Liofilchem®

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)

Digitally signed by Ceaicovschi Tudor
Date: 2024.04.22 16:31:03 EEST
Reason: MoldSign Signature
Location: Moldova

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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

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
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www.zlg.de
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:	\

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TÜV®

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

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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Certified Quality System
ISO 13485:2021
Cert. n° D2001500016
ISO 9001:2015
Cert. n° D2001500017
ISO 14001:2015
Cert. n° AQS/A/104002023

DICHIARAZIONE DI CONFORMITÀ CE PER DISPOSITIVI MEDICI DIAGNOSTICI IN VITRO
EC Declaration of Conformity for IN VITRO DIAGNOSTIC MEDICAL DEVICES

La sottoscritta, fabbricante
We, the undersigned manufacturer

Biolife Italiana S.r.l.

Con Sede Legale in
With Registered Office in

Viale Monza 272, 2018 - Milano

SRN: IT-MF-000018174

Dichiara sotto la propria responsabilità che i prodotti descritti di seguito sono classificati come
DISPOSITIVI DIAGNOSTICI IN VITRO DI CLASSE A
Valutazione della conformità in accordo a: ALLEGATO IV (Dichiarazione CE di conformità)

Herewith declare under our sole responsibility that the products described here below are **IVDs** classified as Class A.
Conformity assessment according to: ANNEX IV (EC Declaration of conformity)

Inoltre dichiara che tali prodotti sono conformi ai requisiti del:
It also declares that these products comply with the requirements of the:

Regolamento (UE) 2017/746 del parlamento Europeo e del consiglio del 5 Aprile 2017, pubblicato su GU L 117 del 5.5.2017, pag. 176
Regulation (UE) 2017/746 of the European Parliament and of the Council of 27th October 1998 of In Vitro Diagnostic Medical Device, published in the Official Journal L117 on 5th May 2017, pag.176.

Inoltre, sono applicate le seguenti Norme Armonizzate:
In addition, the following Harmonized Standards are applied:

Norme Armonizzate/ Harmonized Standards

"REACH" REGULATION 1907/2009/EC
EN ISO 13485:2016
EN ISO 14971:2019
Regulation (CE) n. 1272/2008
UNI EN 18113-1:2012
UNI EN 18113-2:2012
UNI EN 23640:2015
EN ISO 15223-1:2021
EN ISO 20417:2021
EN 12322:1999

Emissione/ Emission *:* 18/09/2023
Rev. 05 - IVDR

Valentina Surace
Quality Assurance &
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TERRENI DI COLTURA PRONTI IN FLACONE / READY-TO USE CULTURE MEDIA IN FLASK			
REF.	**PRODUCT NAME**	**UDI-DI**	**BASIC UDI-DI**
5115412	HEKTOEN ENTERIC AGAR - 6 x 100 mL	08054187137266	805418713MEDIAFLASK0051E4
5115413	HEKTOEN ENTERIC AGAR - 6 x 200 mL	08054187137273	805418713MEDIAFLASK0051E4
5115824	LEGIONELLA AGAR BASE (BCYE) - 6 X 180 mL	08054187137280	805418713MEDIAFLASK0051E4
5116702	MAC CONKEY AGAR - 6 x 100 mL	08054187137419	805418713MEDIAFLASK0051E4
5116703	MAC CONKEY AGAR (EP, USP, JP) - 6 x 200 mL	08054187137426	805418713MEDIAFLASK0051E4
5118102	NUTRIENT AGAR (ISO 8523/6579/10273) - 6 x 100 mL	08054187137501	805418713MEDIAFLASK0051E4
5119632	PSEUDOMONAS SELECTIVE AGAR (CETRIMIDE) (EP, USP, JP) - 6 x 100 mL	08054187137655	805418713MEDIAFLASK0051E4
5120002	SABOURAUD BROTH - 6 x 100 mL	08054187137730	805418713MEDIAFLASK0051E4
5120052	SABOURAUD DEXTROSE AGAR (EP, USP, JP) - 6 x 100 mL	08054187137747	805418713MEDIAFLASK0051E4
5120053	SABOURAUD DEXTROSE AGAR (EP, USP, JP) - 6 x 200 mL	08054187137754	805418713MEDIAFLASK0051E4
5120062	SABOURAUD DEXTROSE AGAR W/CAF 50 - 6 x 100 mL	08054187137761	805418713MEDIAFLASK0051E4
5120063	SABOURAUD DEXTR.AG+CAF - 6 x 200 mL	08054187138973	805418713MEDIAFLASK0051E4
5120252	SELENITE BROTH - 6 x 100 mL	08054187137778	805418713MEDIAFLASK0051E4
5121372	THIOGLYCOLLATE MEDIUM - 6 x 100 mL	08054187137013	805418713MEDIAFLASK0051E4
5121502	TRYPTIC SOY AGAR (EP, USP, JP) - 6 x 100 mL	08054187137853	805418713MEDIAFLASK0051E4
5121503	TRYPTIC SOY AGAR (EP, USP, JP) - 6 x 200 mL	08054187137860	805418713MEDIAFLASK0051E4
5121552	TRYPTIC SOY BROTH (EP, USP, JP) - 6 x 100 mL	08054187137877	805418713MEDIAFLASK0051E4
5121553	TRYPTIC SOY BROTH (EP, USP, JP) - 6 x 200 mL	08056450500012	805645050MEDIAFLASK00518E

TERRENI DI COLTURA PRONTI IN PIASTRA / READY-TO USE CULTURE MEDIA IN PLATES			
REF.	**PRODUCT NAME**	**UDI-DI**	**BASIC UDI-DI**
491013	DERMATOPHYTE TEST MEDIUM/SABOURAUD DEXTROSE AGAR + CAF - 20 piastre	08054187136900	805418713MEDIAPLATES049TG
491032	XLD AGAR/SS AGAR - 20 piastre	08054187136924	805418713MEDIAPLATES049TG
495350	CHROMOGENIC SALMONELLA AGAR/HEKTOEN ENTERIC AGAR - 20 piastre	08054187136979	805418713MEDIAPLATES049TG
495351	CHROMOGENIC SALMONELLA AGAR/XLD AGAR - 20 piastre	08054187136986	805418713MEDIAPLATES049TG
541111	CAMPYLOBACTER AGAR BLASER WANG - 20 piastre	08054187133411	805418713MEDIAPLATES054T9
541136	COLUMBIA BLOOD AGAR - 20 piastre	08054187131875	805418713MEDIAPLATES054T9
541151	BLOOD AGAR SHEEP - 20 piastre	08054187131738	805418713MEDIAPLATES054T9
541153	BCSA BURKHOLDERIA CEPACIA SELECTIVE AGAR NOVITÀ - 20 piastre	08056450505345	805645050MEDIAPLATES054MK
541180	BLOOD AGAR HORSE - 20 piastre	08054187133381	805418713MEDIAPLATES054T9
541235	BRAIN HEART INFUSION AGAR - 20 piastre	08054187133428	805418713MEDIAPLATES054T9
541283	CAMPYLOBACTER BLOOD FREE AGAR (KARMALI) - 20 piastre	08054187131745	805418713MEDIAPLATES054T9
541361	COLUMBIA CNA BLOOD AGAR - 20 piastre	08054187131882	805418713MEDIAPLATES054T9
541363	COLUMBIA CNA-CV BLOOD AGAR - 20 piastre	08054187131899	805418713MEDIAPLATES054T9
541369	DERMATOPHYTE SELECTIVE MEDIUM (DTM) - 20 piastre	08054187136085	805418713MEDIAPLATES054T9
541519	CHOCOLATE AGAR BACITRACINE - 20 piastre	08054187131776	805418713MEDIAPLATES054T9
541521	CHOCOLATE AGAR ENRICHED - 20 piastre	08054187131783	805418713MEDIAPLATES054T9
541522	MODIFIED THAYER MARTIN AGAR - 20 piastre	08054187136641	805418713MEDIAPLATES054T9
541541	HEKTOEN ENTERIC AGAR - 20 piastre	08054187131929	805418713MEDIAPLATES054T9
541595	LEVINE EMB BLUE AGAR - 20 Piastre	08054187136672	805418713MEDIAPLATES054T9
541665	MANNITOL SALT AGAR - 20 piastre	08054187132025	805418713MEDIAPLATES054T9
541670	MAC CONKEY AGAR - 20 piastre	08054187132001	805418713MEDIAPLATES054T9
541672	MAC CONKEY AGAR MUG - 20 piastre	08054187132018	805418713MEDIAPLATES054T9
541740	MUELLER HINTON AGAR II - 20 piastre	08054187132056	805418713MEDIAPLATES054T9
541742	MUELLER HINTON CHOCOLATE AGAR - 20 piastre	08054187136337	805418713MEDIAPLATES054T9
541743	MUELLER HINTON AGAR BLOOD SHEEP - 20 piastre	08054187136344	805418713MEDIAPLATES054T9
541810	NUTRIENT AGAR - 20 piastre	08054187136351	805418713MEDIAPLATES054T9
541901	CLED AGAR - 20 piastre	08054187131820	805418713MEDIAPLATES054T9
541963	PSEUDOMONAS SELECTIVE AGAR - 20 piastre	08054187132070	805418713MEDIAPLATES054T9
541985	ROGOSA BIOS AGAR - 20 piastre	08054187132087	805418713MEDIAPLATES054T9

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542005	SABOURAUD DEXTROSE AGAR - 20 piastre	08054187132100	805418713MEDIAPLATES054T9
542006	SABOURAUD DEXTROSE AGAR + CAF - 20 piastre	08054187132117	805418713MEDIAPLATES054T9
542008	SABOURAUD DEXTROSE AGAR +CAF+CYCLOHEXIMIDE - 20 piastre	08054187132124	805418713MEDIAPLATES054T9
542009	SABOURAUD DEXTROSE AGAR + CAF + GENTAMICIN - 20 piastre	08054187132131	805418713MEDIAPLATES054T9
542075	SS AGAR - 20 piastre	08054187132162	805418713MEDIAPLATES054T9
542106	TCBS KOBAYASHI AGAR - 20 piastre	08054187136443	805418713MEDIAPLATES054T9
542150	TRYPTIC SOY AGAR - 20 piastre	08054187132261	805418713MEDIAPLATES054T9
542181	UREAPLASMA DIFFERENTIAL AGAR A7 - 20 piastre	08054187135804	805418713MEDIAPLATES054T9
542200	WURTZ AGAR - 20 piastre	08054187132278	805418713MEDIAPLATES054T9
542206	XLD AGAR - 20 piastre	08054187132285	805418713MEDIAPLATES054T9
545350	CHROMOGENIC SALMONELLA AGAR - 20 piastre	08054187131790	805418713MEDIAPLATES054T9
546550	STRONGYLOIDES STERCORALIS AGAR - 20 piastre	08054187136719	805418713MEDIAPLATES054T9
548000	CHROMALBICANS AGAR - 20 piastre	08054187136702	805418713MEDIAPLATES054T9
548005	CHROMOGENIC CANDIDA AGAR - 20 piastre	08054187136139	805418713MEDIAPLATES054T9
548010	CHROMOGENIC STREPTO B AGAR - 20 piastre	08054187132346	805418713MEDIAPLATES054T9
548015	CHROMART CRE - 20 piastre	08056450503570	805645050MEDIAPLATES054MK
548020	CHROMART ESBL - 20 piastre	08056450503563	805645050MEDIAPLATES054MK
549510	OXACILLIN-SALT SCREEN AGAR - 20 piastre	08054187136696	805418713MEDIAPLATES054T9
549520	VANCOMYCIN SCREEN AGAR - 20 piastre	08054187136726	805418713MEDIAPLATES054T9
549850	SUPPLEMENTED BRUCELLA AGAR - 20 piastre	08054187135002	805418713MEDIAPLATES054T9
549901	HAEMOPHILUS TEST MEDIUM - 20 piastre	08054187131912	805418713MEDIAPLATES054T9
549905	BORDETELLA SELECTIVE AGAR - 20 piastre	08054187134890	805418713MEDIAPLATES054T9
549907	SCHAEDLER SELECTIVE CNA BLOOD AGAR - 20 piastre	08054187136771	805418713MEDIAPLATES054T9
549943	LEGIONELLA AGAR BASE W/O CYSTEINE - 20 piastre	08054187131974	805418713MEDIAPLATES054T9
549945	LEGIONELLA AGAR - 20 piastre	08054187131967	805418713MEDIAPLATES054T9
549989	SCHAEDLER BLOOD AGAR - 20 piastre	08056450500753	805645050MEDIAPLATES054MK
549990	SCHAEDLER SELECTIVE BLOOD AGAR - 20 piastre	08054187139529	805418713MEDIAPLATES054T9
549993	GARDNERELLA SELECTIVE AGAR - 20 piastre	08054187131905	805418713MEDIAPLATES054T9
549994	HERELLEA AGAR - 20 piastre	08056450501040	805645050MEDIAPLATES054MK
549995	LEGIONELLA SELECTIVE AGAR (GVPC) - 20 piastre	08054187131950	805418713MEDIAPLATES054T9
549997	YERSINIA SELECTIVE MEDIUM - 20 piastre	08054187136603	805418713MEDIAPLATES054T9
549998	SERUM TELLURITE AGAR - 20 piastre	08054187135798	805418713MEDIAPLATES054T9
501740P	MUELLER HINTON AGAR II 150 mm - 5 piastre	08054187132308	805418713MEDIAPLATES054T9
541669S	MAC CONKEY SORBITOL AGAR - 20 piastre	08054187136290	805418713MEDIAPLATES054T9
541740F	MUELLER HINTON AGAR F (MHA-F) - 20 piastre	08054187136320	805418713MEDIAPLATES054T9
549810G	CHROMOGENIC URINE AGAR IV - 20 piastre	08054187132032	805418713MEDIAPLATES054T9
54RPMI15	RPMI AGAR 150 mm - 5 piastre	08054187132339	805418713MEDIAPLATES054T9
54RPMI90	RPMI AGAR 90 mm - 20 piastre	08054187132094	805418713MEDIAPLATES054T9

TERRENI DI COLTURA PRONTI IN PIASTRA - linea COLOREX / READY-TO USE CULTURE MEDIA IN PLATES - COLOREX

REF.	PRODUCT NAME	UDI-DI	BASIC UDI-DI
54AC09	COLOREXTM ACINETOBACTER - 20 piastre	08056450505925	805645050COLOREXPLATE54RE
54AC09R	COLOREXTM ACINETOBACTER MDR - 20 piastre	08056450505956	805645050COLOREXPLATE54RE
54CD12	COLOREXTM CLOSTRIDIUM DIFFICILE - 20 piastre	08056450505901	805645050COLOREXPLATE54RE
54CO26	COLOREXTM COLISTIN RESISTANCE - 20 piastre	08056450505932	805645050COLOREXPLATE54RE
54CP57	COLOREXTM CAMPYLOBACTER - 20 piastre	08056450505963	805645050COLOREXPLATE54RE
54CS17	COLOREXTM SUPERCARBA - 20 piastre	08056450505918	805645050COLOREXPLATE54RE
54LN76	COLOREXTM LINEZOLID RESISTANCE - 20 piastre	08056450506069	805645050COLOREXPLATE54RE
54MR50	COLOREXTM MRSA - 20 piastre	08056450505949	805645050COLOREXPLATE54RE
54SP37	COLOREXTM STREP A - 20 piastre	08056450506052	805645050COLOREXPLATE54RE
54TA67	COLOREXTM STAPHYLOCOCCUS AUREUS - 20 piastre	08056450505994	805645050COLOREXPLATE54RE
54VRE95	COLOREXTM VRE - 20 piastre	08056450505895	805645050COLOREXPLATE54RE
54ST16	COLOREX TM STEC - 20 piastre	08056450506502	805645050COLOREXPLATE54RE

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54CA24	COLOREX TM CANDIDA PLUS - 20 piastre	08056450506571	805645050COLOREXPLATE54RE

