4 BLOOD AGAR / MAC CONKEY AG. MUG / SLANETZ MOD. AGAR
(48) 501832	BLOOD AGAR (5% SANGUE MONTONE) / MAC CONKEY AGAR + MUG / SLANETZ-BARTLEY TTC AGAR
491006	BIOSECTOR 6 COLUMBIA CAN BLOOD AGAR / BLOOD AGAR SHEEP
491010	BIOSECTOR 10 MOD. TAHYER MARTIN AG. / CHOC. AG. ENR. / GARD. SEL. AG.
(48) 501833	THAYER MARTIN AGAR-G.VAGINALIS SEL. AG.-CHOCOLATE (VITOX) AGAR
491013	BIOSECTOR 13 DERMATHOPHYTE TEST MEDIUM / SABOURAUD DEXT. AGAR CAF
(48) 501829	DERMASEL SELECTIVE AGAR / SABOURAUD DEXT. AGAR + CLORAMFENICOLO
491025	BIOSECTOR 25 MOD.THAYER MARTIN AGAR / GARD. SEL. AGAR
491032	BIOSECTOR 32 XLD AGAR / SS AGAR
491037	BIOSECTOR 37 MAC CONKEY AGAR / SS AGAR
491054	BIOSECTOR 54 BLOOD AGAR SHEEP / MAC CONKEY AGAR
491070	CETRIMIDE AGAR / MAC CONKEY AGAR / BP AGAR
495350	BIOSECTOR CHROMOGENIC SALMONELLA AGAR / HEKTOEN ENTERIC AGAR
495351	BIOSECTOR CHROMOGENIC SALMONELLA AGAR / XLD AGAR
491042C	BIOSECTOR 42C MOD. TAHYER MARTIN AGAR / CHOCOLATE. AG. ENR. / CHROMALBICANS AGAR

IVD PER L'IDENTIFICAZIONE MICROBICA / *PRODUCTS FOR MICROBIAL IDENTIFICATION*

EDMA CLASS 14 02 02 / 14 03 04

429936	COAGULASE PLASMA EDTA
429937	COAGULASE PLASMA EDTA
429938	COAGULASE PLASMA EDTA
19171000	KOVACS' REAGENT
19171001	KOVACS' REAGENT
191500	MUCAP TEST
19171002	OXIBIOSWAB
191040ST	OXIDASE TEST STRIPS

IVD ALTRI / IVD OTHER

EDMA CLASS 14 90 / 14 01 13 01

224001	SPUTAFLUID
225020	A.L.L. SOLUTION
225040	PHOSPHATE BUFFER 0,067M pH 6,8
2203454	DIGESTION REAGENT
225000	A.L.L. DIGESTION NEUTRALISATION KIT

Certificate

mdc medical device certification GmbH
certifies that

Biolife Italiana Srl
Viale Monza 272
20128 Milano
Italy

for the scope

Design, manufacturing and distribution of
in-vitro diagnostic microbiological culture media
Distribution of in-vitro diagnostic devices

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 9001

Quality management systems –
Requirements

(ISO 9001:2015)

Valid from	2021-12-20
Valid until	2024-08-29
Registration no.	D2001500017
Report no.	P21-00807-224077
Stuttgart	2021-12-20

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-01-01

mdc medical device certification GmbH
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Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

Certificate

mdc medical device certification GmbH
certifies that

Biolife Italiana Srl
Viale Monza 272
20128 Milano
Italy

for the scope

Design, manufacturing and distribution of
in-vitro diagnostic microbiological culture media
Distribution of in-vitro diagnostic devices

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-12-20
Valid until	2024-08-29
Registration no.	D2001500016
Report no.	P21-00807-224075
Stuttgart	2021-12-20

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

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FRASER BROTH BASE
FRASER SELECTIVE SUPPLEMENT
FRASER HALF SELECTIVE SUPPLEMENT

Dehydrated culture medium and selective supplements

Fraser Broth: uninoculated tube on the left and tube inoculated with *L.monocytogenes* on the right

1 - INTENDED USE

With the addition of selective supplements, Fraser Broth Base is used for primary and secondary enrichment in the procedure for the detection of *Listeria monocytogenes* and *Listeria* spp. in samples of the food chain (ISO 11290-1) and for sample preparation in the enumeration procedure (ISO 11290-2).

2 - COMPOSITION

FRASER BROTH BASE, DEHYDRATED MEDIUM
TYPICAL FORMULA AFTER RECONSTITUTION WITH 1 L OF WATER*

Enzymatic digest of animal tissue	5.00 g
Enzymatic digest of casein	5.00 g
Meat extract	5.00 g
Yeast extract	5.00 g
Sodium chloride	20.00 g
Disodium hydrogen phosphate dihydrate°	12.00 g
Potassium dihydrogen phosphate	1.35 g
Aesculin	1.00 g
Lithium chloride	3.00 g

*The formula may be adjusted and/or supplemented to meet the required performances criteria.
° Equivalent to 9.6 g of disodium hydrogen phosphate anhydrous

FRASER HALF SELECTIVE SUPPLEMENT
(VIAL CONTENTS FOR 225 ML OF MEDIUM)

Ferric ammonium citrate	112.50 mg
Nalidixic acid	2.25 mg
Acriflavine HCl	2.81 mg

FRASER SELECTIVE SUPPLEMENT
(VIAL CONTENTS FOR 500 ML OF MEDIUM)

Ferric ammonium citrate	250.0 mg
Nalidixic acid	10.0 mg
Acriflavine HCl	12.5 mg

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Although improved control measures since the 1990s have significantly reduced the prevalence of *L.monocytogenes* in many food categories, particularly in meat and meat products, it remains a significant cause of foodborne illness.[1]
Identification traditionally involves culture methods based on selective enrichment and plating followed by the characterization of *Listeria* spp. based on colony morphology, sugar fermentation and haemolytic properties.[2]
ISO,[3,4] FDA,[5] USDA-FSIS[6] protocols differ in the recommended culture media but they all involve one or more enrichment steps followed by plating into one or two selective isolation media.
Fraser Broth was developed by Judy A. Fraser and William H. Sperberby[7] by a modification of the USDA secondary enrichment broth through the addition of lithium chloride and ferric ammonium citrate. The efficacy of Fraser Broth was documented by testing a wide range of food and environmental samples from food processing facilities.
Fraser Broth Base contains all the basic ingredients with the exception of ferric ammonium citrate, acriflavine and nalidixic acid which are contained in selective supplements that enable the two complete media Half-Fraser Broth and Fraser Broth to be prepared.
Half-Fraser Broth and Fraser Broth are used for primary and secondary enrichment in the procedure for the detection of *Listeria monocytogenes* and *Listeria* spp. in samples of the food chain according to ISO 11290-1.[3] Half-Fraser Broth may be used for sample preparation in the enumeration procedure according to ISO 11290-2.[4]
Peptones and yeast extract provide nitrogen, carbon, vitamins particularly of the B-group and trace elements for microbial growth; phosphates are used as buffering agents to control the pH in the medium. Selectivity is provided by the presence of nalidixic acid with a marked antibacterial activity against primarily Gram-negative bacteria and acriflavine which inhibits many Gram-positive bacteria; lithium chloride and the high salt (NaCl) tolerance of *Listeria* are used to inhibit growth of enterococci. Half-Fraser Broth contains half the concentrations of acriflavine and nalidixic acid compared to Fraser Broth. Esculin is hydrolysed to glucose and aesculetin (6-7-dihydroxycoumarin): aesculetin reacts with the iron salts in the medium, giving it a brown-black colour. Since all *Listeria* spp. hydrolyse esculin, cultures which do not blacken can be considered to be *Listeria*-free.[7]

4- DIRECTIONS FOR MEDIA PREPARATION

HALF-FRASER BROTH

Suspend 12.91 g of Fraser Broth Base in 225 mL of cold purified water. Heat to boiling to completely dissolve the powder. Autoclave at 121°C for 15 minutes. Cool to room temperature add the contents of one vial of Fraser Half Selective Supplement (code 4240044) reconstituted with 3 mL of ethanol/ sterile distilled water (1:1).

FRASER BROTH

Suspend 28.7 g of Fraser Broth Base in 500 mL of cold purified water. Heat to boiling to completely dissolve the powder. Autoclave at 121°C for 15 minutes. Cool to room temperature add the contents of one vial of Fraser Selective Supplement (code 4240043) reconstituted with 5 mL of ethanol/ sterile distilled water (1:1). Mix well and pour into sterile tubes or flasks under aseptic conditions.

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5 - PHYSICAL CHARACTERISTICS

Dehydrated medium appearance	beige, fine, homogeneous, free-flowing powder
Prepared tubes and flasks appearance	yellow-brown, limpid
Freeze-dried selective supplements	low, fragile yellow ochre tablets; yellow ochre opalescent solutions after reconstitution
Final pH of complete media (at 20-25°C)	7.2 ± 0.2

6 - MATERIALS PROVIDED – PACKAGING

Product	Type	REF	Pack
Fraser Broth Base	Dehydrated medium	4014952 4014954	500 g (8.7 L) 5 kg (87 L)
Fraser Selective Supplement	Freeze-dried supplement	4240043	10 vials, each for 500 mL of medium
Fraser Half Selective Supplement	Freeze-dried supplement	4240044	10 vials, each for 225 mL of medium

7 - MATERIALS REQUIRED BUT NOT PROVIDED

Autoclave, water-bath, sterile loops and pipettes, incubator and laboratory equipment as required, sterile tubes or flasks, Petri dishes, Erlenmeyer flasks, ancillary culture media and reagents.

8 - SPECIMENS

Foods, animal deeding stuffs, food chain and environmental samples. When collecting, storing, transporting and preparing samples, follow the rules of good laboratory practice and refer to applicable international standards.[3,4]

9 - TEST PROCEDURE

Detection of *Listeria monocytogenes* and *Listeria* spp (ISO 11290-1)[3]

1. In general, to prepare the initial suspension, add a test portion of 25 g or 25 mL to 225 mL of Half-Fraser Broth, to obtain a tenfold dilution, and homogenize.
2. Incubate the primary enrichment medium at 30 °C ± 1°C for 25 h ± 1 h.
3. Transfer 0.1 mL of the culture to a tube or bottle containing 10 mL of secondary enrichment medium (Fraser Broth) and incubate for 24 h ± 2 h at 37 °C ± 1°C. In the case of *Listeria* spp. other than *Listeria monocytogenes* detection, additional 24 h incubation can allow for recovery of more species.
4. From the primary enrichment culture inoculate, by means of a loop, the surface of the first selective plating medium, Agar Listeria according to Ottaviani and Agosti (ALOA) (REF 401605), to obtain well-separated colonies. Proceed in the same way with the second selective plating-out medium of choice (e.g., PALCAM or Oxford Agar, REF 401604 or 401600).
5. From the secondary enrichment medium, repeat the procedure with the two selective plating-out media.
6. Incubate ALOA plates at 37°C ± 1°C for 24 ± 2 hours; if there is no growth or no typical colonies, re-incubate for a further 24 ± 2 hours.
7. Incubate the second plating out medium according to the instructions for use
8. Examine the dishes for the presence of presumptive colonies of *L. monocytogenes* or *Listeria* spp.

Notes
It is possible to store at 5 °C the pre-enriched sample after incubation before transfer to Fraser broth for a maximum of 72 h.
Half-Fraser broth and Fraser broth can be refrigerated at 5 °C before isolation on selective agar for a maximum of 72.
After incubation, ALOA plates can be refrigerated at 5 °C for a maximum of 48 h before reading.

Enumeration of *Listeria monocytogenes* and of *Listeria* spp (ISO 11290-2)[4]

1. Prepare a sample suspension in Buffered Peptone Water or other suitable enrichment broth according to ISO 6887 (all parts); in case both detection and enumeration are performed according to parts 1 and 2 of ISO 11290, the sample suspension may be made in half-Fraser broth (with or without the addition of the selective supplement).
2. Inoculate 0.1 mL of the sample suspension and 0.1 mL of further decimal dilutions onto 90 mm plates of ALOA medium.
3. For samples with suspected low number of target-strains, inoculate 1 mL of the sample suspension and 1 mL of further decimal dilutions onto 140 mm plates of ALOA medium.
4. Examine after incubation at 37°C for 24 ± 2 hours and, if there is no growth or no typical colonies, re-incubate for a further 24 ± 2 hours.
5. Count *L. monocytogenes* colonies and *Listeria* spp. colonies in plates with less than 150 colonies (90 mm diameter plates) or 360 colonies (140 mm plates) according to the section "reading and interpretation".

10 - READING AND INTERPRETATION

After incubation, typically *Listeria* spp. produce a blackening of the two enrichment broths.
After subculture on the plating media and incubation, observe the bacterial growth and record the specific morphological and chromatic characteristics of the colonies.
With ALOA plates, consider as presumptive *L. monocytogenes* the blue-green colonies surrounded by an opaque halo; consider as presumptive *Listeria* spp. the blue-green colonies with or without opaque halo.
Second plating-out medium: examine for the presence of typical colonies according to the characteristics of the chosen medium.
Confirm typical colonies by the methods and tests indicated in ISO 11290-1 or ISO 11290-2, after purification of the colonies in Tryptic Soy Yeast Extract Agar (REF 402166).
The mandatory confirmatory tests for *L.monocytogenes*, according to ISO 11290 and using ALOA medium, are the following: β-hemolysis (+), carbohydrate utilization (L-rhamnose +; D-xylose -). Optional confirmatory tests for *L.monocytogenes* are:, catalase (+), mobility at 25°C (+), CAMP test (+). The mandatory confirmatory tests for *Listeria* spp. are: microscopic examination, catalase (+); optional tests are: VP (+), mobility at 25°C (+).
Miniaturized galleries for the biochemical identification of *Listeria monocytogenes* may be used (Listeria Monoconfirm Test REF 193000)

11 - 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 some test strains useful for the quality control.[3]

CONTROL STRAINS		INCUBATION T°/ T / ATM	EXPECTED RESULTS
L.monocytogenes +	ATCC 13932	30 or 37°C / 24h A	> 10 typical colonies after subculture on ALOA
E. faecalis +	ATCC 29212		
E. coli	ATCC 25922		
L.monocytogenes +	NCTC 7973	30 or 37°C / 24h A	> 10 typical colonies after subculture on ALOA
E. faecalis +	ATCC 29212		
E. coli	ATCC 25922		
E. faecalis	ATCC 29212	30 or 37°C / 24h A	< 100 colonies after subculture on TSA
E. coli	ATCC 25922	30 or 37°C / 24h A	totally inhibited after subculture on TSA

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection; NCTC: National Collection of Type Culture: 30°C for Half-Fraser Broth, 37°C for Fraser Broth

12- PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of dehydrated Fraser Broth Base supplemented with Fraser Selective Supplement (REF 4240043) is tested for productivity and selectivity by comparing the results with a previously approved Reference Batch.
Productivity is tested by dilution to extinction method, by inoculating 1 mL of appropriate decimal dilutions of target organisms in test tubes, incubating at 37°C for 24 hours and recording the highest dilution showing growth in Reference Batch (Gr_{RB}) and in Test Batch (Gr_{TB}). Productivity is tested with the following target strains: *L. monocytogenes* ATCC 19111, *L. monocytogenes* ATCC 13932. The productivity index Gr_{RB}-Gr_{TB} for each test strain shall be ≤ 1 and the tubes shall exhibit blackening.
Productivity and selectivity are tested together with mixtures of approximately ≤100 CFU of target organisms and ≥1000 CFU of non-target organisms per test tubes, incubating at 37°C for 24 hours. Mixtures of target and non-target strains: *L. monocytogenes* ATCC 13932 + *E. coli* ATCC 25922 + *E. faecalis* ATCC 29212 and *L. monocytogenes* NCTC 7973 + *E. coli* ATCC 25922 + *E. faecalis* ATCC 29212. After incubation of inoculated tubes and sub-culture on ALOA plates, the target strains will show more than 10 colonies per plate.
Moreover, selectivity is tested by inoculating ≥1000 CFU per tube of the following non-target strains: *E. faecalis* ATCC 29212, and *E. coli* ATCC 25922. After incubation *E. faecalis* exhibits a growth with less than 100 UFC after subculture on Tryptic Soy Agar while *E.coli* is totally inhibited. Selectivity is tested also with the non-target strain *C. albicans* ATCC 18804 by dilution to extinction method: the strain is totally inhibited.

13 - LIMITATIONS OF THE METHOD

- Poor growth and a weak esculin reaction may be seen after 40 hours incubation for some enterococci.
- Since *Listeria* species other than *L. monocytogenes* can grow, an identification of *Listeria monocytogenes* must be confirmed by suitable tests.

14 - PRECAUTIONS AND WARNINGS

- Fraser Broth Base and supplements are for microbiological control and for professional use only; they are to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- The medium base and the supplements shall be used in association according to the described directions. Apply Good Manufacturing Practice in the production process of prepared media.
- Dehydrated media and antibiotics containing supplements must be handled with suitable protection. Fraser and Fraser-Half supplements are classified as hazardous. Before use, consult the Material Safety Data Sheets.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that the product doesn't contain any transmissible pathogen. Therefore, it is recommended that the culture medium be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- Be careful when opening the metal ring of the supplements to avoid injury.
- The selective supplements are sterilized by membrane filtration.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as medium powder and supplement or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and supplements and the sterilized medium inoculated with samples or microbial strains in accordance with current local legislation.
- Do not use the culture medium and the supplements as active ingredients for pharmaceutical preparations or as production materials intended for human and animal consumption.
- The Certificates of Analysis and the Safety Data Sheets 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.

15 - STORAGE CONDITIONS AND SHELF LIFE

Dehydrated medium

Upon receipt, store at +10°C /+30°C away from direct light in a dry place. If properly stored, it may be used up to the expiration date. Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed. Discard the product if the container and/or the cap are damaged, or if the container is not well closed, or in case of evident deterioration of the powder (colour changes, hardening, large lumps).

Freeze-dried selective supplements

Upon receipt, store the product in the original package at +2°C / +8°C away from direct light. If properly stored, the product may be used up to the expiry date printed on the label; do not use beyond this date. Once the vial has been opened and the lyophilised product has been reconstituted, the resulting solution should be used immediately. Before use, examine the lyophilized and reconstituted product and discard if there are obvious signs of deterioration (e.g., contamination, atypical colour or other abnormal characteristics).

The user is responsible for the manufacturing and quality control processes of prepared media and the validation of their shelf life, according to the type and the applied storage conditions (temperature and packaging).

16 - REFERENCES

1. Buchanana RL *et al.* A review of Listeria monocytogenes: An update on outbreaks, virulence, dose-response, ecology, and risk assessments Food Control Volume 75, May 2017, Pages 1-13
2. Gasanov U, Hughes D, Hansbro PM. Methods for the isolation and identification of Listeria spp. and Listeria monocytogenes: a review. FEMS Microbiol Rev. 2005 Nov;29(5):851-75
3. 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.
4. ISO 11290-2:2017. Microbiology of the food chain - Horizontal method for the detection and enumeration of Listeria monocytogenes and of Listeria spp. - Part 2: Enumeration method.
5. U.S. Department of Health and Human Services, F.D.A. Bacteriological Analytical Manual, Chapter 10: Detection of Listeria monocytogenes in Foods and Environmental Samples, and Enumeration of Listeria monocytogenes in Foods, April 2022.
6. USDA-FSIS. Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Ready-To-Eat, Siluriformes (Fish) and Egg Products, and Environmental Samples. MLG 8.13, 10/01/2021
7. Fraser JA, Sperber WH. Rapid Detection of Listeria spp. in Food and Environmental Samples by Esculin Hydrolysis. J Food Prot 1988 Oct;51(10):762-765.

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	Manufacturer	This side up	Store in a dry place	Fragile
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	2022/07

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

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Biolife

DIRECTIONS - ISTRUZIONI - PRÉPARATION - GEBRAUCHSANWEISUNG - INSTRUCCIONES - INSTRUKTIONER - INSTRUÇÕES - ΟΔΗΓΙΕΣ

FRASER HALF SELECTIVE SUPPLEMENT

REF 4240044 10 x 3 mL

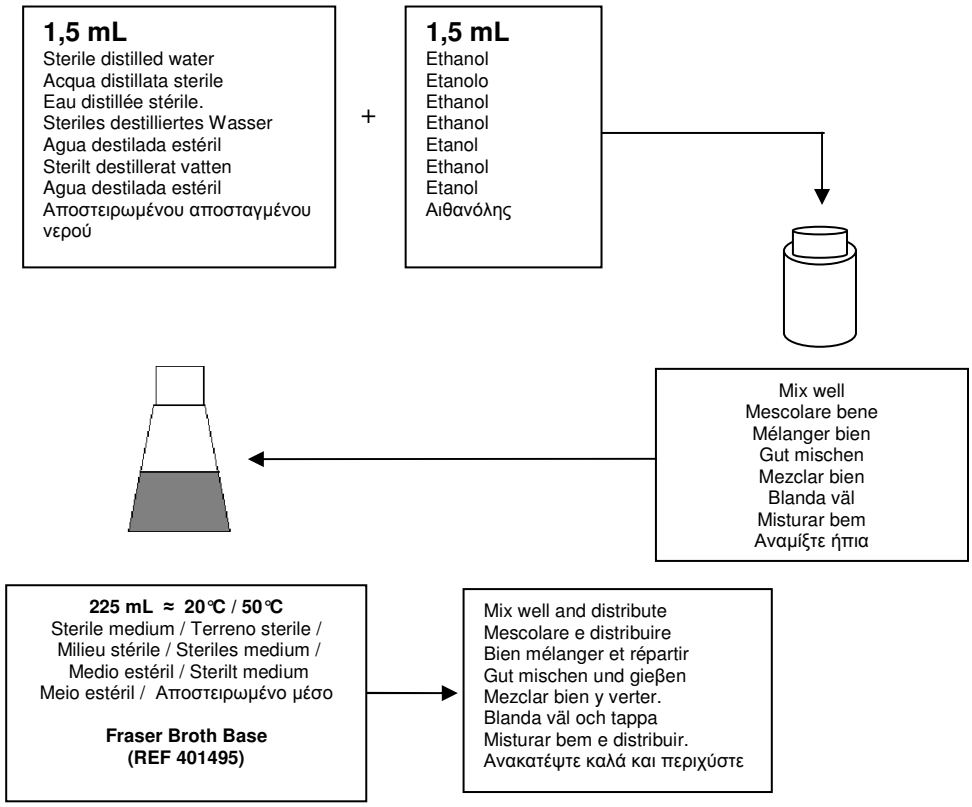
Freeze-dried selective supplement for the isolation of *Listeria s*pp. / Supplemento selettivo liofilizzato per l'isolamento di *Listeria* spp. / Supplément sélectif lyophilisé pour l'isolement de *Listeria* spp. / Gefriergetrocknetes Selektiv-Supplement zur Isolierung von *Listeria* spp. / Suplemento selectivo liofilizado para aislamiento de *Listeria* spp. / Lyophyliserat selektivt supplement för isolering av *Listeria* spp. / Suplemento seletivo liofilizado para o isolamento de *Listeria* spp. / Λυοφιλοποιημένο εκλεκτικό συμπλήρωμα για τον προσδιορισμό *Listeria* spp.

CONTENTS/CONTENUTO/PRESENTATION/PACKUNGSINHALT/CONTENIDO/ INNEHÅLL /CONTEÚDO/ ΠΕΡΙΕΧΟΜΕΝΑ
10 VIALS FOR 225 ML OF MEDIUM / 10 FLACONI PER 225 ML DI TERRENO / 10 FLACONS POUR 225 ML DE MILIEU / 10 RÖHRCHEN FÜR 225 ML NÄHRBODEN / 10 VIALES PARA 225 ML DE MEDIO / 10 AMPULLER, VARJE AMPULL ANVÄNDS TILL 225 ML MEDIUM/ 10 FRASCOS PARA CADA 225 ML DE MEIO / 10 ΦΙΑΛΙΔΙΑ, ΕΚΑΣΤΟ ΓΙΑ 225 ML ΜΕΣΟΥ.

VIAL CONTENTS / CONTENUTO DEL FLACONE /COMPOSITION PAR FLACON / ZUSAMMENSETZUNG JE RÖHRCHEN / CONTENIDO POR VIAL / AMPULLENS INNEHÅLL / CONTEÚDO DO FRASCO / ΠΕΡΙΕΧΟΜΕΝΑ ΦΙΑΛΙΔΙΟΥ

Acriflavine 2.81 mg, Nalidixic Acid 2.25 mg, Fe ammonium citrate 112.5 mg

DIRECTIONS / ISTRUZIONI / PRÉPARATION / ZUBEREITUNG / INSTRUCCIONES /INSTRUKTIONER / INSTRUÇÕES / ΟΔΗΓΙΕΣ.



STORAGE / CONSERVAZIONE / CONSERVATION / LAGERUNG / CONSERVACIÓN / LAGRING / CONSERVAÇÃO / ΑΠΟΘΗΚΕΥΣΗ

Store at 2-8° - When stored as directed the supplement remains stable until the expiry date shown on the label. Do not use beyond stated expiry date. / Conservare a 2 - 8°C- In queste condizioni il prodotto rimane valido fino alla data di scadenza indicata in etichetta. Non utilizzare dopo la data di scadenza. / Conserver à 2-8°C, selon les conditions de conservation indiquées, le produit est stable jusqu'à la date d'expiration mentionnée sur l'étiquette. Ne pas utiliser après la date d'expiration. / Lagerung: 2-8°C. Das Supplement st bei vorschriftsmäßiger Lagerung bis zum aufgedruckten Verfalldatum haltbar. Verfalldatum beachten. / Conservar entre 2-8°C. Estable bajo estas condiciones, hasta la fecha de caducidad que figura en la etiqueta. No utilizar si ha caducado. / Lagras i 2-8°C. Om lagring sker korrekt håller sig supplement hela tiden fram till utgångs datumet som står antecknat på etiketten. Använd ej produkten efter utgångs datum. / Armazenar a 2-8°C. Quando armazenado nestas condições, o suplemento permanece estável até a data de expiração indicada no rótulo. Não utilizar após a data do vencimento. / Φυλάξτε στους 2-8°C. Όταν φυλάσσεται σύμφωνα με τις οδηγίες, το συμπλήρωμα παραμένει σταθερό μέχρι την ημερομηνία λήξης που φαίνεται στην ετικέτα. Μην χρησιμοποιείτε πέραν της αναφερομένης ημερομηνίας λήξεως.

PRECAUTIONS / PRECAUZIONI / PRÉCAUTIONS / VORSICHTSMABNAHMEN / PRECAUCIONES / SÄKERHETSFÖRESKRIFTER PRECAUÇÕES / ΠΡΟΦΥΛΑΞΕΙΣ

For *in vitro* diagnostic use only. The supplement should be used only by adequately trained personnel with knowledge of microbiological techniques in the laboratory./ Solo per uso diagnostico *in vitro*. Il prodotto deve essere usato solo in laboratorio, da operatori addestrati e con conoscenze delle tecniche microbiologiche di base. / Pour usage *in vitro* exclusif. Ce produit ne doit être utilisé qu'en laboratoire par des personnels formés aux techniques de microbiologie. / Zum Gebrauch für *in vitro* Diagnostik. Nur entsprechend ausgebildete Personen mit Kenntnissen in mikrobiologischen Methoden dürfen dieses Produkt nutzen./ Uso sólo para diagnóstico *in vitro*. El suplemento debería ser sólo usado por personal adecuadamente cualificado con conocimientos de las técnicas microbiológicas en laboratorios. / Endast för *in vitro* diagnostik. Supplementet skall endast hanteras av behörig personal med kunskap om mikrobiologiska laboratorietekniker. / Somente para uso diagnostico *in vitro*. O suplemento deve ser utilizado somente no laboratório por pessoas adequadamente treinadas e com conhecimento em técnicas microbiológicas. / Το συμπλήρωμα πρέπει να χρησιμοποιείται από κατάλληλα εκπαιδευμένο προσωπικό με γνώση των μικροβιολογικών τεχνικών στο εργαστήριο.

WARNING / ATTENZIONE / ATTENTION / ACHTUNG / ATENCION / VARNING / ATENÇÃO / ΠΡΟΣΟΧΗ

Consult the material safety data sheet before the use / Consultare la scheda di sicurezza prima dell'uso. / Lire attentivement la fiche de sécurité avant utilisation / Vor Gebrauch Sicherheitsdatenblatt lesen. / Consultar la ficha de datos de seguridad del material antes de su uso. / Kontrollera säkerhets informationen före användning / Consultar a ficha de informações sobre a segurança antes do uso. / Συμβουλευτείτε το φύλλο δεδομένων ασφαλείας υλικού (MSDS) πριν τη χρήση.

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Biolife

DIRECTIONS - ISTRUZIONI - PRÉPARATION - GEBRAUCHSANWEISUNG - INSTRUCCIONES - INSTRUKTIONER - INSTRUÇÕES - ΟΔΗΓΙΕΣ

FRASER SELECTIVE SUPPLEMENT

REF 4240043 10 x 5 mL

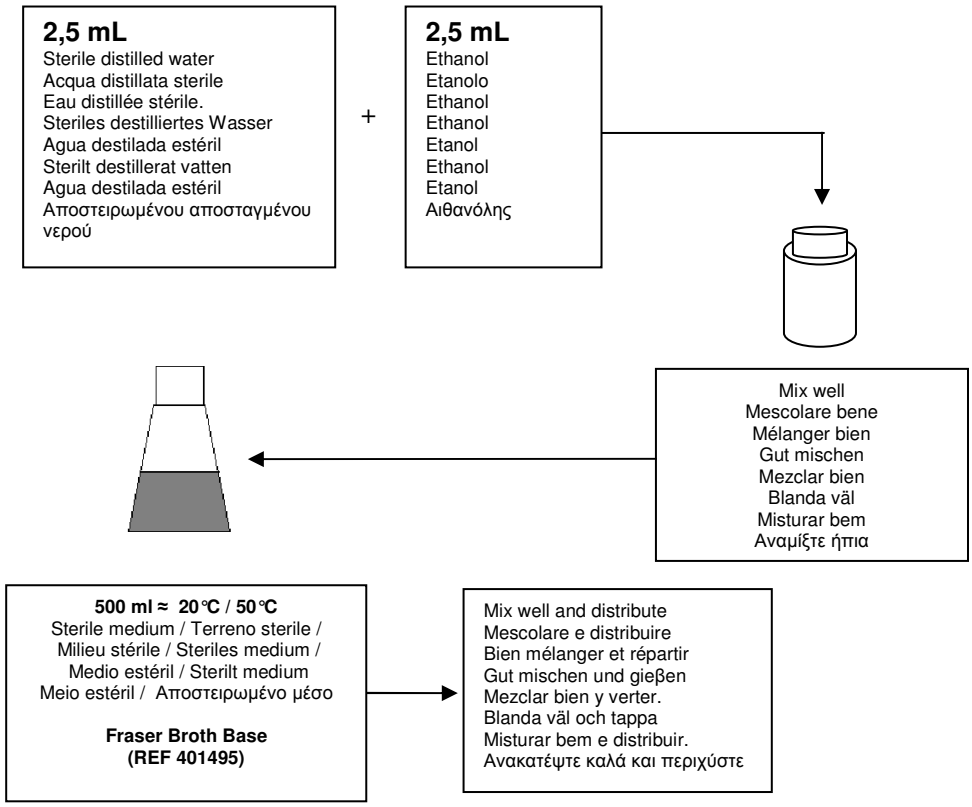
Freeze-dried selective supplement for the isolation of *Listeria s*pp. / Supplemento selettivo liofilizzato per l'isolamento di *Listeria* spp. / Supplément sélectif lyophilisé pour l'isolement de *Listeria* spp. / Gefriergetrocknetes Selektiv-Supplement zur Isolierung von *Listeria* spp. / Suplemento selectivo liofilizado para aislamiento de *Listeria* spp. / Lyophyliserat selektivt supplement för isolering av *Listeria* spp. / Suplemento seletivo liofilizado para o isolamento de *Listeria* spp. / Λυοφιλοποιημένο εκλεκτικό συμπλήρωμα για τον προσδιορισμό *Listeria* spp.

CONTENTS/CONTENUTO/PRESENTATION/PACKUNGSINHALT/CONTENIDO/ INNEHÅLL /CONTEÚDO/ ΠΕΡΙΕΧΟΜΕΝΑ
10 VIALS FOR 500 ML OF MEDIUM / 10 FLACONI PER 500 ML DI TERRENO / 10 FLACONS POUR 500 ML DE MILIEU / 10 RÖHRCHEN FÜR 500 ML NÄHRBODEN / 10 VIALES PARA 500 ML DE MEDIO / 10 AMPULLER, VARJE AMPULL ANVÄNDS TILL 500 ML MEDIUM/ 10 FRASCOS PARA CADA 500 ML DE MEIO / 10 ΦΙΑΛΙΔΙΑ, ΕΚΑΣΤΟ ΓΙΑ 500 ML ΜΕΣΟΥ.

VIAL CONTENTS / CONTENUTO DEL FLACONE /COMPOSITION PAR FLACON / ZUSAMMENSETZUNG JE RÖHRCHEN / CONTENIDO POR VIAL / AMPULLENS INNEHÅLL / CONTEÚDO DO FRASCO / ΠΕΡΙΕΧΟΜΕΝΑ ΦΙΑΛΙΔΙΟΥ

Acriflavine 12.5 mg, Nalidixic Acid 10 mg, Fe ammonium citrate 0.25 g

DIRECTIONS / ISTRUZIONI / PRÉPARATION / ZUBEREITUNG / INSTRUCCIONES /INSTRUKTIONER / INSTRUÇÕES / ΟΔΗΓΙΕΣ.



STORAGE / CONSERVAZIONE / CONSERVATION / LAGERUNG / CONSERVACIÓN / LAGRING / CONSERVAÇÃO / ΑΠΟΘΗΚΕΥΣΗ

Store at 2-8° - When stored as directed the supplement remains stable until the expiry date shown on the label. Do not use beyond stated expiry date. / Conservare a 2 - 8°C- In queste condizioni il prodotto rimane valido fino alla data di scadenza indicata in etichetta. Non utilizzare dopo la data di scadenza. / Conserver à 2-8°C, selon les conditions de conservation indiquées, le produit est stable jusqu'à la date d'expiration mentionnée sur l'étiquette. Ne pas utiliser après la date d'expiration. / Lagerung: 2-8°C. Das Supplement st bei vorschriftsmäßiger Lagerung bis zum aufgedruckten Verfalldatum haltbar. Verfalldatum beachten. / Conservar entre 2-8°C. Estable bajo estas condiciones, hasta la fecha de caducidad que figura en la etiqueta. No utilizar si ha caducado. / Lagras i 2-8°C. Om lagring sker korrekt håller sig supplement hela tiden fram till utgångs datumet som står antecknat på etiketten. Använd ej produkten efter utgångs datum. / Armazenar a 2-8°C. Quando armazenado nestas condições, o suplemento permanece estável até a data de expiração indicada no rótulo. Não utilizar após a data do vencimento. / Φυλάξτε στους 2-8°C. Όταν φυλάσσεται σύμφωνα με τις οδηγίες, το συμπλήρωμα παραμένει σταθερό μέχρι την ημερομηνία λήξης που φαίνεται στην ετικέτα. Μην χρησιμοποιείτε πέραν της αναφερομένης ημερομηνίας λήξεως.

PRECAUTIONS / PRECAUZIONI / PRÉCAUTIONS / VORSICHTSMABNAHMEN / PRECAUCIONES / SÄKERHETSFÖRESKRIFTER PRECAUÇÕES / ΠΡΟΦΥΛΑΞΕΙΣ

For *in vitro* diagnostic use only. The supplement should be used only by adequately trained personnel with knowledge of microbiological techniques in the laboratory./ Solo per uso diagnostico *in vitro*. Il prodotto deve essere usato solo in laboratorio, da operatori addestrati e con conoscenze delle tecniche microbiologiche di base. / Pour usage *in vitro* exclusif. Ce produit ne doit être utilisé qu'en laboratoire par des personnels formés aux techniques de microbiologie. / Zum Gebrauch für *in vitro* Diagnostik. Nur entsprechend ausgebildete Personen mit Kenntnissen in mikrobiologischen Methoden dürfen dieses Produkt nutzen./ Uso sólo para diagnóstico *in vitro*. El suplemento debería ser sólo usado por personal adecuadamente cualificado con conocimientos de las técnicas microbiológicas en laboratorios. / Endast för *in vitro* diagnostik. Supplementet skall endast hanteras av behörig personal med kunskap om mikrobiologiska laboratorietekniker. / Somente para uso diagnostico *in vitro*. O suplemento deve ser utilizado somente no laboratório por pessoas adequadamente treinadas e com conhecimento em técnicas microbiológicas. / Το συμπλήρωμα πρέπει να χρησιμοποιείται από κατάλληλα εκπαιδευμένο προσωπικό με γνώση των μικροβιολογικών τεχνικών στο εργαστήριο.

WARNING / ATTENZIONE / ATTENTION / ACHTUNG / ATENCION / VARNING / ATENÇÃO / ΠΡΟΣΟΧΗ

Consult the material safety data sheet before the use / Consultare la scheda di sicurezza prima dell'uso. / Lire attentivement la fiche de sécurité avant utilisation / Vor Gebrauch Sicherheitsdatenblatt lesen. / Consultar la ficha de datos de seguridad del material antes de su uso. / Kontrollera säkerhets informationen före användning / Consultar a ficha de informações sobre a segurança antes do uso. / Συμβουλευτείτε το φύλλο δεδομένων ασφαλείας υλικού (MSDS) πριν τη χρήση.

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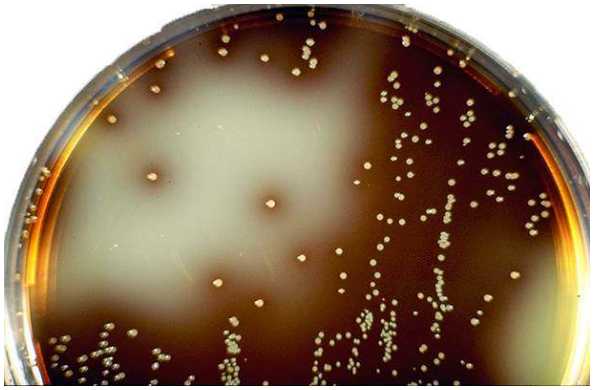
LISTERIA OXFORD AGAR BASE
LISTERIA OXFORD ANTIMICROBIC SUPPLEMENT
LISTERIA MOX-COL ANTIMICROBIC SUPPLEMENT
LISTERIA SELECTIVE AGAR (OXFORD)

Dehydrated culture medium, selective supplements, ready-to use plates



Oxford Medium: colonies of *Listeria monocytogenes*

1 - INTENDED USE

Selective and differential basal medium, selective supplements and ready to use plates for the isolation and enumeration of *Listeria* spp. from foodstuffs.

2 - COMPOSITIONS

LISTERIA OXFORD AGAR BASE

TYPICAL FORMULA (AFTER RECONSTITUTION WITH 1 L OF WATER) *

Peptocomplex	10.00 g
Tryptose	10.00 g
Peptone	3.00 g
Maize starch	1.00 g
Sodium chloride	5.00 g
Aesculin	1.00 g
Ferric ammonium citrate	0.50 g
Lithium chloride	15.00 g
Agar	12.00 g

*The formula may be adjusted and/or supplemented to meet the required performances criteria.

