

DICHIARAZIONE DI CONFORMITÀ CE

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

dichiara sotto la propria responsabilità

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

EC DECLARATION OF CONFORMITY

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

hereby certifies under its own responsibility

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

Roseto degli Abruzzi (TE),
26.05.2022

Signature:



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

Technical Director
(Dr. Silvio Brocco)

Table no.1

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

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

CODE	DESCRIPTION
76031	SensiQuattro Gram-negative
79031	SensiQuattro Gram-negative
76032	SensiQuattro Gram-positive
79032	SensiQuattro Gram-positive
76010	SensiTest Gram-negative
79010	SensiTest Gram-negative
76020	SensiTest Gram-positive
79020	SensiTest Gram-positive
71630	Staf System 18R
79630	Staf System 18R
72560	Strepto System 12R
79560	Strepto System 12R
74161	Urin System Chrom
79161	Urin System Chrom
74160	Urin System Plus
79160	Urin System Plus
80258	AF Genital System Reagent
80252	Enterosystem 18R Reagent
80260	Identification System Reagent
NP Tests	
CODE	DESCRIPTION
76036	Rapid ESBL NP® Test
76046	RapidResa Polymyxin Acinetobacter NP® Test
Agar Dilution AST	
CODE	DESCRIPTION
77001	AD Fosfomycin 0.25-256
77061	AD Fosfomycin 0.25-256
EPT	
CODE	DESCRIPTION
78618	Entero Pluri Test
78619	Entero Pluri Test
78621	Oxi/ferm Pluri Test
78620	Oxi/ferm Pluri Test
Supplements	
CODE	DESCRIPTION
81088	Chromatic CRE supplement
81090	Chromatic ESBL + AmpC supplement
81089	Chromatic ESBL supplement
81078	Chromatic MRSA supplement
81083	Meropenem supplement
81062	Vancomycin supplement
CultiControl ATCC	
CODE	DESCRIPTION
89139	Bordetella bronchiseptica ATCC® 4617
89174	Acinetobacter baumannii ATCC® 19606
89141	Acinetobacter baumannii ATCC® BAA-747
89114	Actinomyces odontolyticus ATCC® 17929
89169	Aeromonas hydrophila ATCC® 35654
89119	Aeromonas hydrophila ATCC® 7966
89091	Aggregatibacter aphrophilus ATCC® 7901
89021	Aspergillus brasiliensis ATCC® 16404
89057	Aspergillus fumigatus ATCC® 204305
89155	Bacillus cereus ATCC® 10876

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

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

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

CODE	DESCRIPTION
89131	Streptococcus salivarius ATCC® 13419
89186	Streptococcus salivarius subsp. thermophilus ATCC® 19258
89064	Streptococcus sanguinis ATCC® 10556
89140	Trichophyton mentagrophytes ATCC® 9533
89144	Vibrio alginolyticus ATCC® 17749
89056	Vibrio parahaemolyticus ATCC® 17802
89050	Yersinia enterocolitica ATCC® 9610
89168	Yersinia enterocolitica subsp. enterocolitica ATCC® 23715
Antibiotic disc in cartridges	
CODE	DESCRIPTION
9004	Amikacin AK 30 µg
9004/1	Amikacin AK 30 µg
9191	Amoxicillin + Clavulanic acid AUG 3 (2+1) µg
9191/1	Amoxicillin + Clavulanic acid AUG 3 (2+1) µg
9133	Amoxicillin AML 10 µg
9133/1	Amoxicillin AML 10 µg
9151/1	Amoxicillin AML 2 µg
9151	Amoxicillin AML 2 µg
9179	Amoxicillin AML 25 µg
9179/1	Amoxicillin AML 25 µg
9005	Amoxicillin AML 30 µg
9005/1	Amoxicillin AML 30 µg
9048	Amoxicillin-clavulanic acid AUG 30 µg
9048/1	Amoxicillin-clavulanic acid AUG 30 µg
9255	Amoxicillin-clavulanic acid AUG 7.5 µg
9255/1	Amoxicillin-clavulanic acid AUG 7.5 µg
9137	Amphotericin B AMB 10 µg
9137/1	Amphotericin B AMB 10 µg
9071	Amphotericin B AMB 20 µg
9071/1	Amphotericin B AMB 20 µg
9006	Ampicillin AMP 10 µg
9006/1	Ampicillin AMP 10 µg
9115/1	Ampicillin AMP 2 µg
9115	Ampicillin AMP 2 µg
9031	Ampicillin-sulbactam AMS 20 µg
9031/1	Ampicillin-sulbactam AMS 20 µg
9122	Ampliclox (Ampicillin-cloxacillin) ACL 30 (25+5) µg
9122/1	Ampliclox (Ampicillin-cloxacillin) ACL 30 (25+5) µg
9105	Azithromycin AZM 15 µg
9105/1	Azithromycin AZM 15 µg
9007	Azlocillin AZL 75 µg
9007/1	Azlocillin AZL 75 µg
9008	Aztreonam ATM 30 µg
9008/1	Aztreonam ATM 30 µg
9051	Bacitracin BA 10 IU
9051/1	Bacitracin BA 10 IU
9009	Carbenicillin CAR 100 µg
9009/1	Carbenicillin CAR 100 µg
9165	Caspofungin CAS 5 µg
9165/1	Caspofungin CAS 5 µg
9010/1	Cefaclor 30 µg
9010	Cefaclor 30 µg
9052	Cefadroxil CDX 30 µg
9052/1	Cefadroxil CDX 30 µg

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

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

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

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

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

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

CODE	DESCRIPTION
9110/1	Trimethoprim TM 5 µg
9082	Tylosin TY 30 µg
9082/1	Tylosin TY 30 µg
9045	Vancomycin VA 30 µg
9045/1	Vancomycin VA 30 µg
9164	Vancomycin VA 5 µg
9164/1	Vancomycin VA 5 µg
9168	Voriconazole VO 1 µg
9168/1	Voriconazole VO 1 µg
99002	ESBL disc kit (acc. to EUCAST)
99003	KPC&MBL disc kit (acc. to EUCAST)
99004	ESBL disc kit (acc. to EUCAST)
99005	ESBL disc kit (acc. to CLSI)
99006	ESBL (Chromos. Ind. AmpC) disc kit (acc. to EUCAST)
99007	KPC&MBL&OXA-48 disc kit (acc. to EUCAST)
99008	ESBL+AmpC screen disc kit
99009	AmpC disc kit
Antibiotic disc in canister	
CODE	DESCRIPTION
9004/2	Amikacin AK 30 µg
9133/2	Amoxicillin AML 10 µg
9005/2	Amoxicillin AML 30 µg
9048/2	Amoxicillin-clavulanic acid AUG 30 µg
9137/2	Amphotericin B AMB 10 µg
9071/2	Amphotericin B AMB 20 µg
9006/2	Ampicillin AMP 10 µg
9115/2	Ampicillin AMP 2 µg
9031/2	Ampicillin-sulbactam AMS 20 µg
9105/2	Azithromycin AZM 15 µg
9007/2	Azlocillin AZL 75 µg
9008/2	Aztreonam ATM 30 µg
9051/2	Bacitracin BA 10 IU
9009/2	Carbenicillin CAR 100 µg
9010/2	Cefaclor 30 µg
9052/2	Cefadroxil CDX 30 µg
9014/2	Cefamandole MA 30 µg
9015/2	Cefazolin KZ 30 µg
9143/2	Cefepime + Clavulanic acid FEL 40 µg
9104/2	Cefepime FEP 30 µg
9266/2	Cefiderocol FDC 30 µg
9089/2	Cefixime CFM 5 µg
9016/2	Cefoperazone CFP 30 µg
9108/2	Cefoperazone CFP 75 µg
9182/2	Cefotaxime + Clavulanic acid CTL 40 (30+10) µg
9017/2	Cefotaxime CTX 30 µg
9152/2	Cefotaxime CTX 5 µg
9018/2	Cefoxitin FOX 30 µg
9064/2	Cefpodoxime PX 10 µg
9053/2	Cefsulodin CSD 30 µg
9198/2	Ceftaroline CPT 30 µg
9195/2	Ceftaroline CPT 5 µg
9145/2	Ceftazidime + Clavulanic acid CAL 40 (30+10) µg
9153/2	Ceftazidime CAZ 10 µg
9019/2	Ceftazidime CAZ 30 µg
9206/2	Ceftazime-avibactam CZA 14 µg
9101/2	Ceftibuten CTB 30 µg

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

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

MIC Test Strip

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

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

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

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

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

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

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

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

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

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

Multodiscs

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

Bacterial suspension - rapid Kit

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

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

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

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)

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	Bruceella 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

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	805518287MCIADJ
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%)	805518287SKKV6
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

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	805518287TALKPWL V
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	805518287BCARB TMH8
402270	Cetrimide Agar	805518287BCETAA6
412270	Cetrimide Agar	805518287BCETAA6
442220	Chocolate Agar	805518287BCHOOA6
470120	Chocolate Agar	805518287BCHOOA6
30099	Chocolate Agar	805518287TCHOAGC
412100	Christensen Urea Agar	805518287BCHR UADK
30081	Christensen Urea Agar	805518287TCHRUALV
481130	Chromatic Detection	805518287BCHR DAM
482190	Chromatic E.coli O157	805518287BCHRECOJM
481140	Chromatic Salmonella	805518287BCHRSBK

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	805518287BGNHBBDD
24119	GN Hajna Broth	805518287TGNHBHKK
24091	Haemophilus Test Broth	805518287THAETBJZ
402230	Hektoen Enteric Agar	805518287BHEKEAC2
412230	Hektoen Enteric Agar	805518287BHEKEAC2
20090	Helicobacter pylori Test	805518287THELPTMQ
30087	Kligler Iron Agar	805518287TKLIAMY
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

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

CODE	DESCRIPTION	BASIC UDI-DI
30119	Lowenstein Jensen Medium w/o Glycerol	805518287TLOWJMW/OG4B
412040	Lysine Iron Agar	805518287BLYSIAKE
30098	Lysine Iron Agar	805518287TLYSIAEQ
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/ml	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/ml	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

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	805518287TTRYAB9C
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

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 + Charcoal	805518287610152MC
620152	Amies Transport Medium + Charcoal	805518287610152MC
6101525	Amies Transport Medium + Charcoal	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

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

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

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

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

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

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 ₂ O ₂ / Catalase Reagent	805518287000084JT
87003	H ₂ O ₂ / Catalase Reagent Droppers	805518287000084JT
88013	H ₂ S 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	Ornithine Decarboxylase Test	805518287000113J9
88004	Oxidase Test Disc	805518287000114JB
88029	Oxidase Test Stick	805518287000115JD
88029N	Oxidase Test Stick	805518287000116JF

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



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](http://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



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: \

CERTIFICAT

CERTIFICADO

СЕРТИФИКАТ

認證證書

CERTIFICATE

ZERTIFIKAT



Italia

CERTIFICATO

Nr. 50 100 11497 Rev.005

SI ATTESTA CHE / THIS IS TO CERTIFY THAT

IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
THE QUALITY MANAGEMENT SYSTEM OF

LIOFILCHEM S.r.l.

SEDE LEGALE:
REGISTERED OFFICE:

**VIA SCOZIA - ZONA INDUSTRIALE
IT - 64026 ROSETO DEGLI ABRUZZI (TE)**

SEDI OPERATIVE: VEDI ALLEGATO 1 / OPERATIONAL SITES: SEE ANNEX 1

È CONFORME AI REQUISITI DELLA NORMA
HAS BEEN FOUND TO COMPLY WITH THE REQUIREMENTS OF

UNI EN ISO 9001:2015

QUESTO CERTIFICATO È VALIDO PER IL SEGUENTE CAMPO DI APPLICAZIONE
THIS CERTIFICATE IS VALID FOR THE FOLLOWING SCOPE OF APPLICATION

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura per microbiologia, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro (IAF 12, 29)

Design and development, production and sales of in-vitro diagnostic medical devices: culture media for microbiology, identification and susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices (IAF 12, 29)



SGQ N° 049A

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

Per l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.

Validità / Validity

Dal / From: **2022-02-11**

Al / To: **2025-02-10**

Francesco Scarlata

Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione /
Issuing Date

2022-01-26

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2022-02-10
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2022-02-10

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
"THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



Italia

ALLEGATO 1 AL CERTIFICATO NR 50 100 11497 Rev.005
ANNEX 1 TO CERTIFICATE NO 50 100 11497 Rev.005
 pagina 1 di 1 / page 1 of 1

IL CERTIFICATO NR 50 100 11497 Rev.005 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
 THE CERTIFICATE N 50 100 11497 Rev.005 COVERS ALSO THE FOLLOWING OFFICES:

LIOFILCHEM S.r.l.

VIA SCOZIA - ZONA INDUSTRIALE IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine

Production and sales of in-vitro diagnostic medical devices: dehydrated and ready-to-use culture media for microbiology

VIA URUGUAY IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura pronti per microbiologia, reagenti e supplementi, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro. Progettazione e sviluppo e commercializzazione di terreni di coltura disidratati per microbiologia

Design and development, production and sales of in-vitro: diagnostic medical devices: ready-to-use culture media for microbiology, reagents and supplements, microbial identification and antimicrobial susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, plasma protein determination kits. Distribution of other in-vitro diagnostic medical devices. Design and development and distribution of dehydrated culture media for microbiology



SGQ N° 049A

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

Per l'Organismo di Certificazione
 For the Certification Body
TÜV Italia S.r.l.