TERRENI DI COLTURA PRONTI IN PROVETTA / READY-TO USE CULTURE MEDIA IN TUBES			
REF.	**PRODUCT NAME**	**UDI-DI**	**BASIC UDI-DI**
551146	BIOTONE BROTH (TRYPTOSE) - 20 x 9 mL	08054187132216	805418713MEDIATUBES0055TC
551230	BRAIN HEART INFUSION BROTH - 20 x 9 mL	08054187131592	805418713MEDIATUBES0055TC
551524	GN BROTH HAJNA (ISTISAN 07/05) - 20 x 9 mL	08054187134746	805418713MEDIATUBES0055TC
551560	KLIGLER IRON AGAR (ISO 6579) - 20 pv incl.	08054187134753	805418713MEDIATUBES0055TC
551634	IUT MEDIUM - 20 pv incl.	08054187131615	805418713MEDIATUBES0055TC
551635	LOWENSTEIN-JENSEN MEDIUM - 20 pv incl.	08054187131622	805418713MEDIATUBES0055TC
551636	LYSINE IRON AGAR - 20 pv incl.	08054187132988	805418713MEDIATUBES0055TC
551743	MULLER KAUFFMANN TETRATHIONATE BROTH - 20 x 10 mL	08054187131646	805418713MEDIATUBES0055TC
551810	NUTRIENT AGAR (ISO 8523/6579/10273) - 20 pv incl.	08054187134791	805418713MEDIATUBES0055TC
551815	NUTRIENT BROTH - 20 x 9 mL	08054187133015	805418713MEDIATUBES0055TC
551980	RAPPAPORT VASSILIADIS BROTH (ISTISAN 96/35) - 20 x 10 mL	08054187131660	805418713MEDIATUBES0055TC
552000	SABOURAUD BROTH (EP, USP, JP) - 20 x 9 mL	08054187131462	805418713MEDIATUBES0055TC
552006	SABOURAUD DEXTROSE AGAR W/CAF 50 - 20 pv incl.	08054187132537	805418713MEDIATUBES0055TC
552008	SABOURAUD DEXTROSE AGAR WITH CAF CEX - 20 pv incl.	08054187132551	805418713MEDIATUBES0055TC
552025	SELENITE BROTH - 20 x 9 mL	08054187131387	805418713MEDIATUBES0055TC
552134	TODD-HEWITT BROTH - 20 x 9 mL	08054187133800	805418713MEDIATUBES0055TC
552137	THIOGLYCOLLATE MEDIUM (EP, USP, JP) - 20 x 10 mL	08054187131400	805418713MEDIATUBES0055TC
552141	TRIPLE SUGAR IRON AGAR USP - 20 pv incl.	08054187132995	805418713MEDIATUBES0055TC
552150	TRYPTIC SOY AGAR (EP, USP, JP) - 20 pv incl.	08054187134852	805418713MEDIATUBES0055TC
552155	TRYPTIC SOY BROTH (EP, USP, JP) - 20 x 9 mL	08054187132513	805418713MEDIATUBES0055TC
552175	UREA AGAR (ISO 6579) - 20 pv incl.	08054187134876	805418713MEDIATUBES0055TC
554002	PERGOLA MEDIUM - 20 pv incl.	08054187134982	805418713MEDIATUBES0055TC
5513311	TRICHOMONAS CPLM SELECTIVE BROTH - 20 x 9 mL	08054187131608	805418713MEDIATUBES0055TC
552134B	TODD-HEWITT CNA BROTH (LIM BROTH) - 20 x 9 mL	08054187133817	805418713MEDIATUBES0055TC

TERRENI DISIDRATATI / DEHYDRATED MEDIA			
REF.	**PRODUCT NAME**	**UDI-DI**	**BASIC UDI-DI**
4011362	COLUMBIA AGAR BASE - 500 g	08054187139147	805418713MEDIAPOWDER040ZN
4011364	COLUMBIA AGAR BASE - 5 Kg	08054187139154	805418713MEDIAPOWDER040ZN
4011462	TRYPTOSE BROTH (BIOTONE) - 500 g	08054187138591	805418713MEDIAPOWDER040ZN
4011464	TRYPTOSE BROTH (BIOTONE) - 5 kg	08054187138607	805418713MEDIAPOWDER040ZN
4011532	BCSA BURKHOLDERIA CEPACIA SELECTIVE AGAR BASE NOVITÀ - 500 g	08056450505314	805645050MEDIAPOWDER040TY
4011552	BLOOD AGAR BASE - 500 g	08054187138638	805418713MEDIAPOWDER040ZN
4011554	BLOOD AGAR BASE - 5 Kg	08054187138645	805418713MEDIAPOWDER040ZN
4011562	BLOOD AGAR BASE N° 2 - 500 g	08054187134043	805418713MEDIAPOWDER040ZN
4011564	BLOOD AGAR BASE N° 3 - 5 Kg	08054187138652	805418713MEDIAPOWDER040ZN
4012302	BRAIN HEART INFUSION BROTH - 500 g	08054187133527	805418713MEDIAPOWDER040ZN
4012304	BRAIN HEART INFUSION BROTH - 5 Kg	08054187133510	805418713MEDIAPOWDER040ZN
4012352	BRAIN HEART INFUSION AGAR - 500 g	08054187138669	805418713MEDIAPOWDER040ZN
4012354	BRAIN HEART INFUSION AGAR - 5 Kg	08054187138676	805418713MEDIAPOWDER040ZN
4012802	CANDIDA AGAR (NICKERSON) - 500 g	08054187138751	805418713MEDIAPOWDER040ZN
4012832	CAMPYLOBACTER BLOOD FREE MEDIUM BASE KARMALI - 500 g	08054187133930	805418713MEDIAPOWDER040ZN
4013022	CIN AGAR BASE - 500 g	08054187135019	805418713MEDIAPOWDER040ZN
4013302	DRIGALSKY LACTOSE AGAR - 500 g	08054187139260	805418713MEDIAPOWDER040ZN
4013662	DECARBOXYLASE MOELLER BASE BROTH - 500 g	08054187139208	805418713MEDIAPOWDER040ZN
4013682	DESOXYRIBONUCLEASE TEST MEDIUM (Dnase) - 500 g	08054187134715	805418713MEDIAPOWDER040ZN
4013702	DESOXYCHOLATE AGAR - 500 g	08054187139215	805418713MEDIAPOWDER040ZN
4013752	DESOXYCHOLATE CITRATE AGAR - 500 g	08054187139239	805418713MEDIAPOWDER040ZN
4015202	GC MEDIUM BASE - 500 g	08054187139420	805418713MEDIAPOWDER040ZN

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4015204	GC MEDIUM BASE - 5 Kg	08054187139437	805418713MEDIAPOWDER040ZN
4015242	GN BROTH HAJNA - 500 g	08054187137365	805418713MEDIAPOWDER040ZN
4015412	HEKTOEN ENTERIC AGAR - 500 g	08054187134081	805418713MEDIAPOWDER040ZN
4015414	HEKTOEN ENTERIC AGAR - 5 Kg	08054187134074	805418713MEDIAPOWDER040ZN
4015432	HERELLEA AGAR - 500 g	08054187139482	805418713MEDIAPOWDER040ZN
4015602	KLIGLER IRON AGAR - 500 g	08054187138836	805418713MEDIAPOWDER040ZN
4015822	LEGIONELLA BCYE AGAR BASE - 500 g	08054187131271	805418713MEDIAPOWDER040ZN
4015824	LEGIONELLA BCYE AGAR B - 5 Kg	08054187131240	805418713MEDIAPOWDER040ZN
4015952	LEVINE EMB BLUE AGAR - 500 g	08054187139581	805418713MEDIAPOWDER040ZN
4015954	LEVINE EMB BLUE AGAR - 5 Kg	08054187139604	805418713MEDIAPOWDER040ZN
4016352	LOWENSTEIN JENSEN MEDIUM BASE - 500 g	08054187133046	805418713MEDIAPOWDER040ZN
4016354	LOWENSTEIN JENSEN MEDIUM BASE - 5 Kg	08054187133053	805418713MEDIAPOWDER040ZN
4016362	LYSINE IRON AGAR - 500 g	08054187139000	805418713MEDIAPOWDER040ZN
4016652	MANNITOL SALT AGAR - 500 g	08054187133534	805418713MEDIAPOWDER040ZN
4016654	MANNITOL SALT AGAR - 5 Kg	08054187133541	805418713MEDIAPOWDER040ZN
4016702	MAC CONKEY AGAR - 500 g	08054187132254	805418713MEDIAPOWDER040ZN
4016704	MAC CONKEY AGAR - 5 Kg	08054187132247	805418713MEDIAPOWDER040ZN
4016722	MAC CONKEY AGAR MUG - 500 g	08054187139741	805418713MEDIAPOWDER040ZN
4016724	MAC CONKEY AGAR MUG - 5 Kg	08054187139758	805418713MEDIAPOWDER040ZN
4016852	MALONATE BROTH - 500 g	08054187139772	805418713MEDIAPOWDER040ZN
4017352	MRVP MEDIUM - 500 g	08054187133176	805418713MEDIAPOWDER040ZN
4017402	MUELLER HINTON AGAR II - 500 g	08054187136245	805418713MEDIAPOWDER040ZN
4017404	MUELLER HINTON AGAR II - 5 Kg	08054187136238	805418713MEDIAPOWDER040ZN
4017412	MUELLER HINTON BROTH - 500 g	08054187139871	805418713MEDIAPOWDER040ZN
4017432	MULLER KAUFFMANN TETRATHIONATE BROTH BASE - 500 g	08054187139888	805418713MEDIAPOWDER040ZN
4017434	MULLER KAUFFMAN TET.BROTH - 5 Kg	08054187139895	805418713MEDIAPOWDER040ZN
4018102	NUTRIENT AGAR - 500 g	08054187133206	805418713MEDIAPOWDER040ZN
4018104	NUTRIENT AGAR - 5 Kg	08054187133213	805418713MEDIAPOWDER040ZN
4018152	NUTRIENT BROTH - 500 g	08054187137105	805418713MEDIAPOWDER040ZN
4018154	NUTRIENT BROTH - 5 Kg	08054187137112	805418713MEDIAPOWDER040ZN
4018362	O/F HUGH LEIFSON BASE - 500 g	08056450500050	805645050MEDIAPOWDER040TY
4019162	PHENYLALANINE AGAR - 500 g	08054187135712	805418713MEDIAPOWDER040ZN
4019632	PSEUDOMONAS SELECTIVE AGAR - 500 g	08054187133978	805418713MEDIAPOWDER040ZN
4019802	RAPPAPORT VASSILIADIS (RV) BROTH - 500 g	08054187132612	805418713MEDIAPOWDER040ZN
4019804	RAPPAP.VASSILIAD(RV)BROTH - 5 Kg	08054187132629	805418713MEDIAPOWDER040ZN
4019852	ROGOSA BIOS AGAR - 500 g	08054187134678	805418713MEDIAPOWDER040ZN
4020002	SABOURAUD BROTH - 500 g	08054187131431	805418713MEDIAPOWDER040ZN
4020004	SABOURAUD BROTH - 5 Kg	08054187131455	805418713MEDIAPOWDER040ZN
4020052	SABOURAUD DEXTROSE AGAR - 500 g	08054187131257	805418713MEDIAPOWDER040ZN
4020054	SABOURAUD DEXTROSE AGAR - 5 Kg	08054187131264	805418713MEDIAPOWDER040ZN
4020062	SABOURAUD DEXTROSE AGAR W/ CAF 50 mg - 500 g	08054187131936	805418713MEDIAPOWDER040ZN
4020064	SABOURAUD DEXTROSE AGAR W/ CAF 50 mg - 5 Kg	08054187131943	805418713MEDIAPOWDER040ZN
4020072	SABOURAUD DEXTROSE AGAR W/ CAF 500 mg - 500 g	08056450500180	805645050MEDIAPOWDER040TY
4020252	SELENITE BROTH - 500 g	08054187136153	805418713MEDIAPOWDER040ZN
4020254	SELENITE BROTH - 5 Kg	08054187136160	805418713MEDIAPOWDER040ZN
4020362	SIM BIOS MEDIUM - 500 g	08056450500289	805645050MEDIAPOWDER040TY
4020452	SIMMONS CITRATE AGAR - 500 g	08054187132179	805418713MEDIAPOWDER040ZN
4020752	SS AGAR - 500 g	08054187138393	805418713MEDIAPOWDER040ZN
4020754	SS AGAR - 5 Kg	08054187138409	805418713MEDIAPOWDER040ZN
4021062	TCBS KOBAYASHI AGAR - 500 g	08054187134562	805418713MEDIAPOWDER040ZN
4021064	TCBS KOBAYASHI AGAR - 5 Kg	08054187134579	805418713MEDIAPOWDER040ZN
4021342	TODD-HEWITT BROTH - 500 g	08056450500456	805645050MEDIAPOWDER040TY
4021372	THIOGLYCOLLATE MEDIUM - 500 g	08054187133282	805418713MEDIAPOWDER040ZN

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4021374	THIOGLYCOLLATE MEDIUM - 5 Kg	08054187133299	805418713MEDIAPOWDER040ZN
4021412	TRIPLE SUGAR IRON AGAR U.S.P. - 500 g	08054187134029	805418713MEDIAPOWDER040ZN
4021502	TRYPTIC SOY AGAR - 500 g	08054187131356	805418713MEDIAPOWDER040ZN
4021504	TRYPTIC SOY AGAR - 5 Kg	08054187131370	805418713MEDIAPOWDER040ZN
4021512	TRYPTIC SOY BLOOD AGAR BASE - 500 g	08054187134197	805418713MEDIAPOWDER040ZN
4021514	TRYPTIC SOY BLOOD AGAR BASE - 5 Kg	08054187134203	805418713MEDIAPOWDER040ZN
4021552	TRYPTIC SOY BROTH - 500 g	08054187133725	805418713MEDIAPOWDER040ZN
4021554	TRYPTIC SOY BROTH - 5 Kg	08054187133732	805418713MEDIAPOWDER040ZN
4021752	UREA AGAR BASE-CHRISTENSEN - 500 g	08056450500470	805645050MEDIAPOWDER040TY
4021802	UREA BROTH BASE - STUART - 500 g	08054187135729	805418713MEDIAPOWDER040ZN
4022062	XLD AGAR - 500 g	08054187131547	805418713MEDIAPOWDER040ZN
4022064	XLD AGAR - 5 Kg	08054187131554	805418713MEDIAPOWDER040ZN
4053502	CHROMOGENIC SALMONELLA AGAR BASE - 500 g	08054187139079	805418713MEDIAPOWDER040ZN
4080002	CHROMALBICANS AGAR - 500 g	08054187133893	805418713MEDIAPOWDER040ZN
4080052	CHROMOGENIC CANDIDA AGAR - 500 g	08054187137556	805418713MEDIAPOWDER040ZN
4080102	CHROMOGENIC STREPTO B AGAR BASE - 500 g	08054187138225	805418713MEDIAPOWDER040ZN
4080252	CHROMART CRE-ESBL AGAR BASE - 500 g	08056450503587	805645050MEDIAPOWDER040TY
40113612	COLUMBIA CNA AGAR BASE - 500 g	08056450500388	805645050MEDIAPOWDER040TY
40113614	COLUMBIA CNA AGAR BASE - 5 Kg	08056450500395	805645050MEDIAPOWDER040TY
40121022	BISMUTH SULPHITE AGAR - 500 g	08054187138621	805418713MEDIAPOWDER040ZN
40129012	CLED MEDIUM - 500 g	08054187139116	805418713MEDIAPOWDER040ZN
40129014	CLED MEDIUM - 5 kg	08056450501545	805645050MEDIAPOWDER040TY
40136912	DERMATOPHYTE SELECTIVE MEDIUM - DTM - (TAPLIN) - 500 g	08056450501002	805645050MEDIAPOWDER040TY
402025B2	SELENITE BROTH BASE - 500 g	08056450501682	805645050MEDIAPOWDER040TY
409810G2	CHROMOGENIC URINE AGAR IV - 500 g	08054187137358	805418713MEDIAPOWDER040ZN
4011534	BCSA BURKHOL.CEP.SEL.AGAR BASE - 5 kg	08056450505321	805645050MEDIAPOWDER040TY
4019634	PSEUDOMONAS SELECTIVE AG. - 5 kg	08054187133961	805418713MEDIAPOWDER040ZN
4053504	CHROMOGENIC SALMO.AG.BASE - 5 kg	08056450503037	805645050MEDIAPOWDER040TY
4080004	CHROMALBICANS AGAR - 5 kg	08054187133909	805418713MEDIAPOWDER040ZN
4080054	CHROMOGENIC CANDIDA AGAR - 5 kg	08056450503181	805645050MEDIAPOWDER040TY