LISTERIA MOX-COL ANTIMICROBIC SUPPLEMENT
(VIAL CONTENTS FOR 500 mL OF MEDIUM)

Moxalactam	10.0 mg
Colistin sulphate	5.0 mg

LISTERIA SELECTIVE AGAR (OXFORD)
(READY -TO-USE PLATES)

Listeria Oxford Agar Base	1000 mL
Cycloheximide	400 mg
Colistin sulphate	20 mg
Cefotetan	2 mg
Fosfomycin	10 mg
Acriflavine	5 mg

LISTERIA OXFORD ANTIMICROBIC SUPPLEMENT
(VIAL CONTENTS FOR 500 mL OF MEDIUM)

Cycloheximide	200.0 mg
Colistin sulphate	10.0 mg
Cefotetan	1.0 mg
Fosfomycin	5.0 mg
Acriflavine	2.5 mg

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Although improved control measures since the 1990s have significantly reduced the prevalence of *L.monocytogenes* in many food categories, particularly in meat and meat products, it remains a significant cause of foodborne illness.[1]
Identification traditionally involves culture methods based on selective enrichment and plating on chromogenic and aesculin containing media followed by the characterization of *Listeria* spp. based on colony morphology, sugar fermentation and haemolytic properties.[2]
Listeria Oxford Agar Base is an aesculin based medium prepared without antibiotics and acriflavine; it can be used with Listeria Oxford Antimicrobic Supplement or with Listeria MOX-COL Antimicrobic Supplement for the isolation and enumeration of *Listeria* spp. in foodstuffs.
The complete medium known as "Oxford Medium" is prepared according to the formula developed by Curtis et al.[3] and is recommended by FDA-BAM[4] as one of the aesculin based Listeria selective agars and may be used as second isolation medium as recommended by ISO 11290-1.[5]
The complete Oxford medium contains peptones which provide nitrogen, carbon and minerals for microbial growth. Selectivity is provided by the presence of lithium chloride, active against streptococci, cycloheximide active against yeasts and moulds, cefotetan and fosfomycin active on Gram-positive and Gram-negative bacteria. Aesculin and ferric iron act as indicator system: *Listeria* spp. hydrolyse aesculin, producing black zones around the colonies because of the formation of black iron phenolic compounds derived from the aglucon.
The "MOX" medium is a modification of the formulation described by McClain and Lee[6], with a reduced concentration of moxalactam in order to obtain a better growth of *Listeria* spp. It is recommended by USDA-FSIS[7,8] and FDA-BAM[2] for the detection of *L.monocytogenes*. MOX formulation with moxalactam, colistin and lithium chloride is considered superior for the inhibition of methicillin resistant staphylococci and *Proteus* spp.

4- DIRECTIONS FOR MEDIA PREPARATION

Suspend 28.7 g of dehydrated medium in 500 mL of cold purified water. Heat to boiling with frequent agitation and sterilize by autoclaving at 121°C for 15 minutes. Cool to 47-50°C.

Oxford medium

Add the content of one vial of Listeria Oxford Antimicrobic Supplement (REF 4240038) reconstituted with 5 mL of a solution of 1:1 ethanol/sterile purified water, under aseptic conditions. Mix well and pour into sterile Petri dishes.

MOX-COL medium

Add the content of one vial of Listeria MOX-COL Antimicrobic Supplement (REF 4240039) reconstituted with 5 mL of sterile purified water, under aseptic conditions. Mix well and pour into sterile Petri dishes.

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5 - PHYSICAL CHARACTERISTICS

Listeria OXFORD Medium

Dehydrated medium appearance	beige, fine, free-flowing powder
Solution and prepared plates appearance	amber, slightly opalescent with a blue ring at the surface of the liquid
Final pH at 20-25 °C	7.0 ± 0.2
Listeria OXFORD Antimicrobic Supplement	
Freeze-dried supplement appearance	short, fragile, yellow-orange pellet
Reconstituted supplement appearance	yellow-orange, limpid
Listeria MOX-COL Antimicrobic Supplement	
Freeze-dried supplement appearance	short, dense, white pellet
Reconstituted supplement appearance	colourless, limpid

6 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Listeria Oxford Agar Base	Dehydrated medium	4016002	500 g (8.7 L)
Listeria Oxford Agar Base	Dehydrated medium	4016004	5 kg (87 L)
Listeria Oxford Antimicrobic Supplement	Freeze-dried supplement	4240038	10 vials, each for 500 mL of medium
Listeria MOX-COL Antimicrobic Supplement	Freeze-dried supplement	4240039	10 vials, each for 500 mL of medium
Listeria Oxford Selective Agar	Ready to use plates	541600	2 x 10 plates ø 90 mm

7 - MATERIALS REQUIRED BUT NOT PROVIDED

Autoclave, water-bath, incubator and laboratory equipment as required, sterile loops and pipettes, Petri dishes, Erlenmeyer flasks, ancillary culture media and reagents.

8 - SPECIMENS

Food, feed, food chain samples. When collecting, storing, transporting and preparing samples, follow the rules of good laboratory practice and refer to applicable international standards.[4,5,7]

9 - TEST PROCEDURE

Perform selective enrichment of the sample with the broths recommended by the chosen method of analysis.
Generally, the primary enrichment broth is incubated at 30°C and the secondary enrichment broth is incubated at 37°C for 24 hours.
The enrichment broths recommended by ISO 11290-1 are Half Fraser Broth and Fraser Broth; the selective broths indicated by USDA-FSIS are UVM1 and MOPS-BLEB, while FDA-BAM includes only one medium, Buffered Listeria Enrichment Broth without and with selective agents, with incubation at 30°C for 48 hours.
Streak a loopful of the incubated enriched broth onto the surface of an Oxford Medium plate or MOX-COL Medium plate and of ALOA plate to obtain well isolated colonies.
Examine the plates after incubation at 37°C for 24 ± 2 hours and after 48 ± 4 hours.

10 - READING AND INTERPRETATION

After incubation, observe the bacterial growth and record the specific morphological and chromatic characteristics of the colonies.
After 24 h incubation at 37° C typical *Listeria* species colonies are approximately 1 mm diameter, grey-brown with brown or black halo.
Following 48 h incubation typical *Listeria* species colonies are approximately 2-3 mm diameter, black with a black halo and sunken centre.

11 - 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 some test strains useful for the quality control.

CONTROL STRAINS		INCUBATION T°/ T / ATM	EXPECTED RESULTS
L.monocytogenes	ATCC 19111	37°C / 48 H / A	grey colonies with black-brown halo
E.faecalis	ATCC 19433	37°C / 48 H / A	inhibited

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

12- PERFORMANCES CHARACTERISTICS

Prior to release for sale representative samples of all lots of dehydrated and ready-to-use medium and supplements are tested for productivity and selectivity by comparing the results with a previously approved Reference Batch and Tryptic Soy Agar.
Productivity is tested by a quantitative test with the target strains *L.monocytogenes* ATCC 13932 and *L.monocytogenes* ATCC 19111: the plates are inoculated with decimal dilutions in saline of a colonies' suspension and incubated at 35-37°C for 48 hours. The colonies are enumerated on both batches and the productivity ratio (Pr: CFU_{TB}/CFU_{TSA}) is calculated. If Pr is ≥ 0.7 and if the colonies morphology and colour are typical (grey colonies with black-brown halo) the results are considered acceptable and conform to the specifications. Furthermore the productivity characteristics are tested by semi-quantitative ecometric technique with the following target strains: *L.innocua* ATCC 33090, and *L.ivanovii* ATCC 19119. The amount of growth and colonies characteristics are evaluated after incubation at 35-37°C for 48 hours: *L.innocua* and *L.ivanovii* exhibits a good growth after 48 hour of incubation with grey colonies with black-brown halo.
The selectivity is evaluated with modified Miles-Misra surface drop method by inoculating the plates with suitable decimal dilutions in saline of a 0.5 McFarland suspension of the non-target strains *E.faecalis* ATCC 19433, *E.coli* ATCC 25922, and *C.albicans* ATCC 10231. After incubation at 37°C for 48 hours, the growth of non-target strains is totally inhibited.

13 - LIMITATIONS OF THE METHOD

- The Oxford medium does not allow the differentiation of *L.monocytogenes* from other species of the genus *Listeria*.
- The identification of *L.monocytogenes* must be confirmed by suitable tests.

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14 - PRECAUTIONS AND WARNINGS

- The medium base, the supplements and the ready to use plates are for microbiological control, and for professional use only; they are to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- The medium base and the supplements shall be used in association according to the described directions.
- Dehydrated media and antibiotics containing supplements must be handled with suitable protection. Before use, consult the Safety Data Sheets.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that the product doesn't contain any transmissible pathogen. Therefore, it is recommended that the culture medium be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- Apply Good Manufacturing Practice in the production process of prepared media.
- Each plate of this culture medium is for single use only.
- Ready-to-use plates are not to be considered a "sterile product" as they are not subject to terminal sterilization but a product with controlled bio contamination, within the limits of defined specifications reported on the Quality Control Certificate.
- The selective supplements are sterilised by membrane filtration.
- Be careful when opening the metal ring of the supplements vials to avoid injury.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as medium powder and supplement or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and supplement and the sterilized medium inoculated with samples or microbial strains in accordance with current local legislation.
- Do not use the culture medium and the supplements as active ingredients for pharmaceutical preparations or as production materials intended for human and animal consumption.
- 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 products for the intended purpose.

15 - STORAGE CONDITIONS AND SHELF LIFE

Ready to use plates

Upon receipt, store plates in their original pack at +2 °C/ + 8°C away from direct light. If properly stored, the plates may be used up to the expiration date. Do not use the plates beyond this date. Plates from opened plastic sachet can be used for 7 days when stored in a clean area at 2-8°C. Do not use the plates if the plastic sachet is damaged or if the dish is broken. Do not use the plates with signs of deterioration (e.g., microbial contamination, dehydration, shrinking or cracking of the medium, atypical colour, excess of moisture).

Dehydrated medium

Upon receipt, store at +10 °C / +30 °C away from direct light in a dry place. If properly stored, it may be used up to the expiration date. Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed. Discard the product if the container and/or the cap are damaged, or if the container is not well closed, or in case of evident deterioration of the powder (colour changes, hardening, large lumps.

Selective supplements

Upon receipt, store the product in the original package at +2 °C/ + 8°C away from direct light. If properly stored, the product may be used up to the expiry date printed on the label; do not use beyond this date. Once the vial has been opened and the lyophilised product has been reconstituted, the resulting solution should be used immediately. Before use, examine the lyophilized and reconstituted product and discard if there are obvious signs of deterioration (e.g., contamination, atypical colour or other abnormal characteristics).

The user is responsible for the manufacturing and quality control processes of prepared media and the validation of their shelf life, according to the type and the applied storage conditions (temperature and packaging).

15 – REFERENCES

1. Buchanana RL *et al.* A review of Listeria monocytogenes: An update on outbreaks, virulence, dose-response, ecology, and risk assessments Food Control Volume 75, May 2017, Pages 1-13
2. Gasanov U, Hughes D, Hansbro PM. Methods for the isolation and identification of Listeria spp. and Listeria monocytogenes: a review. FEMS Microbiol Rev. 2005 Nov;29(5):851-75
3. Curtis GDW, Mitchell RG, King AF, Emma J. A selective differential medium for the isolation of Listeria monocytogenes. Lett Appl Microbiol1989; 8:95-98.
4. U.S. Department of Health and Human Services, F.D.A. Bacteriological Analytical Manual, Chapter 10: Detection of Listeria monocytogenes in Foods and Environmental Samples, and Enumeration of Listeria monocytogenes in Foods, April 2022.
5. 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.
6. Mc Clain D, Lee WH. Development of USDA-FSIS method for isolation of Listeria monocytogenes from raw meat and poultry J Ass Off Assol Chem. 1988; 71: 660
7. USDA-FSIS. Isolation and Identification of Listeria monocytogenes from Red Meat, Poultry, Ready-To-Eat, Siluriformes (Fish) and Egg Products,and Environmental Samples. MLG 8.13, 10/01/2021
8. Laboratory Guidebook, Notice of Change: Media and Reagents. USDA-FSIS, Chapter MLG Appendix 1.09, 12/29/201
9. Curtis GDW, Baird RM. Pharmacopoeia of Culture Media for Food Microbiology: Additional Monographs (II). Proceedings of the 6th International Symposium on Quality Assurance and Quality Control of Microbiological Culture Media, Heidelberg 30 March-3 April, 1992. Int J Food Microbiol 1993; 17:222-4.

TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	Manufacturer	This side up	Store in a dry place	Fragile
Temperature limitation	Content sufficient for <n> tests	Consult Instructions for Use	Use by	Keep away from direct light	For single use only

REVISION HISTORY

Version	Description of changes	Date
Revision 2	Updated layout and content	2022/02
Revision 3	Reorganization and editing of sections 2, 3, 9, 11, 16; inclusion of the section “Performances characteristics”.	2022/08

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

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DIRECTIONS - ISTRUZIONI - PRÉPARATION - GEBRAUCHSANWEISUNG - INSTRUCCIONES - INSTRUKTIONER - INSTRUÇÕES - ΟΔΗΓΙΕΣ

LISTERIA OXFORD ANTIMICROBIC SUPPLEMENT (CCCFA)

REF 4240038 10 x 5 mL

Freeze-dried selective supplement for the isolation of *Listeria s*pp. / Supplemento selettivo liofilizzato per l'isolamento di *Listeria* spp. / Supplément sélectif lyophilisé pour l'isolement de *Listeria* spp. / Gefriergetrocknetes Selektiv-Supplement zur Isolierung von *Listeria* spp. / Suplemento selectivo liofilizado para aislamiento de *Listeria* spp. / Lyophyliserat selektivt supplement för isolering av *Listeria* spp. / Suplemento seletivo liofilizado para o isolamento de *Listeria* spp. / Λυοφιλοποιημένο εκλεκτικό συμπλήρωμα για τον προσδιορισμό *Listeria* spp.

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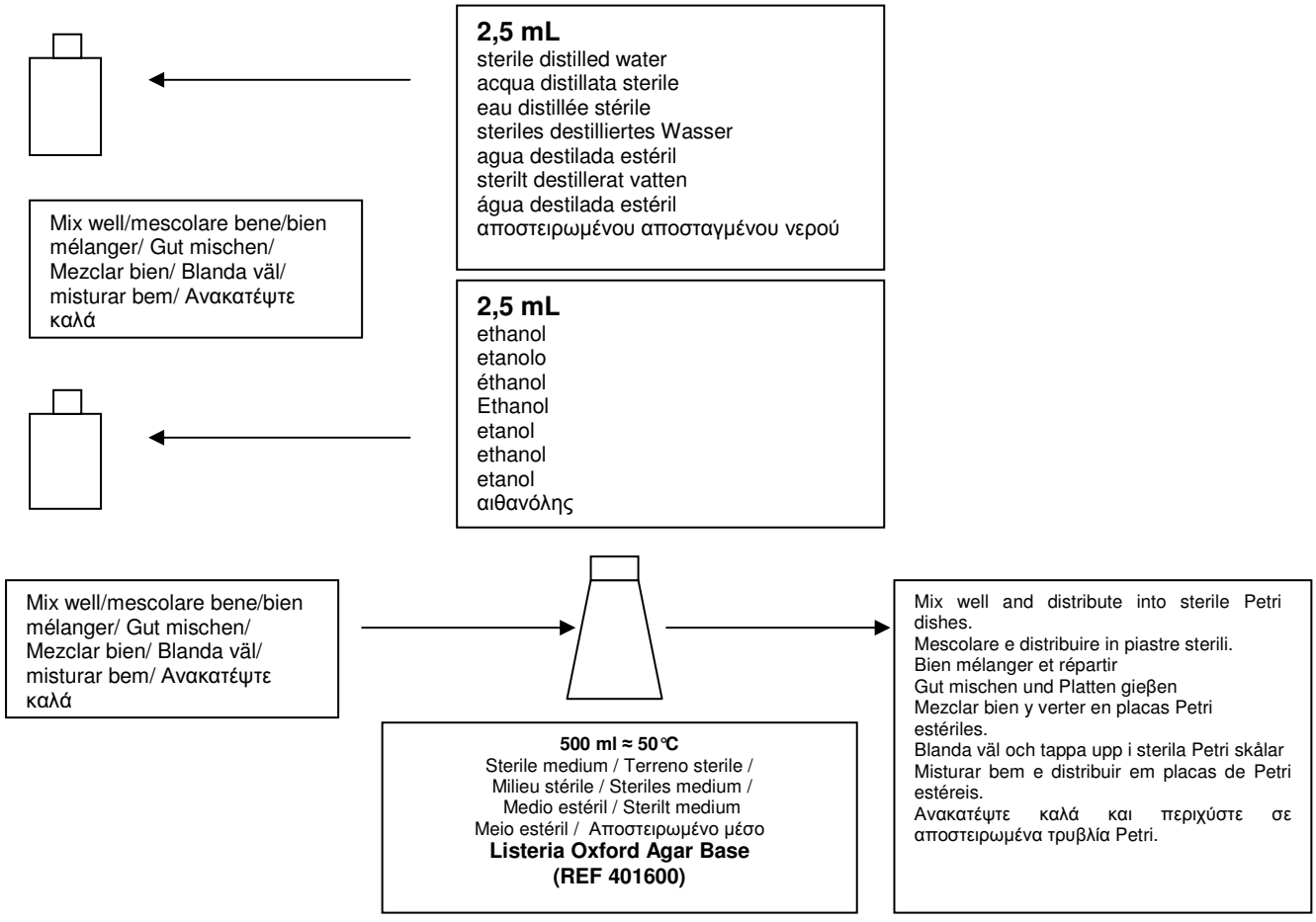
VIAL CONTENTS / CONTENUTO DEL FLACONE /COMPOSITION PAR FLACON / ZUSAMMENSETZUNG JE RÖHRCHEN / CONTENIDO POR VIAL / AMPULLENS INNEHÅLL / CONTEÚDO DO FRASCO / ΠΕΡΙΕΧΟΜΕΝΑ ΦΙΑΛΙΔΙΟΥ

Cycloheximide 200 mg, Colistin sulfate 10 mg, Acriflavin 2.5 mg, Cefotetan 1.0 mg, Fosfomycin 5.0 mg

DIRECTIONS / ISTRUZIONI / PRÉPARATION / ZUBEREITUNG / INSTRUCCIONES /INSTRUKTIONER / INSTRUÇÕES / ΟΔΗΓΙΕΣ.



STORAGE / CONSERVAZIONE / CONSERVATION / LAGERUNG / CONSERVACIÓN / LAGRING / CONSERVAÇÃO / ΑΠΟΘΗΚΕΥΣΗ

Store at 2-8° - When stored as directed the supplement remains stable until the expiry date shown on the label. Do not use beyond stated expiry date. / Conservare a 2 - 8°C- In queste condizioni il prodotto rimane valido fino alla data di scadenza indicata in etichetta. Non utilizzare dopo la data di scadenza. / Conserver à 2-8°C, selon les conditions de conservation indiquées, le produit est stable jusqu'à la date d'expiration mentionnée sur l'étiquette. Ne pas utiliser après la date d'expiration. / Lagerung: 2-8°C. Das Supplement st bei vorschriftsmäβiger Lagerung bis zum aufgedruckten Verfalldatum haltbar. Verfalldatum beachten. / Conservar entre 2-8°C. Estable bajo estas condiciones, hasta la fecha de caducidad que figura en la etiqueta. No utilizar si ha caducado. / Lagras i 2-8°C. Om lagring sker korrekt håller sig supplement hela tiden fram till utgångs datumet som står antecknat på etiketten. Använd ej produkten efter utgångs datum. / Armazenar a 2-8°C. Quando armazenado nestas condições, o suplemento permanece estável até a data de expiração indicada no rótulo. Não utilizar após a data do vencimento. / Φυλάξτε στους 2-8°C. Όταν φυλάσσεται σύμφωνα με τις οδηγίες, το συμπλήρωμα παραμένει σταθερό μέχρι την ημερομηνία λήξης που φαίνεται στην ετικέτα. Μην χρησιμοποιείτε πέραν της αναφερομένης ημερομηνίας λήξεως.

PRECAUTIONS / PRECAUZIONI / PRÉCAUTIONS / VORSICHTSMABNAHMEN / PRECAUCIONES / SÄKERHETSFÖRESKRIFTER PRECAUÇÕES / ΠΡΟΦΥΛΑΞΕΙΣ

For *in vitro* diagnostic use only. The supplement should be used only by adequately trained personnel with knowledge of microbiological techniques in the laboratory./ Solo per uso diagnostico *in vitro*. Il prodotto deve essere usato solo in laboratorio, da operatori addestrati e con conoscenze delle tecniche microbiologiche di base. / Pour usage *in vitro* exclusif. Ce produit ne doit être utilisé qu'en laboratoire par des personnels formés aux techniques de microbiologie. / Zum Gebrauch für *in vitro* Diagnostik. Nur entsprechend ausgebildete Personen mit Kenntnissen in mikrobiologischen Methoden dürfen dieses Produkt nutzen./ Uso sólo para diagnóstico *in vitro*. El suplemento debería ser sólo usado por personal adecuadamente cualificado con conocimientos de las técnicas microbiológicas en laboratorios. / Endast för *in vitro* diagnostik. Supplementet skall endast hanteras av behörig personal med kunskap om mikrobiologiska laboratorietekniker. / Somente para uso diagnostico *in vitro*. O suplemento deve ser utilizado somente no laboratório por pessoas adequadamente treinadas e com conhecimento em técnicas microbiológicas. / Το συμπλήρωμα πρέπει να χρησιμοποιείται από κατάλληλα εκπαιδευμένο προσωπικό με γνώση των μικροβιολογικών τεχνικών στο εργαστήριο.

WARNING / ATTENZIONE / ATTENTION / ACHTUNG / ATENCION / VARNING / ATENÇÃO / ΠΡΟΣΟΧΗ

Consult the material safety data sheet before the use / Consultare la scheda di sicurezza prima dell'uso. / Lire attentivement la fiche de sécurité avant utilisation / Vor Gebrauch Sicherheitsdatenblatt lesen. / Consultar la ficha de datos de seguridad del material antes de su uso. / Kontrollera säkerhets informationen före användning / Consultar a ficha de informações sobre a segurança antes do uso. / Συμβουλευτείτε το φύλλο δεδομένων ασφαλείας υλικού (MSDS) πριν τη χρήση.

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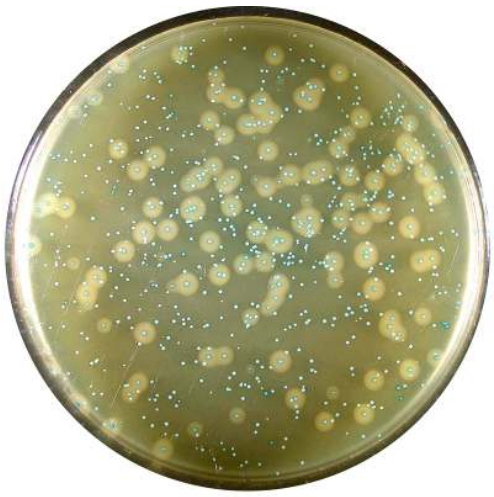
ChromArt

ALOA®
AGAR LISTERIA ACC. TO OTTAVIANI & AGOSTI
ALOA® ENRICHMENT-SELECTIVE SUPPLEMENTS

Dehydrated culture medium, selective supplement and enrichment, ready to use media in plates and flasks



ALOA:
colonies of *L.monocytogenes* and *L.innocua*

1 - INTENDED USE

For the detection and enumeration of *Listeria monocytogenes* and *Listeria* spp. in samples of the food chain and in environmental samples.

2 - COMPOSITION *

(AFTER RECONSTITUTION WITH 1 L OF WATER)

AGAR LISTERIA ACC. TO OTTAVIANI & AGOSTI (ALOA®)

DEHYDRATED MEDIUM AND READY TO USE MEDIUM IN FLASKS: TYPICAL FORMULA FOR 1 L OF WATER

Meat peptone	18.00 g
Tryptone	6.00 g
Yeast extract	10.00 g
Sodium pyruvate	2.00 g
Glucose	2.00 g
Magnesium glycerophosphate	1.00 g
Magnesium sulphate	0.50 g
Sodium chloride	5.00 g
Lithium chloride	10.00 g
Disodium hydrogen phosphate anhydrous	2.50 g
5-bromo-4-chloro-3-indolyl-β-D-glucopyranoside	0.05 g
Agar	13.50 g

ALOA® SELECTIVE SUPPLEMENT	(vial contents for 500 mL of medium)	(vial contents for 200 mL of medium)
Nalidixic acid. sodium slat	0.010 g	0.004 g
Ceftazidime	0.010 g	0.004 g
Cicloheximide	0.025 g	0.01 g
Polymyxin B sulphate	38,350 UI	15,340 UI

ALOA® ENRICHMENT SUPPLEMENT	(vial contents for 500 mL of medium)	(vial contents for 200 mL of medium)
L-α-fosphatidylinositol	1.0 g	0.4 g

ALOA®-AGAR LISTERIA ACC. TO OTTAVIANI & AGOSTI, READY-TO-USE PLATES

Meat peptone	18.000 g
Tryptone	6.000 g
Yeast extract	10.000 g
Sodium pyruvate	2.000 g
Glucose	2.000 g
Magnesium glycerophosphate	1.000 g
Magnesium sulphate	0.500 g
Sodium chloride	5.000 g
Lithium chloride	10.000 g
Disodium hydrogen phosphate anhydrous	2.500 g
5-bromo-4-chloro-3-indolyl-β-D-glucopyranoside	0.050 g
Agar	13.500 g
Nalidixic acid, sodium salt	0.020 g
Ceftazidime	0.020 g
Cicloheximide	0.050 g
L-α-fosphatidylinositol	2.00 g
Polymyxin B sulphate	76,700 IU
Purified water	1000 mL

*The formulas may be adjusted and/or supplemented to meet the required performances criteria.

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

Agar Listeria acc. to Ottaviani and Agosti (ALOA) is a chromogenic and selective medium for the detection and enumeration of *L. monocytogenes* and *Listeria* spp. in samples of the food chain and in environmental samples due to its ability to differentiate *L. monocytogenes* from other *Listeria* species, even in the presence of a mixed flora.
ALOA medium is recommended by ISO 11290-1[1] and ISO 11290-2[2] for detection and enumeration of *L. monocytogenes* and *Listeria* spp. and it is also cited by FDA-BAM[3], APHA[4] and other regulatory agencies[5,6].
ALOA medium was conceived by Franco Ottaviani and Marco Agosti[7] and industrialised by Biolife in the mid-1990s.
ALOA has been compared by several authors with PALCAM and Oxford media and some other chromogenic media: all results confirm the superiority of ALOA medium over conventional media and other chromogenic media.[8-13]

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Lequerq[14] reported that ALOA was the best medium of the four tested and that its introduction into the laboratory methods to replace Oxford and PALCAM increases the isolation and counting of atypical *L. monocytogenes* strains.
Gracieux et al.[15] reported a higher recovery rate of virulent, hypovirulent and avirulent strains of *L. monocytogenes* with ALOA than with PALCAM medium and other chromogenic media.
Sacchetti et al.[16] reported that in an experiment with 132 food samples, ALOA and a second chromogenic medium allowed faster detection of *L. monocytogenes* with greater sensitivity and specificity than PALCAM medium.
According to Jadhav et al.[17], identification with MALDI-TOF was optimal with colonies grown on ALOA medium.
Peptones and yeast extract provide nitrogen, carbon, vitamins particularly of the B-group and trace elements for microbial growth. Glucose is a source of carbon and energy, sodium chloride maintains the osmotic balance, and sodium phosphate bibasic is included as a buffer system. Sodium pyruvate aids in resuscitation of stressed cells and magnesium salts stimulate the growth of *Listeria* spp. The selective action is due to the presence of lithium chloride in the basal medium and the addition of the antimicrobial mixture of the selective supplement containing ceftazidime, polymyxin B, nalidixic acid and cycloheximide. The medium markedly reduces the growth of the majority of concomitant Gram-positive and Gram-negative bacteria, as well as of yeasts and fungi.
The differential property of ALOA is due to the presence of the chromogenic compound 5-bromo-4-chloro-3-indolyl-β-D-glucopyranoside, a substrate for the detection of the enzyme ß-glucosidase, which is common to all *Listeria* species. Specific differential action is achieved with a substrate for phospholipase C (PI-PLC: phosphatidyl inositol phospholipase C). *Listeria monocytogenes* cleaves this specific substrate added to the medium base producing an opaque halo around the colonies. Most *Listeria ivanovii* also produce an opaque halo around the colonies after 48 h incubation. With the combined action of the two substrates, it is possible to differentiate the following colonies: *L. monocytogenes*: blue-green colonies surrounded by an opaque halo, *Listeria* other than-*monocytogenes* and *ivanovii*: blue-green colonies without the opaque halo.

4A- Directions for medium preparation (dehydrated medium)

Suspend 35.3 g in 500 mL of cold purified water, heat to boiling with frequent agitation and sterilise by autoclaving at 121°C for 15 minutes. Cool to 47-50°C add the contents of one vial of ALOA Enrichment Supplement pre-warmed to 48-50°C, and the contents of one vial of ALOA Selective Supplement, reconstituted with 5 mL of ethanol/sterile distilled water (1:1). Mix well and distribute into sterile Petri dishes.

4B- Directions for medium preparation (REF 511605K3 medium in flasks and supplements)

Dissolve the contents (200 mL) of one flask of ALOA medium in a water bath at 100°C. Cool to 47-50°C add the contents of one vial of ALOA Enrichment Supplement pre-warmed to 48-50°C, and the contents of one vial of ALOA Selective Supplement, reconstituted with 5 mL of ethanol/sterile distilled water (1:1). Mix well and distribute into sterile Petri dishes.

5 - Physical characteristics

Dehydrated medium appearance	beige, fine, homogeneous, free-flowing powder
Prepared plates appearance	yellowish, opalescent
Prepared flasks appearance	yellowish, opalescent
Freeze-dried selective supplement	white, high, compact pellet; colourless and clear solution after reconstitution
Enrichment supplement appearance	cloudy, yellow suspension with a slight precipitate
Final pH of complete medium (at 20-25°C)	7.2 ± 0.2

6 - Materials provided – packaging

Product	Type	REF	Pack
Agar Listeria acc. to Ottaviani & Agosti (ALOA®)	Dehydrated medium	4016052	500 g (7,1 L)
Agar Listeria acc. to Ottaviani & Agosti (ALOA®)	Dehydrated medium	4016054	5 kg (71 L)
ALOA® Enrichment Selective Supplements	Freeze-dried and liquid supplements	423501	4+4 vials, each for 500 mL of medium
ALOA® Enrichment Selective Supplements	Freeze-dried and liquid supplements	423505	5+5 vials, each for 200 mL of medium
ALOA® -Agar Listeria acc. to Ottaviani & Agosti	Ready-to-use plates	541605	2 x 10 plates ø 90 mm
ALOA® -Agar Listeria acc. to Ottaviani & Agosti	Ready-to-use plates	501605P	5 plates ø 150 mm
ALOA® Flasks Kit	Ready-to-use flasks and supplements	511605K3	4x200mL ALOA flasks + 4 vials of ALOA Enrichment Supplement and 4 vials of ALOA Selective Supplement, each for 200 mL of medium base

7 - Materials required but not provided

Autoclave, water-bath, sterile loops, swabs and pipettes, incubator and laboratory equipment as required, Petri dishes, Erlenmeyer flasks, ancillary culture media and reagents.

8 - Specimens

Foods, animal deeding stuffs, food chain and environmental samples. When collecting, storing, transporting and preparing samples, follow the rules of good laboratory practice and refer to applicable international standards.[1-6]

9 - test procedure

Detection of *Listeria monocytogenes* and *Listeria* spp (ISO 11290-1)[1]

1. In general, to prepare the initial suspension, add a test portion of 25 g or 25 mL to 225 g or 225 mL of Fraser Broth Half Concentration, to obtain a tenfold dilution, and homogenize.
2. Incubate the primary enrichment medium at 30 °C for 25 h ± 1 h.
3. Transfer 0.1 mL of the culture to a tube or bottle containing 10 mL of secondary enrichment medium (Fraser Broth) and incubate for 24 h ± 2 h at 37 °C. In the case of *Listeria* spp. other than *Listeria monocytogenes* detection, additional 24 h incubation can allow for recovery of more species.

4. From the primary enrichment culture inoculate, by means of a loop, the surface of the first selective plating medium, Agar Listeria according to Ottaviani and Agosti (ALOA), to obtain well-separated colonies. Proceed in the same way with the second selective plating-out medium of choice (e.g., PALCAM or Oxford Agar).
5. From the secondary enrichment medium, repeat the procedure with the two selective plating-out media.
6. Incubate ALOA plates at 37°C ± 1°C for 24 ± 2 hours; if there is no growth or no typical colonies, re-incubate for a further 24 ± 2 hours.
7. Incubate the second plating out medium according to the Instructions for Use
8. Examine the dishes for the presence of presumptive colonies of *L. monocytogenes* or *Listeria* spp.

Notes
It is possible to store at 5 °C the pre-enriched sample after incubation before transfer to Fraser broth for a maximum of 72 h.
Half-Fraser broth and Fraser broth can be refrigerated at 5 °C before isolation on selective agar for a maximum of 72.
After incubation, ALOA plates can be refrigerated at 5 °C for a maximum of 48 h before reading.

Enumeration of *Listeria monocytogenes* and of *Listeria* spp (ISO 11290-2)[2]

1. Prepare a sample suspension in Buffered Peptone Water or other suitable enrichment broth according to ISO 6887 (all parts); in case both determination and counting are performed according to parts 1 and 2 of ISO 11290, the sample suspension may be made in half-Fraser broth (with or without the addition of the selective supplement).
2. Inoculate 0.1 mL of the sample suspension and 0.1 mL of further decimal dilutions onto 90 mm plates of ALOA medium.
3. For samples with suspected low number of target-strains, inoculate 1 mL of the sample suspension and 1 mL of further decimal dilutions onto 140 mm plates of ALOA medium.
4. Examine after incubation at 37°C for 24 ± 2 hours and, if there is no growth or no typical colonies, re-incubate for a further 24 ± 2 hours.
5. Count *L. monocytogenes* colonies and *Listeria* spp. colonies in plates with less than 150 colonies (90 mm diameter plates) or 360 colonies (140 mm plates) according to the section "reading and interpretation".

10 - READING AND INTERPRETATION

After incubation, observe the bacterial growth and record the specific morphological and chromatic characteristics of the colonies on plating out media.
Consider as presumptive *L. monocytogenes* the blue-green colonies surrounded by an opaque halo.
Consider as presumptive *Listeria* spp. the blue-green colonies with or without opaque halo.
Second plating-out medium: after incubation at the temperature described by the Instructions for Use, examine for the presence of typical colonies according to the characteristics of the chosen medium.

Confirm typical colonies by the methods and tests indicated in ISO 11290-1 or ISO 11290-2, after purification of the colonies in Tryptic Glucose Yeast Agar.
The mandatory confirmatory tests for *L.monocytogenes*, according to ISO 11290 and using ALOA medium, are the following: β-hemolysis (+), carbohydrate utilization (L-rhamnose +; D-xylose -). Optional confirmatory tests for *L.monocytogenes* are:, catalase (+), mobility at 25°C (+). The mandatory confirmatory tests for *Listeria* spp. are: microscopic examination, catalase (+); optional tests are: VP (+), mobility at 25°C (+).
Miniaturized galleries for the biochemical identification of *Listeria monocytogenes* may be used (Listeria Monoconfirm Test REF 193000)

11 - 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 some test strains useful for the quality control.

CONTROL STRAINS	INCUBATION T°/ T / ATM	EXPECTED RESULTS
L. monocytogenes ATCC 13932	37°C /24-48h A	green-blue colonies surrounded by an opaque halo
L. monocytogenes NCTC 7973	37°C /24-48h A	green-blue colonies surrounded by an opaque halo
L. innocua ATCC 33090	37°C /24-48h A	green-blue colonies without opaque halo
L. ivanovii ATCC 19119	37°C /24-48h A	green-blue colonies with opaque halo
E. coli ATCC 25922	37°C / 48h A	inhibited
E. faecalis ATCC 19433	37°C / 48h A	inhibited

A: aerobic incubation; ATCC is a trademark of American Type Culture Collection

12- PERFORMANCES CHARACTERISTICS

Prior to release for sale representative samples of all lots of ALOA dehydrated and ready-to-use medium and supplements are tested for productivity and selectivity by comparing the results with Tryptic Soy Agar.
Productivity is tested by a quantitative test with the target strains *L.monocytogenes* ATCC 13932 and NCTC 7973: the plates are inoculated with decimal dilutions in saline of a colonies' suspension and incubated at 35-37°C for 24-48 hours. The colonies are enumerated on both batches and the productivity ratio (*Pr*) is calculated. If *Pr* is ≥ 0.5 and if the colonies morphology and colour are typical (green-blue colonies with opaque halo) the results are considered acceptable and conform to the specifications. Furthermore the productivity characteristics are tested by semi-quantitative ecometric technique with the following target strains: *L.innocua* ATCC 33090, and *L.ivanovii* ATCC 19119. The amount of growth and colonies characteristics are evaluated after incubation at 35-37°C for 24-48 hours: *L.innocua* grows with green-blue colonies without opaque halo while *L.ivanovii* exhibits a good growth after 48 hour of incubation with green-blue colonies and an opaque halo.
The selectivity is evaluated with modified Miles-Misra surface drop method by inoculating the plates with suitable decimal dilutions in saline of a 0.5 McFarland suspension of the non-target strains *E.faecalis* ATCC 19433, *E.coli* ATCC 25922, *S.aureus* ATCC 25923, *S.sciuri* wild strain CB 16.1, and *C.albicans* ATCC 10231. After incubation at 35-37°C for 48 hours, the growth of non-target strains is totally inhibited.

13 - LIMITATIONS OF THE METHOD

- The reading of plates with abundant growth can be facilitated by comparing the opacity of the medium at the edges where there may be no growth with that in the centre of the plate or by comparing with an uninoculated plate. Plates with a confluent and intense growth of *L. monocytogenes* will still appear intensely opaque; in the case of intense growth of *Listeria* sp. other than *monocytogenes* the plates will not be opaque. If there is any doubt, the colonies should be re-isolated.
- *L.ivanovii* at 24 hours and especially after 48 hours of incubation, presents blue-green colonies with an opaque halo. In these cases, confirmatory tests will allow correct identification.
- Some strains of *Bacillus cereus*, which are resistant to the selective agents, may produce flat, wrinkled, non-homogenous white to blue colonies with a large, intense halo.
- It has been reported[18] that some species of 6 genera of Gram-positive bacteria can grow on ALOA and sometimes generate blue or bluish colonies: *Bacillus* spp. (*B. circulans, B. clausii, B. licheniformis, B. oleronius*, *Cellulosimicrobium funkei*), *Enterococcus* spp. (*E. faecalis, E. faecium/durans*), *Kocuria kristinae, Marinilactibacillus psychrotolerans, Rothia terrae, Staphylococcus* spp. (*S.sciuri, S. saprophyticus subsp. saprophyticus/xylosus*), *Streptococcus*.
- Some strains of *L. monocytogenes* exposed to stress conditions, particularly acid stress, can show a very weak halo (or even no halo).[1,2]
- Some rare *L. monocytogenes* are characterized by a slow PIPLC activity. Such bacteria are detected when the total duration of incubation is more than, for example, four days. Some of these strains could be pathogenic. No *L. monocytogenes* strains have been described as PIPLC negative.[1,2]
- Rare strains of *L.monocytogenes* may not exhibit β-haemolysis.[1,2] If typical colonies on ALOA are β-haemolysis negative, additional confirmatory tests (Gram, catalase, mobility, CAMP test, PCR) are recommended.