Validità / Validity
 Dal / From: **2022-02-11**
 Al / To: **2025-02-10**

Francesco Scarlata

Direttore Divisione Business Assurance
 Business Assurance Division Manager

Data emissione /
 Issuing Date
2022-01-26

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2022-02-10
 EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: 2022-02-10

"LA VALIDITÀ DEL PRESENTE CERTIFICATO È SUBORDINATA A SORVEGLIANZA PERIODICA A 12 MESI E AL RIESAME COMPLETO DEL SISTEMA DI GESTIONE AZIENDALE CON PERIODICITÀ TRIENNALE"
 "THE VALIDITY OF THE PRESENT CERTIFICATE DEPENDS ON THE ANNUAL SURVEILLANCE EVERY 12 MONTHS AND ON THE COMPLETE REVIEW OF COMPANY'S MANAGEMENT SYSTEM AFTER THREE-YEARS"



Certificate

No. Q5 071067 0006 Rev. 02

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

Certification Mark:



Scope of Certificate: **Design and development, production and sales of in-vitro diagnostic medical devices: culture media for microbiology, identification and susceptibility testing systems, Minimum Inhibitory Concentration test strips, antibiotic discs, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 071067 0006 Rev. 02

Report No.: ITA 1775694

Valid from: 2021-12-19

Valid until: 2024-12-18

Date, 2021-12-10



Christoph Dicks
Head of Certification/Notified Body

Certificate

No. Q5 071067 0006 Rev. 02

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems -
Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALY

Production and sales of in-vitro diagnostic medical devices:
dehydrated and ready-to-use culture media for microbiology.

Liofilchem S.r.l.
Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALY

Design and development, production and sales of in-
vitro:diagnostic medical devices: ready-to-use culture media for
microbiology, reagents and supplements, microbial identification
and antimicrobial susceptibility testing systems, Minimum Inhibitory
Concentration test strips, antibiotic discs, plasma protein
determination kits. Distribution of other in-vitro diagnostic medical
devices. Design and development and distribution of dehydrated
culture media for microbiology.

/



Product Service

CERTIFICATO

N°Q5 071067 0006 Rev. 02

Titolare del certificato: Liofilchem S.r.l.

Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALIA

**Marchio di
certificazione:****Campo di
applicazione:**

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in-vitro: terreni di coltura per microbiologia, sistemi di identificazione e antibiogramma, strip per determinazione della Minima Concentrazione Inibente, dischetti antibiotici, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro.

L'Organismo di Certificazione TÜV SÜD Product Service GmbH certifica che la società sopramenzionata ha istituito e mantiene un sistema di gestione qualità conforme ai requisiti della(e) norma(e) elencata(e). Tutti i requisiti applicabili del Regolamento "Testing and Certification" del gruppo TÜV SÜD devono essere rispettati. Per dettagli e validità del certificato vedi:

www.tuvsud.com/ps-cert?q=cert:Q5 071067 0006 Rev.

N° del rapporto: ITA 1775694**Valido da:** 2021-12-19**Valido fino al:** 2024-12-18**Data,** 2021-12-10

Christoph Dicks
Head of Certification/Notified Body

CERTIFICATO

N°Q5 071067 0006 Rev. 02

Norma(e) applicata(e): EN ISO 13485:2016
Dispositivi medicali – Sistemi di gestione qualità -
Requisiti per scopi regolamentari
(ISO 13485:2016)
DIN EN ISO 13485:2016

Stabilimento(i): Liofilchem S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE), ITALIA

Produzione e vendita di dispositivi medico diagnostici in-vitro:
terreni di coltura disidratati e terreni di coltura pronti per
microbiologia.

Liofilchem S.r.l.
Via Uruguay, 64026 Roseto degli Abruzzi (TE), ITALIA

Progettazione e sviluppo, produzione e vendita di dispositivi
medico diagnostici in-vitro: terreni di coltura pronti per
microbiologia, reagenti e supplementi, sistemi di identificazione e
antibiogramma, strip per determinazione della Minima
Concentrazione Inibente, dischetti antibiotici, kit per la
determinazione di plasmaproteine. Distribuzione di altri dispositivi
medico diagnostici in-vitro. Progettazione e sviluppo e
commercializzazione di terreni di coltura disidratati per
microbiologia.

/



ACETAMIDE BROTH

Dehydrated medium for the confirmation test of *Pseudomonas aeruginosa* in bottled water

TYPICAL FORMULA (g/L)

Acetamide.....	10.0
Sodium chloride.....	5.00
Dipotassium phosphate.....	1.39
Monopotassium phosphate.....	0.73
Magnesium sulphate.....	0.5
Phenol red.....	0.012
Final pH	7.0 ± 0.2

DESCRIPTION

ACETAMIDE BROTH is a dehydrated medium used for the confirmation of *Pseudomonas aeruginosa* in bottled water.

PRINCIPLE

ACETAMIDE BROTH contains acetamide which, as a sole source of carbon in the medium, is used for the confirmation and identification of *Pseudomonas aeruginosa*. It uses the ability of non-fermenting Gram-negative bacteria to deaminate the acetamide, the resulting alkalization shown by a color change from orange-red to purple-red.

Acetamide deamination is accomplished by *P.aeruginosa*, *P.acidovorans*, Group III (*Achromobacter xylosoxidans*), and *Alcaligenes odorans*.

Acetamide is the single carbon source; the potassium salts have a high buffering capacity; sodium chloride maintains the osmotic balance and phenol red is the pH indicator.

PREPARATION

Suspend 17,2 g of powder in 1 litre of distilled or deionized water. If needed, heat gently to dissolve completely. Sterilize by filtration. Aseptically dispense into sterile test tubes.

TECHNIQUE

Inoculate with one or two loopfuls of growth from a presumptive fresh medium (ASPARAGINE ENRICHMENT BROTH code 610138). Incubate at 36 +/- 1°C for 2-4 days.

INTERPRETATION OF RESULTS

A positive reaction is indicated by a color change of the tube from orange-red to an intense purple-red. The presence of *P.aeruginosa* is confirmed by a positive asparagine test and a positive acetamide test.

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 media at 2-8°C.

WARNING and PRECAUTIONS

The product is classified as hazardous by current legislation. It is recommended that the Safety Data Sheet be consulted before use. The product 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.

REFERENCES

- Kelly, N.M., C.T. Keans (1983). Acetamide broth for isolation of *Pseudomonas aeruginosa* from patients with cystic fibrosis. J.Clin.Microbiol. 17:159:163.
- CeNAN (1982) Técnicas para el Examen microbiológico de Alimentos y Bebidas. Madrid



LIOFILCHEM Bacteriology Products

64026 ROSETO D.A. (TE) ITALY- Via Scozia- Zona Ind.le

Tel.+39 085 8930745 - Fax +39 085 8930330

Sito Web: <http://www.liofilchem.net> E-Mail: liofilchem@liofilchem.net



PRODUCT SPECIFICATIONS

NAME

ACETAMIDE BROTH

PRESENTATION

Dehydrated culture medium

STORAGE

10-30°C

PACKAGING

Code	Content	Packaging
610313	500 gr	500 gr of powder in plastic bottle
620313	100 gr	100 gr of powder in plastic bottle

pH OF THE MEDIUM

7.0 ± 0.2

USE

ACETAMIDE BROTH is a dehydrated medium used for the confirmation of *Pseudomonas aeruginosa* in bottled water.

TECHNIQUE

Refer to technical sheet of the product.

APPEARANCE of the MEDIUM

Dehydrated medium

Appearance: homogeneous.

Colour: beige

Prepared medium

Appearance: clear

Colour: orange-red

SHELFLIFE

4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Sterility control
7 days at 25 ± 1°C, in aerobiosis
7 days at 36 ± 1°C, in aerobiosis
- Microbiological control
Inoculum for productivity: 10-100 UFC/ml
Inoculum for selectivity: 10⁴-10⁵ UFC/ml
Inoculum for specificity: ≤ 10⁴ UFC/ml
Incubation conditions: up to 4 days at 36 ± 1°C, in aerobiosis

Microorganisms		Growth	Acetamide deamination
<i>Escherichia coli</i>	ATCC 25922	-	
<i>Proteus mirabilis</i>	ATCC 29906	-	
<i>Pseudomonas aeruginosa</i>	ATCC 9027	+	+
<i>Pseudomonas aeruginosa</i>	ATCC 27853	+	+

TABLE of SYMBOLS

Symbol	Meanings
	Catalogue number
	Manufacturer
	Temperature limitation
	Kit content
	Use by
	Batch code
	Do not reuse
	Consult accompanying documents



LIOFILCHEM Bacteriology Products

64026 ROSETO D.A. (TE) ITALY- Via Scozia- Zona Ind.le

Tel. +39 085 8930745 - Fax +39 085 8930330

Sito Web: <http://www.liofilchem.net> E-Mail: liofilchem@liofilchem.net

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 signs 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



Yeast Extract Agar

Nutrient medium for the enumeration of microorganisms in water and materials of sanitary importance, according to ISO 6222.

DESCRIPTION

Yeast Extract Agar is a nutrient medium used for the determination of total microbial count in all types of water in accordance with the recommendations of ISO 6222.

TYPICAL FORMULA (g/l)

Enzymatic Digest of Casein	6.0
Yeast Extract	3.0
Agar	15.0
Final pH 7.2 ± 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. Agar is the solidifying agent.

PREPARATION

<u>Dehydrated medium</u>	Suspend 24 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.
<u>Medium in tubes/bottles</u>	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. Make dilutions of the test sample taking into account the level of pollution expected.
2. Inoculate the medium (two sets of plates for each sample) by pour plating or membrane filtration method.
3. Incubate one set of plates at 36 ± 2°C for 40-48 h and the other set at 22 ± 2°C for 64-72 h.

INTERPRETING RESULTS

Count colonies on each plate (reject any plate with confluent growth) and express the results as CFU/ml of sample allowing for dilution factors.

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, 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.
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 $36 \pm 2^\circ\text{C}$ for 40-48 hours.

QC Table.

Microorganism		Growth
<i>Escherichia coli</i>	WDCM 00012	Good
<i>Bacillus subtilis</i>	WDCM 00003	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 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 6222:2009. Water quality – Enumeration of culturable microorganisms – Colony count technique by inoculation in a nutrient agar culture medium.

PRESENTATION		Contents	Ref.
Yeast Extract Agar	60 mm ready-to-use plates	20 plates	163582
Yeast Extract Agar	Tubes	20 x 22 ml tubes	34074
Yeast Extract Agar	Tubes	100 x 22 ml tubes	26074
Yeast Extract Agar	Slant tubes	20 x 9 ml tubes	31102
Yeast Extract Agar	Bottles	6 x 200 ml bottles	412120
Yeast Extract Agar	Bottles	6 x 100 ml bottles	403120
Yeast Extract Agar	Dehydrated medium	500 g of powder	611016
Yeast Extract Agar	Dehydrated medium	100 g of powder	621016

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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Nutrient Agar ISO 16266

Medium for cultivating non-fastidious organisms and confirming *Pseudomonas aeruginosa*, according to ISO 16266.

DESCRIPTION

Nutrient Agar ISO 16266 is a medium used for the cultivation of non-fastidious organisms from water samples. This medium is formulated according to ISO 16266 for the detection and enumeration of *Pseudomonas aeruginosa* in water by the membrane filtration technique.

TYPICAL FORMULA*

	(g/litre)
Peptone	5.0
Meat Extract	1.0
Yeast Extract	2.0
Sodium Chloride	5.0
Agar	15.0
Final pH 7.4 ± 0.2 at 25°C	

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

METHOD PRINCIPLE

Peptone 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. Sodium chloride maintains the osmotic balance of the medium. Agar is the solidifying agent.

PREPARATION

<u>Dehydrated medium</u>	Suspend 28 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.
<u>Medium in bottles</u>	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

According to ISO 16266, transfer the membrane and presumptive *Pseudomonas aeruginosa* to the plate medium.

Incubate aerobically at 36 ± 2°C for 20-24 hours.

Alternatively, the medium can be inoculated by spread plating or direct streaking of the sample over the agar surface.

INTERPRETING RESULTS

Observe for colony growth. Confirm *P. aeruginosa* by performing the oxidase test (ref. 88029).

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.

Avoid quick temperature shifts of plated medium to prevent condensation.

SHELF LIFE

Dehydrated medium: 4 years.

Medium in bottles: 2 years.

Medium in slant tubes: 1 year.

Ready-to-use plates: 6 months.

QUALITY CONTROL

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

Appearance of Prepared Medium: Slightly opalescent, light amber.

Expected Cultural Response:

Control strain		Inoculum	Incubation	Specification
<i>Pseudomonas aeruginosa</i>	WDCM 00025 (ATCC 27853, NCTC 12903)	50-100 CFU	20-24 h 36 ± 1°C	Good growth
<i>Escherichia coli</i>	WDCM 00013 (ATCC 25922, NCTC 12241)			

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

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 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.
Nutrient Agar ISO 16266	Plate 90 mm	20 plates	10044
Nutrient Agar ISO 16266	Slant tube	10 x 7 ml	30083
Nutrient Agar ISO 16266	Bottle	6 x 100 ml	402190
Nutrient Agar ISO 16266	Bottle	6 x 200 ml	412190
Nutrient Agar ISO 16266	Bottle	6 x 500 ml	470060
Nutrient Agar ISO 16266	Dehydrated media	100 g	620036
Nutrient Agar ISO 16266	Dehydrated media	500 g	610036
Nutrient Agar ISO 16266	Dehydrated media	5 kg	6100365

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

liofilchem.com/ifu-sds



Sabouraud CAF Agar

Selective medium for the cultivation and isolation of pathogenic and nonpathogenic fungi.