ADDITIVI PER TERRENI DI COLTURA / ADDITIVES FOR CULTURE MEDIA			
REF.	**PRODUCT NAME**	**UDI-DI**	**BASIC UDI-DI**
423210	LEGIONELLA BCYE α-GROWTH SUPPLEMENT - 4 fl (1x500 mL T)	08054187133770	805418713SUPPLEMENTS042KX
423212	LEGIONELLA BCYE α-GROWTH SUPPLEMENT w/o CYSTEINE - 4 fl (1x500 mL T)	08056450501767	805645050SUPPLEMENTS042E9
423215	LEGIONELLA GVPC SELECTIVE SUPPLEMENT - 4 fl (1x500 mL T)	08054187135460	805418713SUPPLEMENTS042KX
4240007	VCN ANTIMICROBIC SUPPLEMENT - 10 fl (1x500 mL T)	08054187134395	805418713SUPPLEMENTS042KX
4240008	VCNT ANTIMICROBIC SUPPLEMENT - 10 fl (1x500 mL T)	08054187135675	805418713SUPPLEMENTS042KX
4240009	BIOVITEX -RESTORING FLUID - 5+5 (1+1x500 mL T)	08056450503273	805645050SUPPLEMENTS042E9
4240011	YERSINIA SELECTIVE SUPPLEMENT - 10 fl (1x500 mL T)	08054187135521	805418713SUPPLEMENTS042KX
4240013	SALMONELLA SELECTIVE SUPPLEMENT - 5+5 fl (1+1 x500 mL T)	08054187136009	805418713SUPPLEMENTS042KX
4240013A	SALMONELLA SELECTIVE SUPPLEMENT VIAL A	08056450506625	805645050SUPPLEMENTS042E9
4240013B	SALMONELLA SELECTIVE SUPPLEMENT VIAL B	08056450506637	805645050SUPPLEMENTS042E9
425350EAES2	SALMONELLA LIQUID SUPPLEMENT (VIAL A), 6 vials, each for 10 litres of medium base	08056450503754	805645050SUPPLEMENTS042E9
425350SAES2	SALMONELLA SELECTIVE SUPPLEMENT (VIAL B), 6 vials, each for 10 litres of medium base	08056450503761	805645050SUPPLEMENTS042E9
4240016	SKIRROW ANTIMICROBIC SUPPLEMENT - 10 fl (1x500 mL T)	08054187136016	805418713SUPPLEMENTS042KX
4240018	CNA ANTIMICROBIC SUPPLEMENT - 10 fl (1x500 mL T)	08054187134517	805418713SUPPLEMENTS042KX
4240019	GARDNERELLA ANTIMICROBIC SUPPLEMENT	08054187135392	805418713SUPPLEMENTS042KX
4240021	CAMPYLOBACTER GROWTH SUPPLEMENT - 10 fl (1x500 mL T)	08054187134494	805418713SUPPLEMENTS042KX
4240024	DERMATOPHYTE ANTIMICROBIC SUPPLEMENT - 10 fl (1x500 mL T)	08054187135378	805418713SUPPLEMENTS042KX
4240035	KARMALI ANTIMICROBIC SUPPLEMENT - 10 fl (1x500 mL T)	08054187135439	805418713SUPPLEMENTS042KX
4240053	STREPTO B SUPPLEMENT - 10 fl (1x500 mL T)	08054187138300	805418713SUPPLEMENTS042KX
4240073	BCSA Selective supplement - 10 fl (1x500 mL T)	08056450505338	805645050SUPPLEMENTS042E9

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4240080	CHROMART ESBL SUPPLEMENT - 10 fl (1x500 mL T)	08056450503631	805645050SUPPLEMENTS042E9
4240082	CHROMART CRE SUPPLEMENT - 10 fl (1x500 mL T)	08056450503624	805645050SUPPLEMENTS042E9
4240096	UREA 40% SOLUTION - 10 x 5 mL	08056450500425	805645050SUPPLEMENTS042E9
42185011	BIOVITEX -RESTORING FLUID - 1+1 (x 5 Litri T)	08054187135163	805418713SUPPLEMENTS042KX
42211601	UREA 40% SOLUTION - 50 mL	08054187135149	805418713SUPPLEMENTS042KX

IVD PER L'IDENTIFICAZIONE MICROBICA / IVD FOR MICROBIAL IDENTIFICATION

REF.	PRODUCT NAME	UDI-DI	BASIC UDI-DI
191500	MUCAP TEST - 8 mL	08054187132933	805418713MICROIDENTIFICKJ
429936	COAGULASE PLASMA EDTA - 4 fl x 15mL	08054187135538	805418713MICROIDENTIFICKJ
429937	COAGULASE PLASMA EDTA - 4 fl x 7,5mL	08054187132391	805418713MICROIDENTIFICKJ
429938	COAGULASE PLASMA EDTA - 10 x 3mL	08054187132407	805418713MICROIDENTIFICKJ
19171000	KOVACS' REAGENT - 50 mL	08054187138041	805418713MICROIDENTIFICKJ
19171001	KOVACS' REAGENT - 500 mL	08054187138058	805418713MICROIDENTIFICKJ
191040ST	OXIDASE TEST STRIPS - 30 pz	08054187132926	805418713MICROIDENTIFICKJ

SISTEMI DI RACCOLTA - TRATTAMENTO / COLLECTION - TREATMENT SYSTEMS

REF.	PRODUCT NAME	UDI-DI	BASIC UDI-DI
225000	A.L.L. DIGESTION NEUTRALISATION KIT - circa 20 test	08054187132872	805418713COLLECTION00223D
225020	A.L.L. SOLUTION - 50 mL	08054187132896	805418713COLLECTION00223D
225040	PHOSPHATE BUFFER 0,067 M pH 6,8 - 500 mL	08054187132902	805418713COLLECTION00223D
2203454	DIGESTION REAGENT - 500 mL	08054187133008	805418713COLLECTION00223D
224001	SPUTAFLUID - 4 flaconi	08054187132865	805418713COLLECTION00223D

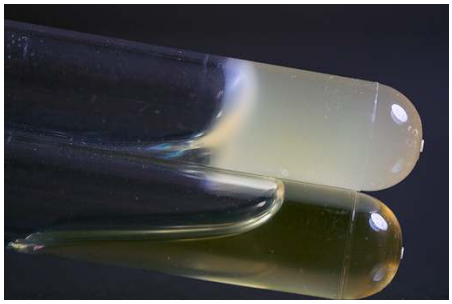
KIT PER PARASSITOLOGIA / PARASITOLOGY KIT

REF.	PRODUCT NAME	UDI-DI	BASIC UDI-DI
25RPP2000	MINI-SYSTEM ECOSAF 150 pezzi	08056450506311	805645050PARASITOLOGY25Q3
25RPP8010	MIDI-SYSTEM ECOSAF 98 pezzi	08056450506328	805645050PARASITOLOGY25Q3
25RPPEY	MINI-SYSTEM EMPTY BULK 500 PZ	08056450506724	805645050PARASITOLOGY25Q3
25RPP7000	MINI-SYSTEM PARAGREEN	08056450506267	805645050PARASITOLOGY25Q3
25RPP8000	MIDI-SYSTEM PARAGREEN	08056450506274	805645050PARASITOLOGY25Q3

INSTRUCTIONS FOR USE

COAGULASE PLASMA EDTA

Biochemical identification reagent



Coagulase Plasma. From the top to bottom: *S.aureus* (+) and *S.epidermidis* (-)

1 - INTENDED USE

In vitro diagnostic. For the qualitative detection of coagulase enzyme in staphylococci.

2 – TYPICAL COMPOSITION – VIAL CONTENT *

REF 429936: Rabbit Plasma EDTA, 5.0 mL (lyophilized)
REF 429937: Rabbit Plasma EDTA, 2.5 mL (lyophilized)
REF 429938: Rabbit Plasma EDTA, 1.0 mL (lyophilized)

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

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

The coagulase test was developed from observations, in the early 1900s, that certain staphylococci clotted plasma from the goose,[1] man, horse, and sheep[2]. Today, the widely used and generally accepted method of differentiating staphylococci associated with acute infection or food poisoning is the identification of extracellular coagulase production using a tube coagulase test.[3,4] Based on their ability to clot plasma, staphylococci may be divided into coagulase-positive or coagulase-negative ones.
The enzyme coagulase acts on a “coagulase reacting factor” present in rabbit plasma, producing a thrombin-like substance which activates fibrinogen to form fibrin, causing the plasma to clot. Coagulase exists in two forms: “bound coagulase” (or clumping factor) which is bound to the cell wall and “free coagulase” which is liberated by the cell wall. Bound coagulase is detected by the slide coagulase test, whereas both free and bound coagulase are detected by the tube coagulase test.[5]
Coagulase Plasma EDTA, in the different proposed formats, is recommended for performing the tube test. Typically, rabbit plasma is inoculated with growth from isolated colonies and examined for the presence of a gel or clot at 4 hours and, if negative, examined again at 24 hours. In addition to *Staphylococcus aureus* also other species, including *Staphylococcus schleiferi* and *Staphylococcus intermedius* may give positive results in the tube coagulase test but are not common isolates from human infections.[3,5]
For the tube coagulase test, EDTA plasma is superior to citrated plasma because citrate-utilizing organisms such as *Pseudomonas* species, *Serratia marcescens, Enterococcus faecalis* and strains of *Streptococcus* will clot citrated plasma.[5]

4 - METHOD OF PREPARATION

REF 429936: reconstitute the content of one vial with 15 mL of sterile distilled water under aseptic conditions.
REF 429937: reconstitute the content of one vial with 7.5 mL of sterile distilled water under aseptic conditions.
REF 429938: reconstitute the content of one vial with 3 mL of sterile distilled water under aseptic conditions.
Stir for 30 seconds by means of a vortex to dissolve completely. The rabbit plasma results to be diluted 1:3.

5 - PHYSICAL CHARACTERISTICS

Appearance of lyophilized pellet	dense pastille
Appearance of coagulase plasma after reconstitution	yellowish to pink opalescent solution

6 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
Coagulase Plasma EDTA	Identification reagent	429936	4 vials with 5 ml of rabbit plasma ⟶ (4 x 15 mL: 120 tests)
Coagulase Plasma EDTA	Identification reagent	429937	4 vials with 2,5 ml of rabbit plasma ⟶ (4 x 7,5 mL: 60 tests)
Coagulase Plasma EDTA	Identification reagent	429938	10 vials with 1 ml of rabbit plasma ⟶ (10 x 3 mL: 60 tests)

7 - MATERIALS REQUIRED BUT NOT PROVIDED

Small sterile culture tubes, water bath or incubator, sterile loops, sterile pipettes, sterile purified water, ancillary culture media and reagents for the identification of the colonies.

8 - SPECIMENS

In clinical and non-clinical microbiology, the specimens consist of suspected staphylococcal colonies grown on plating media. Coagulase Test EDTA cannot be used for the direct testing of clinical specimens.

9 - TEST PROCEDURE

From the surface of each selected colony, remove an inoculum with a sterile loop and transfer it to a tube of Brain Heart Infusion Broth. Incubate the broth at 35-37°C for 18-24 hours.
Aseptically add 0.5 mL of each culture to 0.5 mL of Coagulase Plasma EDTA in small sterile tubes, and incubate at 35-37°C.

10- READING AND INTERPRETATION

Observe every 60 minutes in the first 4 hours of incubation for clotting by gently slanting the tube. Do not shake.
If no clot is observed by 4 hours, the tube should be read again after 18-24 h of incubation at 35-37°C.

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Any degree of clotting represents a positive test. A flocculent or fibrous precipitate is not a true clot and should be recorded as negative.

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 the test strains useful for the quality control.
Positive control: *S.aureus* ATCC 25923
Negative control: *S.epidermidis* ATCC 12228

ATCC is a trademark of American Type Culture Collection

12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of Coagulase Plasma EDTA is tested with positive and negative strains.
Coagulase positive strains (reading after 2, 4, 24 hours of incubation at 35-37°C): *S.aureus* ATCC 25923, *S.aureus* ATCC 6538, *S.aureus* ATCC 33862, *S.aureus* MR ATCC 33592.
Coagulase negative strains (reading after 24 hours of incubation at 35-37°C): *S.epidermidis* ATCC 12228, *S.xylosus* ATCC 35033 , *S. saprophyticus* ATCC 15305, *S.sciuri* CB-BX 16.1, *E.faecalis* ATCC 19433
All the tested strains give a coagulase reaction according to the specifications.

13 - LIMITATIONS OF THE METHOD

- Some species of staphylococci other than *S. aureus* (*S.intermedius, S.hycus, S.schleiferi* subsp. *coagulans, S.delphini, S.lutrae, S.pseudointermedius, S.argenteus*) may give positive reaction to coagulase test.[3-6]
- The colony inoculum used for testing must be pure because a contaminant may produce false results after prolonged incubation.[5]
- The tube coagulase test should not be unduly agitated as this can cause the clot to shrink also giving a false negative result.[5]
- Care should be taken when using tube coagulase test directly on presumptive positive coagulase blood culture broth while recent reports have indicated no loss of sensitivity when the tube coagulase test is performed directly on uncentrifuged blood culture broths.[7,8]
- Observation for clotting should be made within the first 4 h since some staphylococci produce fibrinolysin, which may lyse clots early in the incubation period.[9,10] If no clotting is observed, however, the tube should be incubated overnight and observed again for delayed clotting.
- False-negative coagulase reactions may occur if the test isolate is older than 18-24 hours or if there is scant growth.
- Slide coagulase test has a sensitivity lower than tube test since it detects only bound coagulase enzyme.
- It is recommended that biochemical, immunological, molecular, or mass spectrometry testing be performed for complete identification of the isolates. If relevant, perform antimicrobial susceptibility testing.
- This reagent is intended as an aid in the diagnostic procedures of infectious diseases; the interpretation of the results must be made considering the patient's clinical history, the origin of the sample and the results of other diagnostic tests.

14 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation
- This product 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 this product doesn't contain any transmissible pathogen. Therefore, it is recommended that the product 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.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as the reagent, the culture media or the microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused reagent and the tubes inoculated with microbial strains in accordance with current local legislation.
- Do not use this product as active ingredient for pharmaceutical preparations or as production material 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

Upon receipt, store the product in the original pack at 2-8°C away from direct light. If properly stored, the product may be used up to the expiration date. Do not use the product beyond this date. Opened and reconstituted vial under aseptic conditions can be stored at 2-8°C for up to 5 days or aliquot into 0.5 ml amounts and stored at -20ºC for 14 days. Allow plasma to equilibrate to room temperature before use. Do not use the plasma if is clotted upon rehydration, if it is contaminated or if there are other signs of deterioration (precipitate, atypical colour).

16 – REFERENCES

1. Loeb L. The influence of certain bacteria on the coagulation of the blood. J med Res 1903; 10: 407
2. Much H. Uber eine Vorstufe des Fibrinfermentes in Kulturen von Staphylokokkus aureus. Biochem. Z.1908;14: 143
3. Becker K, Skov R, VonEiff C. Staphylococcus, Micrococcus, and other catalase-positive cocci: Bacteriology. In Carrol KC, Pfaller MA et al. editors. Manual of clinical microbiology, 12th ed. Washington, DC: American Society for Microbiology; 2019
4. ISO 6888-1, 2021 - Microbiology of the food chain — Horizontal method for the enumeration of coagulase-positive staphylococci (Staphylococcus aureus and other species) —Part 1: Method using Baird-Parker agar medium. Second edition, 2021-08
5. Public Health England. (2018). UK Standards for Microbiology Investigations: Coagulase test test Procedures TP 10, Issue no: 6, Issue date: 01.08.18
6. Staphylococcus argenteus: Another Coagulase Positive Staphylococcus. May 28, 202, Podcast. American Society for Microbiology.

7. Davis TE, Fuller DD, Aeschleman EC. Rapid, direct identification of Staphylococcus aureus and Streptococcus pneumoniae from blood cultures using commercial immunologic kits and modified conventional tests. Diagn Microbiol Infect Dis 1992; 15:295-300. B, II
8. McDonald CL, Chapin K. Rapid identification of Staphylococcus aureus from blood culture bottles by a classic 2-hour tube coagulase test. J Clin Microbiol 1995; 33:50-2. B, II
9. Yrios JW. Comparison of rabbit and pig plasma in the tube coagulase test. JClinMicrobiol 1977; 5:221-4. B, II
10. Atlas R, Snyder J. Reagents, Stains and Media: Bacteriology. In Carrol KC, Pfaller MA et al. editors. Manual of clinical microbiology,12th ed. Washington, DC: American Society for Microbiology; 2019

TABLE OF APPLICABLE SYMBOLS

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

REVISION HISTORY

Version	Description of changes	Date
Instructions for Use (IFU) - Revision 1	Updated layout and content	2021/10
Revision 2	Removal of obsolete classification	2023/04

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

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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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Liofilchem®

Microbiolgy products

Tween 80 Supplement

REF 80031 / 80431

Instructions For Use

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This IFU document and the SDS are available from the online Support Center:

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ENGLISH

TWEEN 80 *Supplement*

Supplement for the enrichment of culture media.