14 - PRECAUTIONS AND WARNINGS

- ALOA medium and supplements are for microbiological control and for professional use only; they are to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- The medium base and the supplements shall be used in association according to the described directions. Apply Good Manufacturing Practice in the production process of prepared media.
- Dehydrated media and antibiotics containing supplements must be handled with suitable protection. Before use, consult the Material Safety Data Sheets.
- This culture medium contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that the product doesn't contain any transmissible pathogen. Therefore, it is recommended that the culture medium be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- Be careful when opening screw cap flasks to prevent injury due to breakage of glass.
- Be careful when opening the metal ring of the supplements to avoid injury.
- When using a hot plate and/or a water bath, boil sufficiently long to dissolve the whole medium.
- Wear heat-protective gloves during medium liquefaction. Do not place the hot flasks into an ice bath or in cold water to accelerate cooling as this might cause cracks in the glass.
- The time required for complete liquefaction of the medium may vary considerably and depends on the actual temperature of the heating device, its wattage, the size and volume of the bottle.
- Once the bottled medium is liquefied, it cannot be solidified and dissolved a second time.
- Ready-to-use flasks are subject to terminal sterilization by autoclaving.
- The selective supplement is sterilized by membrane filtration, the enrichment supplement is sterilized by autocalving.
- Each plate of this culture medium is for single use only.
- Ready-to-use plates are not to be considered a "sterile product" as they are not subject to terminal sterilization, but a product with controlled bio contamination, within the limits of defined specifications reported on the Quality Control Certificate.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as medium powder and supplement or microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused medium and supplements and the inoculated plates with samples or microbial strains in accordance with current local legislation.
- Do not use the culture medium and the supplements as active ingredients for pharmaceutical preparations or as production materials intended for human and animal consumption.
- 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.

15 - STORAGE CONDITIONS AND SHELF LIFE

Dehydrated medium

Upon receipt, store at +2°C /+8°C away from direct light in a dry place. If properly stored, it may be used up to the expiration date. Do not use beyond this date. Avoid opening the bottle in humid places. After use, the container must be tightly closed. Discard the product if the container and/or the cap are damaged, or if the container is not well closed, or in case of evident deterioration of the powder (colour changes, hardening, large lumps).

Freeze-dried selective supplement

Upon receipt, store the product in the original package at +2°C /+8°C away from direct light. If properly stored, the product may be used up to the expiry date printed on the label; do not use beyond this date. Once the vial has been opened and the lyophilised product has been reconstituted, the resulting solution should be used immediately. Before use, examine the lyophilized and reconstituted product and discard if there are obvious signs of deterioration (e.g., contamination, atypical colour or other abnormal characteristics).

Liquid supplement

Store until the expiry date stated on the label, at +2°C /+8°C. Do not use beyond this date. Open the liquid enrichment bottle with aseptic precautions and store at 2-8°C until the expiry date if the contents are not fully used.

Ready to use flasks

Upon receipt, store flasks in their original pack at +2°C /+8°C away from direct light. If properly stored, the flasks may be used up to the expiration date. Do not use the flasks beyond this date. Flasks from opened secondary packages can be used up to the expiration date. Opened flasks must be used immediately. Before use, check the closing and the integrity of the screw cap. Do not use flasks with signs of deterioration (e.g., microbial contamination, abnormal turbidity, precipitate, atypical colour).

Ready to use plates

Upon receipt, store plates in their original pack at +2°C /+8°C away from direct light. If properly stored, the plates may be used up to the expiration date. Do not use the plates beyond this date. Plates from opened plastic sachet can be used for 7 days when stored in a clean area at +2°C /+8°C. Do not use the plates if the plastic sachet is damaged or if the dish is broken. Do not use the plates with signs of deterioration (e.g., microbial contamination, dehydration, shrinking or cracking of the medium, atypical colour, excess of moisture).

The user is responsible for the manufacturing and quality control processes of prepared media and the validation of their shelf life, according to the type (plates/flasks) and the applied storage conditions (temperature and packaging). According to Corry *et al.*[19] the self-prepared plates can be stored at +2°C /+8°C in the dark and protected against evaporation for up to four weeks.

16 - REFERENCES

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TABLE OF APPLICABLE SYMBOLS

REF or REF Catalogue number	LOT Batch code	Manufacturer	For single use only	This side up	Store in a dry place
Temperature limitation	Content sufficient for <n> tests	Consult Instructions for Use	Use by	Fragile	Keep away from direct light

REVISION HISTORY

Version	Description of changes	Date
Revision 7	Updated layout and content	2022/06

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

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Biolife

DIRECTIONS - ISTRUZIONI - PRÉPARATION - GEBRAUCHSANWEISUNG - INSTRUCCIONES - INSTRUKTIONER - INSTRUCÕES - ΟΔΗΓΙΕΣ

ALOA®
ENRICHMENT SELECTIVE SUPPLEMENT

REF 423501

Freeze-dried selective and liquid supplements for the isolation of *Listeria monocytogenes* / Supplemento selettivo liofilizzato e supplemento liquido per l'isolamento di *Listeria monocytogenes* / Supplément sélectif lyophilisé et supplément liquide pour l'isolement de *Listeria monocytogenes* / Gefriergetrocknetes Selektiv-Supplement und Emulsion zur Isolierung von *Listeria monocytogenes* / Suplemento selectivo liofilizado y solución para aislamiento de *Listeria monocytogenes* / Lyophyliserat selektivt supplement och selektivt supplement i lösning för isolering av *Listeria monocytogenes* / Suplemento seletivo liofilizado e suplemento seletivo liquido para o isolamento de *Listeria monocytogenes* / Λυοφιλοποιημένο εκλεκτικό συμπλήρωμα για τον προσδιορισμό *Listeria monocytogenes*

CONTENTS/CONTENUTO/PRESENTATION/PACKUNGSINHALT/CONTENIDO/ INNEHÅLL /CONTEÚDO/ ΠΕΡΙΕΧΟΜΕΝΑ
4+4 VIALS FOR 500 ML OF MEDIUM / 4+4 FLACONI PER 500 ML DI TERRENO / 4+4 FLACONS POUR 500 ML DE MILIEU / 4+4 RÖHRCHEN FÜR 500 ML NÄHRBODEN / 4+4 VIALES PARA 500 ML DE MEDIO/ 4+4 AMPULLER, VARJE AMPULL ANVÄNDS TILL 500 ML MEDIUM/4+4 FRASCOS, PARA CADA 500 ML DE MEIO/ 4+4 ΦΙΑΛΙΔΙΑ, ΕΚΑΣΤΟ ΓΙΑ 500 ML ΜΕΣΟΥ.

DIRECTIONS / ISTRUZIONI / PRÉPARATION / ZUBEREITUNG / INSTRUCCIONES /INSTRUKTIONER / INSTRUÇÕES / ΟΔΗΓΙΕΣ.

ALOA Selective Supplement (VIAL CONTENTS) Nalidixic Acid 10 mg, Ceftazidime 10 mg, Cycloheximide 25 mg, Polymyxin B 38350 IU.
ALOA Enrichment Supplement (VIAL CONTENTS) L-α-fosphatidylinositol 1 g (20 ml)

DIRECTIONS Suspend 35.35 g of Agar Listeria acc. to Ottaviani & Agosti (ALOA) (REF 401605) in 500 ml of cold distilled water; heat to boiling and sterilise by autoclaving at 121°C for 15 minutes. Cool to 45-50°C and add the contents of one vial of ALOA Selective Supplement, reconstituted with 5 ml of ethanol/ sterile distilled water (1/1). Then add the contents of one vial of ALOA Enrichment Supplement well shacked mixed and pre-warmed to 45-50°C. Mix well and pour into sterile Petri dishes.

ALOA Selective Supplement (CONTENUTO DEL FLACONE) Acido nalidissico 10 mg, Ceftazidime 10 mg, Cicloeximide 25 mg, Polimixina 38350 UI
ALOA Enrichment Supplement (CONTENUTO DEL FLACONE) L-α-fosfatidilinosito 1 g (20 ml)

ISTRUZIONI Sospendere 35.35 g di Agar Listeria acc. to Ottaviani & Agosti (ALOA) (REF 401605) in 500 ml di acqua distillata fredda; portare ad ebollizione sotto agitazione ed autoclavare a 121°C per 15 minuti. Raffreddare a circa 45-50°C ed aggiungere il contenuto di una fiala di ALOA Selective Supplement, ricostituito con 5 ml di etanolo/acqua distillata sterile (1:1). Aggiungere quindi il contenuto di una fiala di ALOA Enrichment Supplement mescolato e preriscaldato a 45-50°C. Mescolare con cura e distribuire in piastre di Petri.

ALOA Selective Supplement (COMPOSITION (PAR FLACON) Acide nalidixique 10 mg, Ceftazidime 10 mg, Cycloheximide 25 mg Polymyxine B 38350 UI.
ALOA Enrichment Supplement (Composition (par flacon) L-α-fosphatidylinositol 1 g (20 ml).

PREPARATION Ajouter 35.35 g de Agar Listeria acc. to Ottaviani & Agosti (ALOA) (REF 401605) à 500 ml d'eau distillée froide. Chauffer sous continuelle agitation et porter à ébullition jusqu'à dissolution complete. Stérilizer à 121°C pendant 15 minutes. Refroidir à 45-50°C et ajouter aseptiquement, le contenu d'une ampoule de ALOA Selective Supplement, reprise par 5 ml d' éthanol/eau distillée stérile (1 :1). Ajouter stérilement le contenu d'un flacon de ALOA Enrichment Supplement bien mélangé et chauffé à 458-50°C. Bien melanger et couler en boîtes de Pétri stériles.

ALOA Selective Supplement (ZUSAMMENSETZUNG JE RÖHRCHEN) Nalidixinsäure 10 mg, Ceftazidim 10 mg, Cycloheximid 25 mg, Polymyxin B 38350 IU
ALOA Enrichment Supplement (ZUSAMMENSETZUNG JE RÖHRCHEN) L-α-Fosphatidylinositol 1 g (20 ml)

ZUBEREITUNG 35.35 g Agar Listeria acc. to Ottaviani & Agosti (ALOA) (REF 401605) in 500 ml kalten destillierten Wasser suspendieren und bis zum vollständigen Lösen erhitzen. 15 Minuten bei 121°C autoklavieren auf 45-50°C abkühlen. Den Inhalt eines Röhrchens ALOA Selective Supplement aseptisch in 5 ml Ethanol /destilliertes Wasser (1:1) lösen. Den gelösten Inhalt zu 500 ml abgekühlter ALOA -Agar -Basis geben. Den gelösten Inhalt und 20 ml ALOA Enrichment Supplement gewärmter auf 48-50C und gut geschwenkt. Gut mischen und Platten gießen.

ALOA Selective Supplement (CONTENIDO POR VIAL**)** Acido nalidíxico 10 mg, Ceftacidima 10 mg, Cicloheximida 25 mg, Polimixina 38350 UI
ALOA Enrichment Supplement (CONTENIDO POR VIAL) L-α-fosfatidilinositol 1 g (20 ml)

INSTRUCCIONES Agregar 35.35 g de Agar Listeria acc. to Ottaviani & Agosti (ALOA) (REF 401605) a 500 ml de agua destilada fría y llevar a ebullición agitando, hasta completa disolución. fria y llevar a ebulición agitando, hasta completa disolucion. Esterilizar a 121°C durante 15 minutos. Enfriar a 45-50°C y añadir asépticamente el contenido de un vial de ALOA Selective Supplement, reconstituido

con 5 ml de etanol/agua estéril (1:1). Añadir asepticamente el contenido de un vial de ALOA Enrichment Supplement, mezclado y calentado a 45-50°C. Mezclar y distribuir en placas estériles

ALOA Selective Supplement (AMPULLENS INNEHÅLL) Nalidixic Acid 10 mg, Ceftazidime 10 mg, Cycloheximide 25 mg, Polymyxin B 38350 IU.
ALOA Enrichment Supplement (AMPULLENS INNEHÅLL) L-α-fosphatidylinositol 1 g (20 ml)

INSTRUKTIONER Lös upp 35.35 g av Agar Listeria acc. to Ottaviani & Agosti (ALOA) (REF 401605) i 500 ml destillerat vatten. Kokas under omrörning till fullständing upplösning. Sterilisera genom autocklavering i 121°C under 15 minuter. Kiles till 45-50°C. Under rena betingelser, löses innehållet av 1 ampull med ALOA Selective Supplement med 5 ml av ethanol/destillerat vatten (1:1). Tillsätt sedan innehållet i en ampull av ALOA Enrichment Supplement för värmd till 45-50°C. Blanda väl och tappa upp i sterila Petri Skålar.

ALOA Selective Supplement (CONTEÚDO DO FRASCO) Ácido Nalidixico 10 mg, Ceftazidima 10 mg, Ciclohexemida 25 mg, Polimixina B 38350 UI.
ALOA Enrichment Supplement (CONTEÚDO DO FRASCO) L-α-fosfatidilinositol 1 g (20 ml)

INSTRUÇÕES Suspender 35.35 g de Agar Listeria acc. to Ottaviani & Agosti (ALOA) (REF 401605) em 500 ml de água destilada fria. Aquecer até ferver sob agitamento freqüente até completa dissolução. Esterilizar por autoclavagem a 121°C durante 15 minutos. Deixar esfriar a 45-50°C. Adicionar sob condições assépticas o conteúdo de um vial de ALOA Selective Supplement reconstituído com 5 ml de etanol/água destilada estéril (1:1). Adicionar então o conteúdo de um frasco de ALOA Enrichment Supplement bem misturado e pré-aquecido a 45-50°C. Misturar bem e distribuir em placas de Petri estéreis.

ALOA Selective Supplement (ΠΕΡΙΕΧΟΜΕΝΑ ΦΙΑΛΙΔΙΟΥ) Ναλιδιξικό Οξύ 10 mg, Κεφταζιδίμη 10 mg, Κυκλοεξιμίδιο 25 mg, Πολυμυξίνη Β 38350 UI.
ALOA Enrichment Supplement (ΠΕΡΙΕΧΟΜΕΝΑ ΦΙΑΛΙΔΙΟΥ) παράγοντας L-α-fosphatidylinositol 1 g (20 ml)

ΟΔΗΓΙΕΣ Διαλύστε 35.35 g Agar Listeria acc. to Ottaviani & Agosti (ALOA) (REF 401605) σε 500 ml κρύο απεσταγμένο νερό. Θερμάνετε μέχρι βρασμού, με συχνή ανακίνηση, ώσπου να διαλυθεί εντελώς. Αποστειρώστε σε αυτόκαυστο στους 121 °C για 15 λεπτά. Ψύξτε στους 45-50°C. Υπό ασηπτικές συνθήκες, προσθέστε το περιεχόμενο ενός φιαλιδίου ALOA Selective Supplement αναγεννημένο με 5 ml αιθανόλης/αποστειρωμένου απεσταγμένου νερού (1:1). Μετά προσθέστε τα περιεχόμενα ενός φιαλιδίου ALOA Enrichment Supplement προθερμασμένου στους 45-50°C. Αναμείξτε καλά και περιχύστε σε αποστειρωμένα τρυβλία Petri.

STORAGE / CONSERVAZIONE / CONSERVATION / LAGERUNG / CONSERVACIÓN / LAGRING / CONSERVAÇÃO / ΑΠΟΘΗΚΕΥΣΗ
Store at 2-8° - When stored as directed the supplement remains stable until the expiry date shown on the label. Do not use beyond stated expiry date. / Conservare a 2 - 8°C- In queste condizioni il prodotto rimane valido fino alla data di scadenza indicata in etichetta. Non utilizzare dopo la data di scadenza. / Conserver à 2-8°C, selon les conditions de conservation indiquées, le produit est stable jusqu'à la date d'expiration mentionnée sur l'étiquette. Ne pas utiliser après la date d'expiration. / Lagerung: 2-8°C. Das Supplement st bei vorschriftsmäßiger Lagerung bis zum aufgedruckten Verfalldatum haltbar. Verfalldatum beachten. / Conservar entre 2-8°C. Estable bajo estas condiciones, hasta la fecha de caducidad que figura en la etiqueta. No utilizar si ha caducado. / Lagras i 2-8°C. Om lagring sker korrekt håller sig supplement hela tiden fram till utgångs datumet som står antecknat på etiketten. Använd ej produkten efter utgångs datum. / Armazenar a 2-8°C. Quando armazenado nestas condições, o suplemento permanece estável até a data de expiração indicada no rótulo. Não utilizar após a data do vencimento. / Φυλάξτε στους 2-8°C. Όταν φυλάσσεται σύμφωνα με τις οδηγίες, το συμπλήρωμα παραμένει σταθερό μέχρι την ημερομηνία λήξης που φαίνεται στην ετικέτα. Μην χρησιμοποιείτε πέραν της αναφερομένης ημερομηνίας λήξεως.

PRECAUTIONS / PRECAUZIONI / PRÉCAUTIONS / VORSICHTSMABNAHMEN / PRECAUCIONES / SÄKERHETSFÖRESKRIFTER PRECAUÇÕES / ΠΡΟΦΥΛΑΞΕΙΣ
For *in vitro* diagnostic use only. The supplement should be used only by adequately trained personnel with knowledge of microbiological techniques in the laboratory./ Solo per uso diagnostico *in vitro*. Il prodotto deve essere usato solo in laboratorio, da operatori addestrati e con conoscenze delle tecniche microbiologiche di base. / Pour usage *in vitro* exclusif. Ce produit ne doit être utilisé qu'en laboratoire par des personnels formés aux techniques de microbiologie. / Zum Gebrauch für *in vitro* Diagnostik. Nur entsprechend ausgebildete Personen mit Kenntnissen in mikrobiologischen Methoden dürfen dieses Produkt nutzen./ Uso sólo para diagnóstico *in vitro*. El suplemento debería ser sólo usado por personal adecuadamente cualificado con conocimientos de las técnicas microbiológicas en laboratorios. / Endast för *in vitro* diagnostik. Supplementet skall endast hanteras av behörig personal med kunskap om mikrobiologiska laboratorietekniker. / Somente para uso diagnostico *in vitro*. O suplemento deve ser utilizado somente no laboratório por pessoas adequadamente treinadas e com conhecimento em técnicas microbiológicas. / Το συμπλήρωμα πρέπει να χρησιμοποιείται από κατάλληλα εκπαιδευμένο προσωπικό με γνώση των μικροβιολογικών τεχνικών στο εργαστήριο.

WARNING / ATTENZIONE / ATTENTION / ACHTUNG / ATENCION / VARNING / ATENÇÃO / ΠΡΟΣΟΧΗ
Consult the material safety data sheet before the use / Consultare la scheda di sicurezza prima dell'uso. / Lire attentivement la fiche de sécurité avant utilisation / Vor Gebrauch Sicherheitsdatenblatt lesen. / Consultar la ficha de datos de seguridad del material antes de su uso. / Kontrollera säkerhets informationen före användning / Consultar a ficha de informações sobre a segurança antes do uso. / Συμβουλευτείτε το φύλλο δεδομένων ασφαλείας υλικού (MSDS) πριν τη χρήση.

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-IVDR-099

Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 071067 0008 Rev. 00

Manufacturer: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALY

SRN Manufacturer: Not available at the issuance date of this certificate

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).
The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12 071067 0008 Rev. 00

Report No.: ITA1674857

Valid from: 2022-07-25

Valid until: 2027-07-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-25

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
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BS-IVDR-099

TÜV SÜD Product Service

EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 071067 0008 Rev. 00

Classification:	B
Device Group:	W0104 - MICROBIOLOGY (CULTURE)
Intended Purpose:	IVR 0505 - Devices intended to be used to grow/isolate/identify and handle infectious agents

Classification:	B
Device Group:	W0104 - MICROBIOLOGY (CULTURE)
Intended Purpose:	IVR 0503 - Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents

Classification:	C
Device Group:	W0104 - MICROBIOLOGY (CULTURE)
IVP Code:	IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose:	IVR 0505 - Devices intended to be used to grow/isolate/identify and handle infectious agents

The validity of this certificate depends on conditions and/or is limited to the following:	\

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
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TÜV®

Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE

La società Liofilchem® S.r.l., con Sede Legale in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante dei dispositivi medico-diagnostici *in vitro* elencati nella tabella sotto riportata Revisione 37.3 del 26.05.2022

dichiara sotto la propria responsabilità

1. che i dispositivi sottoindicati soddisfano tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato III) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
2. che i dispositivi sottoindicati non sono inclusi nell'Allegato II, lista A e B della Direttiva 98/79/CE
3. che la documentazione tecnica di cui all'allegato III della direttiva Direttiva 98/79/CE è a disposizione delle autorità nazionali presso la sua sede e sarà conservata per 5 anni dall'ultima data di fabbricazione del prodotto;
4. che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
5. di aver attivato e di mantenere aggiornato, un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
6. che i dispositivi sottoindicati sono stati messi in commercio muniti di marcatura CE.

EC DECLARATION OF CONFORMITY

The company Liofilchem® S.r.l., registered office in Via Scozia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the in vitro medical-diagnostic devices listed in the table below, Revision 37.3 of 26.05.2022

hereby certifies under its own responsibility

1. that the below mentioned devices comply with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the below mentioned devices are not included in Annex II, List A and B of Directive 98/79/EC;
3. that the technical documentation referred to at Annex III of the Directive 98/79/EC is available for the national authorities in its facility and that this documentation shall be kept for 5 years after the last product has been manufactured;
4. that the manufacturing process follows suitable principles of quality assurance;
5. that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
6. that the below mentioned devices, were introduced into the market provided with CE mark.

Roseto degli Abruzzi (TE),
26.05.2022

Signature:

LIOFILCHEM s.r.l.
BACTERIOLOGY PRODUCTS
Via Scozia
64026 Roseto degli Abruzzi (TE)
Cod. Fisc. e Partita IVA 00530130673

Technical Director
(Dr. Silvio Brocco)

Liofilchem®

Table no.1

CODE	DESCRIPTION
90 mm agar plates	
11612	Chromatic Candida
11632	Chromatic Clostridium difficile
11640	Chromatic Colistin
11619	Chromatic CRE
11622	Chromatic ESBL
11629	Chromatic ESBL + AmpC
10599	Chromatic MRSA
11631	Chromatic OXA-48
11621	Chromatic VRE
11639	Chromatic GBS
2 sector agar plates	
CODE	**DESCRIPTION**
18021	Chromatic CRE / Chromatic ESBL
18023	Chromatic CRE / Chromatic OXA-48
18007	Chromatic Staph Aureus / MRSA
18011	Chromatic Detection / ESBL
18024	MSA / Chromatic MRSA
Tubes - Bottles	
CODE	**DESCRIPTION**
481110	Chromatic Candida
490010	Hemo-aerobic Culturing
490050	Hemo-aerobic Culturing Neonatal
490030	Hemo-aerobic Culturing Pediatric
490020	Hemo-anaerobic Culturing
490060	Hemo-anaerobic Culturing Neonatal
490040	Hemo-anaerobic Culturing Pediatric
Dip-Slide	
CODE	**DESCRIPTION**
50021	Dermatest
500222	Dermatest modified
500152	Uritest
51015	Uritest
51030	Uritest 2
500302	Uritest 2
51024	Uritest C
500242	Uritest C
51041	Uritest EC
500412	Uritest EC
500702	Uritest EF
51070	Uritest EF
51170	Uritest EF
500182	Uritest M
51018	Uritest M
51040	Uritest Malto
500402	Uritest Malto
51023	Uritest N
51123	Uritest N
500232	Uritest N
51014	Uritest Penta
500142	Uritest Penta
50020	Vagitest

CODE	DESCRIPTION
Dehydrated culture media	
610613	Chromatic candida
620613	Chromatic Candida
611619	Chromatic CRE
621619	Chromatic CRE
610629	Chromatic ESBL
620629	Chromatic ESBL
610615	Chromatic MRSA
620615	Chromatic MRSA
610617	Chromatic Strepto B
620617	Chromatic Strepto B
610501	VRE Agar Base
ComASP	
CODE	**DESCRIPTION**
75011	ComASP® Benzylpenicillin 0.002-32
75009	ComASP® Cefiderocol 0.0008-128
75004	ComASP® Ceftolozane-tazobactam / Ceftazidime-avibactam
75006	ComASP® Ceftolozane-tazobactam 0.008/4 – 128/4
75003	ComASP® Colistin / Piperacillin-tazobactam
75001	ComASP® Colistin 0.25-16
75010	ComASP® Oritavancin 0.001-16
75002	ComASP® Piperacillin-tazobactam 0.008/4-128/4
75005	ComASP® Vancomycin / Teicoplanin
75007	ComASP® Vancomycin 0.008-128
ID-AST Systems	
CODE	**DESCRIPTION**
79156	A.F. Genital System
74156	AF Genital System
71620	Anaerobe System
79620	Anaerobe System
71670	Copro System
79670	Copro System
71675	Copro System Plus
79675	Copro System Plus
71618	Enterosystem 18R
79618	Enterosystem 18R
71619	Enterosystem 24R
71714	Integral System Enterobacteria
79714	Integral System Enterobacteria
71724	Integral System Gardnerella
79724	Integral system Gardnerella
71718	Integral System Stafilococchi
79718	Integral System Stafilococchi
71720	Integral System Streptococchi
79720	Integral system Streptococchi
71822	Integral System Yeasts Plus
79822	Integral System Yeasts Plus
72592	Mycoplasma System Plus
79592	Mycoplasma System Plus
71679	Pathogenic System
71681	Pathogenic System AST
79681	Pathogenic System AST
76033	SensiQuattro Candida
79033	SensiQuattro Candida

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CODE	DESCRIPTION
76031	SensiQuattro Gram-negative
79031	SensiQuattro Gram-negative
76032	SensiQuattro Gram-positive
79032	SensiQuattro Gram-positive
76010	SensiTest Gram-negative
79010	SensiTest Gram-negative
76020	SensiTest Gram-positive
79020	SensiTest Gram-positive
71630	Staf System 18R
79630	Staf System 18R
72560	Strepto System 12R
79560	Strepto System 12R
74161	Urin System Chrom
79161	Urin System Chrom
74160	Urin System Plus
79160	Urin System Plus
80258	AF Genital System Reagent
80252	Enterosystem 18R Reagent
80260	Identification System Reagent

NP Tests

CODE	DESCRIPTION
76036	Rapid ESBL NP® Test
76046	RapidResa Polymyxin Acinetobacter NP® Test

Agar Dilution AST

CODE	DESCRIPTION
77001	AD Fosfomycin 0.25-256
77061	AD Fosfomycin 0.25-256

EPT

CODE	DESCRIPTION
78618	Entero Pluri Test
78619	Entero Pluri Test
78621	Oxi/ferm Pluri Test
78620	Oxi/ferm Pluri Test

Supplements

CODE	DESCRIPTION
81088	Chromatic CRE supplement
81090	Chromatic ESBL + AmpC supplement
81089	Chromatic ESBL supplement
81078	Chromatic MRSA supplement
81083	Meropenem supplement
81062	Vancomycin supplement

CultiControl ATCC

CODE	DESCRIPTION
89139	Bordetella bronchiseptica ATCC ® 4617
89174	Acinetobacter baumannii ATCC ® 19606
89141	Acinetobacter baumannii ATCC ® BAA-747
89114	Actinomyces odontolyticus ATCC ® 17929
89169	Aeromonas hydrophila ATCC ® 35654
89119	Aeromonas hydrophila ATCC ® 7966
89091	Aggregatibacter aphrophilus ATCC ® 7901
89021	Aspergillus brasiliensis ATCC® 16404
89057	Aspergillus fumigatus ATCC ® 204305
89155	Bacillus cereus ATCC ® 10876

CODE	DESCRIPTION
89022	Bacillus Cereus ATCC® 11778
89023	Bacillus subtilis ATCC® 6633
89113	Bacteroides fragilis ATCC ® 23745
89078	Bacteroides fragilis ATCC® 25285
89111	Bacteroides ovatus ATCC ® 8483
89193	Bacteroides ovatus ATCC ® BAA-1296
89079	Bacteroides thetaiotaomicron ATCC® 29741
89147	Burkholderia cepacia ATCC ® 25416
89166	Burkholderia cepacia ATCC ® 25608
89086	Campylobacter jejuni ATCC ® 33291
89167	Campylobacter jejuni subsp. jejuni ATCC ® 29428
89145	Campylobacter jejuni subsp. jejuni ATCC ® 33560
89183	Candida albicans ATCC ® 14053
89177	Candida albicans ATCC ® 18804
89178	Candida albicans ATCC ® 64124
89072	Candida albicans ATCC ® 90028
89024	Candida albicans ATCC® 10231
89098	Candida krusei ATCC ® 14243
89071	Candida parapsilosis ATCC ® 22019
89097	Candida tropicalis ATCC ® 750
89146	Citrobacter freundii ATCC ® 43864
89159	Citrobacter freundii ATCC ® 8090
89090	Clostridium difficile ATCC ® 9689
89112	Clostridium histolyticum ATCC ® 19401
89053	Clostridium perfringens ATCC® 13124
89059	Clostridium sordellii ATCC ® 9714
89095	Clostridium sporogenes ATCC ® 19404
89158	Cronobacter muytjensii ATCC ® 51329
89138	Cronobacter sakazakii ATCC ® 29544
89196	Eikenella corrodens ATCC ® BAA-1152
89156	Enterobacter aerogenes ATCC ® 13048
89200	Enterobacter cloacae ATCC ® 49141
89065	Enterobacter cloacae subsp. cloacae ATCC ® BAA-1143
89195	Enterococcus casseliflavus ATCC ® 700327
89115	Enterococcus faecalis ATCC ® 33186
89066	Enterococcus faecalis ATCC ® 49532
89067	Enterococcus faecalis ATCC ® 49533
89173	Enterococcus faecalis ATCC ® 51299
89025	Enterococcus faecalis ATCC® 19433
89026	Enterococcus faecalis ATCC® 29212
89171	Enterococcus faecium ATCC ® 19434
89117	Enterococcus faecium ATCC ® 51559
89152	Enterococcus faecium ATCC ® 6057
89172	Enterococcus faecium ATCC ® BAA-2319
89184	Escherichia coli ATCC ® 11303
89163	Escherichia coli ATCC ® 35218
89027	Escherichia coli ATCC® 25922
89028	Escherichia coli ATCC® 8739
89118	Fusobacterium nucleatum ATCC ® 25586
89099	Gardnerella vaginalis ATCC ® 14018
89123	Haemophilus haemolyticus ATCC ® 33390
89120	Haemophilus influenzae ATCC ® 10211
89176	Haemophilus influenzae ATCC ® 33391
89124	Haemophilus influenzae ATCC ® 33533
89077	Haemophilus influenzae ATCC® 49247
89076	Haemophilus influenzae ATCC® 49766
89142	Haemophilus influenzae Type c ATCC ® 9007

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CODE	DESCRIPTION
89073	Issatchenkia orientalis ATCC ® 6258
89150	Klebsiella pneumoniae ATCC ® BAA-1144
89088	Klebsiella pneumoniae ATCC ® BAA-1705
89087	Klebsiella pneumoniae ATCC ® BAA-1706
89069	Klebsiella pneumoniae ATCC ® BAA-2146
89089	Klebsiella pneumoniae subsp. pneumoniae ATCC ® 13883
89199	Klebsiella pneumoniae subsp. pneumoniae ATCC ® 31488
89192	Klebsiella pneumoniae subsp. pneumoniae ATCC ® 4352
89070	Klebsiella pneumoniae subsp. pneumoniae ATCC ® 700603
89080	Lactobacillus acidophilus ATCC ® 4356
89100	Lactobacillus fermentum ATCC ® 9338
89055	Lactobacillus paracasei subsp. paracasei ATCC ® BAA-52
89081	Lactobacillus leichmannii ATCC ® 4797
89082	Lactococcus lactis ATCC ® 19435
89151	Legionella pneumophila subsp. fraseri ATCC ® 33156
89052	Legionella pneumophila subsp. pneumophila ATCC® 33152
89101	Listeria grayi ATCC ® 25401
89029	Listeria innocua ATCC® 33090
89030	Listeria ivanovii ATCC® 19119
89085	Listeria monocytogenes ATCC ® 13932
89148	Listeria monocytogenes ATCC ® 35152
89060	Listeria monocytogenes ATCC ® 7644
89143	Listeria monocytogenes ATCC ® BAA-751
89031	Listeria monocytogenes ATCC® 19111
89051	Listeria monocytogenes ATCC® 19115
89096	Micrococcus luteus ATCC ® 10240
89102	Micrococcus luteus ATCC ® 4698
89103	Moraxella (Branhamella) catarrhalis ATCC ® 25238
89074	Neisseria gonorrhoeae ATCC ® 19424
89075	Neisseria gonorrhoeae ATCC ® 31426
89104	Neisseria gonorrhoeae ATCC ® 49226
89122	Neisseria gonorrhoeae ATCC ® 49981
89164	Neisseria meningitidis ATCC ® 13090
89189	Nocardia brasiliensis ATCC ® 19296
89165	Peptostreptococcus anaerobius ATCC ® 27337
89094	Plesiomonas shigelloides ATCC ® 14029
89162	Porphyromonas gingivalis ATCC ® 33277
89134	Prevotella melaninogenica ATCC ® 25845
89135	Propionibacterium acnes ATCC® 11827
89190	Proteus hauseri ATCC ® 13315
89049	Proteus mirabilis ATCC® 12453
89083	Proteus mirabilis ATCC ® 29906
89105	Proteus mirabilis ATCC ® 35659
89106	Proteus mirabilis ATCC ® 43071
89032	Proteus mirabilis ATCC® 25933
89107	Proteus vulgaris ATCC ® 6380
89125	Providencia stuartii ATCC ® 33672
89033	Pseudomonas aeruginosa ATCC® 27853
89034	Pseudomonas aeruginosa ATCC® 9027
89108	Pseudomonas aeruginosa ATCC ® 10145
89109	Pseudomonas aeruginosa ATCC ® 15442

CODE	DESCRIPTION
89110	Pseudomonas fluorescens ATCC ® 13525
89035	Rhodococcus equi ATCC® 6939
89036	Saccharomyces cerevisiae ATCC® 9763
89154	Salmonella enterica subsp. arizonae ATCC ® 13314
89084	Salmonella enterica subsp. enterica serovar Enteritidis ATCC ® 13076
89185	Salmonella enterica subsp. enterica serovar Hillingdon ATCC® 9184
89161	Salmonella enterica subsp. enterica serovar Paratyphi A ATCC ® 9150
89197	Salmonella enterica subsp. enterica serovar Typhimurium ATCC ® 49416
89054	Salmonella enterica subsp. enterica serovar Typhimurium ATCC® 13311
89037	Salmonella typhimurium ATCC® 14028
89191	Serratia marcescens ATCC ® 14756
89121	Serratia marcescens ATCC ® 8100
89179	Shigella boydii ATCC ® 9207
89198	Shigella flexneri ATCC ® 9199
89038	Shigella flexneri ATCC® 12022
89058	Shigella sonnei ATCC ® 25931
89180	Shigella sonnei ATCC ® 9290
89040	Staphylococcus aureus ATCC® 25923
89041	Staphylococcus aureus ATCC® 29213
89042	Staphylococcus aureus ATCC® 33862
89043	Staphylococcus aureus ATCC® 43300
89044	Staphylococcus aureus ATCC® 6538
89182	Staphylococcus aureus subsp. aureus ATCC ® 9144
89137	Staphylococcus aureus subsp. aureus ATCC ® 19095
89116	Staphylococcus aureus subsp. aureus ATCC ® 33591
89181	Staphylococcus aureus subsp. aureus ATCC ® 49476
89093	Staphylococcus aureus subsp. aureus ATCC ® 700699
89170	Staphylococcus aureus subsp. aureus ATCC ® BAA-44
89092	Staphylococcus aureus subsp. aureus ATCC® 700698
89202	Staphylococcus epidermidis ATCC ® 14990
89045	Staphylococcus epidermidis ATCC® 12228
89126	Staphylococcus haemolyticus ATCC ® 29970
89153	Staphylococcus saprophyticus ATCC ® 15305
89133	Staphylococcus xylosus ATCC ® 29971
89149	Stenotrophomonas maltophilia ATCC ® 13637
89194	Stenotrophomonas maltophilia ATCC ® 17666
89046	Streptococcus agalactiae ATCC® 13813
89127	Streptococcus anginosus ATCC ® 33397
89061	Streptococcus bovis ATCC ® 33317
89128	Streptococcus dysgalactiae subsp.equisimilis ATCC ® 12388
89129	Streptococcus mitis ATCC ® 6249
89062	Streptococcus mutans ATCC ® 25175
89063	Streptococcus pneumoniae ATCC ® 27336
89175	Streptococcus pneumoniae ATCC ® 700671
89047	Streptococcus pneumoniae ATCC® 49619
89130	Streptococcus pyogenes ATCC ® 49399
89048	Streptococcus pyogenes ATCC® 19615

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CODE	DESCRIPTION
89131	Streptococcus salivarius ATCC® 13419
89186	Streptococcus salivarius subsp. thermophilus ATCC ® 19258
89064	Streptococcus sanguinis ATCC ® 10556
89140	Trichophyton mentagrophytes ATCC ® 9533
89144	Vibrio alginolyticus ATCC ® 17749
89056	Vibrio parahaemolyticus ATCC ® 17802
89050	Yersinia enterocolitica ATCC® 9610
89168	Yersinia enterocolitica subsp. enterocolitica ATCC ® 23715

Antibiotic disc in cartridges

CODE	DESCRIPTION
9004	Amikacin AK 30 µg
9004/1	Amikacin AK 30 µg
9191	Amoxicillin + Clavulanic acid AUG 3 (2+1) µg
9191/1	Amoxicillin + Clavulanic acid AUG 3 (2+1) µg
9133	Amoxicillin AML 10 µg
9133/1	Amoxicillin AML 10 µg
9151/1	Amoxicillin AML 2 µg
9151	Amoxicillin AML 2 µg
9179	Amoxicillin AML 25 µg
9179/1	Amoxicillin AML 25 µg
9005	Amoxicillin AML 30 µg
9005/1	Amoxicillin AML 30 µg
9048	Amoxicillin-clavulanic acid AUG 30 µg
9048/1	Amoxicillin-clavulanic acid AUG 30 µg
9255	Amoxicillin-clavulanic acid AUG 7.5 µg
9255/1	Amoxicillin-clavulanic acid AUG 7.5 µg
9137	Amphotericin B AMB 10 µg
9137/1	Amphotericin B AMB 10 µg
9071	Amphotericin B AMB 20 µg
9071/1	Amphotericin B AMB 20 µg
9006	Ampicillin AMP 10 µg
9006/1	Ampicillin AMP 10 µg
9115/1	Ampicillin AMP 2 µg
9115	Ampicillin AMP 2 µg
9031	Ampicillin-sulbactam AMS 20 µg
9031/1	Ampicillin-sulbactam AMS 20 µg
9122	Ampliclox (Ampicillin-cloxacillin) ACL 30 (25+5) µg
9122/1	Ampliclox (Ampicillin-cloxacillin) ACL 30 (25+5) µg
9105	Azithromycin AZM 15 µg
9105/1	Azithromycin AZM 15 µg
9007	Azlocillin AZL 75 µg
9007/1	Azlocillin AZL 75 µg
9008	Aztreonam ATM 30 µg
9008/1	Aztreonam ATM 30 µg
9051	Bacitracin BA 10 IU
9051/1	Bacitracin BA 10 IU
9009	Carbenicillin CAR 100 µg
9009/1	Carbenicillin CAR 100 µg
9165	Caspofungin CAS 5 µg
9165/1	Caspofungin CAS 5 µg
9010/1	Cefaclor 30 µg
9010	Cefaclor 30 µg
9052	Cefadroxil CDX 30 µg
9052/1	Cefadroxil CDX 30 µg