DESCRIPTION

Sabouraud CAF Agar is a selective medium used for the cultivation and isolation of fungi from clinical and nonclinical specimens.

TYPICAL FORMULA

	(g/l)
Enzymatic Digest of Casein	5.0
Enzymatic Digest of Animal Tissue	5.0
Glucose	40.0
Chloramphenicol	0.5
Agar	15.0
Final pH 5.6 ± 0.2 at 25°C	

METHOD PRINCIPLE

Enzymatic digests of casein and enzymatic digest of animal tissue provide nitrogen and vitamins for the growth of fungi. The high glucose concentration along with the acid pH make this medium particularly well suited for cultivating fungi. Chloramphenicol is a broad-spectrum antibiotic inhibitory to a wide range of Gram-negative and Gram-positive bacteria. Agar is the solidifying agent.

PREPARATION

Dehydrated medium Suspend 65.5 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 118°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 final containers.

TEST PROCEDURE

Inoculate either plates or slant tubes by streaking directly the sample onto the agar surface. Streak the specimen as soon as possible after it is received in the laboratory. Incubate aerobically at 30°C for 2-7 days.

INTERPRETING RESULTS

Examine containers for fungal colonies exhibiting typical color and morphology. Biochemical tests and serological procedures should be performed to confirm findings.

Transfer of growth from slants to plated media may be required in order to obtain pure cultures of fungi.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light 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, 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: 6 months.

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: 10-100 CFU/ml.

Inoculum for selectivity: 10⁴-10⁵ CFU/ml.

Incubation conditions: aerobically at 30±2°C for 2-7 days.

QC Table.

Microorganism		Growth
<i>Aspergillus niger</i>	ATCC® 16404	Good
<i>Candida albicans</i>	ATCC® 10231	Good
<i>Saccharomyces cerevisiae</i>	ATCC® 9763	Good
<i>Trichophyton mentagrophytes</i>	ATCC® 9533	Good
<i>Escherichia coli</i>	ATCC® 8739	Inhibited

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. Sabouraud. 1892. Ann. Dermatol. Syphil. 3:1061.
2. Larone. 1995. Medically important fungi: a guide to identification, 3rd ed. American Society for Microbiology, Washington, D.C.
3. Wehr and Frank (ed.). 2004. Standard methods for the examination of dairy products, 17th ed. American Public Health Association, Washington, D.C.

PRESENTATION		Contents	Ref.
Sabouraud CAF Agar	90 mm ready-to-use plates	20 plates	11035
Sabouraud CAF Agar	90 mm ready-to-use plates	100 plates	11035*
Sabouraud CAF Agar	140 mm ready-to-use plates	10 plates	10242
Sabouraud CAF Agar	Slant tubes	10 x 10 ml tubes	30023
Sabouraud CAF Agar	Slant tubes	20 x 10 ml tubes	31023
Sabouraud CAF Agar	Bottles	6 x 200 ml bottles	412370
Sabouraud CAF Agar	Bottles	6 x 100 ml bottles	402370
Sabouraud CAF Agar	Dehydrated medium	500 g of powder	610203
Sabouraud CAF Agar	Dehydrated medium	100 g of powder	620203
Sabouraud CAF Agar	Dehydrated medium	5 kg of powder	6102035

TABLE OF SYMBOLS

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



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Iron Sulphite Agar

Medium for detection and enumeration of sulphite-reducing *Clostridium* spp., according to ISO 15213-1.

DESCRIPTION

Iron Sulphite Agar is a medium used for the detection of sulphite-reducing *Clostridium* species by colony-count technique.

This medium complies with ISO 15213-1 and is intended for the examination of foods, animal feeding stuffs and environmental samples in the area of food production and handling.

TYPICAL FORMULA*	(g/l)
Enzymatic Digest of Casein	15.0
Enzymatic Digest of Soya	5.0
Yeast Extract	5.0
Sodium Disulfite (sodium metabisulfite) anhydrous	0.5
Iron(III) Ammonium Citrate	1.0
Agar	15.0

Final pH 7.6 ± 0.2 at 25°C

*Adjusted and/or supplemented as required to meet performance specifications;
Grams per litre of purified water.

METHOD PRINCIPLE

Enzymatic digest of casein and pancreatic digest of soya provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a rich source of vitamins of B-group. Ferric ammonium citrate and sodium metabisulfite are H₂S indicators. Agar is the solidifying agent. *Clostridia* reduce sulfite to sulfide which reacts with iron to form a black iron sulfide precipitate.

PREPARATION

Dehydrated culture medium (DCM)

Suspend 41.5 g of the powder in 1 liter of distilled or deionized water. Heat shaking frequently until completely dissolved. Autoclave at 121°C for 15 minutes.

Medium in bottles

Melt the content of a 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 to 45-50°C, mix well avoiding foam formation before pouring.

TEST PROCEDURE

Following ISO 15213-1, inoculate Iron Sulphite Agar (ISA) using the pour plate method: Transfer 1 ml test sample or 1 ml initial suspension to duplicate plates, pour the medium (12-15 ml for 90 mm Petri dishes or 45-50 ml for 140 mm Petri dishes) molten and tempered at 44-47°C into each Petri dish. Carefully mix the inoculum with the medium. Repeat the procedure with further dilutions. After the agar has solidified, pour the ISA medium (5 ml for 90 mm Petri dishes or 10 ml for 140 mm Petri dishes) as overlay.

If the scope of the test is to count only spores, heat the decimal dilution series to 80°C in a water bath for 10 ± 1 min.

If 60 mm ready-to-use plates are used, inoculate the medium with the membrane filter technique.

Incubate the inoculated plates at 37 ± 1°C for 48 ± 2 hours under anaerobic atmosphere.

INTERPRETING RESULTS

Count all black or grey to yellow-brown colonies as presumptive sulphite-reducing *Clostridium* spp.

Confirmation suspect colonies by subculturing onto two non-selective blood agar plates (e.g. Columbia blood agar) or another nutrient-rich medium (e.g. Tryptone soya agar or Brain heart infusion agar). From each pair of plates, one is incubated aerobically and the other anaerobically at 37°C for 20 ± 2 h. Colonies belonging to the genus *Clostridia* will grow only on the agar plate incubated in an anaerobic atmosphere.

NOTE When no confirmation is performed, the results can be reported as “anaerobic sulphite-reducing bacteria”.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store prepared medium in bottles and 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: 1 year.

Ready-to-use plates: 4 months.

QUALITY CONTROL

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

Appearance of Prepared Medium: Slightly opalescent, light amber.

Expected Cultural Response:

Control strain	Inoculum	Incubation	Specification
<i>Clostridium perfringens</i>	WDCM 00007 (ATCC 13124; NCTC 8237)	50-100 CFU	48 ± 2 h/ 37 ± 1°C
<i>Escherichia coli</i>	WDCM 00012 (ATCC 8739; NCTC 12923)	10 ³ -10 ⁴ CFU	anaerobic atmosphere
			Good growth, black colonies (P _R ≥ 0.5 on TSA)
			Weak to good growth, no blackening of colonies

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

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

WARNING AND PRECAUTIONS

For professional use only. Operators must be trained and have certain experience. 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 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.
Iron Sulphite Agar ISO 15213-1	60 mm agar Plate	20 plates	163372
	Bottle	6 x 100 ml	403180
	Dehydrated Culture Medium	100 g	621401
	Dehydrated Culture Medium	500 g	611401



Buffered Peptone Water

Diluent and non-selective pre-enrichment liquid medium for microbiological examination of food, according to ISO 6887, 11290, 21528 and 6579.

DESCRIPTION

Buffered Peptone Water (BPW) is a liquid medium recommended by ISO 6579 for increasing the recovery of injured *Salmonella* spp. from food and associated samples prior to selective enrichment and isolation.

According to ISO 21528, BPW is used for detection or enumeration of Enterobacteriaceae within foodstuffs.

Used as diluent, BPW complies with ISO 6887 and 11290 for the enumeration of organisms.

TYPICAL FORMULA

	(g/l)
Enzymatic Digest of Casein	10.0
Sodium Chloride	5.0
Disodium Hydrogen Phosphate	3.5*
Potassium Dihydrogen Phosphate	1.5
Final pH 7.0 ± 0.2 at 25°C	

*Equivalent to 9.0 g of disodium hydrogen phosphate dodecahydrate.

METHOD PRINCIPLE

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

PREPARATION

Dehydrated medium Suspend 20.0 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.

TEST PROCEDURE

Suspend the sample in BPW to make dilutions as required.

For pre-enrichment, add sample to BPW at a ratio of 1:10 or 1:9 depending on the method being used. Incubate at 37 ± 1°C for 16-20 hours before transfer to selective enrichment media.

INTERPRETING RESULTS

Turbidity indicates microbial growth.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light 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 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.

Prepared medium: 2 years.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC tables.

Inoculum for use as diluent: 10³-10⁴ CFU.

Incubation conditions: 45 min - 1 h / 18-27°C.

QC Table 1.

Microorganism	WDCM	Specification
<i>Escherichia coli</i>	WDCM 00012	± 30% colonies of original count
<i>Staphylococcus aureus</i>	WDCM 00034	± 30% colonies of original count
<i>Listeria monocytogenes</i> 4b	WDCM 00021	± 30% colonies of original count

Inoculum for productivity: ≤ 100 CFU.

Incubation conditions: 18 ± 2 h / 37 ± 1°C.

QC Table 2.

Microorganism	WDCM	Specification
<i>Salmonella typhimurium</i>	WDCM 00031	Good growth/turbidity of the medium
<i>Salmonella enteritidis</i>	WDCM 00030	Good growth/turbidity of the medium
<i>Escherichia coli</i>	WDCM 00012	Good growth/turbidity of the medium

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. 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. ISO 21528-1:2017. Microbiology of the food chain – Horizontal method for the detection and enumeration of *Enterobacteriaceae* – Part 1: Detection of *Enterobacteriaceae*.
4. ISO 21528-2:2017. Microbiology of the food chain – Horizontal method for the detection and enumeration of *Enterobacteriaceae* – Part 2: Colony-count technique.
5. ISO 6579-1:2017. Microbiology of the food chain – Horizontal method for the detection, enumeration and serotyping of *Salmonella* spp. – Part 1: Detection of *Salmonella* spp.
6. Rose (2001) Isolation and identification of *Salmonella* from meat, poultry and egg products. In Microbiology laboratory guidebook, 3rd ed., Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, D.C.
7. ISO 6887-1:2017. Microbiology of 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.
8. Sadovski (1977) J. Food Technol. 12:85.
9. Edel and Kampelmacher (1973) Bull. W.H.O. 48:167.

PRESENTATION	Category	Packaging	Ref.
Buffered Peptone Water	Media in tubes	20 x 9 ml	24199
Buffered Peptone Water	Media in tubes	100 x 9 ml	26199
Buffered Peptone Water	Media in tubes	20 x 10 ml	24099
Buffered Peptone Water (Double Concentration)	Media in tubes	20 x 9 ml	24463
Buffered Peptone Water	Media in bottles	6 x 90 ml	414030
Buffered Peptone Water	Media in bottles	25 x 90 ml	454030
Buffered Peptone Water	Media in bottles	6 x 200 ml	412090
Buffered Peptone Water	Media in bottles	6 x 225 ml	414020
Buffered Peptone Water	Media in bottles	25 x 225 ml	451402
Buffered Peptone Water - Bags	Media in bags	3 x 3 l	499030
Buffered Peptone Water - Bags	Media in bags	3 x 5 l	499035
Buffered Peptone Water	Dehydrated media	100 g	621014
Buffered Peptone Water	Dehydrated media	500 g	611014
Buffered Peptone Water	Dehydrated media	5 kg	6110145

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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Peptone Water

Instructions For Use

ENGLISH

Liquid medium for the cultivation of non-fastidious microorganisms, indole testing and carbohydrate fermentation studies.

DESCRIPTION

Peptone Water is a liquid medium used for the cultivation of non-fastidious microorganisms and indole testing. It is also a basal medium to which carbohydrates and indicator may be added for fermentation studies. This medium is not intended for use in the diagnosis of disease or other conditions in humans.

TYPICAL FORMULA*

	(g/litre)
Peptone	10.0
Sodium Chloride	5.0

Final pH 7.2 ± 0.2 at 25°C

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

METHOD PRINCIPLE

Peptone provides carbon, nitrogen, vitamins and minerals and is rich in tryptophan content. Sodium chloride maintains the osmotic balance of the medium.

PREPARATION

Dehydrated medium Suspend 15.0 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil and shake until completely dissolved. Dispense into final containers. Sterilize in autoclave at 121°C for 15 minutes.

TEST PROCEDURE

To perform indole test, inoculate a tube of Peptone Water preheated to 44°C, using a sampling loop. Incubate at 35 ± 2°C for 24-48 h. Add 2-3 drops of Kovac's Reagent (ref. 80271 / 87001) and examine soon after.

To study the fermentation ability of carbohydrates, add the sugar solution usually at 10% w/v concentration to the basal medium. Phenol red can be used as pH indicator and Durham tube to detect the gas production. Incubate at 35 ± 2°C for 18-24 h.

INTERPRETING RESULTS

Turbidity of the medium indicates microbial growth (compare to an uninoculated control).