DESCRIPTION

TWEEN 80 *Supplement* is a supplement made of Polysorbate 80, used to prepare culture media HHD Broth (REF 610064 / 620064), Letheen Agar (REF 610076 / 620076), Letheen Broth (REF 610208 / 620208), Microbial Content Test Agar Base (REF 610094 / 620094), MRS Agar (REF 610024 / 620024) MRS Broth (REF 610025 / 620025), Rogosa Agar (REF 610176 / 620176) Rogosa Broth (REF 610177 / 620177), Sierra Lypolitic Agar (REF 611015 / 621015), and other culture media in which the addition of Polysorbate 80 is recommended.

KIT CONTENTS

Each kit contains:

- bottles containing 50 ml of Tween 80

PRINCIPLE OF THE METHOD

TWEEN 80 *Supplement* (Polysorbate 80) is a substance used in the preparation of culture media, where it supports a rapid bacterial growth.

COMPOSITION

TWEEN 80 *Supplement*	
Content / bottle	
Tween 80	50.0 ml

PROCEDURE FOR USE

1. Refer to the specific instructions for the medium concerned on the quantity of Tween 80 *Supplement* that should be added to it, before sterilization.
2. Mix with care.
3. Distribute into the final containers and sterilize in autoclave as indicated in the specific instructions for the medium.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation for the medium being prepared.

QUALITY CONTROL

1. Visual inspection: dense, oily and yellow amber coloured substance.
2. Microbiological control

Prepare the Microbial Content Test Agar Base ref.. 610094 or 620094 and inoculate it with the strains indicated in the microbiological control table. Incubate at 36 ± 1°C for 24-48 hours.

Microbiological control

Control strains		**Growth**
Escherichia coli	ATCC 11229	Excellent
Staphylococcus aureus	ATCC 25923	Excellent

PRECAUTIONS

For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

STORAGE

Store TWEEN 80 *Supplement* at 2-8°C in its original packaging. In such conditions TWEEN 80 *Supplement* maintains its validity until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

REFERENCES

- De Man, J.C., M. Rogosa, and M.E. Sharpe (1960). J. App. Bact. 23:130-135.
- ISO/FDIS 15214 (1998) Microbiology of food and animal feeding stuffs-Horizontal method for the enumeration of mesophilic lactic acid bacteria-colony count technique.
- Briggs, M. (1953) J. Dairy Res. 20: 36.

PRESENTATION

Product	REF	Σ
TWEEN 80 *Supplement*	80031	2 bottles x 50 ml
TWEEN 80 *Supplement*	80431	4 bottles x 50 ml

TABLE OF SYMBOLS

LOT Batch code	Do not reuse	Manufacturer	Contains sufficient for <n> tests	Temperature limitation
REF Catalogue number	Fragile, handle with care	Use by	Consult instructions for use	

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Rev.2 / 15.04.2022

MRS Agar

Medium for isolation and enumeration of mesophilic lactic acid bacteria, according to 15214.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Casein	10.0
Meat Extract	10.0
Yeast Extract	4.0
Triammonium Citrate	2.0
Sodium Acetate	5.0
Magnesium Sulfate Heptaydrate	0.2
Manganese Sulfate Tetrahydrate	0.05
Dipotassium Hydrogen Phosphate	2.0
Glucose	20.0
Agar	15.0
Final pH 5.7 ± 0.1 at 25°C	

DESCRIPTION

MRS Agar is a medium used with supplements for the cultivation of *Lactobacillus* spp from different types of material. It may also support the growth of *Pediococcus* and *Leuconostoc* species as well as other secondary bacteria.

The complete medium complies with the recommendations of ISO 15214 and APHA.

PRINCIPLE

Enzymatic digest of casein and meat extract provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Ammonium citrate and sodium acetate are the selective agents effective against streptococci and moulds. The low pH is also inhibitory for most organisms other than lactobacilli. Magnesium and manganese sulfates are sources of ions and sulfate acting as growth stimulants. Dipotassium phosphate is the buffer. Glucose is the fermentable carbohydrate. Agar is the solidifying agent.

Supplementation with Tween 80 Supplement (ref. 80031) provides a mixture of oleic esters and fatty acids essential for the growth of lactic acid bacteria.

PREPARATION

Suspend 68.3 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Add 1 ml of Tween 80 Supplement. Sterilize in autoclave at 121°C for 15 minutes.

Note. According to ISO 15214, 1.4 g of Sorbic Acid (dissolved in about 10 ml of a 1 mol/l solution of sodium hydroxide) can be added to 1 liter of sterilized medium if extensive yeast contamination is suspected.

TECHNIQUE

1. Use a suitable diluent such as Buffered Peptone Water (ref. 24099) to perform serial dilutions of the test sample in order to achieve a colony count of between 15 and 300 colonies per plate.
2. Inoculate each plate with 1 ml of sample suspension by pour plating. Overlays may be used if required.
3. Incubate at 30°C for 72 hours.

INTERPRETATION OF RESULTS

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

It may be necessary in some cases and for some products to confirm the colonies by simple techniques such as Gram staining, or the test for catalase.

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 away from light.

WARNING AND PRECAUTIONS

For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

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

REFERENCES

1. APHA (2015): Compendium of Methods for the Microbiological Examination of Foods. 5th edition. American Public Health Association, Washington, D.C.
2. EN ISO 11133:2014. Microbiology of food, animal feed and water − Preparation, production, storage and performance testing of culture media.
3. Schillinger U and Holzapfel WH (2012) Culture media for Lactic Acid Bacteria. In: Handbook of Culture Media for Food and Water Microbiology. (Corry JEL, Curtis GDW and Baird RM eds), pp 174-186. Royal Society of Chemistry, Cambridge, UK.
4. ISO 15214:1998. Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of mesophilic lactic acid bacteria – Colony count technique at 30°C.
5. De Man JD, Rogosa M, and Sharpe ME (1960): A Medium for the cultivation of Lactobacilli. J. Appl. Bact. 23: 130-135.

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PRODUCT SPECIFICATIONS

NAME
MRS Agar

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

Ref.	Content	Packaging
610024	500 g	500 g of powder in plastic bottle
620024	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
5.7 ± 0.1

USE
MRS Agar is a medium used with supplements for the cultivation of mesophilic lactic acid bacteria, according to 15214

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Powder medium
Appearance: free-flowing, homogeneous
Colour: beige
Ready-to-use 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: 50-100 CFU
   Inoculum for selectivity: 10^4-10^6 CFU
   Incubation Conditions: 72 ± 3 h at 30 ± 1°C, in microaerobiosis

Microorganism		Growth
Lactobacillus sakei	WDCM 00015	Good
Lactobacillus lactis	WDCM 00016	Good
Escherichia coli	WDCM 00012	Inhibited
Bacillus cereus	WDCM 00001	Inhibited

TABLE OF SYMBOLS

LOT Batch code	Consult instructions for use	Manufacturer	Use by
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Keep away from sunlight

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STRIP Control GST E6

Biological indicators for steam sterilization processes with *G. stearothermophilus* ATCC® 7953 spores inoculated on paper strips.

DESCRIPTION

STRIP Control GST E6 are used to monitor the effectiveness of steam sterilizing process. These biological indicators (BI's) are produced under strictly controlled conditions in order to satisfy the requirements in USP, ISO 11138 and EN 866 standards.

STRIP Control GST E6 contain bacterial spores on special filter paper strips and glass test tubes with screw cap. Each tube contains a validated growth medium with pH indicator. Strips are inoculated with spores of *Geobacillus stearothermophilus* (ATCC 7953) in predefined concentrations.

A Certificate of Analysis including population, strain, D-value (121°C), Z-Value (115°C, 121°C, 124°C), survival time, kill time, lot number and expiration date is inserted in the packaging.

COMPOSITION

Strips contain *G. stearothermophilus* (ATCC 7953) spores in concentrations 1-5 x10^6 CFU/strip. Each strip is enclosed in an envelope; lot number and expiration date are printed on each envelope.

Tubes contain 4 ± 0.5 mL of a sterile modified soybean casein digest broth with a pH indicator (Steri-Test medium); lot number and expiration date are printed on each tube.

PRINCIPLE

Spores are completely killed off after the sterilization at 121°C. If no spores survive, there is no growth during the subsequent incubation and the medium inside the ampoule remains violet. A failure in the sterilization process (lower temperature and/or shorter sterilization time), is detected by the colour change of the medium to yellow due to spores survival and proliferation of bacteria.

TECNIQUE

1. Place one or more strips of STRIP Control GST E6 (each in its envelope) in the most challenging location of the steam sterilizer such as on the bottom shelf, near the door, and over the drain. The number of strips to be used will depend on the size of the sterilize chamber and/or regional requirements or load in the sterilizer. Typically, for autoclaves having an internal volume lower than or equal to 250 litres, two strips are used for each selected point of the autoclave. For autoclaves with volume higher than 250 litres, six or more strips can be used per point.
2. Remove the strip (still in its envelope) after sterilization cycle, aseptically open the envelope with sterile scissors or by tearing the edges, transfer the strip to a tube of Steri-Test medium included in the package.
3. Incubate the tube containing the strip at 55-60°C (131-140°F) for 7 days or for a different time validated by the user.
4. Incubate, at the same conditions of time and temperature, a tube of Steri-Test medium with a strip not submitted to the sterilization cycle and belonging to the same batch, as spore growth control (positive control).
5. Examine the Steri-Test medium and interpret the result as per EVALUATION TABLE: a colour change of medium from violet/clear to yellow/turbid indicates microbial growth and therefore an unsuccessful sterilization. On the contrary, the persistence of the initial colour of the medium (violet/clear) indicates absence of microbial growth and therefore a successful sterilization.

INTERPRETATION OF RESULTS

Geobacillus stearothermophilus (ATCC 7953) spores are killed off if the sterilization cycle has been efficient: in this case the broth contained in STRIP Control GST E6 remains violet/clear even after incubation at 55-60°C (131-140°F) for 7 days or for the selected time. If the sterilization cycle has not been efficient, spores partially survive and the Steri-Test medium turns yellow/turbid after incubation at 55-60°C (131-140°F) for 7 days or for the selected time. The Steri-Test medium not submitted to the sterilization cycle and used as spore growth control has to turn yellow/turbid after incubation. On the contrary, the test must be repeated after having investigated the causes of the negative result.

EVALUATION TABLE		
MEDIUM COLOUR	**SPORE**	**STERILIZATION**
Violet / clear	Killed off	Successful
Yellow / turbid	Vital	Unsuccessful

Note: Any colour change with no turbidity (the medium remains clear after incubation) indicates a successful sterilization cycle (no growth).

STORAGE

Store at room temperature (10-25°C). In these conditions the product maintains its validity until the expiry date indicated on the label.

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 professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

After use, sterilize positive vials (yellow/turbid) in autoclave at 121°C for at least 30 minutes and eliminate them in accordance with the procedures in the laboratory.

REFERENCES

- United States Pharmacopoeia latest edition.
- Deutsches Arzneibuch latest edition.
- European Pharmacopoeia latest edition.
- ISO 11138 and EN 866 latest edition.

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PRODUCT SPECIFICATIONS

NAME
STRIP Control GST E6

PRESENTATION
Paper strips inoculated with *Geobacillus stearothermophilus* ATCC 7953 spores in predefined concentrations and glass tubes with a growth medium

STORAGE
10-25°C

PACKAGING

REF	CONTENT	PACKAGING
91055	20 unities 1 Instruction Sheet 1 Certificate of Performance	20 unities in thermally soldered envelope 20 envelopes + 20 tubes in cardboard boxes

TECHNICAL PROPERTIES

STRIP
Spore carrier type: filter paper
Spore carrier: approximately 38 x 6 mm paper strip
Species: *Geobacillus stearothermophilus* ATCC 7953
Mean Population Recovery: 1 x 10^6 - 5 x 10^6 spores/strip
Purity: Bacterial contaminates less than 1 percent of the labeled population
Resistance data: decimal reduction time (D-Value), survival time and kill time

Steri-Test Medium (growth medium)
pH: 7.4 ± 0.1
Fill volume: 4.0 ± 0.5 mL
Tube: glass tube; height approximately 15 ± 1 mm (screw cap)
Growth promotion: meets USP current edition
Colour: violet (colour change to yellow and/or turbidity indicates bacterial growth)

USE
Biological indicators STRIP Control GST E6 are used for regular control of steam sterilization cycles (i.e. 15 minutes at 121°C) and control of any steam autoclave functionality

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE
Strips are white in colour. The medium is violet, clear

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Purity: < 1% contamination. No moulds
3. Heat shocked population: 1-5 x 10^6 Spores/strip
4. D-Value (121°C): 1.5-4.5 minutes
5. Z-Value (115°C, 121°C, 124°C): ≥ 6°C
6. Growth: 55-60°C for 18-24 hours; colour change of the medium from violet/clear to yellow/turbid

SHELFLIFE
3 years

TABLE OF SYMBOLS

Manufacturer	Contains sufficient for <n> tests	Temperature limitation
REF Catalogue number	Fragile, handle with care	Caution, consult accompanying documents
Use by	LOT Batch code	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

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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

- Kruczak-Filipov, P., and R.G. Shively.1992. Gram stain procedure, p.1.5.1-1.5.18. In H.D. Isenberg (ed.) Clinical Microbiology Procedures Handbook, vol. 1. American Society for Microbiology, Washington, D.C.
- 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

Agar

Purified agar for bacteriological use and culture media preparation

PHYSIC-CHEMICAL CHARACTERISTIC

Clarity (1.5% w/v)	8.2 NTU
pH at 25°C	6.75 ± 0.75
Gel Strength	950 g/cm2 maximum
Loss on Drying	12% maximum (9% on average)
Gelation Point	35°C
Melting Point	88°C
Divalent Cations	250 ppm
Heavy Metals (As, Pb)	< 10 mg/kg

DESCRIPTION

Agar is a solidifying agent used for culture media preparation, it is a purified agar from which the extraneous matter, pigmented portions and salts have been removed or reduced to a minimum. It is an hydrosoluble extract from red algae and can be used as a solidifying agent in bacteriological culture media or for determining motility and growth of anaerobes and microaerophiles.

PREPARATION

Agar is typically used in a final concentration of 1-2% for solidifying culture media. Smaller quantities (0.05-0.5%) are used in media for motility studies (0.5%w/v), growth of anaerobes (0.1%) and microaerophiles. 1.5% aqueous solution supplies solid gel at temperature of 35 °C because agar does not melt at temperature lower than 85 °C. The addition of such amounts of agar to liquid media permits all degrees of oxygen tension to exist, thus aids in the development of many fastidious aerobic and anaerobic organisms.

TECHNIQUE

Agar can be used as an ingredient of dehydrated culture media and need dissolution in distilled or deionized water and sterilization by autoclaving.

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.

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.

DISPOSAL OF WASTE

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

REFERENCES

1. Hitchens, A.P., and M.C.Leikind (1939) The introduction of agar-agar into bacteriology. J. Bacteriology 37:485-493
2. United States Pharmacopeia Convention (1995) The United States Pharmacopeia 23rd ed. Pharmacopeia Convention, Rockville, MD

PACKAGE

Code	Content	Packaging
611001	500 g	500 g of product in plastic bottle
621001	100 g	100 g of product in plastic bottle
6110015	5000 g	5000 g of product in plastic bottle

pH of THE MEDIUM

6.75 ± 0.75

SHELF LIFE

4 years

QUALITY CONTROL

Dehydrated powder
Appearance: free-flowing, homogeneous
Colour: light beige

TABLE OF SYMBOLS

LOT	Batch code		Consult instructions for use		Manufacturer		Contains sufficient for <n> tests
REF	Catalogue number		Temperature limitation		Use by		Keep away from heat sources

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

Physiological Solution

Isotonic diluent for preparing microbial suspensions.

DESCRIPTION

Physiological solution (saline) is an isotonic diluent used to maintain cell integrity and viability in procedures that require preparation of test suspension of organisms.

This solution is recommended by the Clinical and Laboratory Standards Institute (CLSI) and the European Committee on Antimicrobial Susceptibility Testing (EUCAST) to make bacterial suspensions and adjust turbidity for inoculum preparation. It is also used in the preparing of stock solutions and serial dilutions of antimicrobial agents.

TYPICAL FORMULA	(g/l)
Sodium Chloride	8.5
Final pH 7.0 ± 0.2 at 25°C	

METHOD PRINCIPLE

This sterile solution of 0.85% NaCl (w/v) in water provides osmotic protection for microbial cells.

TEST PROCEDURE

Solutions for inoculation should be prepared by inoculating the diluent with one to five isolated colonies of test organism. The suspension should be adjusted to the concentration of the appropriate McFarland inoculum standard.

INTERPRETING RESULTS

See specific references for details on use.

APPEARANCE

Clear, colorless.

STORAGE

Store at 2-30°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

5 years.

QUALITY CONTROL

The solution is inoculated with the microbial strains indicated in the QC table.
Inoculum for use as diluent: 10^3-10^4 CFU.
Incubation conditions: 20-25°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 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

See the references at the end of this document.