CODE	DESCRIPTION
9014	Cefamandole MA 30 µg
9014/1	Cefamandole MA 30 µg
9015	Cefazolin KZ 30 µg
9015/1	Cefazolin KZ 30 µg
9143	Cefepime + Clavulanic acid FEL 40 µg
9143/1	Cefepime + Clavulanic acid FEL 40 µg
9220	Cefepime FEP 10 µg
9220/1	Cefepime FEP 10 µg
9104	Cefepime FEP 30 µg
9104/1	Cefepime FEP 30 µg
9266/1	Cefiderocol FDC 30 µg
9266	Cefiderocol FDC 30 µg
9089	Cefixime CFM 5 µg
9089/1	Cefixime CFM 5 µg
9016	Cefoperazone CFP 30 µg
9016/1	Cefoperazone CFP 30 µg
9108	Cefoperazone CFP 75 µg
9108/1	Cefoperazone CFP 75 µg
9203	Cefotaxime + Clavulanic acid + Cloxacillin CTLC
9203/1	Cefotaxime + Clavulanic acid + Cloxacillin CTLC
9182	Cefotaxime + Clavulanic acid CTL 40 (30+10) µg
9182/1	Cefotaxime + Clavulanic acid CTL 40 (30+10) µg
9224	Cefotaxime + Cloxacillin CTC
9224/1	Cefotaxime + Cloxacillin CTC
9017	Cefotaxime CTX 30 µg
9017/1	Cefotaxime CTX 30 µg
9152	Cefotaxime CTX 5 µg
9152/1	Cefotaxime CTX 5 µg
9134/1	Cefotaxime CTX 75 µg
9081	Cefotetan CTT 30 µg
9081/1	Cefotetan CTT 30 µg
9144	Cefoxitin + Cloxacillin FOC 230 µg
9144/1	Cefoxitin + Cloxacillin FOC 230 µg
9018	Cefoxitin FOX 30 µg
9018/1	Cefoxitin FOX 30 µg
9185	Cefpirome CR 30 µg
9190	Cefpodoxime + Clavulanic acid PXL 11 (10+1) µg
9190/1	Cefpodoxime + Clavulanic acid PXL 11 (10+1) µg
9064	Cefpodoxime PX 10 µg
9064/1	Cefpodoxime PX 10 µg
9112	Cefprozil CPR 30 µg
9112/1	Cefprozil CPR 30 µg
9053/1	Cefsulodin CSD 30 µg
9053	Cefsulodin CSD 30 µg
9198	Ceftaroline CPT 30 µg
9198/1	Ceftaroline CPT 30 µg
9195	Ceftaroline CPT 5 µg
9195/1	Ceftaroline CPT 5 µg
9204	Ceftazidime + Clavulanic acid + Cloxacillin CALC
9204/1	Ceftazidime + Clavulanic acid + Cloxacillin CALC
9145	Ceftazidime + Clavulanic acid CAL 40 (30+10) µg
9145/1	Ceftazidime + Clavulanic acid CAL 40 (30+10) µg
9225	Ceftazidime + Cloxacillin CAC
9225/1	Ceftazidime + Cloxacillin CAC
9153	Ceftazidime CAZ 10 µg
9153/1	Ceftazidime CAZ 10 µg
9019	Ceftazidime CAZ 30 µg
9019/1	Ceftazidime CAZ 30 µg

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CODE	DESCRIPTION
9206	Ceftazime-avibactam CZA 14 µg
9206/1	Ceftazime-avibactam CZA 14 µg
9205	Ceftazime-avibactam CZA 50 µg
9205/1	Ceftazime-avibactam CZA 50 µg
9101	Ceftibuten CTB 30 µg
9101/1	Ceftibuten CTB 30 µg
9054	Ceftizoxime CZX 30 µg
9054/1	Ceftizoxime CZX 30 µg
9242/1	Ceftobiprole BPR 5 µg
9242	Ceftobiprole BPR 5 µg
9246/1	Ceftolozane-tazobactam C/T 40 µg
9246	Ceftolozane-tazobactam C/T 40 µg
9020	Ceftriaxone CRO 30 µg
9020/1	Ceftriaxone CRO 30 µg
9232/1	Cefuroxime CXM 1 µg
9232	Cefuroxime CXM 1 µg
9021	Cefuroxime CXM 30 µg
9021/1	Cefuroxime CXM 30 µg
9011	Cephalexin CL 30 µg
9011/1	Cephalexin CL 30 µg
9013	Cephalothin KF 30 µg
9013/1	Cephalothin KF 30 µg
9055	Cephradine CE 30 µg
9055/1	Cephradine CE 30 µg
9128	Chloramphenicol C 10 µg
9128/1	Chloramphenicol C 10 µg
9022	Chloramphenicol C 30 µg
9022/1	Chloramphenicol C 30 µg
9057	Cinoxacin CIN 100 µg
9057/1	Cinoxacin CIN 100 µg
9056	Ciprofloxacin CIP 5 µg
9056/1	Ciprofloxacin CIP 5 µg
9098	Clarithromycin CLR 15 µg
9098/1	Clarithromycin CLR 15 µg
9146	Clindamycin CD 10 µg
9146/1	Clindamycin CD 10 µg
9047	Clindamycin CD 2 µg
9047/1	Clindamycin CD 2 µg
9097	Clotrimazole CLO 50 µg
9097/1	Clotrimazole CLO 50 µg
9058	Cloxacillin CX 5 µg
9058/1	Cloxacillin CX 5 µg
9023	Colistin sulfate CS 10 µg
9023/1	Colistin sulfate CS 10 µg
9184	Colistin sulfate CS 25 µg
9184/1	Colistin sulfate CS 25 µg
9141	Colistin Sulfate CS 30 IU
9141/1	Colistin Sulfate CS 30 IU
9090	Daptomycin DAP 30 µg
9090/1	Daptomycin DAP 30 µg
9093	Dicloxacillin DCX 1 µg
9093/1	Dicloxacillin DCX 1 µg
9194	Dipicolinic acid DP
9194/1	Dipicolinic acid DP
9154	Doripenem DOR 10 µg
9154/1	Doripenem DOR 10 µg
9059	Doxycycline DXT 30 µg
9059/1	Doxycycline DXT 30 µg

CODE	DESCRIPTION
9072	Econazole ECN 10 µg
9072/1	Econazole ECN 10 µg
9087	EDTA ED
9087/1	EDTA ED
9238/1	Eravacycline ERV 20 µg
9238	Eravacycline ERV 20 µg
9199	Ertapenem + Cloxacillin ET + CL
9199/1	Ertapenem + Cloxacillin ET + CL
9202	Ertapenem + Phenylboronic acid ET + BO
9202/1	Ertapenem + Phenylboronic acid ET + BO
9061	Ertapenem ETP 10 µg
9061/1	Ertapenem ETP 10 µg
9024	Erythromycin E 15 µg
9024/1	Erythromycin E 15 µg
9180/1	Erythromycin E 2 µg
9180	Erythromycin E 2 µg
9069	Fluconazole FLU 100 µg
9069/1	Fluconazole FLU 100 µg
9166	Fluconazole FLU 25 µg
9166/1	Fluconazole FLU 25 µg
9073	Flucytosine AFY 1 µg
9073/1	Flucytosine AFY 1 µg
9148	Flucytosine AFY 10 µg
9148/1	Flucytosine AFY 10 µg
9121	Fosfomycin FOS 100 µg
9121/1	Fosfomycin FOS 100 µg
9109	Fosfomycin FOS 200 µg
9109/1	Fosfomycin FOS 200 µg
9025	Fosfomycin FOS 50 µg
9025/1	Fosfomycin FOS 50 µg
9099	Furazolidon FR 50 µg
9099/1	Furazolidon FR 50 µg
9049	Fusidic acid FC 10 µg
9049/1	Fusidic acid FC 10 µg
9111	Fusidic acid FC 30 µg
9111/1	Fusidic acid FC 30 µg
9169	Gatifloxacin GAT 5 µg
9169/1	Gatifloxacin GAT 5 µg
9026	Gentamicin CN 10 µg
9026/1	Gentamicin CN 10 µg
9124	Gentamicin CN 120 µg
9124/1	Gentamicin CN 120 µg
9125	Gentamicin CN 30 µg
9125/1	Gentamicin CN 30 µg
9074	Griseofulvin AGF 10 µg
9074/1	Griseofulvin AGF 10 µg
9086	Imipenem + Cloxacillin IMI + CL
9183	Imipenem + EDTA IMI + ED 760 (10+750) µg
9183/1	Imipenem + EDTA IMI + ED 760 (10+750) µg
9085	Imipenem + Phenylboronic acid IMI + BO
9085/1	Imipenem + Phenylboronic acid IMI + BO
9079	Imipenem IMI 10 µg
9079/1	Imipenem IMI 10 µg
9107	Itraconazole ITC 50 µg
9107/1	Itraconazole ITC 50 µg
9139	Itraconazole ITC 8 µg
9139/1	Itraconazole ITC 8 µg
9027	Kanamycin K 30 µg

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CODE	DESCRIPTION
9027/1	Kanamycin K 30 µg
9075	Ketoconazole KCA 10 µg
9075/1	Ketoconazole KCA 10 µg
9140	Ketoconazole KCA 15 µg
9140/1	Ketoconazole KCA 15 µg
9102	Levofloxacin LEV 5 µg
9102/1	Levofloxacin LEV 5 µg
9267	Levonadifloxacin LND 10 µg
9267/1	Levonadifloxacin LND 10 µg
9116	Lincomycin MY 15 µg
9116/1	Lincomycin MY 15 µg
9028	Lincomycin MY 2 µg
9028/1	Lincomycin MY 2 µg
9155	Linezolid LNZ 10 µg
9155/1	Linezolid LNZ 10 µg
9136	Linezolid LNZ 30 µg
9136/1	Linezolid LNZ 30 µg
9113	Lomefloxacin LOM 10 µg
9113/1	Lomefloxacin LOM 10 µg
9156	Mecillinam MEC 10 µg
9156/1	Mecillinam MEC 10 µg
9175/1	Meropenem + Cloxacillin MR + CL
9178	Meropenem + EDTA MR + ED
9178/1	Meropenem + EDTA MR + ED
9176	Meropenem + Phenylboronic acid MR + BO
9176/1	Meropenem + Phenylboronic acid MR + BO
9068	Meropenem MRP 10 µg
9068/1	Meropenem MRP 10 µg
9175	Meropenm + Cloxacillin MR + CL
9029/1	Methicillin MET 5 µg
9029	Methicillin MET 5 µg
9076	Metronidazole MTZ 5 µg
9076/1	Metronidazole MTZ 5 µg
9119/1	Metronidazole MTZ 50 µg
9119	Metronidazole MTZ 50 µg
9062	Mezlocillin MEZ 75 µg
9062/1	Mezlocillin MEZ 75 µg
9077	Miconazole MCL 10 µg
9077/1	Miconazole MCL 10 µg
9030	Minocycline MN 30 µg
9030/1	Minocycline MN 30 µg
9103	Moxifloxacin MXF 5 µg
9103/1	Moxifloxacin MXF 5 µg
9157	Mupirocin MUP 200 µg
9157/1	Mupirocin MUP 200 µg
9189	Mupirocin MUP 5 µg
9174	Nafcillin NAF 1 µg
9174/1	Nafcillin NAF 1 µg
9001	Nalidixic acid NA 30 µg
9001/1	Nalidixic acid NA 30 µg
9032	Neomycin N 30 µg
9032/1	Neomycin N 30 µg
9170	Netilmicin NET 10 µg
9170/1	Netilmicin NET 10 µg
9033	Netilmicin NET 30 µg
9033/1	Netilmicin NET 30 µg
9158	Nitrofurantoin F 100 µg
9158/1	Nitrofurantoin F 100 µg

CODE	DESCRIPTION
9034	Nitrofurantoin F 300 µg
9034/1	Nitrofurantoin F 300 µg
9181	Nitrofurantoin F 50 µg
9181/1	Nitrofurantoin F 50 µg
9209/1	Nitroxolin NI 30 µg
9209	Nitroxolin NI 30 µg
9035	Norfloxacin NOR 10 µg
9035/1	Norfloxacin NOR 10 µg
9063	Novobiocin NO 30 µg
9063/1	Novobiocin NO 30 µg
9117/1	Novobiocin NO 5 µg
9117	Novobiocin NO 5 µg
9078	Nystatin NY 100 IU
9078/1	Nystatin NY 100 IU
9080	Ofloxacin OFX 5 µg
9080/1	Ofloxacin OFX 5 µg
9201	Oritavancin ORI 5 µg
9201/1	Oritavancin ORI 5 µg
9036	Oxacillin OX 1 µg
9036/1	Oxacillin OX 1 µg
9135	Oxacillin OX 5 µg
9135/1	Oxacillin OX 5 µg
9002	Oxolinic acid OA 2 µg
9002/1	Oxolinic acid OA 2 µg
9065	Oxytetracycline OT 30 µg
9065/1	Oxytetracycline OT 30 µg
9091	Pefloxacin PEF 5 µg
9091/1	Pefloxacin PEF 5 µg
9130/1	Penicillin G P 1 IU
9130	Penicillin G P 1 IU
9037	Penicillin G P 10 IU
9037/1	Penicillin G P 10 IU
9127	Penicillin G P 2 IU
9127/1	Penicillin G P 2 IU
9171	Phenoxymethylpenicillin PV 10 µg
9171/1	Phenoxymethylpenicillin PV 10 µg
9193	Phenylboronic acid BO
9193/1	Phenylboronic acid BO
9003	Pipemidic acid PI 20 µg
9003/1	Pipemidic acid PI 20 µg
9038	Piperacillin PRL 100 µg
9038/1	Piperacillin PRL 100 µg
9159	Piperacillin PRL 30 µg
9159/1	Piperacillin PRL 30 µg
9100/1	Piperacillin-tazobactam TZP 110 µg
9100	Piperacillin-tazobactam TZP 110 µg
9160	Piperacillin-tazobactam TZP 36 µg
9160/1	Piperacillin-tazobactam TZP 36 µg
9066	Polymyxin B PB 100 IU
9066/1	Polymyxin B PB 100 IU
9120	Polymyxin B PB 300 IU
9120/1	Polymyxin B PB 300 IU
9167	Posaconazole POS 5 µg
9167/1	Posaconazole POS 5 µg
9039	Rifampicin RD 30 µg
9039/1	Rifampicin RD 30 µg
9118	Rifampicin RD 5 µg
9118/1	Rifampicin RD 5 µg

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CODE	DESCRIPTION
9192	Rokitamycin ROK 30 µg
9192/1	Rokitamycin ROK 30 µg
9060	Roxithromycin RXT 15 µg
9060/1	Roxithromycin RXT 15 µg
9046	Sisomycin SIS 30 µg
9046/1	Sisomycin SIS 30 µg
9131	Sodium Fusidate FC 30 µg
9067	Spectinomycin SPC 100 µg
9067/1	Spectinomycin SPC 100 µg
9088	Spiramycin SP 100 µg
9088/1	Spiramycin SP 100 µg
9040	Streptomycin S 10 µg
9040/1	Streptomycin S 10 µg
9162	Streptomycin S 300 µg
9162/1	Streptomycin S 300 µg
9129/1	Sulbactam SU 20 µg
9129	Sulbactam SU 20 µg
9150	Sulfadiazine SUZ 300 µg
9150/1	Sulfadiazine SUZ 300 µg
9041	Sulfafurazole SF 300 µg
9041/1	Sulfafurazole SF 300 µg
9187	Sulfamethoxazole SMX 100 µg
9187/1	Sulfamethoxazole SMX 100 µg
9084	Sulfamethoxazole SMX 50 µg
9084/1	Sulfamethoxazole SMX 50 µg
9132	Sulfaprim SXT 50 µg
9132/1	Sulfaprim SXT 50 µg
9126	Sulfonamide S3 300 µg
9126/1	Sulfonamide S3 300 µg
9243/1	Tedizolid TZD 2 µg
9243	Tedizolid TZD 2 µg
9245/1	Tedizolid TZD 20 µg
9245	Tedizolid TZD 20 µg
9050	Teicoplanin TEC 30 µg
9050/1	Teicoplanin TEC 30 µg
9172	Telithromycin TEL 15 µg
9172/1	Telithromycin TEL 15 µg
9186	Temocillin TMO 30 µg
9186/1	Temocillin TMO 30 µg
9043	Tetracycline TE 30 µg
9043/1	Tetracycline TE 30 µg
9094	Tiamulin T 30 µg
9094/1	Tiamulin T 30 µg
9070	Ticarcillin TC 75 µg
9070/1	Ticarcillin TC 75 µg
9096	Ticarcillin-clavulanic acid TTC 85 µg
9096/1	Ticarcillin-clavulanic acid TTC 85 µg
9147	Tigecyclin TGC 15 µg
9147/1	Tigecyclin TGC 15 µg
9044	Tobramycin TOB 10 µg
9044/1	Tobramycin TOB 10 µg
9163	Tobramycin TOB 30 µg
9163/1	Tobramycin TOB 30 µg
9042	Trimethoprim – Sulfamethoxazole SXT 25 µg
9042/1	Trimethoprim – Sulfamethoxazole SXT 25 µg
9083	Trimethoprim TM 2.5 µg
9083/1	Trimethoprim TM 2.5 µg
9110	Trimethoprim TM 5 µg

CODE	DESCRIPTION
9110/1	Trimethoprim TM 5 µg
9082	Tylosin TY 30 µg
9082/1	Tylosin TY 30 µg
9045	Vancomycin VA 30 µg
9045/1	Vancomycin VA 30 µg
9164	Vancomycin VA 5 µg
9164/1	Vancomycin VA 5 µg
9168	Voriconazole VO 1 µg
9168/1	Voriconazole VO 1 µg
99002	ESBL disc kit (acc. to EUCAST)
99003	KPC&MBL disc kit (acc. to EUCAST)
99004	ESBL disc kit (acc. to EUCAST)
99005	ESBL disc kit (acc. to CLSI)
99006	ESBL (Chromos. Ind. AmpC) disc kit (acc. to EUCAST)
99007	KPC&MBL&OXA-48 disc kit (acc. to EUCAST)
99008	ESBL+AmpC screen disc kit
99009	AmpC disc kit

Antibiotic disc in canister

CODE	DESCRIPTION
9004/2	Amikacin AK 30 µg
9133/2	Amoxicillin AML 10 µg
9005/2	Amoxicillin AML 30 µg
9048/2	Amoxicillin-clavulanic acid AUG 30 µg
9137/2	Amphotericin B AMB 10 µg
9071/2	Amphotericin B AMB 20 µg
9006/2	Ampicillin AMP 10 µg
9115/2	Ampicillin AMP 2 µg
9031/2	Ampicillin-sulbactam AMS 20 µg
9105/2	Azithromycin AZM 15 µg
9007/2	Azlocillin AZL 75 µg
9008/2	Aztreonam ATM 30 µg
9051/2	Bacitracin BA 10 IU
9009/2	Carbenicillin CAR 100 µg
9010/2	Cefaclor 30 µg
9052/2	Cefadroxil CDX 30 µg
9014/2	Cefamandole MA 30 µg
9015/2	Cefazolin KZ 30 µg
9143/2	Cefepime + Clavulanic acid FEL 40 µg
9104/2	Cefepime FEP 30 µg
9266/2	Cefiderocol FDC 30 µg
9089/2	Cefixime CFM 5 µg
9016/2	Cefoperazone CFP 30 µg
9108/2	Cefoperazone CFP 75 µg
9182/2	Cefotaxime + Clavulanic acid CTL 40 (30+10) µg
9017/2	Cefotaxime CTX 30 µg
9152/2	Cefotaxime CTX 5 µg
9018/2	Cefoxitin FOX 30 µg
9064/2	Cefpodoxime PX 10 µg
9053/2	Cefsulodin CSD 30 µg
9198/2	Ceftaroline CPT 30 µg
9195/2	Ceftaroline CPT 5 µg
9145/2	Ceftazidime + Clavulanic acid CAL 40 (30+10) µg
9153/2	Ceftazidime CAZ 10 µg
9019/2	Ceftazidime CAZ 30 µg
9206/2	Ceftazime-avibactam CZA 14 µg
9101/2	Ceftibuten CTB 30 µg

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CODE	DESCRIPTION
9054/2	Ceftizoxime CZX 30 µg
9242/2	Ceftobiprole BPR 5 µg
9246/2	Ceftolozane-tazobactam C/T 40 µg
9020/2	Ceftriaxone CRO 30 µg
9232/2	Cefuroxime CXM 1 µg
9021/2	Cefuroxime CXM 30 µg
9011/2	Cephalexin CL 30 µg
9013/2	Cephalothin KF 30 µg
9055/2	Cephradine CE 30 µg
9022/2	Chloramphenicol C 30 µg
9057/2	Cinoxacin CIN 100 µg
9056/2	Ciprofloxacin CIP 5 µg
9098/2	Clarithromycin CLR 15 µg
9146/2	Clindamycin CD 10 µg
9047/2	Clindamycin CD 2 µg
9097/2	Clotrimazole CLO 50 µg
9058/2	Cloxacillin CX 5 µg
9023/2	Colistin sulfate CS 10 µg
9141/2	Colistin Sulfate CS 30 IU
9090/2	Daptomycin DAP 30 µg
9154/2	Doripenem DOR 10 µg
9059/2	Doxycycline DXT 30 µg
9238/2	Eravacycline ERV 20 µg
9061/2	Ertapenem ETP 10 µg
9024/2	Erythromycin E 15 µg
9180/2	Erythromycin E 2 µg
9166/2	Fluconazole FLU 25 µg
9148/2	Flucytosine AFY 10 µg
9121/2	Fosfomycin FOS 100 µg
9109/2	Fosfomycin FOS 200 µg
9025/2	Fosfomycin FOS 50 µg
9049/2	Fusidic acid FC 10 µg
9026/2	Gentamicin CN 10 µg
9124/2	Gentamicin CN 120 µg
9125/2	Gentamicin CN 30 µg
9079/2	Imipenem IMI 10 µg
9107/2	Itraconazole ITC 50 µg
9139/2	Itraconazole ITC 8 µg
9027/2	Kanamycin K 30 µg
9075/2	Ketoconazole KCA 10 µg
9102/2	Levofloxacin LEV 5 µg
9116/2	Lincomycin MY 15 µg
9028/2	Lincomycin MY 2 µg
9155/2	Linezolid LNZ 10 µg
9156/2	Mecillinam MEC 10 µg
9176/2	Meropenem + Phenylboronic acid MR + BO
9068/2	Meropenem MRP 10 µg
9029/2	Methicillin MET 5 µg
9119/2	Metronidazole MTZ 50 µg
9077/2	Miconazole MCL 10 µg
9030/2	Minocycline MN 30 µg
9103/2	Moxifloxacin MXF 5 µg
9157/2	Mupirocin MUP 200 µg
9189/2	Mupirocin MUP 5 µg
9174/2	Nafcillin NAF 1 µg
9001/2	Nalidixic acid NA 30 µg
9032/2	Neomycin N 30 µg
9033/2	Netilmicin NET 30 µg

CODE	DESCRIPTION
9158/2	Nitrofurantoin F 100 µg
9034/2	Nitrofurantoin F 300 µg
9181/2	Nitrofurantoin F 50 µg
9209/2	Nitroxolin NI 30 µg
9035/2	Norfloxacin NOR 10 µg
9063/2	Novobiocin NO 30 µg
9117/2	Novobiocin NO 5 µg
9078/2	Nystatin NY 100 IU
9080/2	Ofloxacin OFX 5 µg
9201/2	Oritavancin ORI 5 µg
9036/2	Oxacillin OX 1 µg
9002/2	Oxolinic acid OA 2 µg
9065/2	Oxytetracycline OT 30 µg
9091/2	Pefloxacin PEF 5 µg
9130/2	Penicillin G P 1 IU
9037/2	Penicillin G P 10 IU
9193/2	Phenylboronic acid BO
9003/2	Pipemidic acid PI 20 µg
9038/2	Piperacillin PRL 100 µg
9159/2	Piperacillin PRL 30 µg
9100/2	Piperacillin-tazobactam TZP 110 µg
9160/2	Piperacillin-tazobactam TZP 36 µg
9066/2	Polymyxin B PB 100 IU
9120/2	Polymyxin B PB 300 IU
9039/2	Rifampicin RD 30 µg
9118/2	Rifampicin RD 5 µg
9060/2	Roxithromycin RXT 15 µg
9046/2	Sisomycin SIS 30 µg
9067/2	Spectinomycin SPC 100 µg
9040/2	Streptomycin S 10 µg
9041/2	Sulfafurazole SF 300 µg
9243/2	Tedizolid TZD 2 µg
9050/2	Teicoplanin TEC 30 µg
9043/2	Tetracycline TE 30 µg
9094/2	Tiamulin T 30 µg
9070/2	Ticarcillin TC 75 µg
9096/2	Ticarcillin-clavulanic acid TTC 85 µg
9147/2	Tigecyclin TGC 15 µg
9044/2	Tobramycin TOB 10 µg
9042/2	Trimethoprim – Sulfamethoxazole SXT 25 µg
9083/2	Trimethoprim TM 2.5 µg
9110/2	Trimethoprim TM 5 µg
9045/2	Vancomycin VA 30 µg
9164/2	Vancomycin VA 5 µg
9168/2	Voriconazole VO 1 µg

MIC Test Strip

CODE	DESCRIPTION
92018	Amikacin AK 0.016-256 mg/L
920180	Amikacin AK 0.016-256 mg/L
920181	Amikacin AK 0.016-256 mg/L
920210	Amoxicillin AmL 0.016-256 mg/L
92021	Amoxicillin AmL 0.016-256 mg/L
920211	Amoxicillin AmL 0.016-256 mg/L
921800	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0.016-256* mg/L
921801	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0.016-256* mg/L

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CODE	DESCRIPTION
92180	Amoxicillin* - clavulanic acid (2 mg/L) AMC 0.016-256* mg/L 30 MICTest
92024	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L
920240	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L
920241	Amoxicillin* - clavulanic acid (2/1) AUG 0.016-256* mg/L
92153	Amphotericin B AMB 0.002-32 mg/L
921531	Amphotericin B AMB 0.002-32 mg/L
921530	Amphotericin B AMB 0.002-32 mg/L 100 MICTest
920030	Ampicillin AMP 0.016-256 mg/L
920031	Ampicillin AMP 0.016-256 mg/L
92003	Ampicillin AMP 0.016-256 mg/L
92027	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L
920270	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L
920271	Ampicillin* - sulbactam (2/1) AMS 0.016-256* mg/L
92181	Ampicillin* - sulbactam (4 mg/L) SAM 0.016-256* mg/L
921810	Ampicillin* - sulbactam (4 mg/L) SAM 0.016-256* mg/L
921811	Ampicillin* - sulbactam (4 mg/L) SAM 0.016-256* mg/L
92155	Anidulafungin AND 0.002-32 mg/L
921551	Anidulafungin AND 0.002-32 mg/L
921550	Anidulafungin AND 0.002-32 mg/L 100 Test
92030	Azithromycin AZM 0.016-256 mg/L
920300	Azithromycin AZM 0.016-256 mg/L
920301	Azithromycin AZM 0.016-256 mg/L
92033	Aztreonam ATM 0.016-256 mg/L
920330	Aztreonam ATM 0.016-256 mg/L
920331	Aztreonam ATM 0.016-256 mg/L
92173	Aztreonam ATM 0.064-1024 mg/L
921730	Aztreonam ATM 0.064-1024 mg/L
921731	Aztreonam ATM 0.064-1024 mg/L
92019	Bacitracin BA 0.016-256 mg/L
920190	Bacitracin BA 0.016-256 mg/L
920191	Bacitracin BA 0.016-256 mg/L
92154	Caspofungin CAS 0.002-32 mg/L
921541	Caspofungin CAS 0.002-32 mg/L
921540	Caspofungin CAS 0.002-32 mg/L
920360	Cefaclor CEC 0.016-256 mg/L
92036	Cefaclor CEC 0.016-256 mg/L
920361	Cefaclor CEC 0.016-256 mg/L
92174	Cefazolin KZ 0.016-256 mg/L
921740	Cefazolin KZ 0.016-256 mg/L
921741	Cefazolin KZ 0.016-256 mg/L
92127	Cefepime FEP 0.002-32 mg/L
921270	Cefepime FEP 0.002-32 mg/L
921271	Cefepime FEP 0.002-32 mg/L
92126	Cefepime FEP 0.016-256 mg/L
921260	Cefepime FEP 0.016-256 mg/L
921261	Cefepime FEP 0.016-256 mg/L
92161	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0.25-16 / 0.064-4 mg/L
921610	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0.25-16 / 0.064-4 mg/L

CODE	DESCRIPTION
921611	Cefepime/Cefepime + Clavulanic acid (4 mg/L) FEP/FEL 0.25-16 / 0.064-4 mg/L
92067	Cefiderocol FDC 0,016-256 mg/L
920671	Cefiderocol FDC 0,016-256 mg/L
920670	Cefiderocol FDC 0,016-256 mg/L
92060	Cefixime CFM 0.016-256 mg/L
920601	Cefixime CFM 0.016-256 mg/L
920600	Cefixime CFM 0.016-256 mg/L
92023	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L
920230	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L
920231	Cefoperazone* - sulbactam (2/1) CPS 0.016-256* mg/L
92007	Cefotaxime CTX 0.002-32 mg/L
920070	Cefotaxime CTX 0.002-32 mg/L
920071	Cefotaxime CTX 0.002-32 mg/L
920061	Cefotaxime CTX 0.016-256 mg/L
92006	Cefotaxime CTX 0.016-256 mg/L
920060	Cefotaxime CTX 0.016-256 mg/L
92160	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0.25-16/0.016-1 mg/L
921600	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0.25-16/0.016-1 mg/L
921601	Cefotaxime/Cefotaxime + Clavulanic acid (4 mg/L) CTX/CTL 0.25-16/0.016-1 mg/L
920200	Cefotetan CTT 0.016-256 mg/L
920201	Cefotetan CTT 0.016-256 mg/L
92020	Cefotetan CTT 0.016-256 mg/L
92164	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0.5-32/0.5-32 mg/L
921641	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0.5-32/0.5-32 mg/L
921640	Cefotetan/Cefotetan + Cloxacillin CTT/CXT 0.5-32/0.5-32 mg/L
92066	Cefoxitin FOX 0.016-256 mg/L
920660	Cefoxitin FOX 0.016-256 mg/L
920661	Cefoxitin FOX 0.016-256 mg/L
92008	Cefpirome CR 0.016-256 mg/L
920080	Cefpirome CR 0.016-256 mg/L
920081	Cefpirome CR 0.016-256 mg/L
920050	Cefpodoxime PX 0.016-256 mg/L
92005	Cefpodoxime PX 0.016-256 mg/L
920051	Cefpodoxime PX 0.016-256 mg/L
920560	Ceftaroline CPT 0.002-32 mg/L
920561	Ceftaroline CPT 0.002-32 mg/L
92056	Ceftaroline CPT 0.002-32 mg/L
92049	Ceftaroline CPT 0.016-256 mg/L
920491	Ceftaroline CPT 0.016-256 mg/L
920490	Ceftaroline CPT 0.016-256 mg/L
92138	Ceftazidime CAZ 0.016-256 mg/L
921380	Ceftazidime CAZ 0.016-256 mg/L
921381	Ceftazidime CAZ 0.016-256 mg/L
92139	Ceftazidime*- avibactam CZA 0.016/4-256/4 mg/L
921390	Ceftazidime*- avibactam CZA 0.016/4-256/4 mg/L
921391	Ceftazidime*- avibactam CZA 0.016/4-256/4 mg/L
92159	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0.5-32/0.064-4 mg/L
921590	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0.5-32/0.064-4 mg/L

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CODE	DESCRIPTION
921591	Ceftazidime/Ceftazidime + Clavulanic acid (4 mg/L) CAZ/CAL 0.5-32/0.064-4 mg/L
92058	Ceftibuten CTB 0.002-32 mg/L
920580	Ceftibuten CTB 0.002-32 mg/L
920581	Ceftibuten CTB 0.002-32 mg/L
920160	Ceftizoxime CZX 0.016-256 mg/L
920161	Ceftizoxime CZX 0.016-256 mg/L
92016	Ceftizoxime CZX 0.016-256 mg/L
92140	Ceftobiprole BPR 0.002-32 mg/L
921400	Ceftobiprole BPR 0.002-32 mg/L
921401	Ceftobiprole BPR 0.002-32 mg/L
92146	Ceftolozane-Tazobactam C/T 0.016/4-256/4 mg/L
921460	Ceftolozane-Tazobactam C/T 0.016/4-256/4 mg/L
921461	Ceftolozane-Tazobactam C/T 0.016/4-256/4 mg/L
920430	Ceftriaxone CRO 0.002-32 mg/L
92043	Ceftriaxone CRO 0.002-32 mg/L
920431	Ceftriaxone CRO 0.002-32 mg/L
92042	Ceftriaxone CRO 0.016-256 mg/L
920420	Ceftriaxone CRO 0.016-256 mg/L
920421	Ceftriaxone CRO 0.016-256 mg/L
921290	Cefuroxime CXM 0.016-256 mg/L
92129	Cefuroxime CXM 0.016-256 mg/L
921291	Cefuroxime CXM 0.016-256 mg/L
92039	Cephalothin KF 0.016-256 mg/L
920391	Cephalothin KF 0.016-256 mg/L
920390	Cephalothin KF 0.016-256 mg/L 0.016-256
92075	Chloramphenicol C 0.016-256 mg/L
920750	Chloramphenicol C 0.016-256 mg/L
920751	Chloramphenicol C 0.016-256 mg/L
92045	Ciprofloxacin CIP 0.002-32 mg/L
920450	Ciprofloxacin CIP 0.002-32 mg/L
920451	Ciprofloxacin CIP 0.002-32 mg/L
92048	Clarithromycin CLR 0.016-256 mg/L
920480	Clarithromycin CLR 0.016-256 mg/L
920481	Clarithromycin CLR 0.016-256 mg/L
92072	Clindamycin CD 0.016-256 mg/L
920720	Clindamycin CD 0.016-256 mg/L
920721	Clindamycin CD 0.016-256 mg/L
920440	Cloxacillin CX 0.016-256 mg/L
920441	Cloxacillin CX 0.016-256 mg/L
92044	Cloxacillin CX 0.016-256 mg/L
92141	Colistin CS 0.016-256 mg/L
921411	Colistin CS 0.016-256 mg/L
921410	Colistin CS 0.016-256 mg/L
921420	Colistin CS 0.064-1024 mg/L
921421	Colistin CS 0.064-1024 mg/L
92142	Colistin CS 0.064-1024 mg/L
92137	Dalbavancin DAL 0.002-32 mg/L
921370	Dalbavancin DAL 0.002-32 mg/L
921371	Dalbavancin DAL 0.002-32 mg/L
921451	Daptomycin DAP 0.016-256 mg/L
92145	Daptomycin DAP 0.016-256 mg/L
921450	Daptomycin DAP 0.016-256 mg/L
92080	Delafloxacin DLX 0.002-32 mg/L
920800	Delafloxacin DLX 0.002-32 mg/L
920801	Delafloxacin DLX 0.002-32 mg/L
92040	Doripenem DOR 0.002-32 mg/L
920401	Doripenem DOR 0.002-32 mg/L

CODE	DESCRIPTION
920400	Doripenem DOR 0.002-32 mg/L
92156	Doxycycline DXT 0.016-256 mg/L
921560	Doxycycline DXT 0.016-256 mg/L
921561	Doxycycline DXT 0.016-256 mg/L
920130	Enrofloxacin ENR 0.002-32 mg/L
92013	Enrofloxacin ENR 0.002-32 mg/L
920131	Enrofloxacin ENR 0.002-32 mg/L
92104	Eravacycline ERV 0.002-32 mg/L
921040	Eravacycline ERV 0.002-32 mg/L
921041	Eravacycline ERV 0.002-32 mg/L
921570	Ertapenem ETP 0.002-32 mg/L
92157	Ertapenem ETP 0.002-32 mg/L
921571	Ertapenem ETP 0.002-32 mg/L
92169	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0.125-8/ 0.032-2 mg/L
921690	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0.125-8/ 0.032-2 mg/L
921691	Ertapenem/Ertapenem + Cloxacillin ETP/ECX 0.125-8/ 0.032-2 mg/L
92168	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0.125-8/0.032-2 mg/L
921680	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0.125-8/0.032-2 mg/L
921681	Ertapenem/Ertapenem + Phenylboronic acid ETP/EBO 0.125-8/0.032-2 mg/L
92051	Erythromycin E 0.016-256 mg/L
920511	Erythromycin E 0.016-256 mg/L
920510	Erythromycin E 0.016-256 mg/L
92170	Ethambutol EB 0.016-256 mg/L
921701	Ethambutol EB 0.016-256 mg/L
921700	Ethambutol EB 0.016-256 mg/L
92172	Ethionamide ET 0.016-256 mg/L
921720	Ethionamide ET 0.016-256 mg/L
921721	Ethionamide ET 0.016-256 mg/L
92147	Fluconazole FLU 0.016-256 mg/L
921470	Fluconazole FLU 0.016-256 mg/L
921471	Fluconazole FLU 0.016-256 mg/L
92149	Flucytosine FC 0.002-32 mg/L
921490	Flucytosine FC 0.002-32 mg/L
921491	Flucytosine FC 0.002-32 mg/L
92078	Fosfomycin FOS 0.016-256 mg/L
920780	Fosfomycin FOS 0.016-256 mg/L
920781	Fosfomycin FOS 0.016-256 mg/L
92079	Fosfomycin FOS 0.064-1024 mg/L
920790	Fosfomycin FOS 0.064-1024 mg/L
920791	Fosfomycin FOS 0.064-1024 mg/L
920500	Fosmidomycin FOM 0.016-256 mg/L
920501	Fosmidomycin FOM 0.016-256 mg/L
92050	Fosmidomycin FOM 0.016-256 mg/L
92002	Fusidic acid FU 0.016-256 mg/L
920020	Fusidic acid FU 0.016-256 mg/L
920021	Fusidic acid FU 0.016-256 mg/L
920110	Gatifloxacin GAT 0.002-32 mg/L
920111	Gatifloxacin GAT 0.002-32 mg/L
92011	Gatifloxacin GAT 0.002-32 mg/L
92035	Gemifloxacin GEM 0.002-32 mg/L
920350	Gemifloxacin GEM 0.002-32 mg/L
920351	Gemifloxacin GEM 0.002-32 mg/L
92009	Gentamicin CN 0.016-256 mg/L