The formation of a red to purple colour ("cherry-red ring") in the reagent layer on top of the medium within 30 sec indicates a positive reaction for indole production. A negative reaction shows no colour change.

If phenol red has been included, the medium turns yellow in the case of acidic production, that is carbohydrate utilization.

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.

Tubes/Bottles: 2 years.

QUALITY CONTROL

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

Appearance of Prepared Medium: Clear to very slightly opalescent, light amber.

Expected Cultural Response:

Strain	Inoculum	Incubation	Growth	Indole test	Lactose test
<i>Escherichia coli</i>	ATCC 25922	≤100 CFU	18-48 h 35 ± 2°C	Good	Positive
<i>Salmonella</i> Typhimurium	ATCC 14028				Negative

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

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 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.
Peptone Water	Tube	20 x 10 ml	24098
Peptone Water	Bottle	25 x 90 ml	452640
Peptone Water	Bottle	6 x 100 ml	402130
Peptone Water	Bottle (perforable cap)	6 x 100 ml	402530
Peptone Water	Bottle	6 x 500 ml	470320
Peptone Water	Dehydrated medium	500 g of powder	610038
Peptone Water	Dehydrated medium	100 g of powder	620038

This document is available from the online Support Center:

liofilchem.com/ifu-sds



Brilliant Green Agar

Selective medium for isolation of *salmonellae* from clinical specimens and other materials of sanitary importance.

DESCRIPTION

Brilliant Green Agar is a selective medium used for the isolation *Salmonella* spp, other than *S. Typhi* and *S. Paratyphi* from pathogen materials, stool, urine, environmental samples and food.

Brilliant Green Agar is recommended by APHA, FDA and USP.

TYPICAL FORMULA

	(g/l)
Meat Peptone	5.0
Casein Peptone	5.0
Sodium Chloride	5.0
Yeast Extract	3.0
Lactose	10.0
Sucrose	10.0
Phenol Red	0.08
Brilliant Green	0.0125
Agar	20.0
Final pH 6.9 ± 0.2 at 25°C	

METHOD PRINCIPLE

Peptones provide amino acids, carbon, nitrogen, vitamins and minerals for organisms growth. Sodium chloride maintains the osmotic balance of the medium. Yeast extract is a source of vitamins, particularly of B-group. Lactose and sucrose are the fermentable carbohydrates. Lysine is the decarboxylase substrate. Phenol red is the pH indicator. Brilliant green is the selective agent inhibiting Gram-positive bacteria and most Gram-negative bacteria, other than *Salmonella* spp. Agar is the solidifying agent.

PREPARATION

<u>Dehydrated medium</u>	Suspend 58.1 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.
<u>Medium in bottles</u>	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 $45\text{-}50^{\circ}\text{C}$, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Inoculate the plates by directly streaking the sample over the agar surface. Incubate aerobically at $35 \pm 2^{\circ}\text{C}$ for 18-24 hours.

INTERPRETING RESULTS

After incubation observe the color of the colonies and interpret the results as indicated in the ID Table.

ID Table.

Microorganism	Appearance of colonies
<i>Salmonella</i> spp (excepted <i>S. Typhi</i> and <i>S. Paratyphi</i>)	White to pink, with red zone
<i>Escherichia coli</i> , <i>Enterobacter</i> , <i>Klebsiella</i> spp	Yellow-green
<i>Pseudomonas</i> spp	Pink to red

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, pink.

Prepared medium: slightly opalescent, orange-brown.

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.
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
Inoculum for selectivity: 10⁴-10⁶ CFU
Incubation conditions: aerobically at 35 ± 2°C for 18-24 hours.

QC Table.

Microorganism		Growth	Specification
<i>Salmonella</i> Typhimurium	ATCC® 14028	Good	White to red colonies with red zone
<i>Salmonella</i> Enteritidis	ATCC® 13076	Good	White to red colonies with red zone
<i>Shigella flexneri</i>	ATCC® 12022	Inhibited	---
<i>Staphylococcus aureus</i>	ATCC® 25923	Inhibited	---
<i>Escherichia coli</i>	ATCC® 25922	Poor	Yellow-green 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 *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

- Kristensen M, V. Lester and A. Jurgens (1925) On the use of trypsinized casein, bromthymol blue, bromcresol purple, phenol red and brilliant green for bacteriological nutrient media. Br J Exp Pathol. 6:291.
- Taylor W.J. (1965) Isolation of Shigellae I. Xylose lysine agars: new media for isolation of enteric pathogens. Am J Clin Pathol; 44:471-475.
- United States Pharmacopeial Convention (1995) Microbial Limit Test. The United States Pharmacopoeia 23rd ed. The United States Pharmacopeial Convention, Rockville MD, USA.
- US Food and Drug Administrations (1998) Bacteriological Analytical Manual 8th ed. AOAC International. Gaithersburg, MD, USA.

PRESENTATION

		Contents	Ref.
Brilliant Green Agar	90 mm ready-to-use plates	20 plates	10022
Brilliant Green Agar	90 mm ready-to-use plates	100 plates	10022*
Brilliant Green Agar	Bottles	6 x 100 ml bottles	402330
Brilliant Green Agar	Dehydrated medium	500 g of powder	610009
Brilliant Green Agar	Dehydrated medium	100 g of powder	620009

TABLE OF SYMBOLS

LOT Batch code	IVD <i>In vitro</i> 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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Bile Bacteriological

Bacteriological bile obtained by bile purification

PHYSIC-CHEMICAL CHARACTERISTIC

Solubility in water at 2%	Complete
Loss on drying	≤ 5.0%
Bile acids	≤ 45.0%

DESCRIPTION

Bile Bacteriological is ox bile purified and dehydrated. It's a fine beige powder, easily soluble in water. It contains a mix of biliary salts and is used in media for enterobacteria, as selective agent, and for identification of enterococci. Bile Bacteriological 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 signs 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. Cowan, S.T., Steel, K.J. (1979) Manual for the identification of medical bacteria. Edi. Ermes

PACKAGE

Code	Content	Packaging
611367	500 g	500 g of product in plastic bottle
621367	100 g	100 g of product in plastic bottle

pH OF THE MEDIUM

5.5-7.5 (5% solution)

SHELF LIFE

4 years







QUALITY CONTROL

Dehydrated powder

Appearance: free-flowing, homogeneous

Colour: 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



Nutrient Broth

Liquid medium for the cultivation of nonfastidious microorganisms.

DESCRIPTION

Nutrient Broth is a liquid medium used for the cultivation of a wide variety of organisms from clinical specimens and other materials.

This medium can be enriched with other ingredients such as blood, serum, sugars, etc., for special purposes.

TYPICAL FORMULA

	(g/l)
Beef Extract	1.0
Peptone	5.0
Yeast Extract	2.0
Sodium Chloride	5.0

Final pH 6.8 ± 0.2 at 25°C

METHOD PRINCIPLE

Beef extract and peptone 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.

PREPARATION

Dehydrated medium Suspend 13 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

Inoculate broth with test sample. Incubate at 35 ± 2°C for 18-24 hours or longer if necessary.

INTERPRETING RESULTS

Turbidity indicates microbial growth.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, white to light beige.

Prepared medium: clear to 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 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/bottles: 2 years.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: ≤ 100 CFU

Incubation conditions: aerobically at $35 \pm 2^\circ\text{C}$ for 18-24 hours.

QC Table.

Microorganism		Growth
<i>Escherichia coli</i>	ATCC® 25922	Good
<i>Staphylococcus aureus</i>	ATCC® 25923	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. Association of Official Analytical Chemists (1995) Official methods of analysis of AOAC International, 16th ed.
2. Marshall, R.T. (ed.) (1993) Standard methods for the microbiological examination of dairy products, 16th ed.
3. American Public Health Association (1923) Standard methods of water analysis, 5th ed.

PRESENTATION		Contents	Ref.
Nutrient Broth	Tubes	20 x 10 ml tubes	24103
Nutrient Broth	Tubes	50 x 5 ml tubes	27503
Nutrient Broth	Bottles	6 x 100 ml bottles	402000
Nutrient Broth	Bottles	6 x 500 ml bottles	470050
Nutrient Broth	Dehydrated medium	500 g of powder	610037
Nutrient Broth	Dehydrated medium	100 g of powder	620037
Nutrient Broth	Dehydrated medium	5 kg of powder	6100375

TABLE OF SYMBOLS

LOT Batch code	IVD <i>In vitro</i> 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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Brain Heart Infusion Broth

Liquid medium for the cultivation of various fastidious organisms and detection of staphylococci, according to ISO 6888.

DESCRIPTION

Brain Heart Infusion Broth is a liquid medium used for the cultivation of fastidious and nonfastidious microorganisms, including aerobic and anaerobic bacteria, from clinical specimens, food and environmental samples.

This medium is especially suited for the cultivation of coagulase-positive staphylococci for the plasma coagulase test according to ISO 6888.

Brain Heart Infusion Broth is recommended by the APHA for examination of water and wastewater and by the CLSI for preparing inocula used in antimicrobial susceptibility tests.

TYPICAL FORMULA

	(g/l)
Enzymatic Digest of Animal Tissues	10.0
Dehydrated Calf Brain Infusion	12.5
Dehydrated Beef Heart Infusion	5.0
Glucose	2.0
Sodium Chloride	5.0
Disodium Hydrogen Phosphate, Anhydrous	2.5
Final pH 7.4 ± 0.2 at 25°C	

METHOD PRINCIPLE

Enzymatic digest of animal tissues and brain-heart infusion provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Glucose is the carbohydrate source. Sodium chloride maintains the osmotic balance of the medium. Disodium phosphate is the buffering agent.

PREPARATION

Dehydrated medium Suspend 37 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Distribute into final containers. Sterilize in autoclave at 121°C for 15 minutes.

TEST PROCEDURE

If material is being cultured directly from a swab, insert the swab into the broth after inoculation of plated media. For liquid specimens, transfer a loopful of the specimen into the broth medium using a sterile loop or aseptically pipette the specimen onto plated medium and into the broth. Examine for growth after 24-72 hours of incubation.

NB. It is recommended that liquid media for anaerobic incubation should be reduced prior to inoculation by placing tubes (with loosened caps) under anaerobic conditions for 18-24 hours. Alternatively, the media may be reduced by bringing the media up to 100°C in a boiling waterbath. Loosen screw caps slightly before heating, and tighten during cooling to room temperature.

To perform plasma coagulase tests, according to ISO 6888, inoculate tubes of Brain Heart Infusion Broth with selected colony from Baird Parker Agar plates (ref. 10020). Incubate at 37 ± 1°C for 24 ± 2 hours. Add 0.1 ml of each culture to 0.3 ml of the rabbit plasma. Examine after 4-6 hours incubation at 37°C for clotting of the plasma.

INTERPRETING RESULTS

Turbidity indicates microbial growth.

The coagulase test is considered positive if the clot volume is more than half of the original liquid volume.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.

Prepared medium: clear, amber.

STORAGE

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

SHELF LIFE

Dehydrated medium: 4 years.

Medium in bottles: 3 years.

Medium in tubes: 2 years.

QUALITY CONTROL

Tubes are inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: ≤ 100 CFU

Incubation conditions: $37 \pm 1^\circ\text{C}$ for 24 ± 2 hours. 40-48 h under anaerobic atmosphere for *B. fragilis*.

QC Table.

Microorganism		Growth
<i>Staphylococcus aureus</i>	WDCM 00034	Good
<i>Escherichia coli</i>	ATCC® 25922	Good
<i>Streptococcus pneumoniae</i>	ATCC® 6305	Good
<i>Bacteroides fragilis</i>	ATCC® 25285	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

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.
Brain Heart Infusion Broth	Tube	20 x 2 ml tubes	24141
Brain Heart Infusion Broth	Tube	50 x 5 ml tubes	27502
Brain Heart Infusion Broth	Tube	20 x 9 ml tubes	24480
Brain Heart Infusion Broth	Tube	20 x 10 ml tubes	24104
Brain Heart Infusion Broth	Tube	100 x 10 ml tubes	26104
Brain Heart Infusion Broth	Bottle	6 x 200 ml bottles	412010
Brain Heart Infusion Broth	Dehydrated medium	100 g of powder	620008
Brain Heart Infusion Broth	Dehydrated medium	500 g of powder	610008
Brain Heart Infusion Broth	Dehydrated medium	5 kg of powder	6100085

This document is available from the online Support Center:

liofilchem.com/ifu-sds



Selenite Broth

Liquid medium for selective enrichment of *Salmonella* spp, from clinical and nonclinical samples, according to APHA.

DESCRIPTION

Selenite Broth is an enrichment medium used for the selective isolation of *Salmonella* and some species of *Shigella*.

This medium is prepared according to the original formula described as Selenite F Broth by Leifson and recommended by the American Public Health Association for the examination of food.

TYPICAL FORMULA

	(g/l)
Enzymatic Digest of Casein	5.0
Lactose	4.0
Sodium Phosphate	10.0
Sodium Selenite	4.0
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. Lactose is the fermentable carbohydrate. Sodium phosphate is the buffer. Sodium selenite is the selective agent inhibiting many species of Gram-positive and Gram-negative bacteria including enterococci and coliforms.