TABLE OF SYMBOLS

See the table of symbols at the end of this document.

The product is available in the various configurations listed below. There may be additional product ref. numbers as well. For an updated listing of available products, visit **liofilchem.com**

Product Description	Format	Packaging	Ref.	
Physiological Solution	Tube	20 x 3 ml tubes	24142	
Physiological Solution	Vial	20 x 4.5 ml vials	20079	
Physiological Solution	Vial	20 x 7 ml vials	20095	
Physiological Solution	Tube	20 x 9 ml tubes	20196	
Physiological Solution	Tube	20 x 10 ml tubes	20197	
Physiological Solution	Tube	100 x 9 ml tubes	26196	
Physiological Solution	Bottle	6 x 38 ml bottles	471130	
Physiological Solution	Bottle	6 x 240 ml bottles	471120	
Physiological Solution	Bottle	6 x 250 ml bottles (capacity 500 ml)	470400	◆
Physiological Solution	Bottle	6 x 350 ml bottles (capacity 500 ml)	463250	◆
Physiological Solution	Bottle	6 x 500 ml bottles	473000	
Physiological Solution	Bottle	6 x 1000 ml bottles	463200	

◆, not CE marked

This document is available from the online Support Center:
liofilchem.com/ifu-sds

Fermentation Broth Base

Liquid medium for the carbohydrate utilization test, according to ISO 11290.

TYPICAL FORMULA	(g/l)
Proteose Peptone	10.0
Meat Extract	1.0
Sodium Chloride	5.0
Bromocresol Purple	0.02
Final pH 6.8 ± 0.2 at 25°C	

DESCRIPTION

Fermentation Broth Base is a liquid medium used with added carbohydrate in differentiating pure cultures of bacteria. This medium is formulated according to ISO 11290 and is recommended for the confirmation test of *Listeria monocytogenes.*

PRINCIPLE

Peptone and meat extract supply amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. Sodium chloride maintains the osmotic balance of the medium. Bromocresol purple is the pH indicator.

PREPARATION

Suspend 16.0 g of powder in 1 liter of deionized or distilled water. Bring to boil and shake until completely dissolved. Dispense into tubes containing inverted Durham tubes. Sterilize at 121°C for 15 minutes. Cool up to 45-50°C. Add the suitable carbohydrate solution to give a final concentration of 0.5%. Mix well.

TECHNIQUE

Inoculate each tube with a loopful of a pure culture. Incubate at 37°C for up to 7 days.

INTERPRETATION OF RESULTS

Observe daily for colour change from purple to yellow (acid production) and gas formation.

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 sings 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 professional 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

- ISO 11290-1:1996(E). Microbiology of food and animal feeding stuffs – Horizontal method for the detection and enumeration of *Listeria monocytogenes* – Part1: Detection method.
- FDA Bacteriological Analytic Manual (2005) 18th Ed., AOAC, Washington, D.C.

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PRODUCT SPECIFICATIONS

NAME
Fermentation Broth Base

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

Ref.	Content	Packaging
610030	500 g	500 g of powder in plastic bottle
620030	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
6.8 ± 0.2

USE
Fermentation Broth Base is a liquid medium used with added carbohydrate in differentiating pure cultures of bacteria. This medium is formulated according to ISO 11290 and is recommended for the confirmation test of *Listeria monocytogenes*

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Powder medium
Appearance: free-flowing, homogeneous
Colour: light yellow
Ready-to-use medium
Appearance: clear to slightly hazy
Colour: purple

SHELFLIFE
4 years

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Microbiological control
   Carbohydrate: rhamnose
   Inoculum for productivity: ≤100 CFU
   Incubation Conditions: 18-48 h at 35 ± 2°C

Microorganism		Growth	Colour	Gas
Escherichia coli	ATCC® 25922	Good	Yellow	+
Listeria monocytogenes	ATCC® 19111	Good	Yellow	−
Staphylococcus aureus	ATCC® 25923	Good	Purple	−

TABLE OF SYMBOLS

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

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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.
- FDA, Bacteriological Analytical Manual (2005) 18th Ed., AOAC, Washington, DC.Taylor W. I., 1961, Appl. Microbiol., 9:487.
- 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.
- ISO 11290-1:1996. Microbiology of food and animal feeding stuff. Horizontal method for the detection and enumeration of *Listeria monocytogenes*. Part 1: Detection method. Amendment 1: Modification of the media and haemolysis test and inclusion of precision data.
- Vanderzant C. and Splittstoesser D. F., (Eds.) (1992) Compendium of Methods for the Microbiological Examination of Foods, 3rd Ed., APHA, Washington, D.C.

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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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Violet Red Bile Glucose Agar

Selective medium for detection and enumeration of Enterobacteriaceae in food, water and other materials, according to USP/EP/JP and ISO 21528.

Instructions For Use
ENGLISH

DESCRIPTION

Violet Red Bile Glucose Agar is a selective medium used for the detection and enumeration of bile-tolerant Gram-negative bacteria in food, water and other materials of sanitary importance.

This medium complies with the recommendations of the harmonized method in the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP).

The medium is also formulated in accordance with ISO 21528 (all parts).

TYPICAL FORMULA*	(g/litre)
Enzymatic Digest of Animal Tissues	7.0
Yeast Extract	3.0
Glucose	10.0
Sodium Chloride	5.0
Bile Salts	1.5
Neutral Red	0.03
Crystal Violet	0.002
Agar	14.0

Final pH 7.4 ± 0.2 at 25°C

*Adjusted and/or supplemented as required to meet performance specifications.

METHOD PRINCIPLE

Enzymatic digest of animal tissues 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. Sodium chloride maintains the osmotic balance of the medium. Bile salts and Crystal violet are selective agents effective against Gram-positive cocci. Neutral red is the pH indicator. Agar is the solidifying agent.

PREPARATION

Dehydrated medium	Suspend 40.5 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. DO NOT AUTOCLAVE.
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. Use a suitable diluent such as Buffered Peptone Water (ref. 24099) to prepare the sample. The European Pharmacopoeia recommends to perform a pre-incubation step in Tryptic Soy Broth (ref. 24444) for 2-5 h at 20-25°C to resuscitate bacteria followed by 24-48 h enrichment at 30-35°C in EE Broth-Mossel (ref. 24096).
2. Inoculate Violet Red Bile Glucose Agar by pour plating or spread plating method.
3. Incubate aerobically at 30-35°C for 18-24 hours or 37°C for 24 ± 2 hours, depending on the method used.

For environmental hygiene monitoring, use a swab and the sampling template 10x10 (ref. 96762) to sample a well defined area of the test surface. Then, inoculate the medium by streaking the swab over the plate. Otherwise, contact plates can be directly used for surface sampling by firmly pressing the agar medium against the test area.

INTERPRETING RESULTS

Select plates containing less than 150 colonies. Count characteristic pink to red colonies (with or without precipitation halo).

Confirm by subculturing to a non selective agar medium looking for oxidase reaction (ref. 88029) and glucose fermentation (ref. 88202). Colonies that are oxidase-negative and glucose-positive are confirmed as Enterobacteriaceae.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, beige to reddish-beige.
Prepared medium: slightly opalescent, reddish-purple.

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.
Contact plates: 9 months.

QUALITY CONTROL

To check the performance of the medium, QC testing should be carried out following specific requirements for the method used.

ISO compliance

Control strain		Inoculum	Incubation	Criteria	Specification
Escherichia coli	WDCM 00012 or WDCM 00013	50-100 CFU	24 ± 2 h / 37 ± 1°C	$P_R \geq 0.5$	Pink to red colonies with or without precipitation halo
Salmonella Typhimurium	WDCM 00031				
Salmonella Enteritidis	WDCM 00030				
Enterococcus faecalis	WDCM 00009 or WDCM 00087	10^4-10^6 CFU		Total inhibition	—

A productivity ratio (P_R) of 0.5 is equivalent to a recovery rate of 50%

Pharmacopoeia growth promotion

Control strain		Inoculum	Incubation	Expected results
Escherichia coli	ATCC® 8739 (WDCM 00012)	≤ 100 CFU	18-24 h / 30-35°C	Recovery ≥ 50%, pink to red colonies with precipitation halo
Pseudomonas aeruginosa	ATCC® 9027 (WDCM 00026)			Recovery ≥ 50%, colourless to slightly red colonies

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

See the references at the end of this document.

TABLE OF SYMBOLS

See the table of symbols at the end of this document.

The product is available in the various configurations listed below. There may be additional product ref. numbers as well. For an updated listing of available products, visit **liofilchem.com**

Product	Format	Packaging	Ref.
Violet Red Bile Glucose Agar	90 mm Plate	20 plates	11184
Violet Red Bile Glucose Agar	Contact Plate	20 plates	15375
Violet Red Bile Glucose Agar	Bottle	6 x 100 ml	402540
Violet Red Bile Glucose Agar	Bottle	25 x 100 ml	450254
Violet Red Bile Glucose Agar	Bottle	6 x 500 ml	470031
Violet Red Bile Glucose Agar	Dehydrated medium	100 g	620059
Violet Red Bile Glucose Agar	Dehydrated medium	500 g	610059
Violet Red Bile Glucose Agar	Dehydrated medium	5 kg	6100595

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Glucose OF Medium ISO 21528

Semisolid medium for determining oxidative or fermentative metabolism of bacteria.

DESCRIPTION

Glucose OF medium is a semisoild medium used for the identification of gram-negative bacteria on the basis of their ability to oxidize or ferment glucose.

This medium complies with ISO 21528:2017 for confirmation of Enterobacteriaceae from food, animal feeding stuffs and environmental samples.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Casein	2.0
Glucose	10.0
Sodium Chloride	5.0
Dipotassium Hydrogen Phosphate	0.3
Bromthymol Blue	0.08
Agar	3.0

Final pH 6.8 ± 0.2 at 25°C

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Glucose is the fermentable carbohydrate. Sodium chloride maintains the osmotic balance of the medium. Dipotassium phosphate acts as buffer agent. Bromthymol blue is the pH indicator. Agar is the solidifying agent.

PREPARATION

Dehydrated medium	Suspend 20.38 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into tubes. Sterilize in autoclave at 121°C for 15 minutes.

TEST PROCEDURE

Just before use, heat the medium in boiling water or flowing steam for 15 min to remove oxygen, then cool rapidly to the incubation temperature.

Using a wire, inoculate tubes by stabbing colonies into the medium. Overlay with minimal 1 cm of sterile mineral oil (Vaseline Oil Droppers, ref. 87006). Incubate at 37°C for 24 hours.

INTERPRETING RESULTS

If a yellow color develops throughout the medium the fermentation test is positive.

According to ISO 21528, colonies that are oxidase-negative and glucose-positive are confirmed as Enterobacteriaceae.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, beige to greenish.
Prepared medium: slightly opalescent, green.

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 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: 2 years.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.
Incubation conditions: 37 ± 1°C for 24 ± 2 hours.

QC Table.

Microorganism		Growth	Fermentation test
Escherichia coli	WDCM 00012	Good	Positive (+), yellow color
Pseudomonas aeruginosa	WDCM 00025	Good	Negative (–), yellow color only at the top of the tube

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 21528-1:2017. Microbiology of the food chain – Horizontal method for the detection and enumeration of Enterobacteriaceae – Part 1: Detection of Enterobacteriaceae.
2. ISO 21528-2:2017. Microbiology of the food chain – Horizontal method for the detection and enumeration of Enterobacteriaceae – Part 2: Colony-count technique.
3. EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
4. Welch, D.F., et al (1987) Selective and differential medium for recovery of Pseudomonas cepacia from the respiratory tracts of patients with cystic fibrosis. J. Clin. Microbiol., 25; 1730-1734.
5. Costin, I.D. (1967) An outline for the biochemical identification of aerobic and facultatively anaerobic gram-negative rods of medical interest. Intern. Kongr. f. Chemotherapie Wien, B2/1; 73-76.
6. Mossel, D.A.A. Martin, G. (1961) Milieu simplifié permettant l'étude des divers modes d'action des bactéries sur les hydrates des carbone. - Ann. Inst. Pasteur de Lille, 12; 225-226.
7. Hugh, R., A. Leifson, E. (1953) The taxonomic significance of fermentative versus oxidative metabolism of carbohydrates by various gram-negative bacteria. J. Bact., 66; 24-26.

PRESENTATION		Contents	Ref.
Glucose OF Medium ISO 21528	Tubes	20 x 10 ml tubes	24482
Glucose OF Medium ISO 21528	Dehydrated medium	500 g of powder	610388
Glucose OF Medium ISO 21528	Dehydrated medium	100 g of powder	620388
Glucose OF Medium ISO 21528	Dehydrated medium	5 kg of powder	6103885

TABLE OF SYMBOLS

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

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Instructions For Use
ENGLISH

Sabouraud Dextrose Agar

Medium for the cultivation and enumeration of yeasts and moulds
from different materials, according to EN ISO 11133 and USP/EP/JP.

DESCRIPTION

Sabouraud Dextrose Agar (SDA) is a non selective isolation medium used for the growth and maintenance of pathogenic and non-pathogenic fungi from clinical and nonclinical specimens. It is also used for recovery and total counting of yeasts and moulds in environmental monitoring.

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 testing on culture media intended for fungi.

Its formula conforms to the recommendations of the harmonized method in the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for the microbiological examination of non sterile products. The medium is also available as gamma-irradiated triple bagged plates, particularly suitable for use in restricted areas like isolators and clean rooms.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	40.0
Agar	15.0

Final pH 5.6 ± 0.2 at 25°C

METHOD PRINCIPLE

Pancreatic digest of casein and peptic digest of animal tissue provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Dextrose is an energy source. Agar is the solidifying agent. The high concentration of dextrose and the acidic pH of the medium permit selectivity of fungi.

The medium can be supplemented with chloramphenicol to increase bacterial inhibition and recovery of dermatophytes.

PREPARATION

Dehydrated medium	Suspend 65 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

For use in medical microbiology

Streak the specimen as soon as possible after it is received in the laboratory to obtain isolated colonies.
Prepared tubed slants primarily are intended for use with pure cultures for maintenance or other purposes.
Incubation conditions may vary according to the type of specimen and the microorganisms being tested for.

For use in food, animal feed and water testing

Refer to EN ISO 11133 for specific instructions.

For use in industrial microbiology

Control of non-sterile products

Refer to the procedure described in the harmonized chapters of the Pharmacopoeia.

Passive Air Monitoring

Take the lid off the settle plate and leave the medium exposed to the air for a period of time no longer than 4 hours (settling plates filled with 30 ml of medium may compensate for water loss during extended incubation periods). Plates can be placed according to the 1/1/1 scheme (for 1 h, about 1 above the floor, at least 1 m from the walls or any obstacle).

Surfaces and Personnel Hygiene Monitoring

Take a swab sample for irregular surfaces or use the sampling template 10x10 (ref. 96762) to sample a well defined area of the test surface. Inoculate a 90 mm plate by streaking the swab over the agar surface. Furthermore, the medium is suitable for personnel hygiene monitoring to detect microbial contamination of gloves or hands e.g. in a 5-finger-print.

Incubate the plates at 20-25°C for 5-7 days or at 30-35°C for 24-48 hours.

INTERPRETING RESULTS

Transfer of growth from slants to plated media may be required in order to obtain pure cultures of fungi.
Examine for fungal colonies exhibiting typical microscopic and colonial morphology. Biochemical tests may be required for final identification.

The total combined yeasts/moulds count (TYMC) is considered to be equal to the number of CFU found per each plate.
When an acceptable criterion for microbiological quality is prescribed it is interpreted as follows:

- 10^1 CFU: maximum acceptable count = 20;
- 10^2 CFU: maximum acceptable count = 200;
- 10^3 CFU: maximum acceptable count = 2000, and so forth.

In procedures intended for environmental and personnel hygiene monitoring, observe daily for the formation of colonies.

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 bottles: 2 years.
Medium in tubes: 1 year.
Ready-to-use plates (90 and 60 mm): 6 months.
Contact plates (55 mm): 9 months

QUALITY CONTROL
The medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU.
Incubation conditions: 32.5 ± 2.5°C for 24-48 h (*C. albicans*) and at 22.5 ± 2.5°C for up to 5 days (all listed organisms), under aerobic atmosphere.

QC Table.

Microorganism		Growth
Candida albicans	WDCM 00054	Good
Aspergillus brasiliensis	WDCM 00053	Good
Saccharomyces cerevisiae	WDCM 00058	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 *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. EN ISO 11133:2014+Amd1:2018. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. European Pharmacopoeia 6.5 (2009) 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms.
3. United States Pharmacopoeia 32 NF 27 (2009) <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
4. Japanese Pharmacopoeia 4.05 (2008) Microbiological examination of non-sterile products: Test for specified microorganisms.
5. Sabouraud, R. (1892) Ann. Dermatol. Syphilol. 3:1061.