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CODE	DESCRIPTION
920090	Gentamicin CN 0.016-256 mg/L
920091	Gentamicin CN 0.016-256 mg/L
920100	Gentamicin CN 0.064-1024 mg/L
920101	Gentamicin CN 0.064-1024 mg/L
92010	Gentamicin CN 0.064-1024 mg/L
92054	Imipenem IMI 0.002-32 mg/L
920541	Imipenem IMI 0.002-32 mg/L
920540	Imipenem IMI 0.002-32 mg/L
92068	Imipenem IMI 0.016-256 mg/L
920680	Imipenem IMI 0.016-256 mg/L
920681	Imipenem IMI 0.016-256 mg/L
92166	Imipenem/Imipenem + EDTA IMI/IMD 0.125-8/0.032-2 mg/L
921660	Imipenem/Imipenem + EDTA IMI/IMD 0.125-8/0.032-2 mg/L
921661	Imipenem/Imipenem + EDTA IMI/IMD 0.125-8/0.032-2 mg/L
92162	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L
921620	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L
921621	Imipenem/Imipenem + EDTA IMI/IMD 4-256/1-64 mg/L
92076	Imipenem-relebactam I/R 0.002/4-32/4
920760	Imipenem-relebactam I/R 0.002/4-32/4
920761	Imipenem-relebactam I/R 0.002/4-32/4
92184	Isavuconazole IVU 0.002-32 mg/L
921840	Isavuconazole IVU 0.002-32 mg/L
921841	Isavuconazole IVU 0.002-32 mg/L
92171	Isoniazide IZ 0.016-256 mg/L
921710	Isoniazide IZ 0.016-256 mg/L
921711	Isoniazide IZ 0.016-256 mg/L
92148	Itraconazole ITC 0.002-32 mg/L
921480	Itraconazole ITC 0.002-32 mg/L
921481	Itraconazole ITC 0.002-32 mg/L
92034	Kanamycin K 0.016-256 mg/L
920340	Kanamycin K 0.016-256 mg/L
920341	Kanamycin K 0.016-256 mg/L
921510	Ketoconazole KE 0.002-32 mg/L
921511	Ketoconazole KE 0.002-32 mg/L
92151	Ketoconazole KE 0.002-32 mg/L
92064	Lefamulin LMU 0,016-256 mg/L
920641	Lefamulin LMU 0,016-256 mg/L
920640	Lefamulin LMU 0,016-256 mg/L
920810	Levofloxacin LEV 0.002-32 mg/L
920811	Levofloxacin LEV 0.002-32 mg/L
92081	Levofloxacin LEV 0.002-32 mg/L
921350	Linezolid LNZ 0.016-256 mg/L
921351	Linezolid LNZ 0.016-256 mg/L
92135	Linezolid LNZ 0.016-256 mg/L
920170	Mecillinam MEC 0.016-256 mg/L
92017	Mecillinam MEC 0.016-256 mg/L
920171	Mecillinam MEC 0.016-256 mg/L
92084	Meropenem MRP 0.002-32 mg/L
920841	Meropenem MRP 0.002-32 mg/L
920840	Meropenem MRP 0.002-32 mg/L
92085	Meropenem MRP 0.016-256 mg/L
920850	Meropenem MRP 0.016-256 mg/L
920851	Meropenem MRP 0.016-256 mg/L

CODE	DESCRIPTION
92165	Meropenem/Meropenem + EDTA MRP/MRD 0.125-8/0.032-2 mg/L
921650	Meropenem/Meropenem + EDTA MRP/MRD 0.125-8/0.032-2 mg/L
921651	Meropenem/Meropenem + EDTA MRP/MRD 0.125-8/0.032-2 mg/L
92167	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0.125-8/0.032-2 mg/L
921670	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0.125-8/0.032-2 mg/L
921671	Meropenem/Meropenem + Phenylboronic acid MRP/MBO 0.125-8/0.032-2 mg/L
92074	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L
920740	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L
920741	Meropenem-vaborbactam (8 mg/L) M/V 0.016-256mg/L
92087	Metronidazole MTZ 0.016-256 mg/L
920870	Metronidazole MTZ 0.016-256 mg/L
920871	Metronidazole MTZ 0.016-256 mg/L
921820	Micafungin MYC 0.002-32 mg/L
921821	Micafungin MYC 0.002-32 mg/L
92182	Micafungin MYC 0.002-32 mg/L
92032	Minocycline MN 0.016-256 mg/L
920321	Minocycline MN 0.016-256 mg/L
920320	Minocycline MN 0.016-256 mg/L
92090	Moxifloxacin MXF 0.002-32 mg/L
920900	Moxifloxacin MXF 0.002-32 mg/L
920901	Moxifloxacin MXF 0.002-32 mg/L
920380	Mupirocin MUP 0.064-1024 mg/L
92038	Mupirocin MUP 0.064-1024 mg/L
920381	Mupirocin MUP 0.064-1024 mg/L
92132	Nalidixic acid NA 0.016-256 mg/L
921320	Nalidixic acid NA 0.016-256 mg/L
921321	Nalidixic acid NA 0.016-256 mg/L
92093	Netilmicin NET 0.016-256 mg/L
920930	Netilmicin NET 0.016-256 mg/L
920931	Netilmicin NET 0.016-256 mg/L
920220	Nitrofurantoin F 0.032-512 mg/L
92022	Nitrofurantoin F 0.032-512 mg/L
920221	Nitrofurantoin F 0.032-512 mg/L
920960	Norfloxacin NOR 0.016-256 mg/L
920961	Norfloxacin NOR 0.016-256 mg/L
92096	Norfloxacin NOR 0.016-256 mg/L
920990	Ofloxacin OFX 0.002-32 mg/L
92099	Ofloxacin OFX 0.002-32 mg/L
920991	Ofloxacin OFX 0.002-32 mg/L
92071	Omadacycline OMC 0.002-32 mg/L
920710	Omadacycline OMC 0.002-32 mg/L
920711	Omadacycline OMC 0.002-32 mg/L
92015	Oxacillin OX 0.016-256 mg/L
920150	Oxacillin OX 0.016-256 mg/L
920151	Oxacillin OX 0.016-256 mg/L
92041	Pefloxacin PEF 0.016-256 mg/L
920410	Pefloxacin PEF 0.016-256 mg/L
920411	Pefloxacin PEF 0.016-256 mg/L
92103	Penicillin G P 0.002-32 mg/L
921030	Penicillin G P 0.002-32 mg/L
921031	Penicillin G P 0.002-32 mg/L

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CODE	DESCRIPTION
921020	Penicillin G P 0.016-256 mg/L
92102	Penicillin G P 0.016-256 mg/L
921021	Penicillin G P 0.016-256 mg/L
92105	Piperacillin PIP 0.016-256 mg/L
921050	Piperacillin PIP 0.016-256 mg/L
921051	Piperacillin PIP 0.016-256 mg/L
921080	Piperacillin* - tazobactam TZP 0.016-256* mg/L
921081	Piperacillin* - tazobactam TZP 0.016-256* mg/L
92108	Piperacillin* - tazobactam TZP 0.016-256* mg/L
92070	Plazomicin PLZ 0.016-256 mg/L
920700	Plazomicin PLZ 0.016-256 mg/L
920701	Plazomicin PLZ 0.016-256 mg/L
92004	Polymyxin B PB 0.064-1024 mg/L
920041	Polymyxin B PB 0.064-1024 mg/L
920040	Polymyxin B PB 0.064-1024 mg/L
92152	Posaconazole POS 0.002-32 mg/L
921520	Posaconazole POS 0.002-32 mg/L
921521	Posaconazole POS 0.002-32 mg/L
92026	Quinupristin-dalfopristin QDA 0.002-32 mg/L
920260	Quinupristin-dalfopristin QDA 0.002-32 mg/L
920261	Quinupristin-dalfopristin QDA 0.002-32 mg/L
920010	Rifampicin RD 0.002-32 mg/L
920011	Rifampicin RD 0.002-32 mg/L
92001	Rifampicin RD 0.002-32 mg/L
92025	Rifampicin RD 0.016-256 mg/L
920250	Rifampicin RD 0.016-256 mg/L
920251	Rifampicin RD 0.016-256 mg/L
92014	Spectinomycin SPC 0.064-1024 mg/L
920140	Spectinomycin SPC 0.064-1024 mg/L
920141	Spectinomycin SPC 0.064-1024 mg/L
920460	Spiramycin SP 0.002-32 mg/L
920461	Spiramycin SP 0.002-32 mg/L
92046	Spiramycin SP 0.002-32 mg/L
92112	Streptomycin S 0.016-256 mg/L
921120	Streptomycin S 0.016-256 mg/L
921121	Streptomycin S 0.016-256 mg/L
92111	Streptomycin S 0.064-1024 mg/L
921110	Streptomycin S 0.064-1024 mg/L
921111	Streptomycin S 0.064-1024 mg/L
92028	Sulbactam SUL 0.016-256 mg/L
920280	Sulbactam SUL 0.016-256 mg/L
920281	Sulbactam SUL 0.016-256 mg/L
920310	Sulfamethoxazole SMX 0.064-1024 mg/L
920311	Sulfamethoxazole SMX 0.064-1024 mg/L
92031	Sulfamethoxazole SMX 0.064-1024 mg/L
921360	Tedizolid TZD 0.002-32 mg/L
921361	Tedizolid TZD 0.002-32 mg/L
92136	Tedizolid TZD 0.002-32 mg/L
920120	Teicoplanin TEC 0.016-256 mg/L
920121	Teicoplanin TEC 0.016-256 mg/L
92012	Teicoplanin TEC 0.016-256 mg/L
920520	Telavancin TLV 0.002-32 mg/L
92052	Telavancin TLV 0.002-32 mg/L
920521	Telavancin TLV 0.002-32 mg/L
92053	Telavancin TLV 0.016-256 mg/L
920530	Telavancin TLV 0.016-256 mg/L
920531	Telavancin TLV 0.016-256 mg/L
92029	Temocillin TMO 0.064-1024 mg/L

CODE	DESCRIPTION
920290	Temocillin TMO 0.064-1024 mg/L
920291	Temocillin TMO 0.064-1024 mg/L
92114	Tetracycline TE 0.016-256 mg/L
921140	Tetracycline TE 0.016-256 mg/L
921141	Tetracycline TE 0.016-256 mg/L
92200	Tiamulin TIA 0.002-32 mg/L
922000	Tiamulin TIA 0.002-32 mg/L
922001	Tiamulin TIA 0.002-32 mg/L
92183	Ticarcillin TC 0.016-256 mg/L
921830	Ticarcillin TC 0.016-256 mg/L
921831	Ticarcillin TC 0.016-256 mg/L
92117	Ticarcillin* - clavulanic acid TTC 0.016-256* mg/L
921170	Ticarcillin* - clavulanic acid TTC 0.016-256* mg/L
921171	Ticarcillin* - clavulanic acid TTC 0.016-256* mg/L
92144	Tigecycline TGC 0.016-256 mg/L
921440	Tigecycline TGC 0.016-256 mg/L
921441	Tigecycline TGC 0.016-256 mg/L
92201	Tilmicosin TIL 0.002-32 mg/L
922010	Tilmicosin TIL 0.002-32 mg/L
922011	Tilmicosin TIL 0.002-32 mg/L
92121	Tobramycin TOB 0.016-256 mg/L
921210	Tobramycin TOB 0.016-256 mg/L
921211	Tobramycin TOB 0.016-256 mg/L
921200	Tobramycin TOB 0.064-1024 mg/L
921201	Tobramycin TOB 0.064-1024 mg/L
92120	Tobramycin TOB 0.064-1024 mg/L
92037	Trimethoprim TM 0.002-32 mg/L
920370	Trimethoprim TM 0.002-32 mg/L
920371	Trimethoprim TM 0.002-32 mg/L
92123	Trimethoprim* - sulfamethoxazole (1/19) SXT 0.002-32* mg/L
921230	Trimethoprim*-sulfamethoxazole (1/19) SXT 0.002-32* mg/L
921231	Trimethoprim*-sulfamethoxazole (1/19) SXT 0.002-32* mg/L
920570	Vancomycin VA 0.016-256 mg/L
92057	Vancomycin VA 0.016-256 mg/L
920571	Vancomycin VA 0.016-256 mg/L
92163	Vancomycin//Teicoplanin VA/TEC 0.5-32/0.5-32 mg/L
921630	Vancomycin//Teicoplanin VA/TEC 0.5-32/0.5-32 mg/L
921631	Vancomycin//Teicoplanin VA/TEC 0.5-32/0.5-32 mg/L
921500	Voriconazole VO 0.002-32 mg/L
921501	Voriconazole VO 0.002-32 mg/L
92150	Voriconazole VO 0.002-32 mg/L
RID plates	
93001	Easy Rid h-IgG
93002	Easy Rid h-IgA
93003	Easy Rid h-IgM
93004	Easy Rid h-C3c
93005	Easy Rid h-C4
93006	Easy Rid h-Transferrin
93007	Easy Rid h-Albumin
93008	Easy Rid h-Apolipoprotein A1
93009	Easy Rid h-Apolipoprotein B
93010	Easy Rid h-Alfa 1 Acid Glicoprotein
93011	Easy Rid h-Fibrinogen

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CODE	DESCRIPTION
93012	Easy Rid h-Antitrombin III
93013	Easy Rid h-Ig Light Chain K
93014	Easy Rid h-Ig Light Chain Lambda
93015	Easy Rid h-Alfa 1 Antitrypsin
93016	Easy Rid h-Ceruloplasmin
93018	Easy Rid h-Haptoglobin
93104	Multiplate h-IgG/IgA/IgM
93106	Multiplate h-C3c/C4
93110	Multiplate h-Apo A1/Apo B
93115	Multiplate h-Kappa Chain/Lambda Chain
93201	Bence Jones Test
940010	Rid Control Serum

Multodiscs

CODE	DESCRIPTION
95270	Multodisc Acinetobacter
95200	Multodisc Anaerobes
95220	Multodisc Enterobacteria 1
95240	Multodisc Enterobacteria 2
95230	Multodisc Enterobacteria Urine
95210	Multodisc Enterococci
95250	Multodisc Pseudomonas
95260	Multodisc Staph
95290	Multodisc Strepto
95280	Multodisc Yeasts

Bacterial suspension - rapid Kit

CODE	DESCRIPTION
96001	Salmonella typhi H Macro
96002	Salmonella typhi O Macro
96003	Salmonella paratyphi AH Macro
96004	Salmonella paratyphi AO Macro
96005	Salmonella paratyphi BH Macro
96006	Salmonella paratyphi BO Macro
96007	Brucella Totale Macro
96008	Brucella abortus Macro
96009	Salmonella typhi A Totale Macro
96010	Salmonella paratyphi A Totale Macro
96011	Proteus OX2 Macro
96012	Proteus OXK Macro
96013	Proteus OX19 Macro
96015	Febrile Multitest Kit
96016	Strep-Check Kit
96017	Staph Latex Kit
96018	Salmonella paratyphi B Totale Macro
96019	Salmonella paratyphi CH Macro
96020	Salmonella paratyphi CO Macro
96021	Salmonella paratyphi B Totale Macro

CODE	DESCRIPTION
96022	Brucella melitensis Macro
96023	Brucella suis Macro
96031	Salmonella typhi H Slide
96032	Salmonella typhi O Slide
96033	Salmonella typhi Totale Slide
96034	Salmonella paratyphi AH Slide
96035	Salmonella paratyphi AO Slide
96036	Salmonella paratyphi A Totale Slide
96037	Salmonella paratyphi BH Slide
96038	Salmonella paratyphi BO Slide
96039	Salmonella paratyphi B Totale Slide
96040	Salmonella paratyphi CH Slide
96041	Salmonella paratyphi CO Slide
96042	Salmonella paratyphi C Totale Slide
96043	Brucella Totale Slide
96044	Brucella abortus Slide
96045	Brucella melitensis Slide
96046	Brucella Bengal Rose Slide
96047	Proteus OX2 Slide
96048	Proteus OXK Slide
96049	Proteus OX19 Slide
96093	Negative Control
96096	Positive Control for Salmonella
96097	Positive Control for Proteus
96098	Positive Control for Brucella
96142	Legionella Latex Kit
96143	Campylobacter Latex Kit
96148	Shigella Antiserum
96150	E.Coli O157 Latex Kit
96151	Salmonella Latex Kit
96153	Strepto B Latex Kit
96154	Strepto A Latex Kit
96316	Clostridium difficile GDH Card
96317	Clostridium difficile Toxin A+B Card
96318	Giardia Card
96319	Listeria Monocytogenes Card
96320	Salmonella Ag Card
96415/20	Fecal Occult Blood Card
96418	Strepto A Card
96441	Gonorrea Ag Card
96442	Gardnerella Vaginalis Card
96443	Trichomonas Vaginalis Card
97800	One Step Rotavirus Card
97801	RSV Stick One Step
97802	One Step Rota-Adenovirus Combo Panel
97803	Helicobacter pylori Antigen Card
97807	One Step Adenovirus Test

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DICHIARAZIONE DI CONFORMITÀ "UE"
PER DISPOSITIVI MEDICO-DIAGNOSTICI IN VITRO

Nome e indirizzo Fabbricante	Liofilchem® S.r.l., Via Scozia, 64026 Roseto degli Abruzzi (TE) - Italy
SRN (Numero di Registrazione Unico)	IT-MF-000026495
Classificazione in accordo alle regole riportate nell'Allegato VIII	Classe A
UDI-DI di base/Nome/Codice dispositivo(i)	Vedi tabella n°1
Destinazione d'Uso:	La destinazione d'uso di ciascun dispositivo elencato in Tabella n°1 (inclusi eventuali riferimenti a SC) è riportata nella specifica Dichiarazione di Conformità UE redatta in accordo all'Allegato IV del Regolamento (UE) 2017/746

Questa dichiarazione di conformità è rilasciata sotto la sola responsabilità di Liofilchem S.r.l.
Con la presente dichiariamo che i dispositivi medici-diagnostici in vitro riportati in Tabella n°1 soddisfano le disposizioni del Regolamento (UE) 2017/746 per i dispositivi medici-diagnostici in vitro. Tutta la documentazione di supporto è conservata presso la sede del produttore

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EU DECLARATION OF CONFORMITY FOR
IN VITRO DIAGNOSTIC MEDICAL DEVICES

Manufacturers Name/Address:	Liofilchem® S.r.l., Via Scozia, 64026 Roseto degli Abruzzi (TE) - Italy
SRN (Single Registration Number):	IT-MF-000026495
Classification in accordance with the rules set out in Annex VIII:	Class A
Basic UDI-DI/Name/Code(s)	See Table no.1
Intended Purpose:	The intended purpose of each device listed in Table no. 1 (included any references to CS) is indicated in the specific EU Declaration of Conformity drawn up according to Annex IV of Regulation (EU) 2017/746

This declaration of conformity is issued under the sole responsibility of Liofilchem S.r.l.
We hereby declare that the in vitro diagnostic medical device specified above meet the provision of the Regulation (EU) 2017/746 for in vitro diagnostic medical devices.
All supporting documentation is retained at the premises of the manufacturer.

Roseto degli Abruzzi (TE),
13.10.2022

Signature:

LIOFILCHEM s.r.l.
BACTERIOLOGY PRODUCTS
Via Scozia
64026 Roseto degli Abruzzi (TE)
Cod. Fisc. e Partita IVA 00530130673

Technical Director
(Dr. Silvio Brocco)

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Table no.1

CODE	DESCRIPTION	BASIC UDI-DI
90 mm agar plates		
11041	Azide Agar (Sheep Blood 5%)	805518287AZAVF
10020	Baird Parker Agar	805518287BPAL8
10021	Biggy (Nickerson) Agar	805518287BIGGYAE3
10142	Blood Agar (Sheep Blood 7%)	805518287BLOAEN
10353	Bordet Gengou Agar (Sheep Blood 15%)	805518287BOGAED
10060	Brain Heart Infusion Agar	805518287BHAKG
10022	Brilliant Green Agar	805518287BGAKD
10245	Brucella Blood Agar w Hemin and Vitamin K1	805518287BRALE
11506	Burkholderia cepacia Selective Agar (BCSA)	805518287BCSADM
10148	Campylobacter Agar (Sheep Blood 10%)	805518287CAMBA9M
10050	Campylobacter Agar (Sheep Blood 5%)	805518287CAMACY
10050*	Campylobacter Agar (Sheep Blood 5%)	805518287CAMACY
10145	Campylobacter Karmali Agar	805518287CAMKAAG
10602	Campylobacter Skirrow Agar	805518287CSALN
10079	Casitone Agar	805518287CASADJ
10033	Cetrimide Agar	805518287CETAE9
10023	Chocolate Agar	805518287CHAKM
10023*	Chocolate Agar	805518287CHAKM
11023	Chocolate Bacitracin Agar	805518287CBAK3
11611	Chromatic Detection	805518287CHRDETFD
11610	Chromatic E.coli O157	805518287CHRECO157BF
11618	Chromatic MH	805518287CHRMHDE
11614	Chromatic Salmonella	805518287CHRSALGU
11616	Chromatic Staph aureus	805518287CHRSADJ
11633	Chromatic Vibrio	805518287CHRVFU
10026	CLED Agar	805518287CLAKZ
10004	CLED Andrade Agar	805518287CAAJY
11060	Clostridium Agar (Sheep Blood 5%)	805518287CLOAEV
10025	Columbia Agar (Horse Blood 5%)	805518287COLAHCV
11025	Columbia Agar (Sheep Blood 5%)	805518287COLASDK
11025*	Columbia Agar (Sheep Blood 5%)	805518287COLASDK
11024	Columbia CNA Agar (Sheep Blood 5%)	805518287CNAL7
11024*	Columbia CNA Agar (Sheep Blood 5%)	805518287CNAL7
11124	Columbia CNA Mod Agar (Sheep Blood 5%)	805518287CNAMEM
11507	Corn Meal Agar	805518287CMAL4
10017	Czapek Dox Agar	805518287CDAK9
11052	Dermatophyte (DTM) Agar	805518287DTMMN
10013	DNase Test Agar	805518287DNTAFV
10018	Drigalski Lactose Agar	805518287DLAL6
10048	EMB Levine Agar	805518287EMBLG
11501	Enterococcus Agar w Vancomycin	805518287ENTWVANCG7
11057	Enterococco Agar	805518287ENTAG4
10062	Fastidious Anaerobe Agar	805518287FAAKF
11054	Gardnerella Agar (Sheep Blood 5%)	805518287GARAEB
10080	Haemophilus Test Agar	805518287HTAMJ
10043	Hektoen Enteric Agar	805518287HEAL5
10043*	Hektoen Enteric Agar	805518287HEAL5
10082	Helicobacter pylori Agar	805518287HPAM6
10028	IsoSensitest Agar	805518287ISTNS
10128	Legionella Agar (GVPC)	805518287GVPCHJ
10448	Legionella BCYE + AB Agar	805518287BCYEABDF
10051	Legionella BCYE Agar	805518287BCYEEF
10051*	Legionella BCYE Agar	805518287BCYEEF
10424	Legionella BCYE Agar w Vancomycin + Colistin	805518287BCYEVCFG
10412	Legionella BCYE Agar w/o Cysteine	805518287LW/OCYSR6

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CODE	DESCRIPTION	BASIC UDI-DI
10041	Listeria Palcam Agar	805518287LPAMS
10029	MacConkey Agar	805518287MCALQ
10029*	MacConkey Agar	805518287MCALQ
11508	MacConkey Agar w/o NaCl	805518287MCAW/ONACL54
10603	MacConkey Agar no.2	805518287MCIIADJ
10129	MacConkey Mug Agar	805518287MCMMG
11514	MacConkey S-CT Agar E.coli O157	805518287MCSCTAHZ
10005	MacConkey Sorbitol Agar	805518287MCSMU
10030	Mannitol Salt Agar	805518287MSAN8
10030*	Mannitol Salt Agar	805518287MSAN8
10416	Middlebrook 7H11 Agar	805518287MB7H118E
10335	Mueller Hinton Chocolate Agar	805518287MHCAFB
10132	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L beta-NAD)	805518287MHFAFL
10031	Mueller Hinton II Agar	805518287MHIIAEM
10031*	Mueller Hinton II Agar	805518287MHIIAEM
10131	Mueller Hinton II Agar (Sheep Blood 5%)	805518287MHII2SGH
11206	Mueller Hinton II Agar + 2% NaCl	805518287MHNAGC
11205	Mycoplasma Agar	805518287MYANS
11070	Mycosel Agar	805518287MYCAHY
10620	O.A. Listeria Agar	805518287OALAFH
11200	PAR Test Agar	805518287PTANS
11033	Pseudomonas Isolation Agar	805518287PIAMR
10014	Purple Lactose Agar	805518287PLAN2
10039	Rogosa Agar	805518287ROGAHV
11509	RPMI Agar	805518287RPMIAJQ
11335	Sabouraud Agar + Gentamicin	805518287SGAN2
11135	Sabouraud Agar Modified	805518287SAMN8
11236	Sabouraud CAF + Actidione Agar	805518287SCAFAE3
11035	Sabouraud CAF Agar	805518287SCAMN
10235	Sabouraud CAF Agar + Gentamicin	805518287SCGEGG
10035	Sabouraud Dextrose Agar	805518287SDAMR
10425	Scedosporium Selective Agar	805518287SCESELAST
10405	Schaedler CNA Agar (Sheep Blood 5%)	805518287SCHCNAHG
11065	Schaedler K Agar (Sheep Blood 5%)	805518287SKANE
10065	Schaedler KKV Agar (Sheep Blood 5%)	805518287SKKVK6
10046	Serum Tellurite Agar	805518287STAP9
11196	SPS Agar	805518287SPSPZ
10036	SS Agar	805518287SSAP6
11195	TCBS AGAR	805518287TCBSH4
11040	Thayer Martin Agar	805518287TMANR
11250	Tinsdale Agar	805518287TINAJ2
10037	Tryptic Soy Agar	805518287TSAPB
11037	Tryptic Soy Agar (Sheep Blood 5%)	805518287TSSQF
10407	Vancomycin Screen Agar	805518287VSAPM
10054	Wurtz Lactose Agar	805518287WLAP5
10056	XLD Agar	805518287XLDPG
10413	XLD Agar EP, USP, JP Formulation	805518287XLDPKD
10069	XLT4 Agar	805518287XLT4K7
10052	Yersinia Selective Agar	805518287YSAQ4

2 sector agar plates

CODE	DESCRIPTION	BASIC UDI-DI
18500	Baird Parker / MacConkey	805518287BP/MCAAB
18390	Baird Parker / Sabouraud CAF	805518287BP/SCAB9
18015	Biggy (Nickerson) / Malt	805518287BIGGY/MALTZJ
18012	Brilliant Green / SS	805518287BG/SSA9N
18702	CDC Anaerobic / CDC w Kanamycin - Vancomycin	805518287CDCA/CDCKVAYK

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CODE	DESCRIPTION	BASIC UDI-DI
18703	Chocolate Agar /Thayer Martin	805518287CHOC/TMAV9
18008	Chromatic Detection / TSA Blood	805518287CHRDET/TSS88
18009	Chromatic Salmonella/Hektoen Enteric	805518287CHRSALM/HEA3E
18502	CLED / MacConkey	805518287CL/MCA9C
18507	Columbia CNA / Chocolate	805518287CNA/CHAD3
18422	Columbia CNA / Gardnerella	805518287CNA/GARANR
18327	Columbia CNA / MacConkey	805518287CNA/MCAE6
18595	DTM / Sabouraud	805518287DTM/SABN3
18020	EMB Levine / TSA Blood	805518287EMB/TSSJV
18379	Gardnerella / Thayer Martin	805518287GAR/TMAJV
18503	Hektoen Enteric / SS Agar	805518287HE/SSABE
18391	Hektoen Enteric / Yersinia Selective	805518287HE/YSACC
18505	MacConkey / SS	805518287MC/SSACR
18380	MacConkey / TSA Blood	805518287MC/TSSE2
18025	Schaedler K / Schaedler KKV	805518287SK/SKKVQZ
120 mm agar plates		
CODE	**DESCRIPTION**	**BASIC UDI-DI**
12031	Mueller Hinton II Agar	805518287MHIIAEM
12032	Mueller Hinton II Agar (Sheep Blood 5%)	805518287MHII2SGH
140 mm agar plates		
CODE	**DESCRIPTION**	**BASIC UDI-DI**
10224	Baird Parker Agar	805518287BPAL8
10246	Chromatic MH	805518287CHRMHDE
11132	Mueller Hinton Fastidious Agar (Horse blood 5% + 20 mg/L beta-NAD)	805518287MHFAFL
10231	Mueller Hinton II Agar	805518287MHIIAEM
10249	Purple Lactose Agar	805518287PLAN2
10233	RPMI Agar	805518287RPMIAJQ
Tubes - Bottles		
CODE	**DESCRIPTION**	**BASIC UDI-DI**
401990	Alkaline Peptone Water	805518287BALKPWDK
24100	Alkaline Peptone Water	805518287TALKPWLV
442350	Biggy (Nickerson) Agar	805518287BBIGNAB3
30091	Biggy (Nickerson) Agar	805518287TBIGNAJD
24120	Bile Aesculin Broth	805518287TBILABHZ
30084	Brain Heart Infusion Agar	805518287TBRAHIATN
412010	Brain Heart Infusion Broth	805518287BBRAHIBJ6
24104	Brain Heart Infusion Broth	805518287TBRAHIBTQ
24141	Brain Heart Infusion Broth	805518287TBRAHIBTQ
24480	Brain Heart Infusion Broth	805518287TBRAHIBTQ
26104	Brain Heart Infusion Broth	805518287TBRAHIBTQ
27502	Brain Heart Infusion Broth	805518287TBRAHIBTQ
413030	Campylobacter Agar	805518287BCAMA8V
24404	Campylobacter Broth	805518287TCAMBF5
470290	Cary Blair Transport Medium	805518287BCARBTMH8
402270	Cetrimide Agar	805518287BCETAA6
412270	Cetrimide Agar	805518287BCETAA6
442220	Chocolate Agar	805518287BCHOAA6
470120	Chocolate Agar	805518287BCHOAA6
30099	Chocolate Agar	805518287TCHOAGC
412100	Christensen Urea Agar	805518287BCHRUADK
30081	Christensen Urea Agar	805518287TCHRUALV
481130	Chromatic Detection	805518287BCHRDAM
482190	Chromatic E.coli O157	805518287BCHRECOJM
481140	Chromatic Salmonella	805518287BCHRSBK

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CODE	DESCRIPTION	BASIC UDI-DI
481160	Chromatic Staph aureus	805518287BCHRSADD
402180	CLED Agar	805518287BCLEA9U
412180	CLED Agar	805518287BCLEA9U
470110	CLED Agar	805518287BCLEA9U
452210	Columbia Agar Base	805518287BCOLABCC
24071	Cooked Meat Medium	805518287TCOOMMMX
402200	Dermatophyte (DTM) Agar	805518287BDERDABN
33086	Dermatophyte (DTM) Agar	805518287TDERDAJY
402220	Drigalski Lactose Agar	805518287BDRILADU
402350	EMB Levine Agar	805518287BEMBLAD3
21241	Fluid Thioglycollate Medium	805518287TFLUTMPW
24241	Fluid Thioglycollate Medium	805518287TFLUTMPW
24124	Fluid Thioglycollate Medium	805518287TFLUTMPW
26124	Fluid Thioglycollate Medium	805518287TFLUTMPW
20105	Glucose Broth	805518287TGLUBJG
24105	Glucose Broth	805518287TGLUBJG
26105	Glucose broth	805518287TGLUBJG
414070	GN Hajna Broth	805518287BGNHBBD
24119	GN Hajna Broth	805518287TGNHBHK
24091	Haemophilus Test Broth	805518287THAETBJZ
402230	Hektoen Enteric Agar	805518287BHEKEAC2
412230	Hektoen Enteric Agar	805518287BHEKEAC2
20090	Helicobacter pylori Test	805518287THELPTMQ
30087	Kligler Iron Agar	805518287TKLIIAMY
30116	Loeffler Medium	805518287TLOEMK8
34127/1	Lowenstein Jensen + Amikacin 40 µg/ml	805518287LJAMIKACINAU
34127	Lowenstein Jensen + Amikacin 5 µg/ml	805518287LJAMIKACINAU
34138/1	Lowenstein Jensen + Capreomycin 10 µg/ml	805518287LJCAPREOMYCINGV
34138/3	Lowenstein Jensen + Capreomycin 20 µg/ml	805518287LJCAPREOMYCINGV
35090	Lowenstein Jensen + Capreomycin 30 µg/ml	805518287LJCAPREOMYCINGV
34138/4	Lowenstein Jensen + Capreomycin 30 µg/ml	805518287LJCAPREOMYCINGV
34138/2	Lowenstein Jensen + Capreomycin 40 µg/ml	805518287LJCAPREOMYCINGV
34131/2	Lowenstein Jensen + Clarithromycin 32 µg/ml	805518287LJCLARITHROMYCVM
34131/1	Lowenstein Jensen + Clarithromycin 4 µg/ml	805518287LJCLARITHROMYCVM
34139/2	Lowenstein Jensen + Clofazimine 10 µg/ml	805518287LJCLOFAZIMINEJ7
34139/1	Lowenstein Jensen + Clofazimine 5 µg/ml	805518287LJCLOFAZIMINEJ7
34137/2	Lowenstein Jensen + Cycloserine 10 µg/ml	805518287LJCYCLOSERINEV8
34137/3	Lowenstein Jensen + Cycloserine 20 µg/ml	805518287LJCYCLOSERINEV8
34137/1	Lowenstein Jensen + Cycloserine 30 µg/ml	805518287LJCYCLOSERINEV8
34137/4	Lowenstein Jensen + Cycloserine 40 µg/ml	805518287LJCYCLOSERINEV8
34137/5	Lowenstein Jensen + Cycloserine 50 µg/ml	805518287LJCYCLOSERINEV8
34126/6	Lowenstein Jensen + Ethambutol 10 µg/ml	805518287LJETHAMBUTOLCQ
34126/4	Lowenstein Jensen + Ethambutol 1 µg/ml	805518287LJETHAMBUTOLCQ
35030	Lowenstein Jensen + Ethambutol 2 µg/ml	805518287LJETHAMBUTOLCQ
34126/1	Lowenstein Jensen + Ethambutol 2 µg/ml	805518287LJETHAMBUTOLCQ
34126/5	Lowenstein Jensen + Ethambutol 3 µg/ml	805518287LJETHAMBUTOLCQ
34126/2	Lowenstein Jensen + Ethambutol 4 µg/ml	805518287LJETHAMBUTOLCQ
34126/3	Lowenstein Jensen + Ethambutol 5 µg/ml	805518287LJETHAMBUTOLCQ
34132/1	Lowenstein Jensen + Ethionamide 10 µg/ml	805518287LJETHIONAMIDENZ
35040	Lowenstein Jensen + Ethionamide 20 µg/ml	805518287LJETHIONAMIDENZ
34132/2	Lowenstein Jensen + Ethionamide 20 µg/ml	805518287LJETHIONAMIDENZ
35041	Lowenstein Jensen + Ethionamide 30 µg/ml	805518287LJETHIONAMIDENZ
34132/3	Lowenstein Jensen + Ethionamide 30 µg/ml	805518287LJETHIONAMIDENZ
34132/4	Lowenstein Jensen + Ethionamide 40 µg/ml	805518287LJETHIONAMIDENZ
34123	Lowenstein Jensen + Isoniazid 0.1 µg/ml	805518287LJISONIAZIDMF
35001	Lowenstein Jensen + Isoniazid 0.20 µg/ml	805518287LJISONIAZIDMF
34123/1	Lowenstein Jensen + Isoniazid 0.2 µg/ml	805518287LJISONIAZIDMF

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CODE	DESCRIPTION	BASIC UDI-DI
35002	Lowenstein Jensen + Isoniazid 1 µg/ml	805518287LJISONIAZIDMF
34123/4	Lowenstein Jensen + Isoniazid 10 µg/ml	805518287LJISONIAZIDMF
34123/2	Lowenstein Jensen + Isoniazid 1 µg/ml	805518287LJISONIAZIDMF
34123/3	Lowenstein Jensen + Isoniazid 5 µg/ml	805518287LJISONIAZIDMF
34143/1	Lowenstein Jensen + Kanamycin 10 µg/ml	805518287LJKANAMYCINA2
35060	Lowenstein Jensen + Kanamycin 20 µg/ml	805518287LJKANAMYCINA2
34143/2	Lowenstein Jensen + Kanamycin 20 µg/ml	805518287LJKANAMYCINA2
35061	Lowenstein Jensen + Kanamycin 30 µg/ml	805518287LJKANAMYCINA2
34143/3	Lowenstein Jensen + Kanamycin 30 µg/ml	805518287LJKANAMYCINA2
34146/1	Lowenstein Jensen + Levofloxacin 2 µg/ml	805518287LJLEVOFLOXACINBN
34135/1	Lowenstein Jensen + Nicotinamide 10 µg/ml	805518287LJNICOTINAMIDEZG
34135/2	Lowenstein Jensen + Nicotinamide 20 µg/ml	805518287LJNICOTINAMIDEZG
34135/3	Lowenstein Jensen + Nicotinamide 30 µg/ml	805518287LJNICOTINAMIDEZG
34128/2	Lowenstein Jensen + Ofloxacin 10 µg/ml	805518287LJOFLOXACINK2
34128/5	Lowenstein Jensen + Ofloxacin 20 µg/ml	805518287LJOFLOXACINK2
34128/3	Lowenstein Jensen + Ofloxacin 25 µg/ml	805518287LJOFLOXACINK2
35080	Lowenstein Jensen + Ofloxacin 2 µg/ml	805518287LJOFLOXACINK2
34128/4	Lowenstein Jensen + Ofloxacin 2 µg/ml	805518287LJOFLOXACINK2
34128/1	Lowenstein Jensen + Ofloxacin 5 µg/ml	805518287LJOFLOXACINK2
34145	Lowenstein Jensen + PACT	805518287LJPACTJM
34129/4	Lowenstein Jensen + PAS 0.1 µg/ml	805518287LJPASG7
34129/3	Lowenstein Jensen + PAS 0.5 µg/ml	805518287LJPASG7
34129/2	Lowenstein Jensen + PAS 10 µg/ml	805518287LJPASG7
35070	Lowenstein Jensen + PAS 1 µg/ml	805518287LJPASG7
34129/1	Lowenstein Jensen + PAS 1 µg/ml	805518287LJPASG7
34129/5	Lowenstein Jensen + PAS 5 µg/ml	805518287LJPASG7
34136	Lowenstein Jensen + Pefloxacin 2 µg/ml	805518287LJPEFLOXACINHG
35147	Lowenstein Jensen + PNB 500 µg/ml	805518287LJPNBGC
34124/2	Lowenstein Jensen + Pyrazinamide 15 µg/ml	805518287LJPYRAZINAMIDESG
35050	Lowenstein Jensen + Pyrazinamide 1 µg/ml	805518287LJPYRAZINAMIDESG
34124/4	Lowenstein Jensen + Pyrazinamide 200 µg/ml	805518287LJPYRAZINAMIDESG
34124/3	Lowenstein Jensen + Pyrazinamide 20 µg/ml	805518287LJPYRAZINAMIDESG
34124/1	Lowenstein Jensen + Pyrazinamide 5 µg/ml	805518287LJPYRAZINAMIDESG
34144	Lowenstein Jensen + Pyruvate 0.2%	805518287LJPYRUVATE63
34130/1	Lowenstein Jensen + Rifabutin 10 µg/ml	805518287LJRIFABUTINDK
34130/2	Lowenstein Jensen + Rifabutin 30 µg/ml	805518287LJRIFABUTINDK
34130/3	Lowenstein Jensen + Rifabutin 50 µg/ml	805518287LJRIFABUTINDK
34121/2	Lowenstein Jensen + Rifampicin 10 µg/ml	805518287LJRIFAMPICINEH
34121	Lowenstein Jensen + Rifampicin 15 µg/ml	805518287LJRIFAMPICINEH
34121/6	Lowenstein Jensen + Rifampicin 20 µg/ml	805518287LJRIFAMPICINEH
34121/3	Lowenstein Jensen + Rifampicin 25 µg/ml	805518287LJRIFAMPICINEH
35010	Lowenstein Jensen + Rifampicin 40 µg/ml	805518287LJRIFAMPICINEH
34121/5	Lowenstein Jensen + Rifampicin 40 µg/ml	805518287LJRIFAMPICINEH
34121/4	Lowenstein Jensen + Rifampicin 50 µg/ml	805518287LJRIFAMPICINEH
34121/1	Lowenstein Jensen + Rifampicin 5 µg/ml	805518287LJRIFAMPICINEH
34122	Lowenstein Jensen + Rifapentin 9 µg/ml	805518287LJRIFAPENTINFP
35021	Lowenstein Jensen + Streptomycin 10 µg/ml	805518287LJSTREPTOMYCIN38
34125/2	Lowenstein Jensen + Streptomycin 10 µg/ml	805518287LJSTREPTOMYCIN38
34125/3	Lowenstein Jensen + Streptomycin 25 µg/ml	805518287LJSTREPTOMYCIN38
34125/4	Lowenstein Jensen + Streptomycin 2 µg/ml	805518287LJSTREPTOMYCIN38
35020	Lowenstein Jensen + Streptomycin 4 µg/ml	805518287LJSTREPTOMYCIN38
34125/1	Lowenstein Jensen + Streptomycin 4 µg/ml	805518287LJSTREPTOMYCIN38
34125/5	Lowenstein Jensen + Streptomycin 50 µg/ml	805518287LJSTREPTOMYCIN38
35148	Lowenstein Jensen + TCH 2 µg/ml	805518287LJTCHGB
30118	Lowenstein Jensen Medium	805518287TLOWJMRZ
31118	Lowenstein Jensen Medium	805518287TLOWJMRZ
35000	Lowenstein Jensen Medium	805518287TLOWJMRZ