PREPARATION

Dehydrated medium Suspend 23 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into suitable containers (bottles or tubes). A depth of at least 5 cm is recommended, as salmonellae survive better at low oxygen tensions. **DO NOT AUTOCLAVE.**

TEST PROCEDURE

Inoculate the tube with 1-2 g of stool specimen or other solid material (approximately 10-15% by volume) and emulsify in the broth. For urines, the broth should be used at double concentration and inoculated with its own volume of the specimen. Incubate at 35 ± 2°C for 12-24 hours (coliforms may overgrow the pathogens if incubated for longer than 24 hours).

INTERPRETING RESULTS

Turbidity indicates microbial growth.

Subculture to a selective and differential enteric plated medium, such as XLD Agar (ref. 10056), Hektoen Enteric Agar (ref. 10043) or MacConkey Agar (ref. 10029), streaking for isolation. Examine for typical colony morphology. Confirm with further biochemical tests.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, white to light beige.

Prepared medium: clear, very pale yellow.

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

SHELF LIFE

Dehydrated medium: 4 years.

Medium in tubes/bottles: 1 year.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: ≤ 100 CFU.

Inoculum for selectivity: $> 10^3$ CFU.

Incubation conditions: aerobically at $35 \pm 2^\circ\text{C}$ for 18-24 hours.

QC Table.

Microorganism		Growth
<i>Salmonella</i> Typhimurium	ATCC® 14028	Good
<i>Shigella sonnei</i>	ATCC® 25931	Good
<i>Escherichia coli</i>	ATCC® 25922	Partially to completely inhibited

WARNING AND PRECAUTIONS

The product contains hazardous substances and is classified as dangerous. It is 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. Versalovic, J., K.C. Carroll, G. Funke, J.H. Jorgensen, M.L. Landry, and D.W. Warnock (2011) Manual of Clinical Microbiology. 10th ed. ASM Press, Washington, D.C.
2. Quality Control for Commercially Prepared Microbiological Media (2004) - 3rd ed. M22-A3. Clinical and Laboratory Standards Institute - CLSI (NCCLS), Wayne, PA.
3. 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.
4. Leifson, E. (1939) New selenite selective enrichment medium for the isolation of typhoid and paratyphoid bacilli. Am. J. Hyg. 24:423-432.

PRESENTATION		Contents	Ref.
Selenite Broth	Tubes	20 x 10 ml tubes	24110
Selenite Broth	Tubes	20 x 5 ml tubes	24143
Selenite Broth	Bottles	6 x 100 ml bottles	402050
Selenite Broth	Bottles	6 x 200 ml bottles	412050
Selenite Broth (Double Concentration)	Bottles	6 x 200 ml bottles	432050
Selenite Broth	Bottles	6 x 500 ml bottles	470020
Selenite Broth	Bottles	6 x 1000 ml bottles	463130
Selenite Broth	Dehydrated medium	500 g of powder	610145
Selenite Broth	Dehydrated medium	100 g of powder	620145
Selenite Broth	Dehydrated medium	5 kg of powder	6101455

TABLE OF SYMBOLS

LOT Batch code	IVD <i>In vitro</i> 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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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: $32.5 \pm 2.5^\circ\text{C}$ for 48-72 h (*C. albicans*) and at $22.5 \pm 2.5^\circ\text{C}$ for up to 5 days (all listed organisms), under aerobic atmosphere.

QC Table.

Microorganism		Growth
<i>Candida albicans</i>	ATCC® 10231	Good
<i>Aspergillus brasiliensis</i>	ATCC® 16404	Good
<i>Saccharomyces cerevisiae</i>	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

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 <i>In vitro</i> 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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EC Broth

Selective liquid medium for detection and enumeration of coliform bacteria and *E. coli* in water and food, according to ISO 7251.

DESCRIPTION

EC Broth is a liquid medium used for the selective detection of coliform bacteria and *Escherichia coli* in water and wastewater, foods and other materials of sanitary importance, according to ISO 7251.

TYPICAL FORMULA (g/l)

Enzymatic Digest of Casein	20.0
Lactose	5.0
Bile Salts	1.5
Dipotassium Phosphate	4.0
Monopotassium Phosphate	1.5
Sodium Chloride	5.0

Final pH 6.9 ± 0.2 at 25°C

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Lactose is the fermentable carbohydrate. Bile salts inhibit Gram-positive bacteria, especially enterococci. Phosphates act as buffer. Sodium chloride maintains the osmotic balance of the medium.

PREPARATION

Dehydrated medium Suspend 37.0 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Distribute into 10 ml tubes with Durham gas collecting tube. Sterilize in autoclave at 121°C for 15 minutes.

TEST PROCEDURE

For detection and enumeration of *E. coli*, ISO 7251 recommends to first inoculate the initial suspension of the test sample into tubes of Lauryl Sulfate Tryptose Broth (LST), ref. 21453 and Lauryl Sulfate Tryptose Broth (LST) Double, ref. 21454. After incubation at 37°C for 24-48 h, tubes are examined for turbidity and gas production. Then, each positive test tube is subcultured to a EC Broth tube and incubated at 44°C for 24-48 h.

Alternatively, EC Broth can be directly inoculated with the sample and incubated for 24 ± 2 h and up to 48 h at 35 ± 2°C for detection of coliforms or at 44.5 ± 1°C for the isolation of *Escherichia coli*.

INTERPRETING RESULTS

Gas production is to be consider as a preliminary positive result. Indole test as well as other biochemical tests should be carried out for confirmation of *Escherichia coli* after subculturing on suitable media.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light 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 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

Tubes are inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: ≤ 100 CFU

Inoculum for selectivity: $> 10^3$ CFU

Incubation conditions: $44 \pm 2^\circ\text{C}$ for 24 ± 2 hours.

QC Table.

Microorganism		Growth	Gas
<i>Escherichia coli</i>	ATCC® 25922	Good	+
<i>Escherichia coli</i>	ATCC® 8739	Good	+
<i>Enterococcus faecalis</i>	ATCC® 29212	Inhibited	-

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

- ISO 7251:2005. Microbiology of food and animal feeding stuffs – Horizontal method for the detection of presumptive *Escherichia coli* – Most probable Number technique.
- Clesceri, Greenberg and Eaton (1998) Standard methods for the examination of water and wastewater, 20th ed. American Public Health Association (APHA), Washington, D.C.
- Perry C.A. and A.A. Hajna (1944) Further evaluation of EC medium for the isolation of coliform bacteria and *Escherichia coli*. Am. J. Public Health 34:735-738.

PRESENTATION		Contents	Ref.
EC Broth	Tubes	10 x 10 ml tubes	20122
EC Broth	Tubes	20 x 10 ml tubes	24122
EC Broth	Tubes	100 x 10 ml tubes	26122
EC Broth	Dehydrated medium	500 g of powder	610063
EC Broth	Dehydrated medium	100 g of powder	620063

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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COAGULASE TEST

Lyophilic citrate rabbit plasma for coagulase test

DESCRIPTION

COAGULASE TEST is constituted by lyophilic rabbit plasma containing EDTA (Ethylenediaminetetraacetic Acid) used for the detection of coagulase enzyme produced by *Staphylococcus aureus*.

CONTENT OF THE PACKAGES

Each package contains :

- 5 vials containing 4 mL of rabbit plasma
- 1 instruction sheet

ITEMS NECESSARY NOT INCLUDED IN THE PACKAGES

- Physiological Solution (ref. 20095)
- Brain Heart Infusion Broth (ref. 20104)

PRINCIPLE OF THE METHOD

The coagulase produced by *Staphylococcus aureus* acts on fibrinogen transforming it into fibrin. The reaction takes place without calcium which is chelated by EDTA.

COMPOSITION (mL/vial)

Lyophilic rabbit plasma	4.0
-------------------------	-----

USE

- Take one vial of **COAGULASE TEST** from the package and aseptically reconstitute with 4 mL of Physiological Solution (ref. 20095).
- Prepare a culture in Brain Heart Infusion Broth (ref. 20104) picking up one or more colonies from selective media for *Staphylococcus aureus* isolation and incubate at $36 \pm 1^\circ\text{C}$ for 4-6 hours.
- In a sterile tube mix 0.5 mL of **COAGULASE TEST** with 0.5 mL of culture broth and incubate at $36 \pm 1^\circ\text{C}$ for 1-2-4-8-24 hours.

INTERPRETATION OF RESULTS

- Verify the formation of the clot, in case using a sterile loop. Do not incubate over 24 hours because cases of fibrinolysis can take place.

QUALITY CONTROL

Each batch of **COAGULASE TEST** is submitted to the quality control using the following microorganisms:

Microorganism		Coagulation
<i>Escherichia coli</i>	ATCC 25922	-
<i>Staphylococcus aureus</i>	ATCC 25923	+

PRECAUTIONS

COAGULASE TEST cannot be classified as being hazardous according to the current legislation, nor does it contain harmful substances in concentrations $\geq 1\%$. It therefore does not require a Safety Data Sheet to be available.

COAGULASE TEST is a disposable device to be used only for diagnostic use *in vitro*. It must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

Store **COAGULASE TEST** at $2-8^\circ\text{C}$ in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions, **COAGULASE TEST** 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.

DISPOSAL OF USED MATERIAL

After use, **COAGULASE TEST** and 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.







BIBLIOGRAPHY

- W.E. Kloos and J.H. Jorgensen "Staphylococci" p. 143-153. In E.H. Lennette, A. Balows, W.J. Hausler Jr., H.J. Shadomy. *Manual of Clinical Microbiology*, 4th Edition, American Society for Microbiology, Washington, D.C. 1985.

PRESENTATION

Product	REF	Σ
COAGULASE TEST	88030	5

TABLE OF SYMBOLS

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



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Antibiotic Disc

ENGLISH

Antibiotic discs for susceptibility tests

DESCRIPTION

Antibiotic Disc are paper discs with special features, that are impregnated with antibiotic and used for the susceptibility test according to the Kirby-Bauer antibiotic testing (KB testing or disk diffusion antibiotic sensitivity testing).

Antibiotic Disc are available in a large variety of configurations. Each configuration is available in packages of 50 and 250 tests.

CONTENTS OF THE PACKAGES

Discs in cartridge

The 50-test box contains 1 cartridge with 50 discs packed in a desiccant envelope.

The 250-test box contains 5 cartridges of 50 discs, each cartridge individually packed in a desiccant envelope.

Each package also contains a transparent resealable bag.

Discs in canister

The canister contains 250 discs and a desiccant tablet.

METHOD PRINCIPLE

The discs are applied to the surface of a culture medium inoculated with a pure colony suspension of the microorganism under examination. After incubation, the plates are examined, the inhibition halos around each disc are examined and compared with the standard inhibition haloes: in this way the microorganisms are defined as being susceptible, intermediate or resistant to the tested antimicrobial agents.

COMPOSITION

Liofilchem antimicrobial susceptibility test discs are made of high-quality paper in compliance with WHO and FDA specifications.

The discs are manufactured under the quality systems UNI EN ISO 9001 and EN ISO 13485, and to DIN specification for potency, i.e. the concentration of each antibiotic is within 90-125% of the concentration stated on the disc.

GATHERING AND KEEPING SAMPLES

The colonies that are to be subjected to the susceptibility test are taken up by culture media that have been previously swabbed with the sample under examination. In the case of mixed colonies the bacterial strains must be purified before they are swabbed on the plates for the susceptibility test.

TEST PROCEDURE

1. Allow discs to equilibrate to room temperature before opening the container (cartridge or canister) in order to minimize the condensation on the discs, which could affect long-term stability.
2. Make a suspension of the test organism to the density of a 0.5 McFarland turbidity standard.
3. Using a swab, inoculate a suitable agar plate medium by uniformly spreading the suspension over the entire agar surface.
4. Apply discs firmly to the surface of the inoculated agar plate.
5. Incubate plates in an inverted position at the appropriate temperature, atmosphere and time, following the methodology chosen (e.g. CLSI, EUCAST).
6. Return unused discs to the refrigerator/freezer as soon as the application of the discs has been completed (see STORAGE).

NOTE 1: The medium to be used depends on the organism under investigation and the methodology followed, and must be validated by the media manufacturer for antimicrobial susceptibility testing. A list of recommended agar media can be found at the end of this IFU.

NOTE 2: It is recommended to use the inoculum suspension within 15 minutes of preparation, apply discs within 15 minutes of inoculation and incubate plates within 15 minutes of disc application.

For more details, please refer to the current published standards.

EVALUATING THE RESULTS / QUALITY CONTROL

At the end of the incubation period, measure the inhibition halos and interpret according to the current reference standards:

[Antibiotic Disc Interpretative Criteria and Quality Control \(pdf file\)](#)

CLINICAL INTERPRETATION

The susceptibility test carried out *in vitro* cannot exactly reproduce *in vivo* conditions. Nevertheless, it shows the effect of the concentration of the antibiotic, which varies in the culture medium in relation to the growth of the microbial population.

The final choice of antibiotic to administer to the patient is the responsibility of the clinician who possesses all the information on the patient.

LIMITS

Diffusion susceptibility tests use an *in vitro* technique and cannot therefore reproduce the extremely complex *in vivo* conditions. Nevertheless, it is a useful and important tool that helps the clinician choose the correct therapy. Many variable factors influence the final result of the diffusion susceptibility test. The main ones are: the culture medium used, impregnation of the discs, inoculation of the medium, temperature, time and incubation atmosphere of the plates, pre-incubation and pre-diffusion conditions, depth of the medium, etc.

PRECAUTIONS

The Antibiotic Disc cannot be classified as being hazardous according to current legislation. Antibiotic Disc are disposable products. Antibiotic Disc are only for diagnostic *in vitro* use and are intended for professional use. They must be used in the laboratory by properly trained operators using approved aseptic and safety methods for pathogenic agents.