PRESENTATION	Category	Packaging	Ref.	
Sabouraud Dextrose Agar	90 mm plates	20 plates	10035	
Sabouraud Dextrose Agar	90 mm plates	100 plates	10035*	
Sabouraud Dextrose Agar	90 mm plates (triple-wrapped and gamma-irradiated)	20 plates	10035S	ƒ
Sabouraud Dextrose Agar	90 mm plates (triple-wrapped and gamma-irradiated, 30 ml filling volume)	20 plates	10114S	ƒ
Sabouraud Dextrose Agar	60 mm plates	20 plates	163402	ƒ
Sabouraud Dextrose Agar	60 mm plates	450 plates	173402	ƒ
Sabouraud Dextrose Agar	55 mm contact plates	20 plates	15327	ƒ
Sabouraud Dextrose Agar	55 mm contact plates irradiated	20 plates	15327S	ƒ
Sabouraud Dextrose Agar	Tubes - Bottles	10 x 9 ml slant tubes	30093	
Sabouraud Dextrose Agar	Tubes - Bottles	20 x 9 ml slant tubes	31093	
Sabouraud Dextrose Agar	Tubes - Bottles	6 x 500 ml bottles	470040	
Sabouraud Dextrose Agar	Tubes - Bottles	6 x 200 ml bottles	412280	
Sabouraud Dextrose Agar	Tubes - Bottles	25 x 200 ml bottles	452280	
Sabouraud Dextrose Agar	Tubes - Bottles	6 x 100 ml bottles	402280	
Sabouraud Dextrose Agar	Dehydrated culture medium	500 g of powder	610103	
Sabouraud Dextrose Agar	Dehydrated culture medium	100 g of powder	620103	
Sabouraud Dextrose Agar	Dehydrated culture medium	5 kg of powder	6101035	

ƒ: 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

LIOFILCHEM® s.r.l.

Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.com

CE IVD

Instructions For Use
ENGLISH

Sabouraud Dextrose Broth

Liquid medium for the cultivation of yeasts and moulds from different materials, according to USP/EP/JP.

DESCRIPTION

Sabouraud Dextrose Broth (SDB) is a liquid medium recommended for use in qualitative procedures for isolation of yeasts and moulds and for the culture or subculture of fungi from clinical and nonclinical specimens.

This medium conforms to the requirements of the harmonized method in the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for the microbiological examination of non sterile products.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	20.0
Final pH 5.6 ± 0.2 at 25°C	

METHOD PRINCIPLE

Pancreatic digest of casein and peptic digest of animal tissue provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Dextrose is an energy source. The high concentration of dextrose and the acidic pH of the medium permit selectivity of fungi.

The medium can be supplemented with chloramphenicol to increase bacterial inhibition and recovery of dermatophytes.

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. Dispense into appropriate containers. Sterilize in autoclave at 121°C for 15 minutes.

TEST PROCEDURE

For use in medical microbiology

Inoculate the specimen directly into the broth. Incubate aerobically at 25°C for 2-7 days (incubation conditions may vary according to the type of specimen and the microorganisms being tested for).

For use in industrial microbiology

To prepare the fungal test strains grow *C. albicans* or *A. brasiliensis* at 20-25°C for 48-72 hours or 5-7 days, respectively.

To test for *C. albicans*, inoculate the preparation of the product to be examined 1:100 in SDB and incubate at 30-35°C for 3-5 days. Subculture on a plate of Sabouraud Dextrose Agar (ref. 10035).

INTERPRETING RESULTS

Turbidity indicates microbial growth.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.
Prepared medium: clear, light amber, may have a slight precipitate.

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 and bottles 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: 32.5 ± 2.5°C for 48-72 h (*C. albicans*) and at 22.5 ± 2.5°C for up to 5 days (all listed organisms), under aerobic atmosphere.

QC Table.

Microorganism		Growth
Candida albicans	ATCC® 10231	Good
Aspergillus brasiliensis	ATCC® 16404	Good
Saccharomyces cerevisiae	ATCC® 9763	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 *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. European Pharmacopoeia 6.5 (2009) 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms.
2. United States Pharmacopoeia 32 NF 27 (2009) <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
3. Japanese Pharmacopoeia 4.05 (2008) Microbiological examination of non-sterile products: Test for specified microorganisms.
4. Sabouraud, R. (1892) Ann. Dermatol. Syphilol. 3:1061.

PRESENTATION		Contents	Ref.
Sabouraud Dextrose Broth	Tubes	20 x 10 ml tubes	24109
Sabouraud Dextrose Broth	Bottles	6 x 100 ml bottles	402040
Sabouraud Dextrose Broth	Bottles	25 x 100 ml bottles	452040
Sabouraud Dextrose Broth	Bottles	6 x 500 ml bottles	471070
Sabouraud Dextrose Broth	Dehydrated medium	500 g of powder	610104
Sabouraud Dextrose Broth	Dehydrated medium	100 g of powder	620104

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

Fluid Thioglycollate Medium

Liquid medium for sterility test and cultivation of fastidious anaerobic and aerobic microorganisms, according to Harmonized USP/EP/JP and ISO 7937.

Instructions For Use
ENGLISH

DESCRIPTION

Fluid Thioglycollate Medium is a general purpose liquid enrichment medium used for sterility control of pharmaceutical products and for cultivation and isolation of fastidious anaerobic and aerobic microorganisms.

The composition is in accordance with the requirements of the Harmonized US, European and Japanese Pharmacopoeia as well as with ISO 7937 for isolation of *Clostridium perfringens*.

TYPICAL FORMULA*	(g/l)
Enzymatic Digest of Casein	15.0
Yeast Extract	5.0
Glucose	5.5
Sodium Chloride	2.5
Sodium Thioglycollate	0.5
L-Cystine	0.5
Resazurin	0.001
Agar	0.75

Final pH 7.1 ± 0.2 at 25°C

*Formula may be adjusted and/or supplemented as required to meet performance specifications;
Grams per litre of purified water.

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 a source of energy. Sodium chloride maintains the osmotic balance of the medium. Sodium thioglycollate and L-cystine are included to reduce the redox potential of the medium and create an anaerobic atmosphere. These reducing agents also neutralize the bacteriostatic effects of mercury and other heavy metal compounds in the preparation to be tested for sterility. Resazurin is an oxidation-reduction indicator being pink when oxidized ad colorless when reduced. The small amount of agar assists in the maintenance of a low redox potential by stabilizing the medium against convection currents, thereby maintaining anaerobiosis in the lower depths of the medium.

PREPARATION

Dehydrated medium	Suspend 29.8 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into appropriate containers. Sterilize in autoclave at 121°C for 15 minutes.
Medium in tubes/bottles	If the medium exhibits more than 20% pink color (due to oxidation), the medium may be reheated once for 5 minutes with cap slightly loosened in steam or boiling water in order to expel the oxygen.

TEST PROCEDURE

The medium can be directly inoculated with the test sample (the amount of the inoculated sample material should not be exceed 10% volume of the medium). Incubate at 30-35°C for up to 14 days. Growth of strictly aerobic bacteria can be improved by slightly loosening the cap.

According to ISO 7937 for confirmation of *Clostridium perfringens* incoculate each black colony from Sulfite Cycloserine Agar (ref. 402700) into Fluid Thioglycollate Medium. Incubate at 37 ± 1°C for 18-24 hours. Subsequently, transfer 5 drops of the enrichment culture into Lactose Sulfite Medium (ref. 610358) and incubate at 46 ± 1°C for 18-24 hours.

INTERPRETING RESULTS

Turbidity of the medium indicates microbial growth. Obligate anaerobic microorganisms such as *Clostridium sporogenes* are growing in the lower, yellowish part of the broth medium. The growth of facultative anaerobic microorganisms such as *Staphylococcus aureus* is distributed throughout all the medium. Aerobic microorganisms such as *Pseudomonas aeruginosa* are able to grow in the upper slightly pink layer (oxidized part) of the medium.

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 or tubes: 2 years.

QUALITY CONTROL

Appearance of Dehydrated Medium: Free-flowing, homogeneous, light beige.

Appearance of Prepared Medium: Slightly opalescent, light amber (20% or less of upper layer may be pink).

Expected Cultural Response:

Control strain		Inoculum	Incubation	Specification
Bacillus subtilis[a]	WDCM 00003 (ATCC 6633; NCTC 10400)	≤100 CFU	24 h 32.5 ± 2.5°C	Visible turbidity
Clostridium sporogenes[a]	WDCM 0008 (ATCC 19404; NCTC 532)			
Escherichia coli[a]	WDCM 00012 (ATCC 8739; NCTC 12923)			
Pseudomonas aeruginosa[a]	WDCM 00026 (ATCC 9027; NCTC 12924)			
Staphylococcus aureus[a]	WDCM 00032 (ATCC 6538; NCTC 10788)			
Clostridium perfringens[b]	WDCM 00007 (ATCC 13124; NCTC 8237)		18-24 h 37 ± 1°C	
Candida albicans[a]	WDCM 00054 (ATCC 10231; NCPF 3179)		48 h 22.5 ± 2.5°C	
Aspergillus brasiliensis[a]	WDCM 00053 (ATCC 16404; NCPF 2275)		72 h 22.5 ± 2.5°C	Slight to good turbidity

[a] Pharmacopoeia Growth Promotion Test

[b] EN ISO 11133

Please refer to the actual batch related Certificate of Analysis (CoA).

WARNING AND PRECAUTIONS

For *in-vitro* diagnostic use (see the product list the next page). **For professional use only**. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

See the references at the end of this document.

TABLE OF SYMBOLS

See the table of symbols at the end of this document.

The product is available in the various configurations listed on the next page. There may be additional product ref. numbers as well. For an updated listing of available products, visit **liofilchem.com**

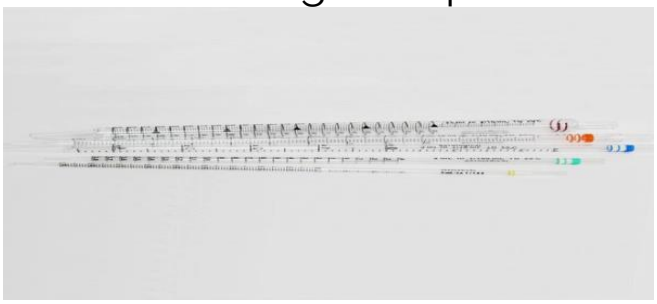
Product	Format	Packaging	Ref.	
Fluid Thioglycollate Medium	Tube	100 x 9 ml	26493	•
Fluid Thioglycollate Medium	Tube	20 x 10 ml	24124	•
Fluid Thioglycollate Medium	Tube	100 x 10 ml	26124	•
Fluid Thioglycollate Medium	Tube	10 x 20 ml	21241	•
Fluid Thioglycollate Medium	Tube	20 x 20 ml	24241	•
Fluid Thioglycollate Medium	Bottle (screw cap)	25 x 90 ml	452110	
Fluid Thioglycollate Medium	Bottle (screw cap)	6 x 100 ml	452060	•
Fluid Thioglycollate Medium	Bottle (screw cap)	25 x 100 ml	453060	
Fluid Thioglycollate Medium	Bottle (flip-off cap)	6 x 100 ml	400020	
Fluid Thioglycollate Medium	Bottle (flip-off cap)	25 x 100 ml	453020	
Fluid Thioglycollate Medium	Bottle (crimp cap)	6 x 100 ml	495020	
Fluid Thioglycollate Medium	Bottle (perforable cap)	6 x 100 ml	493000	
Fluid Thioglycollate Medium	Bottle (wide neck)	6 x 500 ml	470300	
Fluid Thioglycollate Medium	Bottle (screw cap)	6 x 900 ml	463100	
Fluid Thioglycollate Medium	Dehydrated medium	100 g	620050	
Fluid Thioglycollate Medium	Dehydrated medium	500 g	610050	
Fluid Thioglycollate Medium	Dehydrated medium	5 kg	6100505	

• CE-marked product for *in-vitro* diagnostic use

All the other above listed products are not CE-IVD marked.

This IFU document and the SDS are available from the online Support Center:
liofilchem.com/ifu-sds

Serological Pipette



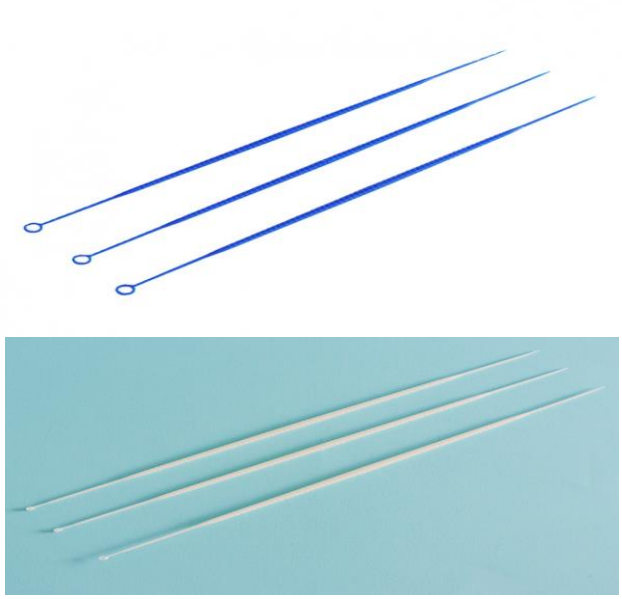
Serological Pipettes

Serological Pipette, designed for quantitatively transferring and dispensing exact volumes of liquid.
Manufactured from virgin polystyrene.
Accurate graduation, easy to read, color-codes by size for identification.
Available with 6 capacity of 1, 2, 5, 10, 25 and 50ml
Serological Pipettes are supplied gamma radiation, available with bulk package or in a paper/ plastic bag.

Dnase & Rnase free.

Cat No.	Description	Qty/Case
640601	**Serological Pipettes, PS, 1ml**	**4000**
640602	Serological Pipettes, PS, 2ml	3200
640603	Serological Pipettes, PS, 5ml	1800
640604	Serological Pipettes, PS, 10ml	1200
640605	Serological Pipettes, PS, 25ml	800
640606	Serological Pipettes, PS, 50ml	800

Inoculating Loops



Inoculating Loops

Disposable inoculating loops for collection and inoculation by streaking or puncture method. Smooth loop surfaces allows easy streaking. No rough plastic edges, flashing or burrs on the loop head. Loops do not cut or gouge the agar surface during streaking.
Being both sterile and disposable eliminates the risk of cross contamination
All loops are free of any lubricants and do not contaminate any media.
Color-coded sizes for easily identification.
Packages:
20pcs/zip-lock pack,50x20pcs/box,10x1000pcs/ctn
10pcs/zip-lock pack,100x10pcs/box,10x1000pcs/ctn
5pcs/zip-lock pack,100x5pcs/box,10x500pcs/ctn
Individual peel pack,500pcs/box,10x500pcs/ctn

Cat No.	**Description**	
Flexible Loops		
620604	Inoculating loops, ABS, white,1ul	10000
620605	Inoculating loops, ABS, blue,10ul	10000
620606	Inoculating loops, ABS, yellow,1ul +10ul	10000

ITALCERT

CERTIFICATO N° 505SGQ06

CERTIFICATE N° 505SGQ06

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 e 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 e dispositivi medici di classe I non sterile. Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I 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 and non-sterile class I medical devices. Marketing of invasive and non-invasive medical devices of class IIa, Is, I and in vitro diagnostics. Marketing of laboratory items.

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	2023-10-24	2026-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A

Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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ITALCERT

CERTIFICATO N° 505DM09

CERTIFICATE N° 505DM09

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 CEI EN ISO 13485-2021 (ISO 13485-2016)

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione e 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 e dispositivi medici di classe I non sterile.
Commercializzazione di dispositivi medici invasivi e non di classe IIa, Is, I e diagnostici in vitro.