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CODE	DESCRIPTION	BASIC UDI-DI
30119	Lowenstein Jensen Medium w/o Glycerol	805518287TLOWJMW/OG4B
412040	Lysine Iron Agar	805518287BLYSIAKE
30098	Lysine Iron Agar	805518287TLYSIASQ
402240	MacConkey Agar	805518287BMACAA5
412240	MacConkey Agar	805518287BMACAA5
470090	MacConkey Agar	805518287BMACAA5
402290	Mannitol Salt Agar	805518287BMSAF7
412290	Mannitol Salt Agar	805518287BMSAF7
470080	Mannitol Salt Agar	805518287BMSAF7
30368	Middlebrook 7H10 Agar	805518287TMID7H10AG8
37001	Middlebrook 7H11 + Amikacin 2 µg/ml	8055182877H11AMIKACIN62
37002	Middlebrook 7H11 + Amikacin 4 µg/ml	8055182877H11AMIKACIN62
37056	Middlebrook 7H11 + Cycloserine 30 µg/ml	8055182877H11CYCLOSERINK6
37006	Middlebrook 7H11 + Ethambutol 7.5 µg/ml	8055182877H11ETHAMBUTOLC4
37011	Middlebrook 7H11 + Ethionamide 10 µg/mll	8055182877H11ETHIONAMIDER
37016	Middlebrook 7H11 + Isoniazid 0.2 µg/ml	8055182877H11ISONIAZIDKH
37017	Middlebrook 7H11 + Isoniazid 1 µg/ml	8055182877H11ISONIAZIDKH
37051	Middlebrook 7H11 + Ofloxacin 8 µg/ml	8055182877H11OFLOXACINH4
37026	Middlebrook 7H11 + PAS 8 µg/ml	8055182877H11PAS2K
37031	Middlebrook 7H11 + Pyrazinamide 25 µg/ml	8055182877H11PYRAZINAMI2H
37036	Middlebrook 7H11 + Rifabutin 1 µg/ml	8055182877H11RIFABUTINBM
37041	Middlebrook 7H11 + Rifampicin 1 µg/mll	8055182877H11RIFAMPICINDV
37046	Middlebrook 7H11 + Streptomycin 2 µg/ml	8055182877H11STREPTOMYC6B
37000	Middlebrook 7H11 Agar	805518287TMID7H114E
24436	Middlebrook 7H9 Broth	805518287TMID7H9B66
31204	MIU Agar	805518287TMIUAK9
23002	Mueller Hinton Broth w/ horse blood	805518287TMHBWHBX8
27507	Mueller Hinton Fastidious Broth	805518287TMUEHFBZT
21105	Mueller Hinton Fastidious Broth	805518287TMUEHFBZT
402250	Mueller Hinton II Agar	805518287BMHIIAEG
412250	Mueller Hinton II Agar	805518287BMHIIAEG
470070	Mueller Hinton II Agar	805518287BMHIIAEG
402020	Mueller Hinton II Broth	805518287BMUEHIIB5R
24107	Mueller Hinton II Broth	805518287TMUEHIIBGF
402030	Muller Kauffmann Broth	805518287BMULKBJ2
24108	Muller Kauffmann Broth	805518287TMULKBRC
20162	Mycoplasma Selective Broth	805518287TMYCSBRK
20158	Mycoplasma Transport Broth	805518287TMYCTBRN
402000	Nutrient Broth	805518287BNUTBF5
24103	Nutrient Broth	805518287TNUTBMB
26103	Nutrient Broth	805518287TNUTBMB
27503	Nutrient Broth	805518287TNUTBMB
30117	Pergola Medium	805518287TPERMKR
412170	Phenylalanine Agar	805518287BPHEAC3
30085	Phenylalanine agar	805518287TPHEAJ9
463200	Physiological Solution	805518287BPHYSF3
471120	Physiological Solution	805518287BPHYSF3
473000	Physiological Solution	805518287BPHYSF3
20079	Physiological Solution	805518287TPHYSM9
20095	Physiological Solution	805518287TPHYSM9
20196	Physiological Solution	805518287TPHYSM9
20197	Physiological Solution	805518287TPHYSM9
24142	Physiological Solution	805518287TPHYSM9
26196	Physiological Solution	805518287TPHYSM9
412130	Pseudomonas Agar Base	805518287BPSABDG
24450	Rappaport Broth w/o Soy	805518287RAPBW/OS6T
24400	Rappaport Vassiliadis Soy (RVS) Broth	805518287TRAPVSB2V

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CODE	DESCRIPTION	BASIC UDI-DI
26400	Rappaport Vassiliadis Soy (RVS) Broth	805518287TRAPVSB2V
24461	RPMI Broth	805518287TRPMBLR
442280	Sabouraud Agar Modified	805518287BSABAMDW
30024	Sabouraud CAF + Actidione Agar	805518287TSABCAATE
31024	Sabouraud CAF + Actidione Agar	805518287TSABCAATE
402370	Sabouraud CAF Agar	805518287BSABCADC
412370	Sabouraud CAF Agar	805518287BSABCADC
31023	Sabouraud CAF Agar	805518287TSABCALN
402280	Sabouraud dextrose Agar	805518287BSABDADF
412280	Sabouraud Dextrose Agar	805518287BSABDADF
452280	Sabouraud Dextrose Agar	805518287BSABDADF
470040	Sabouraud Dextrose Agar	805518287BSABDADF
30093	Sabouraud Dextrose Agar	805518287TSABDALR
402040	Sabouraud Dextrose Broth	805518287BSABDBDH
471070	Sabouraud Dextrose Broth	805518287BSABDBDH
24109	Sabouraud Dextrose Broth	805518287TSABDBLT
452040	Sabouraud Dextrose Broth (screw cap)	805518287BSABDBDH
24430	Schaedler Broth	805518287TSCHBJG
402050	Selenite Broth	805518287BSELBCY
412050	Selenite Broth	805518287BSELBCY
463130	Selenite Broth	805518287BSELBCY
470020	Selenite Broth	805518287BSELBCY
24110	Selenite Broth	805518287TSELBK6
24143	Selenite Broth	805518287TSELBK6
26110	Selenite Broth	805518287TSELBK6
403050	SIM Medium	805518287BSIMMED
24479	SIM Medium	805518287TSIMMLK
26095	SIM Medium	805518287TSIMMLK
412030	Simmons Citrate Agar	805518287BSIMCAGT
30011	Simmons Citrate Agar	805518287TSIMCAQ5
401930	SPS Agar	805518287BSPSAFA
442490	SPS Agar	805518287BSPSAFA
33065	SPS Agar	805518287TSPSAMG
402300	SS Agar	805518287BSSAG5
412300	SS Agar	805518287BSSAG5
24412	Streptococcus Broth	805518287TSTREBTK
403140	TCBS Agar	805518287BTCBABV
30022	TCBS Agar	805518287TTCBSK7
24451	Tetrathionate Broth	805518287TTETBL5
33040	Thayer Martin Agar	805518287TTHAMAPB
20171	Thioglycollate Medium w Vit.K1 & Hemin	805518287TTHIMWVK&H3F
412060	Todd Hewitt Broth	805518287BTODHBHL
24111	Todd Hewitt Broth	805518287TTODHBQW
27501	Todd Hewitt Broth	805518287TTODHBQW
24145	Todd Hewitt Broth w/ Colistin/Nalidixic acid	805518287TTODHBWCNAVS
24115	Trichomonas Broth	805518287TTRIBM5
24494	Trichomonas Broth	805518287TTRIBM5
432290	Tryptic Soy Agar	805518287BTRYSANH
442290	Tryptic Soy Agar	805518287BTRYSANH
452290	Tryptic Soy Agar	805518287BTRYSANH
470010	Tryptic Soy Agar	805518287BTRYSANH
30082	Tryptic Soy Agar	805518287TTRYSAB9C
26475	Tryptic Soy Agar	805518287TTRYSAVT
24469	Tryptic Soy Broth	805518287TTRYSBVV
24513	Tryptic Soy Broth	805518287TTRYSBVV
26513	Tryptic Soy Broth	805518287TTRYSBVV
27500	Tryptic Soy Broth	805518287TTRYSBVV

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CODE	DESCRIPTION	BASIC UDI-DI
453030	Tryptic Soy Broth (flip-off cap)	805518287BTRYSBNK
432080	Tryptic Soy Broth (screw cap)	805518287BTRYSBNK
442080	Tryptic Soy Broth (screw cap)	805518287BTRYSBNK
452080	Tryptic Soy Broth (screw cap)	805518287BTRYSBNK
452100	Tryptic Soy Broth (screw cap)	805518287BTRYSBNK
455208	Tryptic Soy Broth (screw cap)	805518287BTRYSBNK
470370	Tryptic Soy Broth (screw cap)	805518287BTRYSBNK
452080S	Tryptic Soy Broth (triple wrapped and gamma-irradiated)	805518287BTRYSBNK
400030	Tryptic Soy Broth EP, USP (flip-off cap)	805518287BTRYSBNK
401980	Tryptone Water	805518287BTRYWHR
24136	Tryptone Water	805518287TTRYWPX
402320	Tryptose Agar	805518287BTRYAGD
30097	Tryptose Agar	805518287TTRYANK
24112	Tryptose Broth	805518287TTRYBNM
455209	Tryptose Phosphate Broth (screw cap)	805518287BTRYPBNA
30096	TSI Agar	805518287TTSIAM8
24416	Urea Broth	805518287TUREBLY
403060	Urea Indole Broth	805518287BUREIBJU
20340	Vagitube	805518287TVAGK8
442300	Wurtz Lactose Agar	805518287BWURLANF
402570	XLD Agar	805518287BXLDAEC
24432	Yersinia Broth	805518287TYERBM2

VTM

CODE	DESCRIPTION	BASIC UDI-DI
26490	VTM	805518287TVTMMD

Dehydrated culture media

CODE	DESCRIPTION	BASIC UDI-DI
610098	Alkaline Peptone Water	805518287610098MX
620098	Alkaline Peptone Water	805518287610098MX
610191	Amies Transport Medium (w/o Charcoal)	805518287610191MN
620191	Amies Transport Medium (w/o Charcoal)	805518287610191MN
610152	Amies Transport Medium + Charchoal	805518287610152MC
620152	Amies Transport Medium + Charchoal	805518287610152MC
6101525	Amies Transport Medium + Charchoal	805518287610152MC
610118	Andrade Lactose Peptone Water	805518287610118MC
610306	Arginine Decarboxylase Broth	805518287610305MD
610153	Azide Blood Agar Base	805518287610153ME
620153	Azide Blood Agar Base	805518287610153ME
610135	Biggy (Nickerson) Agar	805518287610135MC
620135	Biggy (Nickerson) Agar	805518287610135MC
620005	Blood Agar Base	805518287610005LQ
610005	Blood Agar Base	805518287610005LW
6100055	Blood Agar Base	805518287610005LW
610188	Blood Agar Base No.2	805518287610188MZ
620188	Blood Agar Base No.2	805518287610188MZ
6101885	Blood Agar Base No.2	805518287610188MZ
610006	Bordet Gengou Agar Base	805518287610006LY
610007	Brain Heart Infusion Agar	805518287610007M2
620007	Brain Heart Infusion Agar	805518287610007M2
6100075	Brain Heart Infusion Agar	805518287610007M2
610008	Brain Heart Infusion Broth	805518287610008M4
620008	Brain Heart Infusion Broth	805518287610008M4
6100085	Brain Heart Infusion Broth	805518287610008M4
610009	Brilliant Green Agar	805518287610009M6
620009	Brilliant Green Agar	805518287610009M6

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CODE	DESCRIPTION	BASIC UDI-DI
610079	Brucella Agar Base	805518287610079MT
620079	Brucella Agar Base	805518287610079MT
611007	Campylobacter Agar Base	805518287611007M9
621007	Campylobacter Agar Base	805518287611007M9
610130	Campylobacter Blood Free Medium Base	805518287610130M2
610200	Campylobacter Karmali Agar Base	805518287610200LW
620200	Campylobacter Karmali Agar Base	805518287610200LW
611402	Cary Blair Transport Medium	805518287611402MK
621402	Cary Blair Transport Medium	805518287611402MK
610041	Cetrimide Agar	805518287610041M2
620041	Cetrimide Agar	805518287610041M2
6100415	Cetrimide Agar	805518287610041M2
610612	Chromatic Detection	805518287610612MR
620612	Chromatic Detection	805518287610612MR
6106125	Chromatic Detection	805518287610612MR
620614	Chromatic E. coli O157	805518287610614MV
610614	Chromatic E.coli O157	805518287610614MV
611618	Chromatic MH	805518287611618NC
621618	Chromatic MH	805518287611618NC
610611	Chromatic Salmonella	805518287610611MP
620611	Chromatic Salmonella	805518287610611MP
610616	Chromatic Staph aureus	805518287610616MZ
620616	Chromatic Staph aureus	805518287610616MZ
610633	Chromatic Vibrio	805518287610633MZ
610012	CLED Agar	805518287610012LT
620012	CLED Agar	805518287610012LT
6100125	CLED Agar	805518287610012LT
610112	CLED Andrade Agar	805518287610112LY
620112	CLED Andrade Agar	805518287610112LY
610056	Clostridium Broth	805518287610056MF
620056	Clostridium Broth	805518287610056MF
6100565	Clostridium Broth	805518287610056MF
610115	Clostridium difficile Agar Base	805518287610115M6
620115	Clostridium difficile Agar Base	805518287610115M6
610013	Columbia Agar Base	805518287610013LV
620013	Columbia Agar Base	805518287610013LV
6100135	Columbia Agar Base	805518287610013LV
610113	Columbia CNA Agar Base	805518287610113M2
610372	Cooked Meat Medium	805518287610372MU
610123	Corn Meal Agar	805518287610123M5
620123	Corn Meal Agar	805518287610123M5
610095	Czapek Dox Agar	805518287610095MR
620095	Czapek Dox Agar	805518287610095MR
610072	Czapek Dox Broth	805518287610072MD
610160	Dermatophyte (DTM) Agar	805518287610160MB
620160	Dermatophyte (DTM) Agar	805518287610160MB
610015	Desoxycholate Citrate Agar	805518287610015LZ
620015	Desoxycholate Citrate Agar	805518287610015LZ
610002	Dextrose Agar	805518287610002LQ
610161	Dextrose Broth	805518287610161MD
620161	Dextrose Broth	805518287610161MD
610205	DNase Test Agar	805518287610205M8
620205	DNase Test Agar	805518287610205M8
610016	Drigalski Lactose Agar	805518287610016M3
620016	Drigalski Lactose Agar	805518287610016M3
610019	EMB Levine Agar	805518287610019M9
620019	EMB Levine Agar	805518287610019M9

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CODE	DESCRIPTION	BASIC UDI-DI
610022	GC Medium	805518287610022LW
620022	GC Medium	805518287610022LW
610163	GN Hajna Broth	805518287610163MH
610021	Hektoen Enteric Agar	805518287610021LU
620021	Hektoen Enteric Agar	805518287610021LU
6100215	Hektoen Enteric Agar	805518287610021LU
610164	Herellea Agar	805518287610164MK
6101645	Herellea Agar	805518287610164MK
611265	IsoSensitest Agar	805518287611265MZ
621265	IsoSensitest Agar	805518287611265MZ
610023	Kligler Iron Agar	805518287610023LY
620023	Kligler Iron Agar	805518287610023LY
6100235	Kligler Iron Agar	805518287610023LY
610165	Koser Citrate Medium	805518287610165MM
610049	Legionella BCYE Agar Base	805518287610049MJ
620049	Legionella BCYE Agar Base	805518287610049MJ
610125	Legionella CYE Agar Base	805518287610125M9
620125	Legionella CYE Agar Base	805518287610125M9
610168	Listeria Palcam Agar	805518287610168MT
620168	Listeria Palcam Agar	805518287610168MT
610143	Liver Broth	805518287610143MB
610026	Lowenstein Jensen Medium	805518287610026M6
620026	Lowenstein Jensen Medium	805518287610026M6
610027	Lysine Iron Agar	805518287610027M8
620027	Lysine Iron Agar	805518287610027M8
610028	MacConkey Agar	805518287610028MA
620028	MacConkey Agar	805518287610028MA
6100285	MacConkey Agar	805518287610028MA
610057	MacConkey Agar no.2	805518287610057MH
610128	MacConkey Agar w/o Bile Salt	805518287610128MF
610195	MacConkey Agar w/o Crystal Violet	805518287610195MW
620195	MacConkey Agar w/o Crystal Violet	805518287610195MW
610223	MacConkey Agar w/o Salt	805518287610223MA
610170	MacConkey Mug Agar	805518287610170ME
6101705	MacConkey Mug Agar	805518287610170ME
610108	MacConkey Sorbitol Agar	805518287610108M9
620108	MacConkey Sorbitol Agar	805518287610108M9
610172	Malonate Broth	805518287610172MJ
620172	Malonate Broth	805518287610172MJ
610235	Mannitol Motility Test Medium	805518287610235MH
620235	Mannitol Motility Test Medium	805518287610235MH
610029	Mannitol Salt Agar	805518287610029MC
620029	Mannitol Salt Agar	805518287610029MC
6100295	Mannitol Salt Agar	805518287610029MC
611022	Middlebrook 7H10 Agar Base	805518287611022M5
610213	Middlebrook 7H11 Agar Base	805518287610213M7
610214	Middlebrook 7H9 Broth Base	805518287610214M9
611020	Mitis Salivarius Agar	805518287611020LZ
6110205	Mitis Salivarius Agar	805518287611020LZ
610236	Motility Indole Urea Agar (MIU)	805518287610236MK
610627	Mueller Hinton II Agar	805518287610627N6
620627	Mueller Hinton II Agar	805518287610627N6
6106275	Mueller Hinton II Agar	805518287610627N6
610218	Mueller Hinton II Broth	805518287610218MH
620218	Mueller Hinton II Broth	805518287610218MH
610035	Muller Kauffmann Broth	805518287610035M7
620035	Muller Kauffmann Broth	805518287610035M7

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CODE	DESCRIPTION	BASIC UDI-DI
610037	Nutrient Broth	805518287610037MB
620037	Nutrient Broth	805518287610037MB
6100375	Nutrient Broth	805518287610037MB
610305	Ornithine Decarboxylase Broth	805518287610245ML
610308	Phenol Red Agar Base	805518287610306MF
610174	Phenol Red Broth Base	805518287610174MN
620174	Phenol Red Broth Base	805518287610174MN
610039	Phenylalanine Agar	805518287610039MF
620039	Phenylalanine Agar	805518287610039MF
610071	Pseudomonas Agar Base	805518287610071MB
620071	Pseudomonas Agar Base	805518287610071MB
610309	Pseudomonas Agar F	805518287610308MK
620309	Pseudomonas Agar F	805518287610308MK
610310	Pseudomonas Agar P	805518287610309MM
610044	Purple Lactose Agar	805518287610044M8
620044	Purple Lactose Agar	805518287610044M8
610175	Rappaport Vassiliadis Soy (RVS) Broth	805518287610175MQ
620175	Rappaport Vassiliadis Soy (RVS) Broth	805518287610175MQ
610096	Reinforced Clostridial Agar	805518287610096MT
620096	Reinforced Clostridial Agar	805518287610096MT
610176	Rogosa Agar	805518287610176MS
620176	Rogosa Agar	805518287610176MS
610177	Rogosa Broth	805518287610177MU
620177	Rogosa Broth	805518287610177MU
611203	Sabouraud CAF (1 g/L) Agar	805518287611203MB
610625	Sabouraud CAF (50 mg/L) Agar	805518287610625N2
610179	Sabouraud CAF + Actidione Agar	805518287610179MY
620179	Sabouraud CAF + Actidione Agar	805518287610179MY
610203	Sabouraud CAF Agar	805518287610203M4
620203	Sabouraud CAF Agar	805518287610203M4
6102035	Sabouraud CAF Agar	805518287610203M4
610103	Sabouraud Dextrose Agar	805518287610103LX
620103	Sabouraud Dextrose Agar	805518287610103LX
6101035	Sabouraud Dextrose Agar	805518287610103LX
610104	Sabouraud Dextrose Broth	805518287610104LZ
620104	Sabouraud Dextrose Broth	805518287610104LZ
610146	Sabouraud Maltose Agar	805518287610146MH
620146	Sabouraud Maltose Agar	805518287610146MH
610043	Schaedler Agar Base	805518287610043M6
620043	Schaedler Agar Base	805518287610043M6
610137	Schaedler Broth	805518287610137MG
620137	Schaedler Broth	805518287610137MG
610145	Selenite Broth	805518287610145MF
620145	Selenite Broth	805518287610145MF
6101455	Selenite Broth	805518287610145MF
610181	SIM Medium	805518287610181MK
620181	SIM Medium	805518287610181MK
610046	Simmons Citrate Agar	805518287610046MC
620046	Simmons Citrate Agar	805518287610046MC
6100465	Simmons Citrate Agar	805518287610046MC
610148	SPS Agar	805518287610148MM
620148	SPS Agar	805518287610148MM
610042	SS Agar (Modified)	805518287610042M4
620042	SS Agar (Modified)	805518287610042M4
6100425	SS Agar (Modified)	805518287610042M4
611366	Staphylococcus 110 Agar	805518287611366N8
612203	Streptococcus Broth	805518287612203MJ

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CODE	DESCRIPTION	BASIC UDI-DI
610182	Stuart Transport Medium	805518287610182MM
620182	Stuart Transport Medium	805518287610182MM
6101825	Stuart Transport Medium	805518287610182MM
611010	TCBS Agar	805518287611010LW
621010	TCBS Agar	805518287611010LW
610183	Tetrathionate Broth Base	805518287610183MP
620183	Tetrathionate Broth Base	805518287610183MP
610051	Todd Hewitt Broth	805518287610051M5
620051	Todd Hewitt Broth	805518287610051M5
6100515	Todd Hewitt Broth	805518287610051M5
610061	Trichomonas Broth	805518287610061M8
620061	Trichomonas Broth	805518287610061M8
610185	Tryptic (CTA) Medium	805518287610185MT
620185	Tryptic (CTA) Medium	805518287610185MT
610052	Tryptic Soy Agar	805518287610052M7
620052	Tryptic Soy Agar	805518287610052M7
6100525	Tryptic Soy Agar	805518287610052M7
610053	Tryptic Soy Broth	805518287610053M9
620053	Tryptic Soy Broth	805518287610053M9
6100535	Tryptic Soy Broth	805518287610053M9
610206	Tryptone Water	805518287610206MA
620206	Tryptone Water	805518287610206MA
610197	Tryptophan Broth	805518287610197N2
620197	Tryptophan Broth	805518287610197N2
610193	Tryptose Agar	805518287610193MS
620193	Tryptose Agar	805518287610193MS
610233	Tryptose Broth	805518287610233MD
610055	TSI Agar	805518287610055MD
620055	TSI Agar	805518287610055MD
6100555	TSI Agar	805518287610055MD
610107	Urea Agar Base (Christensen)	805518287610107M7
620107	Urea Agar Base (Christensen)	805518287610107M7
6101075	Urea Agar Base (Christensen)	805518287610107M7
610311	Urea Broth	805518287610310M6
620311	Urea Broth	805518287610310M6
610080	Wort Broth w/o NaCl	805518287610080MC
610060	XLD Agar	805518287610060M6
620060	XLD Agar	805518287610060M6
6100605	XLD Agar	805518287610060M6
610092	XLT4 Agar	805518287610092MK
620092	XLT4 Agar	805518287610092MK
610111	Yersinia Selective Agar Base	805518287610111LW
620111	Yersinia Selective Agar Base	805518287610111LW
Supplements		
81013	Bordetella supplement	805518287000008JB
81003	Brucella supplement	805518287000009JD
81051	Campylobacter Blaser Wang supplement	805518287000010HW
81015	Campylobacter Butzler supplement	805518287000011HY
81037	Campylobacter CCDA supplement	805518287000013J4
81038	Campylobacter CTVN supplement	805518287000012J2
81050	Campylobacter Growth supplement	805518287000014J6
81036	Campylobacter Karmali supplement	805518287000015J8
81004	Campylobacter Preston supplement	805518287000016JA
81055	Campylobacter Skirrow supplement	805518287000017JC
81082	Cefixime tellurite supplement	805518287000018JE
81017	Chloramphenicol supplement	805518287000019JG

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CODE	DESCRIPTION	BASIC UDI-DI
81102	Chromatic Salmonella Selective supplement	805518287000024J9
81085	Chromatic Staph aureus supplement	805518287000025JB
81007	Clostridium difficile supplement	805518287000026JD
81006	CN (Pseudomonas supplement)	805518287000087JZ
81048	CNA (Staf/Strep) supplement	805518287000138JR
80060	Decontam-Kit	805518287000076JU
81025	Dermatophyte supplement	805518287000028JH
80124	Egg Yolk Emulsion	805518287000002HX
80219	Egg Yolk Emulsion	805518287000002HX
81040	Gardnerella vaginalis supplement	805518287000029JK
81033	Gentamycin supplement	805518287000030J4
81014	Haemophilus supplement	805518287000031J6
80409	Iodine solution	805518287000003HZ
81009	Iodine solution	805518287000003HZ
81012	LCAT supplement	805518287000032J8
81099	Legionella (AB) supplement	805518287000037JJ
81056	Legionella (BCYE) Growth supplement	805518287000034JC
81091	Legionella (BCYE) Growth supplement w/o L-Cysteine	805518287000033JA
81008	Legionella (GVPC) supplement	805518287000035JE
81019	Legionella (MWY) supplement	805518287000036JG
80056	Legionella Growth supplement	805518287000038JL
81026	Listeria Palcam supplement	805518287000039JN
81035	Middlebrook 7H10 (OADC) supplement	805518287000041J9
81063	Middlebrook 7H9 (ADC) supplement	805518287000042JB
81020	Mug supplement	805518287000043JD
80047	Muller Kauffmann (Iodio/B.G. 0.1%) supplement	805518287000004J3
81032	ONPG 1.5% supplement	805518287000044JF
81093	Pseudomonas PP supplement	805518287000045JH
81054	Schaedler supplement	805518287000046JK
80110	Urea 40 % supplement	805518287000005J5
80292	Urea 40 % supplement	805518287000005J5
81041	VCAT supplement	805518287000047JM
81022	VCN supplement	805518287000048JP
81024	VCNT supplement	805518287000049JR
81023	Vitalex Growth supplement	805518287000052JE
80053	Vitamin K 1% supplement	805518287000006J7
80453	Vitamin K 1% supplement	805518287000006J7
80010	XLT4 supplement	805518287000007J9
80410	XLT4 supplement	805518287000007J9
81039	Yersinia supplement	805518287000053JG
Sugar Fermentation		
CODE	**DESCRIPTION**	**BASIC UDI-DI**
88208	Adonitol Test	805518287000061JF
88209	Arabinose Test	805518287000061JF
88207	Arabitol Test	805518287000061JF
88210	Dulcitol Test	805518287000061JF
88201	Galactose Test	805518287000061JF
88202	Glucose Test	805518287000061JF
88211	Inositol Test	805518287000061JF
88212	Inulin Test	805518287000061JF
88203	Lactose Test	805518287000061JF
88213	Levulose Test	805518287000061JF
88204	Maltose Test	805518287000061JF
88214	Mannitol Test	805518287000061JF
88215	Mannose Test	805518287000061JF
88205	Raffinose Test	805518287000061JF

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CODE	DESCRIPTION	BASIC UDI-DI
88216	Rhamnose Test	805518287000061JF
88217	Salicin Test	805518287000061JF
88218	Sorbitol Test	805518287000061JF
88206	Sucrose Test	805518287000061JF
88219	Trehalose Test	805518287000061JF
88220	Xylose Test	805518287000061JF
Test for Microbial ID		
CODE	**DESCRIPTION**	**BASIC UDI-DI**
88008	Aesculin Bile Test	805518287000062JH
80350	Antibiotic Test	805518287000063JK
88016	Arginine Decarboxylase Test	805518287000066JR
9502	Bacitracin Test	805518287000142JG
88033	Beta Lactamase Test	805518287000067JT
88040	C 390	805518287000068JV
88027	Camp Test-R	805518287000069JX
88021	Camp Test-S	805518287000070JG
88023	Catalase/Oxy Test	805518287000071JJ
88042	Citrate Test	805518287000072JL
88030	Coagulase Test	805518287000073JN
80299	Crystal Violet Solution	805518287000074JQ
80295	Decolourizing Solution	805518287000075JS
88006	E.coli Test	805518287000078JY
80293	Gram Color Kit	805518287000082JP
87101	Gram Color Kit Droppers	805518287000082JP
88031	Gram Test Stick	805518287000083JR
80057	H_2O_2 / Catalase Reagent	805518287000084JT
87003	H_2O_2 / Catalase Reagent Droppers	805518287000084JT
88013	H_2S Rapid Test	805518287000085JV
88007	Hippurate Test	805518287000086JX
88017	Indole Test	805518287000088K3
88032	Indole Test Stick	805518287000089K5
80380	Kinyoun Color Kit	805518287000092JS
80294	Kit Color Albert	805518287000093JU
80282	Kit May Grunwald Giemsa	805518287000094JW
80271	Kovac's Reagent	805518287000095JY
87001	Kovac's Reagent Droppers	805518287000095JY
87008	Lactophenol Cotton Blue Droppers	805518287000096K2
88010	Listeria Mono Test	805518287000099K8
80296	Lugol PVP Solution	805518287000100HY
80298	Lugol PVP Solution	805518287000100HY
88014	Lysine Decarboxylase Test	805518287000101J2
87009	Methyl Red Droppers	805518287000105JA
80277	Methylene Blue Solution	805518287000106JC
9508	Metronidazole Test	805518287000146JQ
80275	MIF Color Kit	805518287000107JE
80273	Ninhydrin 7% Reagent	805518287000108JG
88009	Nitrate Test	805518287000109JJ
88044	O129 Disc 10 ug	805518287000112J7
88043	O129 Disc 150 ug	805518287000112J7
88005	ONPG Test	805518287000110J3
88105	ONPG Test	805518287000110J3
9501	Optochine Test	805518287000141JE
88015	Ornhitine Decaraboxylase Test	805518287000113J9
88004	Oxidase Test Disc	805518287000114JB
88029	Oxidase Test Stick	805518287000115JD
88029N	Oxidase Test Stick	805518287000116JF

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CODE	DESCRIPTION	BASIC UDI-DI
88003	Oxidase Test Swab	805518287000117JH
88034	Peptidase A Stick	805518287000118JK
88028	Peptidase A Test	805518287000119JM
80272	Phenylalanine Reagent	805518287000079K2
87004	Phenylalanine Reagent Droppers	805518287000079K2
88020	S F Rapid Test	805518287000123JC
80290	Safranin Solution	805518287000124JE
9511	Sulphonamide Test	805518287000147JS
81079	Urea-arginine screen	805518287000131JB
88011	Urea Rapid Test	805518287000130J9
88024	Urea/Indole Test	805518287000129JQ
9504	V Factor Test	805518287000144JL
9505	V+X Factor Test	805518287000145JN
80279	Vaseline Oil	805518287000001HV
87006	Vaseline Oil Droppers	805518287000001HV
80281	VP (KOH) Reagent	805518287000132JD
87007	VP (KOH) Reagent Droppers	805518287000132JD
80280	VP (NaOH) Reagent	805518287000133JF
87002	VP (NaOH) Reagent Droppers	805518287000133JF
9503	X Factor Test	805518287000143JJ
80276	Ziehl-Neelsen Color Kit	805518287000137JP
Instruments		
CODE	**DESCRIPTION**	**BASIC UDI-DI**
91203	Disc Dispenser 6 cartridges	805518287000140JC
91200	Disc Dispenser 8 cartridges	805518287000139JT
96899	Giotto 2	805518287000020HZ

Campylobacter Blood Free Medium Base

Selective medium for detection of *Campylobacter* spp from clinical specimens and other materials, according to ISO 10272.

TYPICAL FORMULA	(g/l)
Meat Extract	10.0
Enzymatic Digest of Animal Tissues	10.0
Sodium Chloride	5.0
Charcoal	4.0
Enzymatic Digest of Casein	3.0
Sodium Deoxycholate	1.0
Iron(II) Sulfate	0.25
Sodium Pyruvate	0.25
Agar	12.0
Final pH 7.4 ± 0.2 at 25°C	

DESCRIPTION

Campylobacter Blood Free Medium Base is a selective medium used with supplements for the isolation and enumeration of *Campylobacter* spp from food, environmental samples and clinical specimens.

The complete medium, also known as modified charcoal cefoperazone deoxycholate agar (mCCDA), is formulated according to the APHA and ISO 10272 and was developed to replace blood with charcoal, ferrous sulfate and sodium pyruvate.

PRINCIPLE

Meat extract, enzymatic digest of animal tissues and enzymatic digest of casein provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients for organisms growth. Sodium chloride maintains the osmotic balance of the medium. Charcoal absorbs toxic compounds and metabolites. Sodium deoxycholate inhibits most Gram-positive bacteria. Ferrous sulfate and sodium pyruvate are oxygen scavengers. Agar is the solidifying agent.

Supplementation with Campylobacter CCDA Supplement (ref. 81037), containing Cefoperazone and Amphotericin B, inhibits the accompanying microbial flora.

PREPARATION

Suspend 45.5 g of powder in 1 liter of deionized or distilled water. Bring to boil and shake until completely dissolved. Sterilize at 121°C for 15 minutes. Cool up to 45-50°C. Aseptically, add rehydrated content of 2 vials (10 ml) of Campylobacter CCDA Supplement. Mix well. Pour in Petri dishes.

TECHNIQUE

Inoculate the plates by directly spreading the sample material over the agar surface (*). Incubate at 41.5°C for 40-48 hours in a microaerobic atmosphere (approximately 5-6% oxygen, 3-10% CO_2 and 84-85% nitrogen).

* ISO 10272 recommends to perform a first enrichment step in Bolton Broth (ref. 470340) prior to inoculate the mCCDA.

INTERPRETATION OF RESULTS

Examine the plates for typical colonies of *Campylobacter* spp which appear greyish, flat and moist, often with a metallic sheen and a tendency to spread. Other form of colonies may occur.

For confirmation of *Campylobacter* spp, subculture suspected colonies to Columbia Blood Agar plates (ref. 11025) and examine pure cultures for morphology, motility, microaerobic growth at 25°C, aerobic growth at 41.5°C and oxidase activity.

STORAGE AND TRANSPORT CONDITIONS

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed and use it before the expiry date on the label or until signs of deterioration or contamination are evident. Store prepared plates at 2-8°C away from light.

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. it is nevertheless recommended to consult the safety data sheet for its correct use. The product is designed for *in vitro* diagnostic use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

- EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
- ISO 10272-1:2006. Microbiology of food and animal feeding stuffs – Horizontal method for detection and enumeration of Campylobacter spp. – Part 1: Detection method. – Part 2: Colony-count technique.
- MAFF Validated Methods for the Analysis of Foodstuffs (1993) Method for the detection of thermotolerant Campylobacter in Foods. J. Assoc. Publ. Analysts. 29: 253-262.
- Vandersant C et al. (1992) Compendium of Methods for Microbiological Examination of Food. 3rd Edition. American Public Health Association. Washington D.C.
- Bolton F.J., D.N. Hutchinson and D. Coates (1984) J. Clin. Microbiol. 19: 169-171.

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CE IVD

PRODUCT SPECIFICATIONS

NAME
Campylobacter Blood Free Medium Base

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

Ref.	Content	Packaging
610130	500 g	500 g of powder in plastic bottle
620130	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
7.4 ± 0.2

USE
Campylobacter Blood Free Medium Base is a selective medium used with supplements for the isolation and enumeration of *Campylobacter* spp from food, environmental samples and clinical specimens, according to ISO 10272

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Powder medium
Appearance: free-flowing, homogeneous
Colour: grey-black
Ready-to-use medium
Appearance: opaque
Colour: black

SHELFLIFE
4 years

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Microbiological control
   Inoculum for productivity: 50-100 CFU
   Inoculum for selectivity: 10^4-10^6 CFU
   Incubation Conditions: 40-48 h at 41.5 ± 1°C, in microaerobic atmosphere

Microorganism		Growth
Campylobacter jejuni	WDCM 00156	Good
Campylobacter jejuni	WDCM 00005	Good
Escherichia coli	WDCM 00013	Inhibited
Staphylococcus aureus	WDCM 00034	Inhibited

TABLE OF SYMBOLS

LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult instructions for use	Do not reuse

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CE IVD

ENGLISH

CAMPYLOBACTER CCDA *Supplement*

Selective supplement for the enrichment of CAMPYLOBACTER BLOOD FREE MEDIUM BASE medium for the isolation of *Campylobacter jejuni, C. coli* and *C. laridis.*

DESCRIPTION

CAMPYLOBACTER CCDA *Supplement* is a selective supplement for the isolation of *Campylobacter jejuni, C. coli* and *C. laridis*, made of a freeze-dried mixture of Cefoperazone and Amfophericin B. CAMPYLOBACTER CCDA *Supplement* is used for the selective enrichment of CAMPYLOBACTER BLOOD FREE MEDIUM BASE medium code 610130 r 620130.

KIT CONTENTS

Each kit contains:

- 10 bottles of freeze-dried CAMPYLOBACTER CCDA SUPPLEMENT
- 1 instruction sheet

PRINCIPLE OF THE METHOD

CAMPYLOBACTER CCDA *Supplement* is based on the original formulation described by Bolton and others; an increase of selectivity was obtained by the substitution of Cefazolin with Cefoperazone from the original formulation. Amphotericin B is active against micetes. More recent studies demonstrated that a higher percentage of isolation of *Campylobacter* is obtainable by the incubation of plates at 37 °C rather than at 42 °C.

COMPOSITION

CAMPYLOBACTER CCDA *Supplement*		
	Content / bottle	*Content / l of medium*
Cefoperazone	16.0 mg	32.0 mg
Amphotericin B	5.0 mg	10.0 mg

TEST PROCEDURE

1. Reconstitute aseptically the content of one bottle of CAMPYLOBACTER CCDA *Supplement* with 5 ml of sterile distilled water. Shake until completely dissolved, avoiding foam formation.
2. Add aseptically the entiroe content of one bottle (5 ml) to 500 ml of the medium CAMPYLOBACTER BLOOD FREE MEDIUM BASE 610130 or 620130 autoclaved and cooled at 45-50 °C.
3. Mix with care.
4. Distribute into Petri dishes.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation for CAMPYLOBACTER BLOOD FREE MEDIUM BASE 610130 or 620130.