STORAGE

The unopened package of Antibiotic Disc can be stored in most cases at -20°C to $+8^{\circ}\text{C}$ till the expiry date. Some products have to be stored at -20°C as maximum storage temperature. The recommended temperature limits can be found both on the product envelop and on the box label. Leftover discs from an opened CARTRIDGE need to be stored at $2-8^{\circ}\text{C}$ for no more than 7 days. The cartridge containing unused discs should be returned into its desiccant envelope and then inserted into the resealable bag. Discs in a CANISTER can be used for up to 2 months from first opening and must be stored at the label storage temperature. Dispose of expired discs.

ELIMINATING USED MATERIAL

After use, Antibiotic Disc and the material that comes into contact with the sample must be decontaminated and disposed of in accordance with current laboratory techniques for the decontamination and disposal of potentially infected material.



Antibiotic Disc

ITALIANO

Dischi antibiotici per antibiogramma

DESCRIZIONE

Antibiotic Disc sono dischi di carta, con caratteristiche peculiari, impregnati con antibiotico, utilizzati per l'antibiogramma secondo il metodo Kirby-Bauer (test KB o antibiogramma a disco diffusione).

Antibiotic Disc sono previsti in una larga varietà di configurazioni. Ciascuna configurazione è disponibile nella variante da 50 e 250 test.

CONTENUTO DELLE CONFEZIONI

Dischi in cartuccia

La confezione da 50 test contiene 1 cartuccia con 50 dischi inserita in una bustina con film essiccante.

La confezione da 250 test contiene 5 cartucce da 50 dischi, ognuna in una bustina con film essiccante.

Ciascuna confezione contiene inoltre una bustina trasparente con chiusura a pressione.

Dischi in barattolo

Il barattolo contiene 250 dischi e una compressa essiccante.

PRINCIPIO DEL METODO

I dischi vengono applicati sulla superficie di un terreno di coltura inoculato con una sospensione di una coltura pura del microrganismo in esame. Dopo l'incubazione, vengono esaminate le piastre, misurati gli aloni di inibizione intorno a ciascun disco e confrontati con i diametri degli aloni di inibizione standard: in tal modo i microrganismi vengono definiti sensibili, intermedi o resistenti agli agenti antimicrobici testati.

COMPOSIZIONE

I dischi Liofilchem per i test di sensibilità agli antimicrobici sono preparati con carta di alta qualità in conformità alla specifiche fornite dall'OMS e dalla FDA. I dischi sono prodotti secondo i sistemi di qualità UNI EN ISO 9001 ed EN ISO 13485, ed in conformità con le specifiche DIN per la potenza, ovvero la concentrazione di ciascun antibiotico rientra nell'intervallo del 90-125% della concentrazione indicata sul disco.

E.M.B. LEVINE AGAR

Selective medium for gram-negative enteric bacteria isolation (harmonized US Pharmacopeia)

TYPICAL FORMULA	(g/l)
Peptone	10.0
Lactose	10.0
Dipotassium Phosphate	2.0
Eosin Y	0.4
Methylene Blue	0.065
Agar	15.0
Final pH 7.2 ± 0.2 at 25°C	

DESCRIPTION

E.M.B. LEVINE AGAR is a selective medium for gram-negative enteric bacteria isolation conforms with specifications of the United States Pharmacopeia (USP). E.M.B. LEVINE AGAR is used for testing clinical materials, food and dairy products primary for the detection and confirmation of coliforms.

PRINCIPLE

Peptone is the nitrogen source, lactose is the fermentable carbohydrate and dipotassium phosphate is the buffer. Eosin Y and methylene blue are the indicators. These dyes also play a role in differentiating between lactose fermenters and lactose non fermenters due to the presence or absence of dye uptake in the bacterial colonies. Methylene blue works also as selective agent inhibiting gram-positive bacteria to a limited degree.

PREPARATION

Suspend 37.5 g of powder in 1 liter of distilled water. Heat until completely dissolved. Autoclave at 121°C for 15 minutes. Cool to 45-50°C. Mix thoroughly. Dispense in petri dishes.

TECHNIQUE

Use standard procedures to obtain isolated colonies from specimens. A non selective medium should also be streaked to increase the chance of recovery when the population of gram-negative organisms is low and to provide an indication of other organisms present in the specimen. Incubate plates, protected from light, at 35±2 for 18-24 hours. If negative after 24 hours, reincubate an additional 24 hours.

INTERPRETATION OF RESULTS

Lactose-fermenting microorganisms, such as coliforms, are visualized as blue-black colonies, whereas lactose non fermenters, such as *Salmonella* spp and *Shigella* spp, appear colorless, transparent or amber. Some gram-positive bacteria, such as fecal streptococci, staphylococci and yeast, will grow in this medium and usually form pinpoint colonies. A number of non pathogenic lactose non fermenting gram-negative bacteria will grow in this medium and must be distinguished from pathogenic strains by additional biochemical tests.

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

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 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

1. Holf-Harris and Tongue (1916) J. infect. Dis. 18:596.
2. Levine (1918) J. Infect. Dis. 23:43.
3. Marshall ed. (1993) Standard methods for the examination of dairy products, 16th ed. American Public Health Association, Washington, D.C.
4. Downes and Ito ed. (2001) Compendium of methods for the microbiological examination of foods, 4th ed. American Public Health Association, Washington, D.C.
5. United States Pharmacopeial Convention, Inc. (2001) The United States Pharmacopeia 25/The National formulary 20 – 2002. The United States Pharmacopeial Convention, Rockville, Md.



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PRODUCT SPECIFICATIONS

NAME

E.M.B. LEVINE AGAR

PRESENTATION

Dehydrated medium

STORAGE

10-30°C

PACKAGE

Ref.	Content	Packaging
610019	500 g	500 g of powder in plastic bottle
620019	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM

7.2 ± 0.2

USE

E.M.B. LEVINE AGAR is a selective medium for gram-negative enteric bacteria isolation conforms with specifications of the United States Pharmacopeia (USP)

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Dehydrated medium

Appearance: homogeneous, free-flowing light red-purple

Colour: light red-purple

Prepared medium

Appearance: slightly hazy

Colour: dark red to blue-purple

SHELF LIFE










4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Inoculum for productivity: 10-100 CFU/ml
Inoculum for selectivity: 10⁴-10⁵ CFU/ml
Inoculum for specificity: ≤10⁴ CFU/ml
Incubation conditions: 18-24 h at 36 ± 1°C

Microorganism	ATCC	Growth	Features
<i>Escherichia coli</i>	25922	Good	Green metallic sheen
<i>Klebsiella pneumoniae</i>	13883	Good	Pink
<i>Proteus mirabilis</i>	25933	Good	Colorless
<i>Pseudomonas aeruginosa</i>	27853	Good	Colorless
<i>Salmonella typhimurium</i>	14028	Good	Colorless
<i>Streptococcus faecalis</i>	19433	Inhibition	---

TABLE OF SYMBOLS

 Batch code	 <i>In vitro</i> diagnostic medical device	 Manufacturer	 Use by	 Keep away from heat sources
 Catalogue number	 Temperature limitation	 Contains sufficient for <n> tests	 Consult instructions for use	



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GIOLITTI-CANTONI BROTH BASE

Basal medium for *Staphylococcus aureus* enrichment from foods, recommended by ISO 6888-3: 2003.

TYPICAL FORMULA (g/l)

Tryptone	10.0
Beef Extract	5.0
Yeast Extract	5.0
D-Mannitol	20.0
Lithium Chloride	5.0
Sodium Chloride	5.0
Glycine	1.2
Sodium Pyruvate	3.0

Final pH = 6.9 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 54.2 g of powder in 1 liter of distilled or deionized water. Heat gently and shake until completely dissolved. Distribute into tubes in amounts of 19 ml. Sterilize in autoclave at 121 °C for 15 minutes. Cool to 45-50 °C. Aseptically add 0.3 ml of Potassium Tellurite 3.5% supplement (code 80291) to each tube or 0.03 ml when testing meat products or quality control organisms. Mix well.

DESCRIPTION

GIOLITTI-CANTONI BROTH BASE is used with Potassium Tellurite 3.5% supplement in enriching *Staphylococcus aureus* from foods during isolation procedures, as recommended by ISO 6888-3: 2003.

TECHNIQUE

Inoculate 1 g or 1 ml of test sample (0.1 g or 0.1 ml when testing meat or meat products) and 1 ml of each of a suitable decimal dilution series of the test sample into duplicate tubes. Overlay each tube with 5 ml of sterile molten paraffin wax to an approximate height of 2 cm. Incubate at 36 ± 1 °C for 40-48 hours. Examine daily. Read tubes for blackening of the medium (a positive reaction) or no blackening (a negative reaction). If blackening occurs subculture on Baird Parker Agar, it confirms the isolation of *S. aureus*.

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: tan.

Prepared medium

Appearance: clear without significant precipitate.

Color: medium amber.

Incubation conditions: 36 ± 1 °C for 40-48 hours.

Microorganism	ATCC	Growth	Characteristics
<i>Escherichia coli</i>	25922	inhibited	no blackening
<i>Micrococcus luteus</i>	10240	inhibited	no blackening
<i>Staphylococcus aureus</i>	25923	good	blackening
<i>Staphylococcus aureus</i>	6538	good	blackening



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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 tubes at 2-8 °C.








REFERENCES

1. Giolitti, G., and C. Cantoni. (1996). A medium for the isolation of staphylococci from foodstuffs. J. Appl. Bacteriol. **29**: 395-398.
2. International Dairy Federation. (1978). IDF Standard 60A.
3. ISO 6888-3: 2003. Microbiology of food and animal feeding stuffs- Horizontal medium for the enumeration of coagulase – positive staphylococci (*Staphylococcus aureus* and other species).

PRESENTATION

Product	REF	Σ
GIOLITTI CANTONI BROTH BASE (9.2 l)	610100	500 g
GIOLITTI CANTONI BROTH BASE (1.8 l)	620163	100 g
POTASSIUM TELLURITE 3.5% supplement	80291	5 x 10 ml

TABLE OF SYMBOLS

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



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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 $30 \pm 1^\circ\text{C}$ for 72 ± 3 hours.

QC Table.

Microorganism		Growth
<i>Bacillus subtilis</i>	WDCM 00003	Good
<i>Enterococcus faecalis</i>	WDCM 00009	Good
<i>Escherichia coli</i>	WDCM 00012	Good
<i>Staphylococcus aureus</i>	WDCM 00034	Good
<i>Pseudomonas aeruginosa</i>	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 feeding 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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MRS Broth ISO 15214

Medium for the cultivation of lactobacilli.

TYPICAL FORMULA	(g/l)
Peptospecial	10.0
Beef Extract	10.0
Yeast Extract	5.0
Glucose	20.0
Triammonium Citrate	2.0
Sodium Acetate	5.0
Magnesium Sulfate	0.2
Manganese Sulfate	0.05
Dipotassium Phosphate	2.0
Final pH 6.2 ± 0.2 at 25°C	

DESCRIPTION

MRS Broth ISO 15214 is a non-selective medium for profuse growth of lactobacilli from nonclinical specimens. It can be used for preparing inocula in microbiological assays.

This medium complies with ISO/DIS 15214 for the inspection of foods.

PRINCIPLE

Peptospecial and beef extract provide nitrogen, carbon, amino acids, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Glucose is the fermentable carbohydrate. Ammonium citrate, at a low pH, inhibits most microorganisms, but allows the growth of lactobacilli. Sodium acetate and dipotassium phosphate are buffer agents to maintain a low pH. Magnesium and manganese sulfates are sources of ions and sulfate.

PREPARATION

Suspend 54.3 g of powder in 1 liter of distilled or deionized water and add 1 ml of Tween 80 (ref. 80031). Heat to boiling and mix until completely dissolved. Adjust the pH so that after sterilization it is 5.7 ± 0.1 at 25 °C. Distribute into final containers and sterilize in autoclave at 121 °C for 15 minutes.

TECHNIQUE

Inoculate and incubate at 30°C for 72 ± 3 h.

If lactobacilli other than mesophilic have to be cultivated, incubate as described below:

- For thermophilic lactobacilli, 48 h at 42°C;
- For psychrophilic lactobacilli, 5 days at 25°C;
- For both mesophilic and psychrophilic lactobacilli, 48 h at 30°C and then for further 48 h at 22°C.

INTERPRETATION OF RESULTS

Turbidity indicates microbial growth.

STORAGE CONDITIONS

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

WARNING AND PRECAUTIONS

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

- Briggs, M. (1953). J. Dairy Res. 20:36.
- Cox, G.P., and M. Briggs (1954). J. App. Bact. 17:18.
- 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.



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PRODUCT SPECIFICATIONS

NAME

MRS Broth ISO 15214

PRESENTATION

Dehydrated medium

STORAGE

10-30°C

PACKAGING

Ref.	Content	Packaging
610025	500 g	500 g of powder in plastic bottle
620025	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM

6.2 ± 0.2

USE

MRS Broth ISO 15214 is a liquid medium used for the cultivation of lactobacilli from nonclinical specimens

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: clear

Colour: light amber

SHELF LIFE

4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Inoculum for productivity: ≤100 CFU
Incubation Conditions: 72 h at 30 ± 2°C

Microorganism

Lactobacillus fermentum

ATCC® 9338

Growth

Good

Lactobacillus gassari

ATCC® 19992









Good

Staphylococcus aureus

ATCC® 25923

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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LAURYL TRYPTOSE BROTH (LAURYL SULPHATE BROTH)

Selective medium for coliforms detection in water and wastewater.