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 and non-sterile class I medical devices.
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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*
2007-10-30	2011-10-30	2023-10-24	2026-10-29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 023A
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
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CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
22.11.2021

ARTICOLO: **PIPETTE STERILI PER SIEROLOGIA**
ITEM : ***STERILE SEROLOGICAL PIPETTES***

DESCRIZIONE / *DESCRIPTION*

PIPETTE MONOUSO IN PLASTICA PER SIEROLOGIA AD ESPULSIONE TOTALE

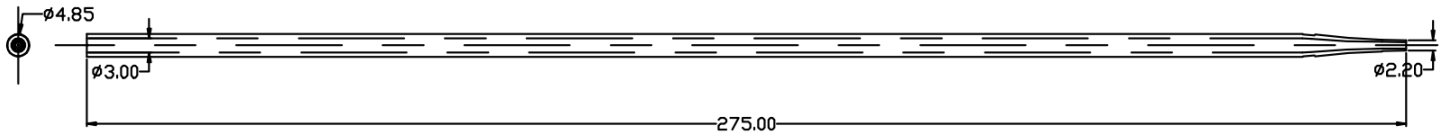
Pipette sierologiche sterili, graduate, prodotte in polistirolo vergine. Punta antigoccia per una massima precisione. La scala graduata stampata in nero è particolarmente visibile e di facile lettura e garantisce una accuratezza del ±2%. La scala graduata discendente & ascendente agevola l'utilizzo e la gradazione negativa consente una capacità extra. Pipette cotonate per la protezione del dispositivo di pipettaggio dal liquido aspirato. Le pipette e il confezionamento sono dotate di codice colore per una facile identificazione. Confezionate singolarmente in peel-pack carta/plastica pelabile per una apertura agevolata. Sterili per irraggiamento. Dispositivi latex free, certificati non pirogenici, non citotossici (UNI EN ISO 10993-5), non emolitici (UNI EN ISO 10993-4)

DISPOSABLE PLASTIC SEROLOGY PIPETTES TOTAL EXPULSIONS TYPE

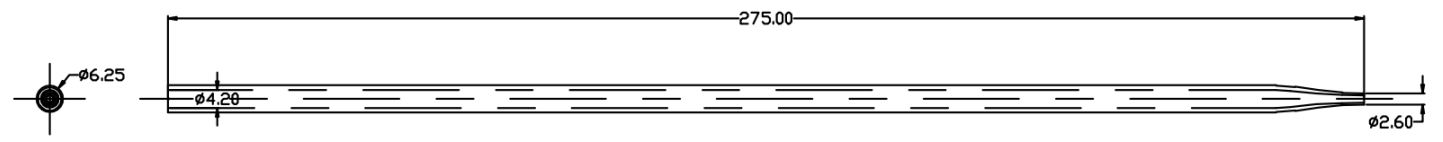
Sterile serological pipettes manufactured in virgin polystyrene, graduated. Non-dripping tip for pipette precision. Clear black graduations with easy-to-read scale markings guarantee maximum an accuracy of ±2%. Descending & ascending graduations to help pipetting and negative graduations for extra capacity. Supplied with a cotton plug for protection against the suction of liquid into the pipetting device. Pipettes and packaging are colour coded to simplify identification. Individually wrapped in paper/plastic peel-pack: peel for easy opening.
Sterile by irradiation. Latex free, certified non-pyrogenic, not cytotoxic devices (UNI EN ISO 10993-5), non-hemolytic (UNI EN ISO 10993-4)

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**STERILE / *STERILE***	*Microbilogical status*
Materiale impiegato	POLISTIROLO / POLYSTYRENE	*Raw material*
Temperature tollerate	MIN -10°C MAX +70°C	*Temperature range*
Accuratezza volume nominale	± 2% (A/*AT* 20°C)	*Accuracy for nominal volume*
Apirogene	0,25 EU/ML (FDA)	*Pyrogen free*
Validità del prodotto	5 ANNI / *YEARS*	*Shelf life*

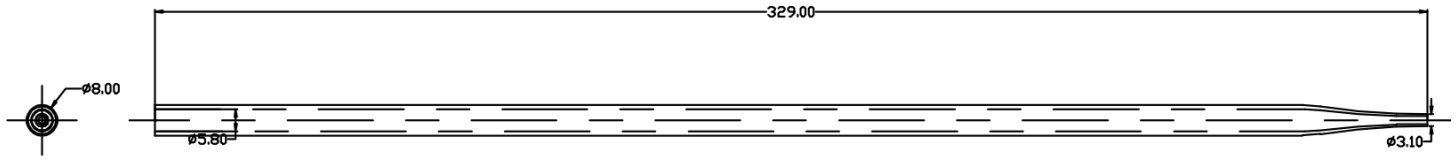
Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
Tel. (+39) 0141/83.50.75 – Fax (+39) 0141/83.52.92
E-Mail: info@aptaca.com – Website: www.aptaca.com



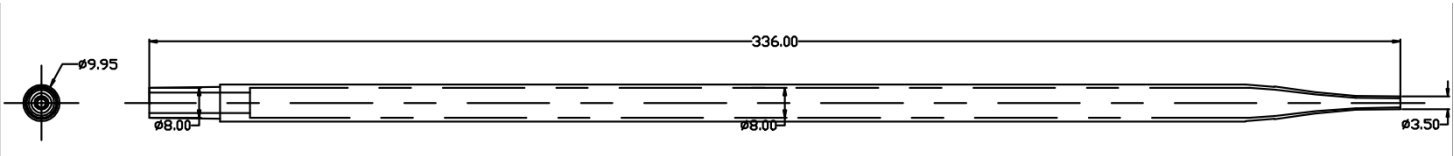
CODICE *CODE*	VOLUME *(ML)*	DIV. ML	GRAD. NEGATIVA *NEGATIVE GRAD.*	LUNGHEZZA *LENGHT*	COLORE *COLOUR*	SCATOLA *BOX*
31014	1 ml	1/100	- 0,3 ml	275 mm	Giallo / *Yellow*	500 pcs 40 x 30 x 14 cm (0,017 m³) – 2,3 Kg.



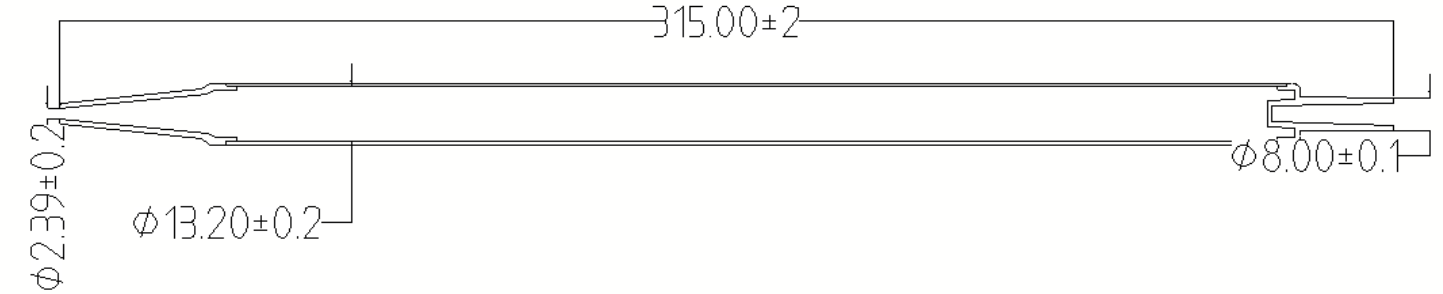
CODICE *CODE*	VOLUME *(ML)*	DIV. ML	GRAD. NEGATIVA *NEGATIVE GRAD.*	LUNGHEZZA *LENGHT*	COLORE *COLOUR*	SCATOLA *BOX*
31024	2 ml	1/100	- 0,4 ml	275 mm	Green / *Verde*	500 pcs 40 x 30 x 14 cm (0,017 m³) – 3,3 Kg.



CODICE *CODE*	VOLUME *(ML)*	DIV. ML	GRAD. NEGATIVA *NEGATIVE GRAD.*	LUNGHEZZA *LENGHT*	COLORE *COLOUR*	SCATOLA *BOX*
31054	5 ml	1/10	- 1,5 ml	329 mm	Blu / *Blue*	200 pcs 40 x 30 x 14 cm (0,017 m³) – 2,3 Kg.



CODICE *CODE*	VOLUME *(ML)*	DIV. ML	GRAD. NEGATIVA *NEGATIVE GRAD.*	LUNGHEZZA *LENGHT*	COLORE *COLOUR*	SCATOLA *BOX*
31104	10 ml	1/10	- 3 ml	336 mm	Viola / *Violet*	200 pcs 40 x 30 x 14 cm (0,017 m³) – 2,8 Kg.



CODICE *CODE*	VOLUME *(ML)*	DIV. ML	GRAD. NEGATIVA *NEGATIVE GRAD.*	LUNGHEZZA *LENGHT*	COLORE *COLOUR*	SCATOLA *BOX*
31254	25 ml	1/5	- 7 ml	315 mm	Rosso / *Red*	150 pcs 40 x 30 x 14 cm (0,017 m³) – 2,8 Kg.

Aptaca S.p.A. Regione Monforte, 30 - 14053 Canelli (Asti) Italy
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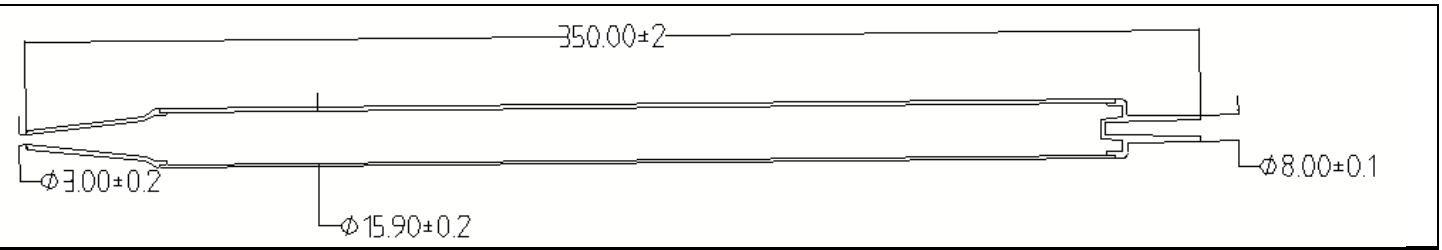

CODICE *CODE*	*VOLUME (ML)*	DIV. ML	GRAD. NEGATIVA *NEGATIVE GRAD.*	LUNGHEZZA *LENGHT*	COLORE *COLOUR*	SCATOLA *BOX*
31504	50 ml	1/2	- 6 ml	350 mm	Nero / *Black*	150 pcs 43.5 x 24 x 31 cm (0,032 m^3) – 4,2 Kg.

DESTINAZIONE D'USO / *INTENDED PURPOSE*

Le pipette sierologiche non sono soggette a marcatura CE (per usi generici di laboratorio per applicazioni in ricerca)
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale in laboratori di analisi

Pipettes are not CE Marked (For general laboratory use for research applications)
For use in professional test laboratory only

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 substance 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

LOT
Numero di lotto
Lot number

Monouso
Disposable

STERILE R
Sterilizzazione con radiazioni ionizzanti
Sterilization by ionizer rays

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CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

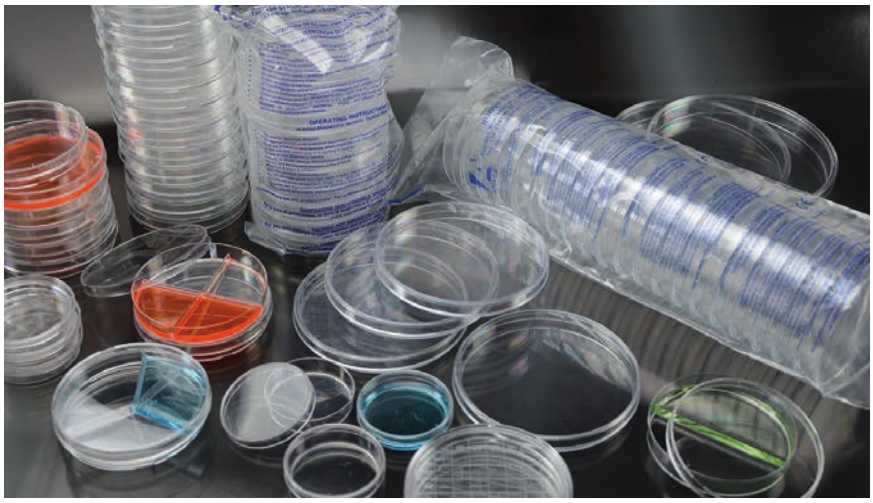
SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

Data emissione / Date of issue
19.02.2021

MADE IN ITALY

Articolo: **Piastre di Petri Ø 90 mm**
Item: **Petri dishes Ø 90 mm**

DESCRIZIONE / *DESCRIPTION*



Le Piastre di Petri sono prodotte con un elevato standard di qualità garantito da un processo produttivo completamente automatizzato, in condizioni di asetticità controllata. Ideali per lavori di routine, ricerca batteriologica e per l'utilizzo in riempitori automatici. Le piastre sono **conformi allo standard UNI EN ISO 24998**. Il processo produttivo e il controllo qualità sono eseguiti in base a specifiche procedure ed istruzioni come richiesto dal Sistema Qualità conforme alle Norme UNI EN ISO 9001 e UNI EN ISO 13485 (Conformità a tali Norme rilasciata da Ente notificato esterno).

*Petri Dishes are produced with a high quality standard guaranteed by a fully automated production process, under controlled aseptic conditions. Ideal for routine use, bacteriuria screening and for their use in automatic filling machines. Petri dishes are **conform to UNI EN ISO 24998 standard**. The production process and the quality controls are executed in accordance with specific procedures and instructions as required by the Quality System in compliance with UNI EN ISO 9001 and UNI EN ISO 13485 Rules (Conformity issued by external Notified Body).*

Prodotto con marchio CE - conforme alla Direttiva 98/79/CE e al D.lgs 332 del 08/09/2000

CE Marked product - manufactured in compliance with 98/79/CE Directive and D.lgs 332 dtd 08/09/2000

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" Dispositivo atto a contenere terreni di coltura idonei ad essere inoculati con campioni biologici umani (per esempio urina, saliva, espettorato, pus, etc) al fine di effettuare analisi diagnostiche di laboratorio. **Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.**
Classificazione Nazionale dei Dispositivi Medici (CND) > W0503030101 (Capsule di Petri)
Classificazione EDMA > 14909090 - Other Other Microbiology

*Intended purpose is "IN VITRO MEDICAL DEVICE" Device suitable to contain culture media suitable to be inoculated with human biological samples (for example, urine, saliva, sputum, pus, etc) in order to carry out diagnostic laboratory analysis. **For professional use only.***
National classification of medical devices (CND - For Italian law) > W0503030101 (Petri dishes)
EDMA > *14909090 - Other Other Microbiology*

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PRODUCT IDENTIFICATION / *IDENTIFICAZIONE DEL PRODOTTO*

COD.	Descrizione *Description*	Confezionamento *Packaging*	RDM[1]
91	Piastre di petri Ø 90 mm, ventilate, asettiche *Petri dishes Ø 90 mm, with triple vents, aseptic*	500 pcs (25 x 20 pcs)	1898166/R
91/AN	Piastre di petri Ø 90 mm, ventilate, asettiche, anonime *Petri dishes Ø 90 mm, with triple vents, aseptic, anonymous*	500 pcs (25 x 20 pcs)	1898169/R
91*	Piastre di petri Ø 90 mm, ventilate, asettiche *Petri dishes Ø 90 mm, with triple vents, aseptic*	480 pcs (24 x 20 pcs)	1898167/R
91/SG	Piastre di petri Ø 90 mm, ventilate, **sterili irraggiate** *Petri dishes Ø 90 mm, with triple vents, **sterile irradiated***	500 pcs (25 x 20 pcs)	1898211/R
91/SG/AN	Piastre di petri Ø 90 mm, ventilate, **sterili irraggiate**, anonime *Petri dishes Ø 90 mm, with triple vents, **sterile irradiated**, anonymous*	500 pcs (25 x 20 pcs)	1898213/R
91/SG*	Piastre di petri Ø 90 mm, ventilate, **sterili irraggiate** *Petri dishes Ø 90 mm, with triple vents, **sterile irradiated***	480 pcs (24 x 20 pcs)	1898212/R
101	Piastre di petri Ø 90 mm, non ventilate, asettiche *Petri dishes Ø 90 mm, without triple vents, aseptic*	500 pcs (25 x 20 pcs)	1898143/R
101/AN	Piastre di petri Ø 90 mm, non ventilate, asettiche, anonime *Petri dishes Ø 90 mm, without triple vents, aseptic, anonymous*	500 pcs (25 x 20 pcs)	1898149/R
101/SG	Piastre di petri Ø 90 mm, non ventilate, **sterili irraggiate** *Petri dishes Ø 90 mm, without triple vents, **sterile irradiated***	500 pcs (25 x 20 pcs)	1898182/R
101/SG/AN	Piastre di petri Ø 90 mm, non ventilate, **sterili irraggiate,** anonime *Petri dishes Ø 90 mm, without triple vents, **sterile irradiated,** anonymous*	500 pcs (25 x 20 pcs)	1898184/R