QUALITY CONTROL

1. Control of the appearance: freeze-dried product, light yellow colour.
2. Microbiological control.

Prepare plates using as base the medium CAMPYLOBACTER BLOOD FREE MEDIUM BASE 610130 or 620130 enriched with Campylobacter CCDA supplement (1 bottle in 500 ml of medium).
Plates are inoculated with the strains indicated in the microbiological control table.
Incubation conditions: 48 h at 36 ± 1 °C, in atmosphere of microaerophilia for Campylobacter.
Microbiological control:

	Control strains	**Growth**
Campylobacter jejuni	ATCC 33291	Good
Candida albicans	ATCC 10231	Inhibited
Staphylococcus aureus	ATCC 25923	Inhibited

PRECAUTIONS

The product CAMPYLOBACTER CCDA *Supplement* is classifiable as hazardous under current legislation; it is recommended that the Safety Data Sheet be consulted on its use. CAMPYLOBACTER CCDA *Supplement* is a selective supplement to be used only for *in vitro* diagnostic use. It is intended for use in a professional environment and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

STORAGE

Store CAMPYLOBACTER Skirrow *Supplement* at 2-8 °C in its original packaging. In such conditions CAMPYLOBACTER Skirrow *Supplement* will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

REFERENCES

- Bolton, F.J., Hutchinson, D.N. and Coates, D. (1984) J. Clin. Microbiol. **19**: 169-171.
- Hutchinson, D.N., and Bolton, F.J. (1984). J. Clin. Path. 34: 956-957.
- Bolton, F.J., Hutchinson, D.N. and Parker G. (1988). Eur. J. Clin. Microbiol. Infect. Dis. 7: 155-160.
- MAFF Validated methods for the analysis of foodstuffs: method for the detection of thermotolerant Campylobacter in foods (v30) j. Assoc. Publ. Analysts (1993) **29**: 253-262.
- Association of Official Analytical Chemists. 1995. Bacteriological analytical manual, 8th Ed.

PRESENTATION

Product	REF	Σ
CAMPYLOBACTER CCDA *Supplement*	**81037**	10 bottles

One bottle is sufficient to prepare 500 ml of medium.

TABLE OF SYMBOLS

IVD *In Vitro* Diagnostic Medical Device	Do not reuse	Manufacturer	Contains sufficient for <n> tests	Temperature limitation
REF Catalogue number	Fragile, handle with care	Use by	Caution, consult accompanying documents	LOT Batch code

LIOFILCHEM Bacteriology Products
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CE IVD

Rev.0 / 06.04.2005

COLUMBIA AGAR BASE

Medium for fastidious microorganisms isolation from clinical samples.

TYPICAL FORMULA	(g/l)
Peptospecial	23.0
Starch	1.0
Sodium Chloride	5.0
Agar	14.0

Final pH = 7.3 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 43.0 g of powder in 1 liter of distilled or deionized water. Heat to boiling until completely dissolved. Sterilize in autoclave at 121 °C for 15 minutes. Cool to 45-50 °C and aseptically add 5% defibrinated sterile sheep blood. Mix well. Dispense in petri dishes.
Columbia Agar Base can be also enriched in various way:
· with 2 vials of CNA (Staf / Strep) supplement (colistin sulphate 5 mg/vial, nalidixic acid 8 mg/vial, code 81048), each one reconstituted with 5 ml of sterile distilled water; final medium will contain colistin sulphate 10 mg/l and nalidixic acid 16 mg/l.
· with 2 vials of *Gardnerella vaginalis* supplement (gentamicin 3 mg/vial, amphotericin B 1mg/vial, nalidixic acid 15 mg/vial, code 81040), each one reconstituted with 5 ml of a 1:1 solution of ethyl alcohol and sterile distilled water; final medium will contain gentamicin 6 mg/l, amphotericin B 2 mg/l and nalidixic acid 30 mg/l.

DESCRIPTION

COLUMBIA AGAR BASE, enriched with sterile sheep blood (5%), is suitable for isolation and growth of fastidious microorganisms such as streptococci, staphylococci, pneumococci and listeriae from clinical samples.

TECHNIQUE

Inoculate the medium with the specimen streaking by a sterile loop and incubate at 36 ± 1 °C for 18-48 hours aerobically, anaerobically or under conditions of increased CO_2 (5-10%), in accordance with established laboratory procedures.
Examine plates for growth and hemolytic reactions. Four types of hemolysis on blood agar media can be described:
1. α-hemolysis is the reduction of hemoglobin to methemoglobin in the medium surrounding the colony, causing a greenish discolorization of the medium.
2. β-hemolysis is the lysis of red blood cells, producing a clear zone surrounding the colony.
3. γ-hemolysis indicates no destruction of red blood cells and no change in the color of the medium.
4. ά-hemolysis indicates a partial lysis.

QUALITY CONTROL

Dehydrated medium
Appearance: free-flowing, homogeneous.
Color: beige.
Prepared medium
Appearance: opaque.
Color: cherry red.
Incubation conditions: 36 ± 1°C for 18-48 hours at 5-10% CO_2.

Microorganism	ATCC	Growth	Characteristics
Streptococcus pyogenes	19615	good	β-hemolysis
Streptococcus pneumoniae	6303	good	α -hemolysis
Staphylococcus aureus	25923	good	β-hemolysis
Gardnerella vaginalis	14018	good	β-hemolysis

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CE IVD

PERFORMANCE AND LIMITATIONS

When this medium is enriched with 10% sterile sheep blood, heated at 80 °C for 10 minutes until a chocolate color is obtained, and an antibiotic mixture is added (vancomycin, colimycin, trimethoprim, amphoterycin B) it is suitable for the selective isolation of the pathogens neisseria. If used without the addition of blood, the medium is suitable for growing of *Brucella abortus, Yersinia pestis, Clostridium perfrigens and enterobacteria.* Hemolytic reactions of some strains of Group D streptococci have been shown to be affected by differences in animal blood. Such strains are beta –hemolytic on horse and rabbit blood agar and alpha-hemolytic on sheep blood agar.

STORAGE

The powder is very hygroscopic: store the powder at 10-30 °C, in a dry environment, in its original container tightly closed and use it before the expiry date on the label or until signs of deterioration or contamination are evident.
Store prepared plates at 2-8 °C.

REFERENCES

1. Ellner, P.D., C.J. Stoessel., E. Drakeford, and F. Vasi (1966). A new culture medium for medical bacteriology. Am. J.Clin. Path. **45**, 502-504.
2. Isenberg, H.D. (ed.) (1992). Clinical microbiology procedures handbook, vol. 1 American Society for Microbiolgy, Washington, DC.

PRESENTATION

Product	REF	Σ
COLUMBIA AGAR BASE (11.6 l)	610013	500 g
COLUMBIA AGAR BASE (2.3 l)	620013	100 g
COLUMBIA AGAR BASE (116.2 l)	6100135	5 Kg
SHEEP BLOOD DEFIBRINATED	83296	50 ml
CNA (Staf / Strep) supplement	81048	10 vials
Gardnerella vaginalis supplement	81040	10 vials

TABLE OF SYMBOLS

LOT Batch code	Caution, consult accompanying documents	Manufacturer	Contains sufficient for <n> tests	IVD *In Vitro* Diagnostic Medical Device
REF Catalogue number	Fragile, handle with care	Use by	Temperature limitation	Keep away from heat source

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CE IVD

Instructions For Use
ENGLISH

Tryptone Soy Yeast Extract Agar

Medium for detection and enumeration of *Listeria monocytogenes* and *Listeria* spp, according to ISO 11290 Part 1 and Part 2.

DESCRIPTION

Tryptone Soy Yeast Extract Agar (TSYEA) is a medium used for confirmation of *L. monocytogenes* or *Listeria* spp in the food chain.

This medium complies with the recommendations of ISO 11290-1 and ISO 11290-2.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Casein	17.0
Papaic Digest of Soyabean Meal	3.0
Yeast Extract	6.0
Sodium Chloride	5.0
Dipotassium Hydrogen Phosphate	2.5
Glucose	2.5
Agar	13.0
Final pH 7.3 ± 0.2 at 25°C	

METHOD PRINCIPLE

Enzymatic digest of casein and papaic digest of soyabean meal provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Sodium chloride maintains the osmotic balance of the medium. Dipotassium phosphate is the buffering agent. Glucose is the fermentable carbohydrate. Agar is the solidifying agent.

PREPARATION

Dehydrated medium	Suspend 49 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 min.
Medium in bottles	Melt the content of the bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Inoculate the plates by streaking suspect colonies from selective agars, i.e. O.A. Listeria Agar (ref. 10620), Listeria Palcam Agar (ref. 10041), trying to achieve well isolated colonies. Incubate at 37°C for 18-24 hours under aerobic atmosphere.

INTERPRETING RESULTS

Typical colonies of *Listeria* spp on TSYEA are 1-2 mm in diameter, convex, colorless and opaque with an entire edge. Colonies display a bluish color and a granular surface under obliquely transmitted light.

Confirmation tests should be performed. Refer to appropriate references for specific procedures.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, beige.
Prepared medium: slightly opalescent, amber.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles: 2 years.
90 mm ready-to-use plates: 6 months.

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: ≤100 CFU.
Incubation conditions: 18-24 h at 37 ± 1°C.

QC Table.

Microorganism		Specification
Listeria monocytogenes 4b	WDCM 00021	Weak to good growth
Listeria monocytogenes 1/2a	WDCM 00109	Weak to good growth

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. ISO 11290-1:2017.Microbiology of the food chain – Horizontal method for the detection and enumeration of *Listeria monocytogenes* and *Listeria* spp. – Part 1: Detection Method.
2. ISO 11290-2:2017.Microbiology of the food chain – Horizontal method for the detection and enumeration of *Listeria monocytogenes* and *Listeria* spp. – Part 2: Enumeration Method.
3. EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.

PRESENTATION	Category	Packaging	Ref.
Tryptone Soy Yeast Extract Agar	90 mm agar plates	20 plates	10432
Tryptone Soy Yeast Extract Agar	Tubes - Bottles	6 x 200 ml bottles	412440
Tryptone Soy Yeast Extract Agar	Dehydrated culture media	500 g of powder	610349
Tryptone Soy Yeast Extract Agar	Dehydrated culture media	100 g of powder	620349

TABLE OF SYMBOLS

LOT Batch code	Keep away from sunlight	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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Tryptic Soy Agar

General purpose medium for the cultivation of a wide variety of organisms from clinical and nonclinical specimens, according to EN ISO 11133.

DESCRIPTION

Tryptic Soy Agar (TSA) is a non selective isolation medium used for the growth of bacteria which do not have specific nutritional requirements and for the preparation of reference strains with the aim of growth promotion tests of culture media.

This medium complies with EN ISO 11133 for microbiological examination of food, animal feed and water, where it is described as the main reference medium to carry out quantitative and qualitative testing of specific culture media.

Tryptic Soy Agar is also recommended in the harmonized chapters of the United States (USP), European (EP) and Japanese Pharmacopoeia (JP). For the usage in Pharmaceutical Industry, Liofilchem offers products having the same composition as TSA described in the ISO standard, but which are specifically controlled according to the Pharmacopoeial performance requirements. **See the IFU available for the product ref. number 10037S**.

TYPICAL FORMULA	(g/l)
Casein Peptone	15.0
Soy Peptone	5.0
Sodium Chloride	5.0
Agar	15.0

Final pH 7.3 ± 0.2 at 25°C

METHOD PRINCIPLE

Casein peptone and soy peptone provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Sodium chloride maintains osmotic balance in the medium. Agar is the solidifying agent.

The medium can be supplemented with blood for the growth of fastidious organisms and study of haemolytic reactions.

PREPARATION

Dehydrated medium	Suspend 40 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes. If desired, add appropriate volume of sterile defibrinated blood for preparing 5 to 10% blood agar.
Medium in tubes/ bottles	Melt the content of the tube/bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the tube/bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Perform serial dilutions of the test sample in order to achieve a colony count of between 15 and 300 colonies per plate. Use a suitable diluent such as Buffered Peptone Water (ref. 24099) or Maximum Recovery Broth (ref. 20071).

Inoculate the medium by pour plating, spread/streak method or membrane filtration.

Incubation conditions may vary depending on the organisms under study. For a general aerobic count, incubate aerobically at 30°C for 72 hours.

For use as standard medium, refer to EN ISO 11133 for specific instructions.

INTERPRETING RESULTS

Observe colony growth.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.
Prepared medium: slightly opalescent, light amber.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles, tubes and prepared plates at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in tubes/bottles: 2 years.
Medium in slant tubes: 1 year.
Ready-to-use plates: 6 months.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU.
Incubation conditions: set according to EN ISO 11133 and shown on the quality control certificate that is available for each lot on liofilchem's website.

QC Table.

Microorganism		Growth
Listeria monocytogenes 4b	WDCM 00021	Good
Staphylococcus aureus	WDCM 00034	Good
Clostridium perfringens	WDCM 00007	Good
Bacillus cereus	WDCM 00001	Good
Escherichia coli	WDCM 00012	Good
Bacillus subtilis	WDCM 00003	Good
Pseudomonas aeruginosa	WDCM 00024	Good
Enterococcus faecalis	WDCM 00087	Good

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. EN ISO 11133:2014+Amd1:2018. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. United States Pharmacopoeia 41 NF 33 (2018) <61> Microbiological examination of non-sterile products: Microbial enumeration tests; <1116> Microbiological control and monitoring of aseptic processing environments.
3. European Pharmacopoeia 9.0 (2016) 2.6.12. Microbiological examination of non-sterile products: Microbial enumeration tests.
4. Japanese Pharmacopoeia 16th ed. (2011): 4.05 Microbial limit test.
5. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.
6. Vanderzant C. and D.F. Splittstoesser (1992) Compendium of methods for the microbiological examination of foods, 3rd ed. American Public Health Association, Washington D.C.
7. Greenberg A.E, L.S. Clesceri and A.D. Eaton (1995) Standards methods for the examination of water and wastewater, 19th ed. American Public Health Association, Washington D.C.

PRESENTATION	Format	Packaging	Ref.
Tryptic Soy Agar	90 mm Plate	20 plates	10037
Tryptic Soy Agar	90 mm Plate	100 plates	10037*
Tryptic Soy Agar	60 mm Plate (membrane placement)	20 plates	163682 ◆
Tryptic Soy Agar	Slant tubes	10 x 9 ml tubes	30082
Tryptic Soy Agar	Slant tubes	20 x 9 ml tubes	31082
Tryptic Soy Agar	Tubes	100 x 20 ml tubes	26475
Tryptic Soy Agar	Bottles	6 x 500 ml bottles	470010
Tryptic Soy Agar	Bottles	6 x 225 ml bottles	414110 ◆
Tryptic Soy Agar	Bottles	6 x 200 ml bottles	432290
Tryptic Soy Agar	Bottles	25 x 200 ml bottles	452290
Tryptic Soy Agar	Bottles	6 x 100 ml bottles	442290
Tryptic Soy Agar	Dehydrated media	500 g of powder	610052
Tryptic Soy Agar	Dehydrated media	100 g of powder	620052
Tryptic Soy Agar	Dehydrated media	5 kg of powder	6100525

◆, not CE marked

TABLE OF SYMBOLS

LOT Batch code	**IVD** *In vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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CE IVD

Instructions For Use
ENGLISH

Maximum Recovery Diluent

Diluent for preparation of food samples for microbiological examination, according to ISO 6887.

DESCRIPTION

Maximum Recovery Diluent is a protective and isotonic diluent used to maximize the recovery of microorganisms in the preparation of the initial suspension and decimal dilutions of test samples.

This diluent is also known as Peptone Salt Solution and complies with the recommendations of ISO 6887 for the microbiological examination of food.

TYPICAL FORMULA (per liter of purified water)

Enzymatic Digest of Casein	1.0 g
Sodium Chloride	8.5 g

Final pH 7.0 ± 0.2 at 25°C

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon and minerals. Sodium chloride maintains the osmotic balance of the medium.

PREPARATION

Dehydrated medium: Suspend 9.5 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

TEST PROCEDURE

Use this diluent according to specific procedures for microbiological examination of food samples.

For ISO method, put 10 g or 10 ml of the test sample into a sterile vessel or sterile plastic bag. Add 90 ml of Maximum Recovery Diluent and homogenize with a blender or Stomacher.
Transfer 1 ml of the macerate, within 15 minutes, to 9 ml of sterile diluent and mix well. The number of further decimal dilutions depends on the expected contamination of the sample.

INTERPRETING RESULTS

Due to the isotonic propriety of the diluent, several organisms, even stressed or injured cells are allowed to recover and maintain their viability for 1-2 h without multiplication.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, beige.
Prepared medium: clear, light amber.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store tubes, bottles and bags at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in tubes, bottles or bags: 2 years.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for use as diluent: 10^3-10^4 CFU.
Incubation conditions: 18-27°C for 45-60 minutes.

QC Table.

Microorganism		Growth on Tryptic Soy Agar
Escherichia coli	WDCM 00012	± 30% colonies of original count
Staphylococcus aureus	WDCM 00034	± 30% colonies of original count

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. ISO 6887-3:2017+Amd1:2020. Microbiology of food the food chain s – Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 3: Specific rules for the preparation of fish and fishery products.
2. EN ISO 11133:2014+Amd1:2018. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
3. ISO 6887-4:2017. Microbiology of food the food chain – Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 4: Specific rules for the preparation of products other than milk and milk products, meat and meat products, and fish and fishery products.
4. ISO 6887-2:2017. Microbiology of food the food chain – Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 2: Specific rules for the preparation of meat and meat products.
5. ISO 6887-1:2017. Microbiology of food the food chain – Preparation of test samples, initial suspension and decimal dilutions for microbiological examination – Part 1: General rules for the preparation of the initial suspension and decimal dilutions.
6. Vanderzant, C., and D. F. Splittstoesser (eds.). Compendium of methods for the microbiological examination of foods, 3rd ed. American Public Health Association, Washington, D.C.
7. U.S. Food and Drug Administration. Bacteriological analytical manual, 8th ed., AOAC International, Gaithersburg, MD.

PRESENTATION	Format	Package	Ref.
Maximum Recovery Diluent	Tubes	20 x 9 ml tubes	20071
Maximum Recovery Diluent	Tubes	100 x 9 ml tubes	26071
Maximum Recovery Diluent	Bottles	6 x 90 ml bottles	402660
Maximum Recovery Diluent	Bottles	6 x 100 ml bottles	402590
Maximum Recovery Diluent	Bottles	6 x 200 ml bottles	412400
Maximum Recovery Diluent	Bottles	6 x 225 ml bottles	412420
Maximum Recovery Diluent	Bottles	25 x 225 ml bottles	452420
Maximum Recovery Diluent	Bags	3 x 3 liters bags	499040
Maximum Recovery Diluent	Bags	3 x 5 liters bags	499045
Maximum Recovery Diluent	Dehydrated medium	500 g of powder	610077
Maximum Recovery Diluent	Dehydrated medium	100 g of powder	620077

TABLE OF SYMBOLS

LOT Batch code	Keep away from sunlight	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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Instructions For Use
ENGLISH

Oxidase Test Stick

Rapid test for detection of cytochrome oxidase enzymatic activity.

DESCRIPTION

Oxidase Test Stick is a diagnostic test used for differentiation and microbial identification, particularly of Gram-negative bacteria, on the basis of the presence of enzyme cytochrome oxidase.

The product matches with recommendations of EN ISO 16266 and ISO 9308-1 for detection of *Pseudomonas aeruginosa* and for confirmation of *Escherichia coli* and coliform bacteria, respectively.

CONTENTS OF THE PACKAGES

Each package contains 50 Oxidase Test Stick.

METHOD PRINCIPLE

Oxidase-positive bacteria produces the enzyme cytochrome oxidase (indophenol oxidase) that catalyzes the transport of electrons from donor compounds (NADH) to electron acceptors (usually oxygen).

Tetramethyl-p-phenylenediamine dihydrochloride contained in Oxidase Test Stick acts as an artificial electron donor and is oxidized by oxidase-positive bacteria forming the coloured compound indophenol blue.

COMPOSITION

Oxidase Test Stick is made of a special paper with a zone impregnated with a solution of N,N,N´,N´-tetramethyl-p-phenylenediamine dihydrochloride.

TEST PROCEDURE

1. Allow container to come to room temperature before opening, for minimizing condensation on the stick.
2. Pick up one or more than one well isolated colony and wipe off by the zone of the stick indicated by arrows. Alternatively, transfer a drop of the suspension of the test organism to the reaction zone of the stick or dip directly the point of the stick into the microbial suspension.
3. Examine for an immediate color change (within 60 seconds) at the position of the inoculated area (NB. The usage of very dilute microbial suspensions may result in longer reactions time)

INTERPRETING RESULTS

The development of a blue-purple color indicates a positive reaction. No color change corresponds to a negative test, i.e. the organism under investigation does not produce the enzyme cytochrome oxidase.

LIMITATIONS

The most suitable cultures for the oxidase test are those from culture media without dyes, indicators or inhibitors. Bacterial colonies taken from media with pH values below 5.5 (e.g. after the metabolism of carbohydrates with subsequent acidification of the culture medium) can give a false negative oxidase reaction. Colonies taken from media containing nitrate may give unreliable results. Do not use steel, nichrome or iron containing loops to pick the colony. A platinum or plastic loop, or wooden applicator stick is recommended.

STORAGE

Store at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

2 years.

QUALITY CONTROL

Control strains are indicated in the QC table.

QC Table.

Microorganism		Oxidase reaction
Escherichia coli	WDCM 00013	Negative, no color change
Pseudomonas aeruginosa	WDCM 00025	Positive, deep blue-purple coloration

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for *in vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

- ISO 9308-1:2014. Water quality – Enumeration of *Escherichia coli* and coliform bacteria – Part 1: Membrane filtration method for waters with low bacterial background flora.
- EN ISO 16266:2008. Water quality – Detection and Enumeration of *Pseudomonas aeruginosa* – Method by membrane filtration (ISO 16266:2006).
- Steel K. J. (1962) J. Appl. Bact. 25:445-447.

PRESENTATION	Contents	Ref.
Oxidase Test Stick	50 sticks	88029

TABLE OF SYMBOLS

LOT Batch code	**IVD** *In vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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CE IVD

Instructions For Use
ENGLISH

Plate Count Agar

Medium for the enumeration of bacteria in food, water and other materials, according to APHA and ISO 4833.

DESCRIPTION

Plate Count Agar is a medium used for the determination of the total microbial content from food and animal feed, water and other materials.

This medium, also known as Tryptone Glucose Yeast Agar or Casein-Peptone Dextrose Yeast Agar, complies with the specifications given by the American Public Health Association and ISO 4833.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Casein	5.0
Yeast Extract	2.5
Glucose	1.0
Agar	15.0

Final pH 7.0 ± 0.2 at 25°C

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Glucose is the fermentable carbohydrate. Agar is the solidifying agent.

PREPARATION

Dehydrated medium	Suspend 23.5 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes. Note: ISO 4833 recommends to add 1.0 g of skimmed milk powder per liter of medium when dairy products are examined.
Medium in tubes/bottles	Melt the content of the tube/bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the tube/bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

1. Perform serial dilutions of the test sample in order to achieve a colony count of between 15 and 300 colonies per plate. Use a suitable diluent such as Buffered Peptone Water (ref. 24099) or Maximum Recovery Broth (ref. 20071).
2. Inoculate the medium by pour plating, spread plating or membrane filtration method.
3. Incubation conditions may vary depending on the organisms under study. For a general aerobic count, incubate aerobically at 30°C for 72 hours.

INTERPRETING RESULTS

Count colonies on all plates containing 15-300 colonies. Report the count as CFU per ml of sample allowing for dilution factors.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.
Prepared medium: slightly opalescent, light amber.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles, tubes and prepared plates at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in tubes/bottles: 2 years.
Medium in slant tubes: 1 year.
Ready-to-use plates: 6 months.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU.
Incubation conditions: aerobically at 30 ± 1°C for 72 ± 3 hours.

QC Table.

Microorganism		Growth
Bacillus subtilis	WDCM 00003	Good
Enterococcus faecalis	WDCM 00009	Good
Escherichia coli	WDCM 00012	Good
Staphylococcus aureus	WDCM 00034	Good
Pseudomonas aeruginosa	WDCM 00024	Good

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. ISO 4833 (2003) Microbiology of food and animal feeing stuffs – Horizontal method for the enumeration of microorganisms – Colony count technique at 30°C.
3. Davidson, Roth, and Gambrel-Lenarz (2004) In Wehr and Frank (ed.) Standard methods for the microbiological examination of dairy products, 17th ed. American Public Health Association, Washington, D.C.
4. Kornacki and Johnson (2001) In Downes and Ito (ed.) Compendium of methods for the microbiological examination of foods, 4th ed. American Public Health Association, Washington D.C.
5. Greenberg A.E, L.S. Clesceri and A.D. Eaton (1992) Standards methods for the examination of water and wastewater, 18th ed. American Public Health Association, Washington D.C.

PRESENTATION		Contents	Ref.
Plate Count Agar	90 mm ready-to-use plates	20 plates	10032
Plate Count Agar	90 mm ready-to-use plates	100 plates	10032*
Plate Count Agar	140 mm ready-to-use plates	10 plates	10232
Plate Count Agar	55 mm ready-to-use RODAC plates	20 plates	15325
Plate Count Agar	60 mm ready-to-use plates	20 plates	163452
Plate Count Agar	Tubes	20 x 22 ml tubes	31073
Plate Count Agar	Tubes	10 x 22 ml tubes	34073
Plate Count Agar	Slant tubes	10 x 9 ml tubes	33070
Plate Count Agar	Bottles	6 x 500 ml bottles	470180
Plate Count Agar	Bottles	6 x 200 ml bottles	412260
Plate Count Agar	Bottles	6 x 150 ml bottles	401940
Plate Count Agar	Bottles	6 x 100 ml bottles	402260
Plate Count Agar	Dehydrated medium	500 g of powder	610040
Plate Count Agar	Dehydrated medium	100 g of powder	620040
Plate Count Agar	Dehydrated medium	5 kg of powder	6100405

TABLE OF SYMBOLS

LOT Batch code	Keep away from sunlight	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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Instructions For Use
ENGLISH

Milk Plate Count Agar

Medium for the enumeration of microorganisms in milk and dairy products, according to the APHA and ISO 4833.

DESCRIPTION

Milk Plate Count Agar is a nutrient medium used for the enumeration of bacteria in milk and dairy products.

The medium complies with the recommendations of the APHA, International Dairy Federation and ISO 4833 for the microbiological examination of milk and milk products.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Casein	5.0
Yeast Extract	2.5
Glucose	1.0
Skimmed Milk	1.0
Agar	10.0
Final pH 6.9 ± 0.1 at 25°C	

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Glucose is the fermentable carbohydrate. Skimmed milk is a source of casein also providing optimal conditions for bacteria which typically grow in milk. Agar is the solidifying agent.

PREPARATION

Dehydrated medium	Suspend 19.5 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.
Medium in bottles	Melt the content of the bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

1. Perform serial dilutions of the test sample in order to achieve a colony count of between 15 and 300 colonies per plate. Use a suitable diluent such as Buffered Peptone Water (ref. 24099) or Maximum Recovery Broth (ref. 20071).
2. Inoculate the medium by pour plating or spread plating method.
3. Incubation conditions may vary depending on the organisms under study. For a general aerobic count, incubate aerobically at 30°C for 72 hours.

INTERPRETING RESULTS

Count colonies on all plates containing 15-300 colonies. Report the count as CFU/ml of sample allowing for dilution factors.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.
Prepared medium: slightly opalescent, light amber.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles: 2 years.
Ready-to-use plates: 6 months.

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU
Incubation conditions: aerobically at 30 ± 1°C for 72 ± 3 hours.

QC Table.

Microorganism		Growth
Bacillus subtilis	WDCM 00003	Good
Escherichia coli	WDCM 00012	Good
Staphylococcus aureus	WDCM 00034	Good

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. ISO 4833:2003. Microbiology of food and animal feeing stuffs – Horizontal method for the enumeration of microorganisms – Colony count technique at 30°C.
2. Marshall, R.T. (1993) Standard methods for the microbiological examination of dairy products, 16th ed. American Public Health Association, Washington D.C.
3. International Dairy Federation (1987) Milk and Milk Products: Enumeration of Microorganisms – Colony Count at 3°C. Provisional IDF Standard 100A. IDF, Brussels, Belgium.

PRESENTATION		Contents	Ref.
Milk Plate Count Agar	90 mm ready-to-use plates	20 plates	10433
Milk Plate Count Agar	90 mm ready-to-use plates	100 plates	10433*
Milk Plate Count Agar	Bottles	6 x 500 ml bottles	463120
Milk Plate Count Agar	Dehydrated medium	500 g of powder	610073
Milk Plate Count Agar	Dehydrated medium	100 g of powder	620073
Milk Plate Count Agar	Dehydrated medium	5 kg of powder	6100735

TABLE OF SYMBOLS

LOT Batch code	Keep away from sunlight	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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ENGLISH

POTASSIUM TELLURITE 1% *Supplement*

Selective supplement for the isolation of Staphylococci

DESCRIPTION

POTASSIUM TELLURITE 1% *Supplement* is a selective supplement consisting of a 1% potassium tellurite aqueous solution for microbiological use, to be used in preparation of VOGEL JOHNSON AGAR culture medium (REF. 610186 or 620186) for isolation of Staphylococci and in other culture media the composition of which provides for the inclusion of potassium tellurite.

KIT CONTENTS

Each kit contains:

- bottles containing 10 ml of POTASSIUM TELLURITE 1% *Supplement*
- 1 Instruction sheet

PRINCIPLE OF THE METHOD

POTASSIUM TELLURITE 1% *Supplement* is a selective supplement used in preparation of the VOGEL JOHNSON AGAR medium (REF. 610186 or 620186) for isolation of Staphylococci. These micro-organisms, which reduce the tellurite to tellurium, grow with grey-black colonies. Potassium tellurite is also included in the composition of other culture media.

COMPOSITION

POTASSIUM TELLURITE 1% *Supplement*	
Contents / bottle	
Potassium tellurite	100.0 mg
Distilled water	10.0 ml

PROCEDURE FOR USE

1. Aseptically add the entire contents of a bottle of POTASSIUM TELLURITE 1% *Supplement* (10 ml) to 500 ml of VOGEL JOHNSON AGAR medium (REF. 610186 or 620186) autoclaved and cooled to 45-50°C. When potassium tellurite is included in the composition of other media, refer to the specific instructions for the medium concerned on the quantity of POTASSIUM TELLURITE 1 % *Supplement* that should be added to it.
2. Mix with care.
3. Distribute into Petri dishes.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation for VOGEL JOHNSON AGAR medium (REF. 610186 or 620186), or for the specific medium being prepared.

QUALITY CONTROL

1. Visual inspection: clear, colourless solution.
2. Microbiological control.

Prepare the plates using as base VOGEL JOHNSON AGAR medium (REF. 610186 or 620186) supplemented with POTASSIUM TELLURITE 1% *Supplement* (1 bottle in 500 ml of medium). The plates are seeded with the strains indicated in the microbiological control table.

Incubation conditions: 24-48 h at 36±1°C.

Microbiological control

Control strains		**Growth**	**Colonies**
Staphylococcus aureus	ATCC 25923	Good	Black
Escherichia coli	ATCC 25922	Inhibited	-------

PRECAUTIONS

The product POTASSIUM TELLURITE 1 % *Supplement* is not classified as dangerous under current legislation; it is nevertheless recommended that the Safety Data Sheet be consulted on its correct use.
POTASSIUM TELLURITE 1 % *Supplement* is a supplement to be used only for *in vitro* diagnostic use. It is intended for use in a professional environment and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

STORAGE

Store POTASSIUM TELLURITE 1 % *Supplement* at 2-8°C in its original packaging. In such conditions POTASSIUM TELLURITE 1% *Supplement* will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

REFERENCES

- United States Pharmacopoeia XXI (1985) Microbial Limit Tests. Rockville. Md.
- Vogel, R.A., and Johnson, M.J. (1961). Pub. Hlth. Lab. 18: 131.

PRESENTATION

product	REF	Σ
POTASSIUM TELLURITE 1% *Supplement*	80022	5 bottles x 10 ml
POTASSIUM TELLURITE 1% *Supplement*	80422	10 bottles x 10 ml

TABLE OF SYMBOLS

IVD *In Vitro* Diagnostic Medical Device	Do not reuse	Manufacturer	Contains sufficient for <n> tests	Temperature limitation
REF Catalogue number	Fragile, handle with care	Use by	Caution, consult accompanying documents	LOT Batch code

LIOFILCHEM® S.r.l.
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CE IVD

ENGLISH

GRAM COLOR KIT

DESCRIPTION
GRAM COLOR KIT is a kit for staining micro-organisms that allows them to be differentiated into two categories: Gram-positives (Gram+), which are coloured blue, and Gram-negatives (Gram-), which are coloured red. Combined with direct observation of the cell morphology, this staining constitutes the first level in the taxonomic classification of prokaryotes.

CONTENT OF THE PACKAGES
The reagents are contained in plastic bottles, sealed by thermo-induction and provided with a dropper lid. Each pack contains:
- 1 bottle containing 250 ml of Crystal Violet Solution
- 1 bottle containing 250 ml of Lugol-PVP Solution
- 1 bottle containing 250 ml of Decolourant Solution
- 1 bottle containing 250 ml of Safranine Solution

PRINCIPLE OF THE METHOD
Gram staining is based on the property of Crystal Violet of combining with iodine to form compounds that cannot be decoloured with alcohol or with an alcohol-acetone mixture. Some bacteria have a special affinity for this reaction and, once stained with crystal violet, do not lose the colour if treated with alcohol or alcohol-acetone mixture, thus retaining the blue colouring (Gram-positive bacteria). Others lose the blue colour and are stained by Safranine, taking a red colour (Gram-negative bacteria).

COLLECTION OF SAMPLES
Samples to be subjected to Gram staining are usually clinical material and microbial cultures. The colonies to be subjected to Gram staining must be taken from young cultures (18-24 hours) preferably on an agar medium.

TEST PROCEDURE
Preparation and fixing

On clean slides, make a smear of the culture or pathological material. Leave to dry in the air and fix by heat, passing rapidly over the flame. Do not overheat the sample when fixing. Other fixing methods may be used.

Staining
1. Cover the slide with the Crystal Violet Solution. Wait 1 minute, then rinse gently with water.
2. Cover the slide with the Lugol-PVP Solution. Wait 1 minute, then rinse delicately with water.
3. Decolour with the Decolourant Solution for as long as the preparation releases colour (about 30-60 seconds), then rinse delicately with water.
4. Cover the slide with the Safranine Solution. Wait 30-60 seconds, then rinse delicately with water.
5. Dry.
6. Examine the preparation under the microscope with the objective for immersion.

INTERPRETATION OF THE RESULTS
The Gram-negative micro-organisms appear as red in colour.
The Gram-positive micro-organisms appear as blue in colour.
The Gram staining makes it possible to distinguish between:
- Gram-negative bacilli from Gram-positive ones;
- Gram-negative cocci from Gram-positive ones;
- Gram-negative coccobacilli from Gram-positive ones;
- Gram-negative diplococci from Gram-positive ones.

QUALITY CONTROL
Each lot of GRAM COLOR KIT is subjected to quality control using a culture of *Escherichia coli* ATCC 25922 for the test for Gram-negative bacteria (red colour) and a culture of *Staphylococcus aureus* ATCC 25923 for the test for Gram-positive bacteria (blue colour).

LIMITS
- Gram staining provides a preliminary identification but does not replace normal cultural studies of the sample.
- Antibiotic therapy may make Gram-positive bacteria more
- sensitive to decolouration, so that they appear pinkish-red instead of blue.
- Cells taken from young, 18-24 hour cultures have a greater affinity for the stains than cells taken from older cultures.
- Gram staining is altered by the physical destruction of the cell wall or protoplasm. In fact the cell wall of Gram-positive bacteria constitutes a barrier which impedes release of the Crystal Violet-iodine complex from the cytoplasm, and the cell wall of Gram-negative bacteria contains lipids soluble in organic solvents that permit decolouration of the cytoplasm. Hence, micro-organisms physically destroyed by an excess of heat do not react as expected to the Gram stain test.

PRECAUTIONS
The GRAM COLOR KIT package contains substances classified as hazardous by current legislation. It recommended that the Safety Data Sheets be consulted on their use. GRAM COLOR KIT is a kit for bacteria staining, only for diagnostic use *in vitro.* It is intended for use in a professional environment and must be used in a laboratory by adequately trained personnel using approved asepsis and safety methods for dealing with pathogenic agents.

CONSERVATION
Store GRAM COLOR KIT at 10-25°C in the original packaging. Keep away from sources of heat and avoid excessive changes of temperature. In such conditions the product GRAM COLOR KIT will be valid until the expiry date shown on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration (changes in the colour of the solutions or presence of substantial precipitates).

DISPOSAL OF USED MATERIAL
After use, the slides stained with the GRAM COLOR KIT and any material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

BIBILIOGRAPHY

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- Murray, P.R. (ed.) 1999. Manual of Clinical Microbiology, 7th ed. American Society of Microbiology, Washington, D.C.

PRESENTATION

Product	Ref	Content
GRAM COLOR KIT	80293	4 x 250 ml

TABLE OF SYMBOLS

IVD	*In Vitro* Diagnostic Medical Device		Do not reuse
	Manufacturer	Σ	Contains sufficient for <n> tests
REF	Catalogue number		Fragile, handle with care
	Use by		Caution, consult accompanying documents
	Temperature limitation	LOT	Batch code

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F00411
Rev.3 / 09.05.2017

MOTILITY TEST AGAR

Dehydrated medium for detection of motility of gram-negative enteric bacilli according to UNI EN ISO 11290-1:2005

TYPICAL FORMULA	(g/l)
Casein Peptone	20.0
Meat	6.1
Agar	3.5

Final pH 7.2 ± 0.2

DESCRIPTION

MOTILITY TEST AGAR is a dehydrated medium for detection of motility of gram-negative enteric bacilli according to UNI EN ISO 11290-1:2005

PRINCIPLE

Casein peptones and meat provide nitrogen, vitamins, minerals and amino acids essential for growth. Agar is the solidifying agent in a low concentration to enable the motility to be seen.

PREPARATION

Suspend 29.6 g of powder in 1 litre of distilled or deionized water. Heat to boiling and shake until completely dissolved. Dispense in final containers. Sterilise at 121°C for 15 minutes.

TECHNIQUE

Inoculate tubes with a pure culture by stabbing the center of the column of medium to greater than half the depth.
Incubate tubes for 24-48 hours at 36±1°C in an aerobic atmosphere.

INTERPRETATION OF RESULTS

Motility is evidenced by the presence of diffuse growth away from the line or spot of inoculation. Nonmotile organisms grow only along the line of inoculation. Negative tubes can be reincubated at 25±2°C for an additional 5 days, if desired.
Consult appropriate texts for results with specific organisms[2,3].

STORAGE AND TRANSPORT CONDITIONS

The powder is very hygroscopic: store the powder at 10-30°C, in a dry environment, in its original container tightly closed until the expiry date on the label or until signs of deterioration or contamination are evident. Storage or transport at 2-10°C do not alter in any way the performance of the product. Store prepared media at 2-8°C.

WARNING AND PRECAUTIONS

TThe product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. it is nevertheless recommended to consult the safety data sheet for its correct use.. The product is designed for *In vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to the national and local regulations in force.

REFERENCES

1. Jordan, Caldwell and Reiter.1934. *J.Bacteriology* 27:165.
2. Holt, Krieg, Sneath, Staley and Williams (ed.).1994., Bergey's Manual of determinative bacteriology, 9th ed. Williams & Wilkins, Baltimore, Md.
3. Farmer, 1999.*In* Murray, Baron, Pfaller, Tenorev and Yolken (ed.), Manual of Clinical microbiology, 7th ed. American Society for Microbiology, Washington, D.C.
4. Macfaddin.1985.Media for isolation-cultivation-identification-maintenance of medical bacteria, vol.1.Williams & Wilkins, Baltimore, Md.