TYPICAL FORMULA	(g/l)
Tryptose	20.0
Lactose	5.0
Sodium Chloride	5.0
Sodium Lauryl Sulphate	0.1
Dipotassium Phosphate	2.75
Monopotassium Phosphate	2.75
Final pH 6.8 ± 0.2 at 25°C	

DESCRIPTION

LAURYL TRYPTOSE BROTH provides a selective medium which is used for the detection of coliform organisms in water and wastewater, according to the formula of the American Public Health Association.

PRINCIPLE

Tryptose provides the nitrogen and vitamins required for organism growth. Lactose is the fermentable carbohydrate. Sodium chloride maintains the osmotic balance of the medium. Sodium lauryl sulphate is the selective agent used to inhibit organism other than coliforms. Potassium phosphates are the buffering agents.

PREPARATION

Suspend 35.6 g of powder in 1 liter of distilled or deionized water. Heat until completely dissolved. Dispense into final containers provided with Durham tubes. Autoclave at 121°C for 15 minutes.

TECHNIQUE

Inoculate 1 ml of the sample (or of its serial tenfold dilutions) into a tube of LAURYL TRYPTOSE BROTH. Invert once the tube to permit the coming out of air from the Durham tube. Incubate for 24-48 hours at 36±1°C.

INTERPRETATION OF RESULTS

Turbidity of the medium and formation of gas is a positive presumptive test for the presence of coliforms. Perform indole test directly in the tubes for confirmation.

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

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 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.

REFERENCES

1. Christen, G.L., P.M. Davidson, J.S. McAllister, and L.A. Roth (1992). Coliforms and other indicator bacteria, p. 247-267.
2. Eaton, A.D., L.S. Clesceri, and A.E. Greenberg (ed.) Standard methods for the examination of water and wastewater, 19th ed.
3. Association of Official Analytical Chemists (1995). Bacteriological analytical manual 8th ed.
4. American Public Health Association (1980) Standard methods for the examination of water and wastewater. 15th ed. APHA.
5. ISO Standard 11866-2 Milk and milk products-Enumeration of presumptive *Escherichia coli*.



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PRODUCT SPECIFICATIONS

NAME

LAURYL TRYPTOSE BROTH (LAURYL SULPHATE BROTH)

PRESENTATION

Dehydrated medium

STORAGE

10-30°C

PACKAGE

Ref.	Content	Packaging
610085	500 g	500 g of powder in plastic bottle
620085	100 g	100 g of powder in plastic bottle
6100855	5000 g	5 kg of powder in plastic container

pH OF THE MEDIUM

6.8 ± 0.2

USE

LAURYL TRYPTOSE BROTH provides a selective medium which is used for the detection of coliform organisms in water and wastewater, according to the formula of the American Public Health Association.

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Dehydrated medium

Appearance: free-flowing, homogeneous

Colour: beige

Prepared medium

Appearance: clear to very slightly opalescent

Colour: light amber

SHELF LIFE










4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Inoculum for productivity: 10-100 CFU/ml
Inoculum for selectivity: 10⁴-10⁵ UFC/ml
Inoculum for specificity: ≤ 10⁴ UFC/ml
Incubation conditions: 48 h at 30 ± 1°C

Microorganism	ATCC®	Growth	Gas
<i>Escherichia coli</i>	25922	Good	+
<i>Salmonella thymurium</i>	14028	Good	-
<i>Staphylococcus aureus</i>	25923	Inhibited	-
<i>Klebsiella pneumoniae</i>	13883	Good	+

TABLE OF SYMBOLS

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



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Chromatic™ Vibrio

Chromogenic medium for detection of enteropathogenic *Vibrio* spp, from clinical and nonclinical samples.

DESCRIPTION

Chromatic™ Vibrio is a chromogenic medium used for the selective isolation and cultivation of vibrios, including *V. cholerae*, *V. parahaemolyticus*, *V. vulnificus* and *V. alginolyticus* from stool specimens, food, water and environmental samples.

TYPICAL FORMULA

	(g/l)
Peptone	15.0
Yeast Extract	3.0
Salts	59.1
Chromogenic Mix	0.3
Agar	15.0
Final pH 8.4 ± 0.2 at 25°C	

METHOD PRINCIPLE

Peptone and yeast extract provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Salts included in the medium have the dual effect of stimulating vibrios growth and suppressing Gram-positive bacteria and coliforms. The alkaline pH is also inhibitory for most contaminant microorganisms while enhances the recovery of *V. cholerae*. Chromogenic mix allows to identify the *Vibrio* genus on the basis of the color and morphology of the colonies. Agar is the solidifying agent.

PREPARATION

Dehydrated medium Suspend 92.4 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.

TEST PROCEDURE

Inoculate the medium by direct streaking or spread plating.
Incubate aerobically at 35 ± 2°C for 18-24 hours.

NB. Heavy inoculation is recommended. Swabs containing specimen material should be transported to the laboratory in Cary Blair Transport Medium (ref. 470290) if a delay in reaching the laboratory is anticipated. Specimens for cultivation of vibrios should not be frozen.

INTERPRETING RESULTS

After incubation observe the color of the colonies and interpret the results as indicated in the ID table. Confirm typical colonies with proper biochemical tests.

ID Table.

Microorganism	Typical colony color
<i>V. parahaemolyticus</i>	Mauve
<i>V. vulnificus</i> / <i>V. cholerae</i>	Green blue to turquoise blue
<i>V. alginolyticus</i>	Colorless

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige to green beige.
Prepared medium: clear to 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 prepared plates at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 2 years.
Ready-to-use plates: 4 months.

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: 50-100 CFU.

Inoculum for selectivity: 10⁴-10⁶ CFU.

Incubation conditions: aerobically at 35 ± 2°C for 18-24 hours.

QC Table.

Microorganism		Growth	Specification
<i>Vibrio vulnificus</i>	ATCC® 27562	Good	Green colonies
<i>Vibrio parahaemolyticus</i>	ATCC® 17802	Good	Mauve colonies
<i>Vibrio alginolyticus</i>	ATCC® 17749	Good	Creamy colonies
<i>Escherichia coli</i>	ATCC® 25922	Inhibited	---
<i>Staphylococcus aureus</i>	ATCC® 25923	Inhibited	---

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. American Public Health Association (1992): compendium of methods for the microbiological examination of foods, 3rd edition.
2. Dewitt, W.E., E.J. Gangarosa, I. Huq, and A. Zarifi (1971) Holding media for the transport of *Vibrio cholerae* from field to laboratory. Am. J. Trop. Med. Hyg. 20:685-688.
3. Kobayashi, T., S. Enomoto, R. Sakazaki, and S. Kuwahara (1963) A new selective medium for pathogenic vibrios: T.C.B.S. Agar (Modified Nakanishi's Agar). Jap. J. Bacteriol. 18:387-391.

PRESENTATION		Contents	Ref.
Chromatic™ Vibrio	90 mm ready-to-use plates	20 plates	11633
Chromatic™ Vibrio	Dehydrated medium	500 g of powder	610633

TABLE OF SYMBOLS

LOT Batch code	IVD <i>In Vitro</i> 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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MR-VP BROTH

Medium for Gram-negative bacteria differentiation, recommended by ISO 6785: 2001 and IDF 93: 2001.

TYPICAL FORMULA (g/l)

Peptospecial	7.0
Dipotassium Phosphate	5.0
Glucose	5.0

Final pH = 7.0 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 17.0 g of powder in 1 liter of distilled or deionized water. Heat to boiling until completely dissolved. Dispense into final tubes. Sterilize in autoclave at 121°C for 15 minutes.

DESCRIPTION

MR-VP BROTH is used for differentiating coliform organisms based on the Methyl Red and Voges-Proskauer tests, as recommended by ISO 6785: 2001 and IDF 93: 2001. The methyl red test is based on the use of a pH indicator to detect acidity when an organism ferments glucose. This is the reason of a development of a red color. The Voges-Proskauer test differentiates microorganisms which ferment carbohydrates to acids from those that ferment them by decarboxylation to acetylmethylcarbinol, which is oxidised to diacetyl by atmospheric oxygen in an environment made basic by KOH. Diacetyl, under the catalytic action of α -naphthol and creatine, is converted into a red complex.

TECHNIQUE

Inoculate MR-VP Broth with growth from a single colony. Incubate at 36 ± 1°C for 48 hours. Transfer 3 ml of MR-VP Broth culture to a clean tube.

VP Test

Prepare the following solutions:

- creatine monohydrate: 0.5 g in 100 ml of distilled water;
- 5% α -naphthol: 5 g in 100 ml of ethyl alcohol 96%.
- 40% KOH: 40 g in 100 ml of distilled water.

To 3 ml of broth culture add 2 drops of creatine solution, 3 drops of α -naphthol solution and 2 drops of KOH solution. Gently shake the tube to expose the medium to oxygen. A positive test is indicated by the development of a pink to bright red coloration 15 minutes after the addition of reagents.

Methyl Red Test

After 5 days of incubation, transfer 5 ml of broth into a clean test tube. Suspend 0.1 g of methyl red in 300 ml of 95% ethyl alcohol, and make up to 500 ml with distilled water. Add 5 drops of methyl red to the broth culture. The reaction is positive if a red coloration develops immediately. A negative reaction is indicated by a yellow color on the surface of the liquid medium.

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: very light beige to light beige.

Prepared medium

Appearance: clear.

Color: light amber.

Incubation conditions: 36 ± 1°C for 24-48 hours.

Microorganism	ATCC	Growth	MR test	VP test
<i>Enterobacter aerogenes</i>	13048	good	-	+
<i>Klebsiella pneumoniae</i>	13883	good	-	+
<i>Escherichia coli</i>	25922	good	+	-



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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 tubes at 2-8 °C.








REFERENCES

1. Barn, M.M. (1986). J. Pathot. Bacteriol. , **42** : 441.
2. Edwards, P.R., and V.H. Ewing (1965). Identification of *Enterobacteriaceae*.
3. ISO 6785: 2001. IDF 93: 2001. Milk and milk products- Detection of *Salmonella* spp.

PRESENTATION

Product	REF	Σ
MR-VP BROTH (29.4 l)	610032	500 g
MR-VP BROTH (5.8 l)	620032	100 g

TABLE OF SYMBOLS

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



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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 Heptahydrate	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

SHELF LIFE

4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Inoculum for productivity: 50-100 CFU
Inoculum for selectivity: 10^4 - 10^6 CFU
Incubation Conditions: 72 ± 3 h at $30 \pm 1^\circ\text{C}$, in microaerobiosis

Microorganism

Lactobacillus sakei

WDCM 00015

Growth

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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EE Broth-Mossel

Liquid medium for the cultivation and selective enrichment of Enterobacteriaceae from different types of samples, according to USP/EP/JP.

DESCRIPTION

Enterobacteriaceae Enrichment Broth-Mossel is a selective medium used for the detection of bile-tolerant Gram-negative bacteria in food 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) for the microbiological examination of nonsterile products.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Gelatin	10.0
Glucose Monohydrate	5.0
Dehydrated Ox Bile	20.0
Potassium Dihydrogen Phosphate	2.0
Disodium Hydrogen Phosphate, Anhydrous	6.4*
Brilliant Green	0.015
Final pH 7.2 ± 0.2 at 25°C	

* Equivalent to 8.0 g of Disodium Hydrogen Phosphate Dihydrate.

METHOD PRINCIPLE

Pancreatic digest of gelatin provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Glucose is the fermentable carbohydrate. Ox bile and brilliant green are selective agents effective against Gram-positive cocci. Potassium phosphate and sodium phosphate act as buffer.

PREPARATION

Dehydrated medium Suspend 43.4 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.

TEST PROCEDURE

As in the Pharmacopoeia, prepare the sample using a 1 in 10 dilution of not less than 1 g of the product to be examined by choosing Tryptic Soy Broth (ref. 24513 or 452080) as diluent and incubate at 20-25°C for 2-5 hour to resuscitate bacteria.

For qualitative test (test for absence), transfer the volume of the pre-enrichment broth corresponding to 1 g of the product to be examined to EE Broth-Mossel.

For quantitative test, enumerate Enterobacteriaceae found per milliliter or per gram of test sample by using the Most Probable Number (MPN) technique. Use the volume of the pre-enrichment broth containing 0.1 g, 0.01 g and 0.001 g (or 0.1 ml, 0.01 ml and 0.001 ml) of the product to be examined to inoculate EE Broth-Mossel.

For both types of test incubate EE Broth-Mossel at 30-35°C for 24-48 h and continue analysis by subculturing on Violet Red Bile Glucose Agar (ref. 11184). Incubate plates aerobically at 30-35°C for 18-24 hours.

INTERPRETING RESULTS

Turbidity of EE Broth-Mossel indicates microbial growth; acid production causes a color change of the medium to yellow.

No growth of colonies on Violet Red Bile Glucose Agar is reported as absence of bile-tolerant Gram-negative bacteria. Growth of colonies constitutes a positive result and the probable number of bacteria is determined from the table below.

MPN Table.

Results for each quantity of product			Probable number of bacteria per gram or per milliliter of product
0.1 g or 0.1 ml	0.01 g or 0.01 ml	0.001 g or 0.001 ml	
+	+	+	>10 ³
+	+	-	10 ³ - 10 ²
+	-	-	10 ² - 10
-	-	-	<10

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige to light green.