COD.	Descrizione *Description*	Confezionamento *Packaging*	RDM[1]
251	Petri dishes Ø 90 mm, with 2 sectors and triple vents, aseptic *Piastre di petri Ø 90 mm, a 2 settori, ventilate, asettiche*	500 pcs (25 x 20 pcs)	1898157/R
251/SG	Petri dishes Ø 90 mm, with 2 sectors and triple vents, **sterile irradiated** *Piastre di petri Ø 90 mm, a 2 settori, ventilate, **sterili irraggiate***	500 pcs (25 x 20 pcs)	1898198/R
261	Petri dishes Ø 90 mm, with 3 sectors and triple vents, aseptic *Piastre di petri Ø 90 mm, a 3 settori, ventilate, asettiche*	500 pcs (25 x 20 pcs)	1898160/R
261/SG	Petri dishes Ø 90 mm, with 3 sectors and triple vents, **sterile irradiated** *Piastre di petri Ø 90 mm, a 3 settori, ventilate, **sterili irraggiate***	500 pcs (25 x 20 pcs)	1898201/R
271	Petri dishes Ø 90 mm, with 4 sectors and triple vents, aseptic *Piastre di petri Ø 90 mm, a 4 settori, ventilate, asettiche*	500 pcs (25 x 20 pcs)	1898163/R
271/SG	Petri dishes Ø 90 mm, with 4 sectors and triple vents, **sterile irradiated** *Piastre di petri Ø 90 mm, a 4 settori, ventilate, **sterili irraggiate***	500 pcs (25 x 20 pcs)	1898204/R

[1] Repertorio Nazionale dei Dispositivi Medici

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MATERIALE DI PRODUZIONE / *MANUFACTURING MATERIAL*

Le piastre di petri sono otticamente trasparenti, atossiche, biologicamente inerti, prodotte in polistirolo cristallo antigraffio (PS - Numero CAS: 9003-53-6 - Numero CE: 500-008-9) unicamente di prima scelta.
La materia prima utilizzata è conforme ed idonea per il contatto alimentare in base a:

- ITALIA: Decreto Ministeriale 21/03/1973 e successivi aggiornamenti e modifiche; DPR 777/82 e successivi aggiornamenti e modifiche
- UE: Regolamento 1935/2004/CE (oggetti destinati a contatto con alimenti) e s.m.i.; Regolamento 10/2011 (limiti di migrazione) e s.m.i.; Regolamento 1895/2005/CE (restrizione d'uso sostanze per contatto con alimenti) e s.m.i.; Direttiva 2002/72/CE e successivi aggiornamenti e modifiche (contatto alimenti) e s.m.i.
- USA: Approvazione del Food and Drug Administration (FDA) - Title 21 §177 1640 (Styrene polymers).

Altresì il polistirolo da noi utilizzato non contiene metalli pesanti, è conforme alla Direttiva RoHS (2011/65/UE), alla Direttiva 2005/84/CE (restrizione d'uso sostanze - ftalati, solfati)

Nella fabbricazione dei Dispositivi non sono state usati materiale che contengono gomma naturale, latex, gomme sintetiche che contengono gomme naturali (ad esclusione degli articoli in lattice)
Le piastre in oggetto sono apirogene, non contenendo endotossine batteriche.

Petri dishes have high optical clarity and are atoxic, biologically inert, made in crystal Polystyrene non-scratch (PS – CAS number: 9003-53-6 - CE number: 500-008-9) of top quality only.
Raw material used is conform and idoneous to foodstuff contact according to:

- *Italy: 21/03/1973 Ministerial Decree and following updating and changes; 777/82 DPR and following updating and changes*
- *European Union: 1935/2004/CE Rule (objects intended to come in contact with food) and following updates and changes; 10/2011 Regulation (specific migration limits) and following updates and changes; 1895/2005/CE Rule (substances use restriction for food contact) and following updates and changes; 2002/72/CE Directive and following updating and changes (food contact) and following updates and changes*
- *USA: FDA's approval – Title 21 § 177 1640 (Styrene Polymers).*

Moreover the polystyrene we use does not contain heavy metals and is conform to RoHS Directive (2011/65/UE), Directive 2005/84/CE (substances use restriction – phthalates, sulphates).

During Devices manufacturing no materials containing natural rubber, latex, synthetic rubber are used (except for Articles of latex) Dishes in object are pyrogen-free as do not contain bacterial endotoxins.

STATO MICROBIOLOGICO / *MICROBIOLOGICAL STATUS*

Tutte le piastre in oggetto sono prodotte in condizioni di asetticità controllata tali da garantire una contaminazione microbiologica ad un livello trascurabile, garantendo un SAL[2] di 1 x 10^{-3} in accordo, ove applicabile, con la British Standard BS-EN 556-2. Sempre in base alla citata BS, le piastre sono libere da contaminazione di particelle sparse, maggiori di 100 micrometri di diametro, individuate da un esame visivo. Lo stato microbiologico delle piastre, in base alle prove di invecchiamento effettuate e alla validazione del confezionamento, è garantito 5 (cinque) anni dalla data di fabbricazione.

Verifica dell'asetticità
Gli ambienti di produzione sono verificati ed igienizzati periodicamente in base alle procedure interne, in particolare le presse di produzione e gli automatismi di assemblaggio sono igienizzati ad ogni inizio turno di lavoro.
Ogni confezione (20 piastre) viene ispezionata visivamente dagli operatori a bordo macchina al fine di garantire l'assenza di eventuali particelle sparse. Con cadenza settimanale viene prelevata una confezione da 20 petri da ogni macchina e viene testata l'asetticità (carica microbica, muffe, lieviti, funghi) da un laboratorio esterno certificato ed accreditato. Per la verifica dell'asetticità sono utilizzati protocolli ufficiali, incubando per 5 giorni le piastre con terreni Plate Count Agar (PCA) e Malt Extract Agar (MEA). Nel caso di esito positivo delle analisi (presenza di UFC[3]) l'intero lotto di produzione viene segregato ed inviato in sterilizzazione.

Sterilizzazione
Le piastre di petri vendute "sterili" sono sterilizzate per irraggiamento tramite radiazioni ionizzanti raggi Beta (Dose di sterilizzazione: 21,6 kGy - Energia del fascio: 10 MeV). Il processo di sterilizzazione è validato e verificato con cadenza trimestrale tramite audit esterno. **Per le piastre "sterili" è garantito un SAL di 1 x 10^{-6}.**

[2] Sterilty Assurrance Level (SAL)
[3] Unità Formanti Colonie (UFC)

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All dishes in object are manufactured under controlled aseptic conditions so as to grant a negligible microbiological contamination, assuring a SAL[4] of 1x10^{-3} in accordance, where applicable, with the British Standard BS-EN 556-2:2003. Always in accordance with the said BS, dishes are free from contamination of scattered particles, with a diameter bigger than 100 micrometers, identified by a visual examination. The microbiological status of dishes, according to the executed ageing proofs and packing validation, is granted for 5 (five) years from manufacturing date.

Aseptic Conditions Control
Manufacturing rooms are periodically verified and hygienized according to internal procedures, in particular moulding machines and assembling automatisms are hygienized at each shift change.
Each pack (20 dishes) is visually examined by workers by machine's side in order to grant the absence of possible scattered particles. Every week a pack of 20 dishes is drawn out of each machine and aseptic conditions (microbical charge, molds, leavens, fungus) are tested by an external certified and accredited laboratory. Official protocols are used for the aseptic conditions control, incubating dishes with Plate Count Agar and Malt Extract Agar transport media for 5 days. If analysis have a positive result (presence of UFC[5]) the whole production lot is segregated and sent to sterilization.

Sterilization
Petri dishes sold in sterile version are sterilized by ionizing radiations (Beta Rays - Applied dose: 21.6 kGy – Bundle energy: 10 MeV). Sterilization process is validated and verified every three months by external audit. ***A SAL of 1x10^{-6} is granted for "sterile" dishes.***

CARATTERISTICHE FISICHE / *PHYSICAL FEATURES*

L'elevato peso, l'ottima planarità e le dimensioni altamente standard, in accordo con la Normativa UNI EN ISO 24998, rende le piastre in oggetto prodotte dall'Aptaca particolarmente idonee per l'utilizzo in riempitrici e macchinari automatizzati:

- Gli spigoli della base e del coperchio sono paralleli, entro 5°, con la superficie piana della base;
- Né la base né il coperchio hanno sporgenze pungenti che potrebbero causare tagli accidentali, punture o abrasioni sulla pelle degli utilizzatori o compromettere il corretto utilizzo nei macchinari automatizzati;
- Nel caso di piastre a comparti separati (settori), l'altezza dei divisori è superiore al 50% dell'altezza della base tali da non permettere perdite tra i comparti. L'altezza dei comparti è di 7,5 ±0,5 mm;
- Nel caso di piastre ventilate, vi sono n°3 protuberanze, di 0,25 mm di altezza, uniformemente distribuite sulla circonferenza del coperchio, tali da consentire una idonea ventilazione della piastra;
- La particolare conformazione della base rende le piastre facilmente impilabili; è possibile inclinare una pila di 10 piastre per un angolo di 12° dalla verticale senza che la pila crolli.

Ogni confezione di piastre viene esaminata visivamente dal controllo qualità al fine di garantire l'assenza di imperfezioni estetiche e/o funzionali delle piastre. Altresì è verificata l'integrità del sacchetto e la sua corretta chiusura (termosaldatura).

Con cadenza settimanale è prelevata una campionatura di piastre da ogni pressa di produzione e sono verificati i seguenti aspetti:

- Rigidità;
- Resistenza alla distorsione termica (testato con soluzione acquosa 1,5% di agar a 60°C) in accordo ISO 24998;
- Resistenza alla rottura;
- Stabilità nell'impilaggio;
- Controlli dimensionali.

The high weight, the excellent steadiness and the highly standard dimensions, in accordance with the Standard UNI EN ISO 24998, make dishes produced by Aptaca particularly appropriate for the use with automatic filling machines:

- *Plate and lid edges are parallel, within 5°, to the flat bottom surface;*
- *Neither plate nor lid have thorny protrusions that could cause accidental cuts, punctures or abrasions on the users' skin or compromise the correct use in automatic machines;*
- *In case of dishes with sectors, divisors height is higher than 50% of bottom height as not to permit leaking among sectors. Sectors height is 7.5 ±0.5 mm;*
- *In case of dishes with triple vent, there are three protuberances, of a height of 0.25mm, uniformly distributed on the cover circumference, as to allow an appropriate dish ventilation;*
- *The particular plate shape makes dishes easily stackable; it's possible to incline a pile of 10 dishes to a 12° angle from the vertical line without pile falling.*

Each pack of dishes is visually examined by quality control in order to grant the absence of aesthetic and/or functional imperfections of dishes. Moreover, the pack completeness and its correct closing (welding) is verified.

[4] Sterilty Assurance Level (SAL)
[5] Unit Forming Colonies (UFC)

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Every week a dishes sampling is drawn from every production press and the following features are verified:

- *Stiffness*
- *Thermal distortion resistance (tested in aqueous solution containing 1,5% Agar at +60°C according to ISO 24998)*
- *Breaking resistance*
- *Stacking stability*
- *Dimensional controls*

DIMENSIONI / *DIMENSIONS*

Codice *Code*	**Base** *Base*			**Coperchio** *Lid*		**Base + Coperchio (assemblati)** *Base + Lid (assembled)*				
	Diametro interno *Internal diameter*	Diametro esterno *External diameter*	Altezza esterna *External height*	Diametro esterno *External diameter*	Altezza esterna *External height*	Altezza *Height*	Spazio laterale tra il coperchio e la base *Side space between lid and plate*	Altezza tra la base della piastra e il piano di appoggio *Height between dish plate and support level*	Peso *Weight*	Superficie interna utilizzabile *Internal usable surface*
91	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15 ±1	mm^2 5.809 ±35
101	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15 ±1	mm^2 5.809 ±35
251	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15 ±1	mm^2 5.800 ±35
261	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15,02 ±1	mm^2 5.795 ±35
271	mm 86,0 ±0,5	mm 89 ±0,5	mm 14,5 ±1	mm 92,5 ±1	mm 8,2 ±1	mm 15,9 ±2	mm 0,75 ±0,2	mm 0,5 ±0,2	gr. 15,05 ±1	mm^2 5.790 ±35

IMBALLAGGIO ED IDENTIFICAZIONE / *PACKING AND IDENTIFICATION*

Le piastre sono confezionate in sacchetti di LDPE contenenti ognuno 20 pezzi. La chiusura del sacchetto avviene tramite termosaldatura. Sia la consistenza del sacchetto che la qualità della chiusura garantiscono lo stato microbiologico del prodotto per 5 (cinque) anni dalla data di fabbricazione.
Su ogni sacchetto sono serigrafate (in lingua italiana, inglese e francese) le istruzioni d'uso per un utilizzo corretto e sicuro del dispositivo (ad esclusione delle piastre cod. 91/AN, 91/SG/AN, 101/AN e 101/SG/AN).

L'unità di vendita è rappresentata dall'imballaggio secondario composto dalla scatola di cartone (con rivestimento kraft) contenente:

- 500 piastre (25 sacchetti da 20 pezzi). Il volume della scatola è di 0,078 m^3 (dimensioni 48,5 x 48,5 x 33 cm) – Peso 9,200 Kg. circa

Per i codici 91* e 91/SG*:

- 480 piastre (24 sacchetti da 20 pezzi). Il volume della scatola è di 0,077 m^3 (dimensioni 58,5 x 38,5 x 34 cm) – Peso 8,7 Kg. circa

Su ogni scatola è apposta l'etichetta identificativa del prodotto riportante:

- Codice articolo;
- Quantità;
- Descrizione articolo;
- Lotto di produzione;
- Data di produzione e data di scadenza;
- Codice a barre;
- Indicazione di conformità CE;
- Indicazione del produttore Aptaca;
- Simbologia conforme alla UNI CEI EN ISO 15223-1

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Dishes are packed in LDPE bags each containing 20 pieces. Bag closing is made by heat welding. Both bag consistency and closing quality grant the microbiological status of the product for 5 (five) years from manufacturing date. Use instructions for a correct and safe utilization of the device are silk-screen printed on each bag in Italian, English and French (excluding codes 91/AN, 91/SG/AN, 101/SG and 101/SG/AN).

Sale unit is represented by the secondary packing made of cardboard box (with kraft lining) which contains:

- *500 dishes (25 bags of 20 pieces). The box volume is 0.078 m^3 (dimensions 48.5 x 48.5 x 33 cm) – Weight about 9.2 Kg.*

For codes 91 e 91/SG*:*

- *480 dishes (24 bags of 20 pieces). The box volume is 0.077 m^3 (dimensions 58,5 x 38,5 x 34 cm) – Weight about 8.7 Kg.*

On each box is put a label identifying the product and indicating:

- *Item code;*
- *Quantity;*
- *Item description;*
- *Production lot;*
- *Manufacturing and expiry date;*
- *Bar code;*
- *CE Conformity indication;*
- *Aptaca Manufacturer indication;*
- *Symbology conform to UNI CEI EN ISO 15223-1*

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

- Utilizzare esclusivamente per effettuare analisi di laboratorio
- In caso di fuoriuscita del contenuto usare dispositivi di protezione individuale: PERICOLO DI CONTAMINAZIONE
- Non avvicinare il Dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare
- Non utilizzare il prodotto scaduto o con la confezione aperta
- Non riutilizzare: Dispositivo monouso
- Nel caso di prodotto sterile o asettico: stato microbiologico garantito a confezione integra
- Non variare la destinazione d'uso
- Prodotto non adatto ai bambini
- Utilizzare il Dispositivo unicamente con accessori in dotazione
- Non esporre direttamente ai raggi solari; proteggere dall'umidità
- Conservare in luogo asciutto, temperatura min. -10°C (14°F) – max +50°C (122°F)
- Per lo smaltimento utilizzare gli appositi D.P.I. e smaltire secondo le normative vigenti
- Materiale di produzione: polistirolo. Prima dell'utilizzo con sostanze particolari verificare la resistenza/compatibilità del materiale.

- *Use only for laboratory analysis*
- *Use appropriate personal protective equipment: contamination risk if contents leak*
- *Keep out of flame or heat sources which might damage the product*
- *Do not use after expiry date or if packing is opened*
- *Do not re-use: Disposable Device*
- *If sterile or aseptic Device: Microbiological status in undamaged pack*
- *Do not vary the intended purpose of the product*
- *Keep out of reach of children*
- *Use with provided accessories only*
- *Do not put under direct sun rays; store in a dry, cool place*
- *Store in dry place, temperature range: min. -10°C (14°F) – max +50°C (122°F)*
- *Disposal: use appropriate personal protective equipment and act according to applicable regulations*
- *Raw material: polystyrene. Before use with particular substances check the resistance/compatibility*

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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.

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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