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CE IVD

PRODUCT SPECIFICATIONS

NAME
MOTILITY TEST AGAR

PRESENTATION
Dehydrated culture medium

STORAGE
10-30°C

PACKAGING

Ref.	Content	Packaging
610132	500 g	500 g of powder in plastic bottle
620132	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
7.2 ± 0.2

USE
MOTILITY TEST AGAR is a dehydrated medium for detection of motility of gram-negative enteric bacilli according to UNI EN ISO 11290-1:2005

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Dehydrated medium
Appearance: free-flowing, homogeneous
Colour: light beige
Prepared medium
Appearance: slightly opalescent
Colour: medium amber

SHELFLIFE
4 years

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Sterility control
   7 days at 22 ± 1°C, in aerobiosis
   7 days at 36 ± 1°C, in aerobiosis
3. Microbiological control
   Inoculum for productivity: 10-100 UFC/ml
   Incubation Conditions: 18-24 h at 36 ± 1°C, in aerobiosis

Microorganisms		Growth	Motility
Enterobacter aerogenes	ATCC 13048	Good	+
Escherichia coli	ATCC 25922	Good	+
Klebsiella pneumoniae	ATCC 13883	Good	-

TABLE OF SYMBOLS

LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult accompanying documents	Do not reuse

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CE IVD

Tryptone Soya Yeast Extract Broth

Liquid culture medium for the confirmation of *Listeria monocytogenes* according to ISO 11290.

TYPICAL FORMULA	(g/l)
Tryptone	17.0
Soya Peptone	3.0
Yeast Extract	6.0
Sodium Chloride	5.0
Dipotassium Phosphate	2.5
D-Glucose	2.5
Final pH 7.3 ± 0.2 at 25°C	

DESCRIPTION

Tryptone Soya Yeast Extract Broth (TSYEB) is a liquid medium used for the isolation and cultivation of *Listeria* spp in foods.

This medium complies with the recommendations given in ISO 11290, APHA and FDA for the detection and enumeration of *Listeria monocytogenes*.

PRINCIPLE

Tryptone and soya peptone provide nitrogen, vitamins, minerals and amino acids for organisms growth. Yeast extract is a source of vitamins, particularly of the B-group. Glucose is the fermentable carbohydrate providing carbon and energy. Dipotassium phosphate is the buffer. Sodium chloride supplies essential electrolytes for transport and osmotic balance.

PREPARATION

Suspend 36 g of powder in 1 liter of distilled water. Mix well and dissolve by heating with frequent agitation. Dispense into appropriate containers. Autoclave at 121°C for 15 minutes.

TECHNIQUE

Take an isolated colony obtained in TSYEA (ref. 610367) and suspend in a tube of TSYEB. Incubate at 25°C for 8-24 h until a cloudy medium is observed. Use a drop of this broth culture to examine for motility at the microscope.

A culture from TSYEB can be used for inoculating carbohydrate utilization broths and other test media. This culture may be kept at 4°C several days and used repeatedly as inoculum.

INTERPRETATION OF RESULTS

Refer to appropriate references and procedures for results.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed and use it before the expiry date on the label or until sings of deterioration or contamination are evident. Store the prepared medium at 2-8°C away from light.

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. it is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

REFERENCES

- EN ISO 11133:2014. Microbiology of food, animal feed and water − Preparation, production, storage and performance testing of culture media.
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- Atlas R. M. (2004) 3rd Ed., Handbook of Microbiological Media, Parks, L.C. (Ed.), CRC Press, Boca Raton.
- ISO 11290-2:1998. Microbiology of food and animal feeding stuffs -- Horizontal method for the detection and enumeration of *Listeria monocytogenes* -- Part 2: Enumeration method.
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PRODUCT SPECIFICATIONS

NAME
Tryptone Soya Yeast Extract Broth

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGE

Ref.	Content	Packaging
610241	500 g	500 g of powder in plastic bottle
620241	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
7.3 ± 0.2

USE
Tryptone Soya Yeast Extract Broth (TSYEB) is a liquid medium used for the isolation and cultivation of *Listeria monocytogenes* in food and foodstuffs, according to ISO 11290, APHA and FDA

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Dehydrated medium
Appearance: free-flowing, homogeneous
Colour: beige
Prepared medium
Appearance: slightly opalescent
Colour: amber

SHELFLIFE
4 years

QUALITY CONTROL
1. Control of general characteristics, label and print

2. Microbiological control
   Inoculum for productivity: ≤100 CFU
   Incubation conditions:18-24 h at 25 ± 1°C

Microorganism		Growth
Listeria monocytogenes 4b	WDCM 00021	Good
Listeria monocytogenes 1/2a	WDCM 00109	Good

TABLE OF SYMBOLS

LOT Batch code	Keep away from heat sources	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Consult instruction for use	

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IODINE MKTT SOLUTION

Supplemento di arricchimento per la determinazione di *Salmonella* spp
Enrichment supplement for *Salmonella* spp detection

DESCRIZIONE

IODINE MKTT SOLUTION è un supplemento per la determinazione di *Salmonella* spp impiegato per l'arricchimento del terreno MULLER KAUFFMANN TETRATHIONATE BROTH BASE ref. 610239 o 620239.

CONTENUTO DELLE CONFEZIONI

Ciascuna confezione contiene:

- 10 provette di IODINE MKTT SOLUTION da 10 mL
- 1 foglio istruzioni

COMPOSIZIONE

IODINE MKTT SOLUTION

	Contenuto / flacone	*Contenuto / l di terreno*
Ioduro di potassio	2.5 g	5.0 g
Iodio	2.0 g	4.0 g

PROCEDURA DI UTILIZZO

Aggiungere asetticamente l'intero contenuto di una provetta (10 ml) a 500 ml di MULLER KAUFFMANN TETRATHIONATE BROTH BASE ref. 610239 o 620239, portato ad ebollizione, raffreddato a 45-50°C ed addizionato con NOVOBIOCIN MKTT Supplement. Mescolare con cura. Distribuire in provette sterili.

TECNICA ED INTERPRETAZIONE DEI RISULTATI

Fare riferimento alla scheda tecnica di MULLER KAUFFMANN TETRATHIONATE BROTH BASE ref. 610239 o 620239.

CONTROLLO QUALITÀ

Controllo microbiologico.

Si procede alla preparazione delle provette utilizzando come base il terreno MULLER KAUFFMANN TETRATHIONATE BROTH BASE ref. 610239 o 620239 arricchito con NOVOBIOCIN MKTT Supplement e IODINE MKTT SOLUTION. Le provette vengono seminate con i ceppi indicati nella tabella del controllo microbiologico. Condizioni di incubazione: 24 ± 3 h a 37 ± 1°C.

Controllo microbiologico:

Ceppi di controllo		**Crescita**
Salmonella typhimurium	ATCC 14028	Buona
Escherichia coli	ATCC 25922	Inibita
Salmonella seftenberg	ATCC 10384	Buona

CONDIZIONI DI CONSERVAZIONE E TRASPORTO

Il prodotto deve essere conservato a 2-8°C al riparo dalla luce, fino alla data di scadenza indicata in etichetta. Tuttavia i nostri studi di stabilità hanno dimostrato che la conservazione o il trasporto a 18-25°C per 4 giorni, oppure a 35-39°C per 48 ore, non alterano in nessun modo l'efficienza del prodotto. Eliminare se vi sono segni evidenti di deterioramento o contaminazione.

AVVERTENZE E PRECAUZIONI

Il prodotto è classificabile come pericoloso ai sensi della legislazione vigente; per il suo impiego si consiglia di consultare la scheda di sicurezza. Il prodotto è destinato esclusivamente per Uso Diagnostico *in vitro* e deve essere utilizzato da parte di personale qualificato.

SMALTIMENTO DEI RIFIUTI

Lo smaltimento del prodotto deve essere effettuato secondo le vigenti regolamentazioni nazionali e locali.

DESCRIPTION

IODINE MKTT SOLUTION is a supplement for the detection of *Salmonella* spp used for enrichment of MULLER KAUFFMANN TETRATHIONATE BROTH BASE ref. 610239 or 620239.

KIT CONTENT

Each kit contains:

- 10 tubes of IODINE MKTT SOLUTION with 10 mL of solution
- 1 instructions sheet

COMPOSITION

IODINE MKTT SOLUTION

	Content / tube	*Content / l of medium*
Potassium iodide	2.5 g	5.0 g
Iodine	2.0 g	4.0 g

PROCEDURE OF USE

Aseptically add the content of one tube (10 ml) to 500 ml of MULLER KAUFFMANN TETRATHIONATE BROTH BASE ref. 610239 or 620239, boiled, cooled to 45-50°C and added with NOVOBIOCIN MKTT Supplement. Carefully mix. Distribute into sterile tubes.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation of MULLER KAUFFMANN TETRATHIONATE BROTH BASE ref. 610239 or 620239.

QUALITY CONTROL

Microbial control.

Prepare the tubes using as base MULLER KAUFFMANN TETRATHIONATE BROTH BASE ref. 610239 or 620239 enriched with NOVOBIOCIN MKTT Supplement (1 bottle in 500 ml of medium) and IODINE MKTT SOLUTION. The tubes are seeded with the strains indicated in the microbiological control table.

Incubation conditions: 24 ± 3 h at 37 ± 1°C.

Microbial control:

Control strains		**Growth**
Salmonella typhimurium	ATCC 14028	Good
Escherichia coli	ATCC 25922	Inhibited
Salmonella seftenberg	ATCC 10384	Good

STORAGE AND TRANSPORT CONDITIONS

2-8°C away from light, until the expiry date on the label. However, our stability studies have shown that the storage or transport at 18-25°C for 4 days, or at 35-39°C for 48 hours, do not alter in any way the performance of the product. Eliminate if signs of deterioration or contamination are evident.

WARNING AND PRECAUTIONS

The product is classifiable as hazardous under current legislation; it is recommended to consult the Safety Data Sheet for its correct use. The product is designed for *In vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAFIA / BIBLIOGRAPHY

1. ISO 6785 Milk and milk products – Detection of Salmonella 1st Ed. 1985.
2. Muller, L.(1923) C.R. Soc. Biol. (Paris) 89, 434-443.
3. Kauffmann, F. (1935) Z.f.Hyg. 11,26-32.

PRESENTAZIONE/ PRESENTATION

Prodotto/ Product	REF	Σ
IODINE MKTT SOLUTION	**80009**	**10 provette / tubes**

TABELLA DEI SIMBOLI / TABLE OF SYMBOLS

LOT Codice del lotto / Batch code	IVD Dispositivo medico diagnostico *in vitro* / *in Vitro* Diagnostic Medical Device	Fabbricante / Manufacturer	Σ Contenuto della confezione / Kit content	Limiti di temperatura / Temperature limitations	Non riutilizzare / Do not reuse
REF Numero di catalogo / Catalogue number	Fragile, maneggiare con cura / Fragile, handle with care	Utilizzare entro / Use by	Attenzione, consultare le istruzioni per l'uso / Caution, consult accompanying documents	Mantenere al riparo dalla luce / Keep away from light	

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CE IVD

Rev. 1 / 07.02.2012

Instructions For Use
ENGLISH

Tryptic Soy Broth
Casein Soya Bean Digest Broth

Liquid medium for the isolation and cultivation of
a wide variety of organisms, according to USP/EP/JP.

DESCRIPTION

Tryptic Soy Broth (TSB) is a nutritious medium used for the detection, isolation and cultivation of fastidious and nonfastidious microorganisms including bacteria and fungi from clinical specimens, environmental sources and other materials.

This medium meets the requirements of the harmonized method in the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for sterility testing and for microbiological examination of non-sterile products. It is recommended by the Clinical and Laboratory Standards Institute (CLSI) for inoculum preparation in antibiotic susceptibility testing.

TSB is also available as triple-wrapped and gamma-irradiated bottles, particularly suitable for use in restricted areas and for aseptic process simulations (media fill trial) in the pharmaceutical industry.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Casein	17.0
Papaic Digest of Soya Bean	3.0
Sodium Chloride	5.0
Dipotassium Hydrogen Phosphate	2.5
Glucose Monohydrate	2.5
Final pH 7.3 ± 0.2 at 25°C	

METHOD PRINCIPLE

Pancreatic digest of casein and papaic digest of soya bean provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Sodium chloride maintains osmotic balance in the medium. Dipotassium phosphate is a buffering agent. Glucose is an energy source.

PREPARATION

Dehydrated medium — Suspend 30 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

TEST PROCEDURE

For use in clinical microbiology, inoculate TSB directly with the clinical specimen or with a small amount of growth from an overnight culture on a solid medium. Usually, incubation at 35 ± 2°C for 18-24 hours is adequate.

For use in industrial microbiology, inoculate the sample or material to be tested into the medium. Incubate under appropriate atmosphere at 30-35°C for 18-72 hours (for the bacteria) and at 20-25°C for a maximum of 5 days (for the fungi).

For sterility testing, the way of inoculation depends on the type and size of test material. If membrane filtration is carried out, a suitable diluent such as Fluid A (ref. 400010) may be used. For direct inoculation, it is recommended a minimum 1:10 dilution of the sample to the culture medium. Incubate at 20-25°C for 14 days.

For media fill test in biopharmaceutical manufacturing, two incubation temperatures are used. The initial incubation at 20-25°C for 7 days, and then at 30-35°C for further 7 days.

For all applications notice that:
- it is important to provide sufficient aeration during incubation by slightly loosening the caps;
- Fluid Thioglycollate Medium (ref. 24124) should be used for the cultivation of strict anaerobes.

INTERPRETING RESULTS

The presence of turbidity compared to an uninoculated control or a pellicle formation indicate microbial growth. Subculture to suitable solid media for complete identification of the isolated colonies.

If the material being tested renders the medium turbid and a visual examination is not possible at the end of the incubation period, subculture to fresh TSB or onto appropriate solid media to ensure that turbidity is caused by the sample only and it is not a result of microorganisms multiplying in the broth.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.
Prepared medium: clear to very slightly opalescent, light amber to amber.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and tubes at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles/tubes: 2 years.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: ≤100 CFU.
Incubation conditions: bacteria at 32.5 ± 2.5°C for 18-24 h and up to 72 h (*Clostridium*)
yeasts and molds at 22.5 ± 2.5°C for up to 5 days.

QC Table.

Microorganism		Growth
Staphylococcus aureus	ATCC® 6538	Good
*Staphylococcus aureus**	ATCC® 25923	Good
Escherichia coli	ATCC® 8739	Good
*Escherichia coli**	ATCC® 25922	Good
Pseudomonas aeruginosa	ATCC® 9027	Good
Bacillus subtilis	ATCC® 6633	Good
Salmonella Typhimurium	ATCC® 14028	Good
Clostridium sporogenes	ATCC® 11437	Good
Candida albicans	ATCC® 10231	Good
Aspergillus brasiliensis	ATCC® 16404	Good

*CLSI recommended organisms

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for *In vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. CLSI. Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria that Grow Aerobically; Approved Standard - Tenth Edition. CLSI document M07-A10. Wayne, PA: Clinical and Laboratory Standards Institute; 2015.
2. United States Pharmacopeial Convention (2014) The United States Pharmacopeia 38/National Formulation 33, Supp. 2. Chapter <61> Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter <62> Microbiological examination of non-sterile products: Test for specified products. Chapter <71> Sterility Tests. Rockville, Md., USA.
3. European Directorate for the Quality of Medicines and Healthcare (2014) The European Pharmacopoeia. 8th Ed. Chapter 2.6.12 Microbiological examination of non-sterile products: Microbial enumeration tests and Chapter 2.6.13 Microbiological examination of non-sterile products: Test for specified products. Strasbourg, France.
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5. Japanese Ministry of Health, Labour and Welfare (2011) The Japanese Pharmacopoeia. 16th Ed. Chapter 4.05 Microbial Limit Test I. Microbiological examination of non-sterile products: Total viable aerobic count and II. Microbiological examination of non-sterile products: Test for specified products. Japanese Ministry of Health, Labour and Welfare. Tokyo, Japan.

6. Pharmaceutical Inspection Convention Co-operation Scheme (PIC/S). Recommendation on the Validation of Aseptic Processes (2011) Revision 6.
7. CLSI. Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard - Tenth Edition. CLSI document M02-A10. Wayne, PA: Clinical and Laboratory Standards Institute; 2009.
8. FDA (2004) Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing – Current Good Manufacturing Practice.

PRESENTATION		**Contents**	**Ref.**
Tryptic Soy Broth	Tubes	50 x 5 ml tubes	27500
Tryptic Soy Broth	Tubes	20 x 9 ml tubes	24469
Tryptic Soy Broth	Tubes	20 x 10 ml tubes	24513
Tryptic Soy Broth	Tubes	100 x 10 ml tubes	26513
Tryptic Soy Broth	Tubes	10 x 15 ml tubes	20129
Tryptic Soy Broth	Bottles	6 x 100 ml bottles (flip-off cap)	400030
Tryptic Soy Broth	Bottles	6 x 100 ml bottles (screw cap)	452080
Tryptic Soy Broth	Bottles (triple wrapped and gamma-irradiated)	6 x 100 ml bottles (screw cap)	452080S
Tryptic Soy Broth	Bottles	6 x 100 ml bottles (crimp cap)	495010
Tryptic Soy Broth	Bottles	25 x 100 ml bottles (flip-off cap)	453030
Tryptic Soy Broth	Bottles	25 x 100 ml bottles (screw cap)	455208
Tryptic Soy Broth	Bottles	6 x 200 ml bottles (screw cap)	442080
Tryptic Soy Broth	Bottles	6 x 225 ml bottles (screw cap)	432080
Tryptic Soy Broth	Bottles	6 x 500 ml bottles (screw cap)	470370
Tryptic Soy Broth	Dehydrated medium	500 g of powder	610053
Tryptic Soy Broth	Dehydrated medium	100 g of powder	620053
Tryptic Soy Broth	Dehydrated medium	5 kg of powder	6100535

TABLE OF SYMBOLS

LOT Batch code	**IVD** *In vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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CE IVD

Certificate

mdc medical device certification GmbH
certifies that

sifin

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

for the scope

development, manufacturing and distribution of
in vitro diagnostic medical devices for the product groups:
blood grouping, bacteriological test reagents and culture media as well as
manufacturing of raw materials for manufacturing of
in vitro diagnostic medical devices

has introduced and applies a

Quality Management System

The mdc audit has proven that this quality management system
meets all requirements of the following standard

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

EN ISO 13485:2016 + AC:2016 - ISO 13485:2016

Valid from	2021-10-23
Valid until	2024-10-22
Registration no.	D1058700050
Report no.	P21-00883-206453
Stuttgart	2021-07-23

Head of Certification Body

medical device certification mdc

DAkkS Deutsche Akkreditierungsstelle D-ZM-16002-06-00

mdc medical device certification GmbH
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Internet: http://www.mdc-ce.de

Translation from German

IFTA AG
Natürlich. Für Zukunft.

CERTIFICATE

The certification body IFTA AG certifies

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

the conformity of the introduced quality management system for the field of development, manufacturing and sale of products for human and veterinary medical in-vitro diagnostics as well as for the production and purification of monoclonal antibodies, the provision of services in the field of monoclonal antibodies and the sale of products for microbiological analysis with the standard

DIN EN ISO 9001:2015

Start of validity:	07.07.2023
End of validity:	06.07.2026
Report and certificate number:	IC00016 038 23
The certificate consists of	1 page

This certificate includes an annual examination of the QMS by IFTA AG according to the specified standard.

Berlin, 07.06.2023

Prof. Dr. Jörn Karge
CEO

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-16072-01-00

sifin

EG-Konformitätserklärung

CE-Declaration de Conformité / EC-Declaration of Conformity

CE

Polyspezifische Testreagenzien Anti-Salmonella O, Vi

Réactifs de test polyspécifiques Anti-Salmonella O, Vi
Polyspecific Test Reagents Anti-Salmonella O, Vi

Wir / Nous / We

sifin diagnostics gmbh
Berliner Allee 317-321, 13088 Berlin, Germany
phone +49-30-700-144-0, fax +49-30-700-144-30, info@sifin.de, www.sifin.de

erklären in eigener Verantwortung, dass
déclarons sous notre propre responsabilité que / declare on our own responsibility that

die Medizinprodukte (IVD):
les dispositifs médical (IVD) :
the medical devices (IVD):

Polyspezifische Testreagenzien Anti-Salmonella O, Vi
Réactifs de test polyspécifiques Anti-Salmonella O, Vi
Polyspecific Test Reagents Anti-Salmonella O, Vi

TR1101	Anti-Salmonella A - 67 + Vi, omnivalent
TR1101-01	Anti-Salmonella A - 67 + Vi, omnivalent
TR1111	Anti-Salmonella I (A - E + Vi)
TR1111-01	Anti-Salmonella I (A - E + Vi)
TR1121	Anti-Salmonella II (F - 67)
TR1121-01	Anti-Salmonella II (F - 67)

Sonstige Produkte
Autres dispositifs/Other devices

allen Anforderungen der Richtlinie 98/79/EG entsprechen.
remplirent toutes les exigences de la Directive 98/79/EG qui le concernait.
meet all the provisions of the Directive 98/79/EG which apply to it.

Angewandte harmonisierte Normen:
Normes nationales appliqués:
Applied national standards:

DIN EN ISO 13485:2016,
DIN EN 13612:2002,
DIN EN 13641:2002,
DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2021,
DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013,
DIN EN ISO 23640:2015

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Polyspezifische Testreagenzien Anti-Salmonella O, Vi

Réactifs de test polyspécifiques Anti-Salmonella O, Vi

Polyspecific Test Reagents Anti-Salmonella O, Vi

Konformitätsbewertungsverfahren: Procèdure d'évaluation de la conformità: Conformity assessment procedure:	Anhang III Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2027-05-25

Berlin, 25.01.2022

Dr. Kathrin Landgrebe
Sicherheitsbeauftragte für Medizinprodukte
Agent de sécurité / Safety Officer

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Testreagenzien Anti-Salmonella O-Gruppen-Pools

Réactifs de test Pools anti-salmonelles du groupe O
Test Reagents Anti-Salmonella O-group Pools

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die Medizinprodukte (IVD):
les dispositifs médical (IVD) :
the medical devices (IVD):

Testreagenzien Anti-Salmonella O-Gruppen-Pools
Réactifs de test Pools anti-salmonelles du groupe O
Test Reagents Anti-Salmonella O-group Pools

TR1151	Anti-Salmonella OMA
TR1151-01	Anti-Salmonella OMA
TR1161	Anti-Salmonella OMB
TR1161-01	Anti-Salmonella OMB
TR1170	Anti-Salmonella OMC
TR1171	Anti-Salmonella OMD
TR1172	Anti-Salmonella OME
TR1173	Anti-Salmonella OMF
TR1174	Anti-Salmonella OMG

Sonstige Produkte
Autres dispositifs/Other devices

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DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013,
DIN EN ISO 23640:2015

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Testreagenzien Anti-Salmonella O-Gruppen-Pools

Réactifs de test Pools anti-salmonelles du groupe O

Test Reagents Anti-Salmonella O-group Pools

Konformitätsbewertungsverfahren: Procèdure d'évaluation de la conformità: Conformity assessment procedure:	Anhang III Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2027-05-25

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Testreagenzien Anti-Salmonella O, Vi

Réactifs de test Anti-Salmonella O, Vi
Test Reagents Anti-Salmonella O, Vi

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the medical devices (IVD):

Testreagenzien Anti-Salmonella O, Vi
Réactifs de test Anti-Salmonella O, Vi
Test Reagents Anti-Salmonella O, Vi

TR1201	Anti-Salmonella Group B
TR1201-01	Anti-Salmonella Group B
TR1202	Anti-Salmonella Group C
TR1203	Anti-Salmonella Group D
TR1203-01	Anti-Salmonella Group D
TR1204	Anti-Salmonella Group E
TR1301	Anti-Salmonella O:2
TR1302	Anti-Salmonella O:4
TR1302-01	Anti-Salmonella O:4
TR1303	Anti-Salmonella O:5
TR1303-01	Anti-Salmonella O:5
TR1304	Anti-Salmonella O:6_1
TR1305	Anti-Salmonella O:7
TR1306	Anti-Salmonella O:8
TR1307	Anti-Salmonella O:9
TR1307-01	Anti-Salmonella O:9
TR1308	Anti-Salmonella O:10
TR1323	Anti-Salmonella O:11
TR1325	Anti-Salmonella O:13
TR1309	Anti-Salmonella O:14
TR1310	Anti-Salmonella O:15
TR1328	Anti-Salmonella O:16
TR1329	Anti-Salmonella O:17
TS1330	Anti-Salmonella O:18
TR1311	Anti-Salmonella O:19
TR1312	Anti-Salmonella O:20
TR1331	Anti-Salmonella O:21

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Testreagenzien Anti-Salmonella O, Vi

Réactifs de test Anti-Salmonella O, Vi

Test Reagents Anti-Salmonella O, Vi

TS1332	Anti-Salmonella O:22
TR1335	Anti-Salmonella O:25
TR1313	Anti-Salmonella O:27
TR1336	Anti-Salmonella O:28
TR1339	Anti-Salmonella O:30
TR1314	Anti-Salmonella O:34
TR1341	Anti-Salmonella O:35
TR1344	Anti-Salmonella O:38
TR1345	Anti-Salmonella O:39
TR1346	Anti-Salmonella O:40
TR1347	Anti-Salmonella O:41
TR1348	Anti-Salmonella O:42
TR1349	Anti-Salmonella O:43
TR1350	Anti-Salmonella O:44
TR1351	Anti-Salmonella O:45
TR1315	Anti-Salmonella O:46
TR1353	Anti-Salmonella O:47
TR1354	Anti-Salmonella O:48
TR1355	Anti-Salmonella O:50
TR1356	Anti-Salmonella O:51
TR1357	Anti-Salmonella O:52
TR1358	Anti-Salmonella O:53
TR1359	Anti-Salmonella O:54
TR1360	Anti-Salmonella O:55
TR1361	Anti-Salmonella O:56
TR1362	Anti-Salmonella O:57
TR1363	Anti-Salmonella O:58
TR1364	Anti-Salmonella O:59
TR1365	Anti-Salmonella O:60
TR1366	Anti-Salmonella O:61
TR1367	Anti-Salmonella O:62
TR1368	Anti-Salmonella O:63
TR1369	Anti-Salmonella O:65
TR1370	Anti-Salmonella O:66
TR1371	Anti-Salmonella O:67
TR1316	Anti-Salmonella Vi

Sonstige Produkte
Autres dispositifs/Other devices

allen Anforderungen der Richtlinie 98/79/EG entsprechen.
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meet all the provisions of the Directive 98/79/EG which apply to it.

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Testreagenzien Anti-Salmonella O, Vi

Réactifs de test Anti-Salmonella O, Vi

Test Reagents Anti-Salmonella O, Vi

Angewandte harmonisierte Normen: Normes nationales appliqués: Applied national standards:	DIN EN ISO 13485:2016, DIN EN 13612:2002, DIN EN 13641:2002, DIN EN ISO 14971:2013, DIN EN ISO 15223-1:2021, DIN EN ISO 18113-1:2013, DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015
Konformitätsbewertungsverfahren: Procèdure d'évaluation de la conformità: Conformity assessment procedure:	Anhang III Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2027-05-25

Berlin, 25.01.2022

Dr. Kathrin Landgrebe
Sicherheitsbeauftragte für Medizinprodukte
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Testreagenzien Anti-Salmonella H-Phasen-Pools

Réactifs pour tests Anti-Salmonella H-Phase Pools
Test Reagents Anti-Salmonella H-Phases pools

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the medical devices (IVD):

Testreagenzien Anti-Salmonella H-Phasen-Pools
Réactifs pour tests Anti-Salmonella H-Phase Pools
Test Reagents Anti-Salmonella H-Phases pools

TR1181	Anti-Salmonella HMA
TR1181-01	Anti-Salmonella HMA
TR1183	Anti-Salmonella HMB
TR1183-01	Anti-Salmonella HMB
TR1185	Anti-Salmonella HMC
TR1185-01	Anti-Salmonella HMC

Sonstige Produkte
Autres dispositifs/Other devices

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Testreagenzien Anti-Salmonella H-Phasen-Pools

Réactifs pour tests Anti-Salmonella H-Phase Pools

Test Reagents Anti-Salmonella H-Phases pools

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Testreagenzien Anti-Salmonella H

Réactifs pour tests Anti-Salmonella H
Test Reagents Anti-Salmonella H

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the medical devices (IVD):

Testreagenzien Anti-Salmonella H
Réactifs pour tests Anti-Salmonella H
Test Reagents Anti-Salmonella H

TR1401	Anti-Salmonella H:a
TR1402	Anti-Salmonella H:b
TR1403	Anti-Salmonella H:c
TR1404	Anti-Salmonella H:d
TR1405	Anti-Salmonella H:E
TR1405-01	Anti-Salmonella H:E
TR1407	Anti-Salmonella H:f
TR1406	Anti-Salmonella H:g
TR1406-01	Anti-Salmonella H:g
TR1408	Anti-Salmonella H:g,m
TR1408-01	Anti-Salmonella H:g,m
TR1409	Anti-Salmonella H:h
TR1410	Anti-Salmonella H:i
TR1410-01	Anti-Salmonella H:i
TR1411	Anti-Salmonella H:k
TR1412	Anti-Salmonella H:L
TR1412-01	Anti-Salmonella H:L
TS1413	Anti-Salmonella H:m
TR1438	Anti-Salmonella H:n
TS1414	Anti-Salmonella H:p
TS1415	Anti-Salmonella H:q
TR1416	Anti-Salmonella H:r
TS1417	Anti-Salmonella H:s
TS1418	Anti-Salmonella H:t
TS1419	Anti-Salmonella H:u
TS1420	Anti-Salmonella H:v
TS1421	Anti-Salmonella H:w
TS1422	Anti-Salmonella H:x
TR1423	Anti-Salmonella H:y

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Testreagenzien Anti-Salmonella H
Réactifs pour tests Anti-Salmonella H
Test Reagents Anti-Salmonella H

TR1424	Anti-Salmonella H:z
TS1425	Anti-Salmonella H:z_4,z_{23}
TS1426	Anti-Salmonella H:z_6
TR1427	Anti-Salmonella H:z_{10}
TS1428	Anti-Salmonella H:z_{15}
TR1440	Anti-Salmonella H:z_{23}
TS1429	Anti-Salmonella H:z_{24}
TS1449	Anti-Salmonella H:z_{28}
TS1430	Anti-Salmonella H:z_{29}
TS1431	Anti-Salmonella H:z_{32}
TR1445	Anti-Salmonella H:z_{35}
TR1447	Anti-Salmonella H:z_{38}
TR1448	Anti-Salmonella H:z_{41}
TR1437	Anti-Salmonella H:1
TR1437-01	Anti-Salmonella H:1
TR1433	Anti-Salmonella H:2
TR1433-01	Anti-Salmonella H:2
TS1434	Anti-Salmonella H:5
TR1435	Anti-Salmonella H:6
TS1436	Anti-Salmonella H:7

Sonstige Produkte
Autres dispositifs/Other devices

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meet all the provisions of the Directive 98/79/EG which apply to it.

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DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013,
DIN EN ISO 23640:2015

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Testreagenzien Anti-Salmonella H

Réactifs pour tests Anti-Salmonella H

Test Reagents Anti-Salmonella H

Konformitätsbewertungsverfahren: Procèdure d'évaluation de la conformità: Conformity assessment procedure:	Anhang III Annexe III Annex III
Gültig bis: Valable jusqu'au: Valid until:	2027-05-25

Berlin, 25.01.2022

Dr. Kathrin Landgrebe
Sicherheitsbeauftragte für Medizinprodukte
Agent de sécurité / Safety Officer

ВИНАР®
НАУЧНО-ПРОИЗВОДСТВЕННАЯ ФИРМА

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)
105094, Москва, ул. Госпитальный вал, дом 5, стр. 7А, пом. VIII
105094, Россия, г. Москва, а/я 26 vinar@vinar.ru www.vinar.ru
+7 (495) 988 7667
+7 (800) 201 0202

ПАСПОРТ КАЧЕСТВА

Изделие	**Индикаторы паровой стерилизации химические одноразовые «СТЕРИТЕСТ-П-132/20-02»**
Технические условия	ТУ 9398-042-11764404-2003
Регистрационное удостоверение	№ РЗН 2013/40 от 08.02.2013 г.
Сертификат соответствия	№ НРК RU. РЦ01.Н.00043 от 18.06.2020
Код ОКПД 2	32.50.50.190
Партия	**1262032**
Дата изготовления	**Март 2022 г.**
Гарантийный срок	**36 месяцев**
Условия хранения	В соответствии с инструкцией по применению

Технические показатели:

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-042-11764404-2003	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Вывод: *Продукция соответствует всем установленным требованиям*

Ответственный за контроль качества
М.П.

ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА

ПОСАДСКАЯ В.И.

ВИНАР®
НАУЧНО-ПРОИЗВОДСТВЕННАЯ ФИРМА

Общество с ограниченной ответственностью
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ПАСПОРТ КАЧЕСТВА

Изделие	**Индикаторы воздушной стерилизации химические одноразовые «ИнТЕСТ-В4» (180°С - 60 мин)**
Технические условия	ТУ 9398-105-11764404-2013
Регистрационное удостоверение	№ РЗН 2014/1567 от 11.02.2022 г.
Код ОКПД 2	32.50.50.190
Партия	**2080052**
Дата изготовления	**Май 2022 г.**
Гарантийный срок	**60 месяцев**
Условия хранения	В соответствии с инструкцией по применению

Технические показатели:

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-105-11764404-2013	Соответствует
Соответствие ГОСТ	класс 4, класс 5 по ГОСТ ISO 11140-1-2011	Соответствует

Вывод: *Продукция соответствует всем установленным требованиям*

Ответственный
за контроль качества
м.п.

ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА

ПОСАДСКАЯ В.И.

CERTIFICATO N° 505SGQ05

CERTIFICATE N° 505SGQ05

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messo in atto da
implemented by

APTACA S.p.A.

Via Monte Bianco, 4 – IT 20900 MONZA (MB)

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

UNI EN ISO 9001-2015 (ISO 9001-2015)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico. Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi. Gestione della fabbricazione ed immissione in commercio di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Fabbricazione di dispositivi medici invasivi in relazione agli orifizi del corpo in Classe I Sterile. Commercializzazione di dispositivi medici e diagnostici in vitro. Commercializzazione di articoli da laboratorio

Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories of analysis. Management of the manufacturing and placing on the market of invasive medical devices with respect to body orifices (class I sterile). Manufacturing of invasive medical devices with respect to body orifices (class I sterile). Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dai Regolamenti per la certificazione in vigore applicabili.
This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.
In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana
In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2020-10-30	2023-10-29

Settore IAF 14 - 29

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

ITALCERT S.r.l. | Viale Sarca, 336 – 20126 Milano (MI) | tel. +39 0266104876 | fax. +39 0266101479 | www.italcert.it | italcertsrl@legalmail.it

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
25.11.2020

MADE IN ITALY

CODICE ARTICOLO: **SACCHETTI PER AUTOCLAVE IN POLIPROPILENE**
ITEM CODE: ***POLYPROPYLENE AUTOCLAVE BAGS***

DESCRIZIONE / *DESCRIPTION*

Sacchetti in polipropilene (PP), per sterilizzazione in autoclave, resistenti fino a 134°C. Sacchetto tipo "monopiega".
Questi sacchetti sono particolarmente utili per eliminare, mediante sterilizzazione in autoclave, sostanze patogene presenti in recipienti contaminati (pipette, provette, piastre Microtiter, ecc.).
Simbolo "BIOHAZARD" ed istruzioni per l'uso stampate direttamente sul sacchetto.
Spessore 40 my.

Polypropylene (PP) bags for autoclave sterilization, resistant up to 134°C. Bags single fold type.
These bags are particularly useful in order to remove, by autoclave sterilization process, pathogenic substances normally present in contaminated containers (pipettes, test tubes, Microtiter plates, ecc.).
"BIOHAZARD" symbol and operating instructions directly printed on the bag.
Thickness 65 my

SIMBOLO "BIOHAZARD" ED ISTRUZIONI PER L'USO STAMPATE DIRETTAMENTE SUL SACCHETTO.
STAMPA MONOCOLORE GIALLA CONFORME ALLA UNI 7545/1-10 (PANTONE 109C / RAL 1023) SU SACCHETTO TRASPARENTE.

"BIOHAZARD" SYMBOL AND OPERATING INSTRUCTIONS DIRECTLY PRINTED ON THE BAG. WRITTEN IN YELLOW COLOUR CONFORM TO UNI 7545/1-10 (PANTONE 109C / RAL 1023) PRINTED ON TRANSPARENT BAG.

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbiological status*
Materiale impiegato	POLIPROPILENE / *POLYPROPYLENE*	*Raw material*
Temperatura massima di utilizzo	+ 134 °C (+273.2 °F)	*Max working temperature*
Spessore	40 MY	*Thickness*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

CODICE *CODE*	DIMENSIONI (MM) *DIMENSIONS (MM)*	SPESSORE (MY) *THICKNESS (MY)*	VOLUME (L) *VOLUME (L)*	QUANTITÀ PER CONFEZIONE *QUANTITY FOR BOX*	DIMENSIONE DELLA CONFEZIONE *BOX DIMENSIONS*
10570	300 x 660	40	about 15	1.000	460 x 360 x 250 mm Vol. 0,041 m^3 15,0 Kg.
10571	400 x 660	40	about 30	1.000	460 x 360 x 250 mm Vol. 0,041 m^3 20,0 Kg.
10572	600 x 760	40	about 80	500	460 x 360 x 250 mm Vol. 0,041 m^3 16,5 Kg.
Tolleranze dimensionali / *Dimensional tollerances:* ± 5 mm					

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella per "USI GENERALI DI LABORATORIO". Prodotto adatto per effettuare la sterilizzazione in autoclave.
IL PRODOTTO NON È SOGGETTO A MARCATURA CE
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale in laboratori di analisi.

Intended purpose: "GENERAL LABORATORY USE". Product suitable for autoclave sterilization.
PRODUCT NOT SUBJECT TO CE MARKING.
For use in professional test laboratory only

RACCOMANDAZIONI PER L'USO

> I contenitori riempiti con liquido non devono essere sigillati o tappati;
> Non introdurre oggetti appuntiti, come vetreria rotta, nei sacchi per autoclave;
> Aggiungere un po' d'acqua ai sacchi contenenti residui solidi. L'acqua vaporizzerà convogliando all'esterno l'aria residua una volta raggiunta la temperatura di sterilizzazione internamente ai sacchi;
> Non chiudere il sacco, in quanto ciò impedirà all'aria di allontanarsi durante il processo di sterilizzazione;
> Non sovraccaricare l'autoclave e lasciare uno spazio sufficiente alla circolazione del vapore;
> Per la decontaminazione ed inertizzazione di rifiuti biologici particolarmente resistenti, autoclavare a +134°C

> Containers filled with liquid, must not be sealed or tapped;
> Do not introduce sharp objects, such as broken glassware, into the autoclave bags;
> Add a little high of water into the bags containing solid residues. The water will vaporize channeling outside the residual air once reached the sterilization temperature internally to the bags;
> Do not close the bag as this will avoid to the air to move out during the sterilization process;
> Do not overload the autoclave and leave enough space for the steam circulation;
> For the decontamination and deactivation of biological waste, particularly resistant, to do autoclave process at +134 °C.

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AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, Temperatura min -10°C max +50°C
Store in dry place, Temperature range: min -10°C max +50°C

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substances, check the resistance / compatibility chart on our catalogue

SIMBOLI UTILIZZATI SULL'IMBALLO / PACKING SYMBOLS


Data di fabbricazione
Manufacturing date


Data di scadenza
Expiry date


Consultare i documenti accompagnatori
Please consult accompanying documents

Numero di lotto
Lot number


Monouso
Disposable