Prepared medium: clear, 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 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 tubes/bottles: 1 year.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: ≤100 CFU.

Inoculum for selectivity: >100 CFU.

Incubation conditions: 18-24 h at 30-35°C (Pharmacopoeia growth promotion).

QC Table.

Microorganism		Specification
<i>Escherichia coli</i>	ATCC® 8739	Good growth
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Good growth
<i>Staphylococcus aureus</i>	ATCC® 6538	Inhibition

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. 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. ISO 21528-1:2004. Microbiology of food and animal feeding stuffs – Horizontal method for the detection and enumeration of Enterobacteriaceae – Detection and enumeration by MPN technique with pre-enrichment.
6. ISO 21528-2:2004. Microbiology of food and animal feeding stuffs – Horizontal method for the detection and enumeration of Enterobacteriaceae – Colony count method.
7. 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.
8. 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.
9. Mossel, Vissar, and Cornellisen (1963) J. Appl. Bacteriol. 26:444.

PRESENTATION		Contents	Ref.
EE Broth-Mossel	Tubes	20 x 10 ml tubes	24096
EE Broth-Mossel	Bottles (screw cap)	6 x 100 ml bottles	402480
EE Broth-Mossel	Bottles (flip-off cap)	25 x 100 ml bottles	453080
EE Broth-Mossel	Bottles (perforable cap)	6 x 100 ml bottles	495000
EE Broth-Mossel	Dehydrated medium	500 g of powder	610017
EE Broth-Mossel	Dehydrated medium	100 g of powder	620017

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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Mannitol Salt Agar

Selective medium for isolation and enumeration of staphylococci from clinical samples and other materials, according to USP/EP/JP.

DESCRIPTION

Mannitol Salt Agar is a selective medium used for isolating pathogenic staphylococci from clinical samples, food and other materials of sanitary importance.

This medium is prepared according to recommendations of the harmonized USP/EP/JP method for the detection of *S. aureus* in non sterile pharmaceutical products.

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Beef Extract	1.0
D-Mannitol	10.0
Sodium Chloride	75.0
Phenol Red	0.025
Agar	15.0
Final pH 7.4 ± 0.2 at 25°C	

METHOD PRINCIPLE

Pancreatic digest of casein, peptic digest of animal tissue and beef extract provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Mannitol is the fermentable carbohydrate. The high salt content of 7.5% inhibits most bacteria other than staphylococci. Phenol red is the pH indicator. Agar is the solidifying agent.

PREPARATION

- Dehydrated medium Suspend 111 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil for 1 minute 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

Inoculate plates by the direct streaking of the material to be examined over the agar surface. Incubate aerobically at 35 ± 2°C for 24-48 hours.

Harmonized USP/EP/JP method for microbiological examination of non sterile products recommends to inoculate the sample in Tryptic Soy Broth (ref. 24444). Subculture on a plate of Mannitol Salt Agar and incubate at 30-35°C for 18-72 hours.

INTERPRETING RESULTS

S. aureus cultivates with yellow or white colonies surrounded by a yellow zone. Confirm by identification tests*.

Coagulase-negative Staphylococci form small colorless to red colonies with no color change to the medium

*Suspect colonies can be subcultured to a moderately selective medium such as Baird Parker RPF Agar (ref. 10521, 402210) for the determination of coagulase activity (ISO 6888-2).

APPEARANCE OF THE MEDIUM

Dehydrated medium: free-flowing, homogeneous, beige-pink.

Prepared medium: slightly opalescent, pinkish-red.

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: 10-100 CFU
 Inoculum for selectivity: 10⁴-10⁶ CFU
 Incubation conditions: aerobically at 35 ± 2°C for 24-48 hours.
 *30-35°C for 18-72 h (USP/EP/JP Growth Promotion Testing).

QC Table.

Microorganism		Growth	Specification
<i>Staphylococcus aureus</i>	ATCC® 25923	Good	Yellow colonies with yellow zone
<i>Staphylococcus aureus</i> *	ATCC® 6538	Good	Yellow colonies with yellow zone
<i>Staphylococcus epidermidis</i>	ATCC® 12228	Good	Red colonies
<i>Escherichia coli</i>	ATCC® 25922	Inhibited	---
<i>Escherichia coli</i> *	ATCC® 8739	Inhibited	---

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

- European Pharmacopoeia 6.5 (2009). 2.6.13 Microbiological examination of non-sterile products: Test for specified microorganisms.
- United States Pharmacopoeia 32 NF 27 (2009). <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
- Japanese Pharmacopoeia 4.05 (2008). Microbiological examination of non-sterile products: Test for specified microorganisms.
- ISO 6888-2:1999 + A1:2003. Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species) – Part 2: Technique using rabbit plasma fibrinogen agar medium.
- Kloos, W.E., and T.L. Bannerman (1995) *Staphylococcus* and *Micrococcus*. In *Manual of clinical microbiology*, 6th ed.
- Chapman, G.H. (1945) The significance of sodium chloride in studies of staphylococci. *J. Bacteriol.* 50:201-203.

PRESENTATION		Contents	Ref.
Mannitol Salt Agar	90 mm ready-to-use plates	20 plates	10030
Mannitol Salt Agar	90 mm ready-to-use plates	100 plates	10030*
Mannitol Salt Agar	Bottles	6 x 500 ml bottles	470080
Mannitol Salt Agar	Bottles	6 x 200 ml bottles	412290
Mannitol Salt Agar	Bottles	6 x 100 ml bottles	402290
Mannitol Salt Agar	Dehydrated medium	500 g of powder	610029
Mannitol Salt Agar	Dehydrated medium	100 g of powder	620029
Mannitol Salt Agar	Dehydrated medium	5 kg of powder	6100295

TABLE OF SYMBOLS

LOT Batch code	IVD <i>In vitro</i> Medical Diagnostic 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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Yersinia Selective Agar Base

Differential and selective medium for the isolation of *Y. enterocolitica* from clinical and nonclinical specimens, according to ISO 10273.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Gelatin	17.0
Enzymatic Digest of Casein and Animal Tissues	3.0
Yeast Extract	2.0
Sodium Chloride	1.0
Sodium Pyruvate	2.0
Magnesium Sulfate	0.01
Mannitol	20.0
Sodium Deoxycholate	0.5
Crystal Violet	0.001
Neutral Red	0.03
Agar	14.0
Final pH 7.4 ± 0.2 at 25°C	

DESCRIPTION

Yersinia Selective Agar Base is a medium used with supplements for the selective isolation and differentiation of *Yersinia enterocolitica*. The complete medium (CIN agar) is recommended by ISO 10273 for the examination of food and animal feed stuffs as well as environmental samples in the area of food production and food handling.

PRINCIPLE

Enzymatic digest of gelatin and enzymatic digest of casein and animal tissues provide amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganisms. Yeast extract is a source of vitamins, particularly of B-group. Sodium chloride maintains the osmotic balance of the medium. Sodium pyruvate and magnesium sulfate stimulate organisms growth. Mannitol is the carbohydrate which allows to differentiate between mannitol fermenting and non-fermenting bacteria. Sodium deoxycholate and crystal violet inhibit Gram-positive bacteria. Neutral red is the pH indicator. Agar is the solidifying agent.

Supplementation with Yersinia Supplement (ref. 81039), containing cefsulodin, irgasan (triclosan) and novobiocin, inhibits the growth of most Gram-negative enteric bacteria.

PREPARATION

Suspend 59.6 g of powder in 1 liter of deionized or distilled water. Bring to boil and shake until completely dissolved. Sterilize at 121°C for 15 minutes. Cool up to 45-50°C. Aseptically, add the contents of 2 vials (6 ml) of Yersinia Supplement reconstituted as directed in the instructions for use that accompany the product. Pour in Petri dishes.

TECHNIQUE

Inoculate the specimen onto the medium by either direct plating or pour plating (*). Incubate aerobically at 30 ± 1°C for 18-24 h.

(*) The ISO method for the detection of presumptive pathogenic *Yersinia enterocolitica* recommends to first perform enrichment in Peptone, Sorbitol and Bile Salts (PSB) Broth for 48-72 hours at 22-25°C with agitation, or 5 days without agitation.

INTERPRETATION OF RESULTS

Organisms capable of fermenting mannitol cause a localized pH reduction, forming colonies with red centre surrounded by a transparent border (characteristic "bull's-eye" colony). Organisms that do not ferment mannitol form colorless, translucent colonies. Some strains of *Serratia*, *Citrobacter* and *Enterobacter* may give a colonial morphology resembling *Yersinia enterocolitica*. Final identification should be confirmed by standard biochemical tests.

STORAGE AND TRANSPORT CONDITIONS

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

REFERENCES

- EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
- ISO 10273:2003. Microbiology of food and animal feeding stuffs – Horizontal method for the detection of presumptive pathogenic *Yersinia enterocolitica*.
- Schieman, D.A. (1979) Synthesis of a selective agar medium for *Yersinia enterocolitica*. Can. J. Microbiol. 25:1298-1304.
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- Devenish, J.A., and D.A. Schieman (1981) An abbreviated scheme for identification of *Yersinia enterocolitica* isolated from food enrichments on CIN (cefsulodin-irgasan-novobiocin) agar. Can. J. Microbiol. 27:937-941.



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PRODUCT SPECIFICATIONS

NAME

Yersinia Selective Agar Base

PRESENTATION

Dehydrated medium

STORAGE

10-30°C

PACKAGING

Ref.	Content	Packaging
610111	500 g	500 g of powder in plastic bottle
620111	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM

7.4 ± 0.2

USE

Yersinia Selective Agar Base is a differential and selective medium used with supplements for the isolation of *Yersinia enterocolitica* from clinical specimens and other types of samples, according to ISO 10273

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Powder medium

Appearance: free-flowing, homogeneous

Colour: pink-beige to beige

Ready-to-use medium

Appearance: slightly opalescent

Colour: reddish-orange

SHELF LIFE











4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Inoculum for productivity: 50-100 CFU
Inoculum for selectivity: 10⁴-10⁶ CFU
Incubation Conditions: 18-24 h at 30 ± 1°C, in aerobiosis

Microorganism	WDCM	Growth	Colony Appearance
<i>Yersinia enterocolitica</i>	WDCM 00038	Good	Colonies with red center
<i>Escherichia coli</i>	WDCM 00012	Partially to totally inhibited	---
<i>Staphylococcus aureus</i>	WDCM 00034	Inhibited	---

TABLE OF SYMBOLS

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



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Yersinia Supplement

Selective supplement for the isolation of *Yersinia enterocolitica*.

DESCRIPTION

Yersinia Supplement is a selective lyophilized supplement used for the preparation of Yersinia Selective Agar Base (ref. 610111, 620111). The complete medium is used for the isolation of *Yersinia enterocolitica* from clinical and nonclinical specimens.

KIT CONTENTS

Each kit contains:

- 10 vials of freeze-dried Yersinia Supplement
- 1 instruction sheet

PRINCIPLE OF THE METHOD

Yersinia Supplement is an antibiotic mix that inhibits the growth of most Gram-negative enteric bacteria.

COMPOSITION

Antibiotic	Content / vial	Content / liter of medium
Cefsulodin	7.5 mg	15.0 mg
Irgasan	2.0 mg	4.0 mg
Novobiocin	1.25 mg	2.5 mg

PROCEDURE FOR USE

1. Aseptically reconstitute the content of one vial of Yersinia Supplement with 2 ml sterile distilled water and 1 ml ethanol(*).
2. Mix to complete dissolution and add to 500 ml Yersinia Selective Agar Base, autoclaved and cooled to 45-50°C.
3. Mix well and dispense in Petri dishes.

(*) Ethanol 50% purity minimum.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation of the medium being prepared.

QUALITY CONTROL

1. Control of the appearance: freeze-dried white in colour.
2. Microbiological control.
Prepare the medium per label directions. Inoculate the plates with the strains indicated below and incubate at 30 ± 1°C for 18-24 hours.

Control strains

Control strains	WDCM	Growth
<i>Yersinia enterocolitica</i>	WDCM 00038	Good
<i>Escherichia coli</i>	WDCM 00012	Partially to totally inhibited
<i>Staphylococcus aureus</i>	WDCM 00034	Inhibited

PRECAUTIONS

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

STORAGE

2-8°C in its original packaging. Keep away from sources of heat and avoid excessive changes of temperature. Use until the expiry date indicated on the label. Eliminate without using if there are signs of deterioration. Once reconstituted, the product can be stored for a maximum duration of 30 days at -20°C, shielded from light.

REFERENCES











- EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
- ISO 10273:2003. Microbiology of food and animal feeding stuffs – Horizontal method for the detection of presumptive pathogenic *Yersinia enterocolitica*.
- Schieman, D.A. (1979) Synthesis of a selective agar medium for *Yersinia enterocolitica*. Can. J. Microbiol. 25:1298-1304.
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- Devenish, J.A., and D.A. Schieman (1981) An abbreviated scheme for identification of *Yersinia enterocolitica* isolated from food enrichments on CIN (cef sulodin-irgasan-novobiocin) agar. Can. J. Microbiol. 27:937-941.

PRESENTATION

Product	Ref.	Contents
Yersinia Supplement	81039	10 vials

One vial is sufficient to prepare 500 ml of medium.

TABLE OF SYMBOLS

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



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Rev.3 / 18.09.2015

Clostridium perfringens Agar Base

Basal medium for detection of *C. perfringens* from clinical specimens and other materials according to ISO 7937 and ISO 14189.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Casein	15.0
Enzymatic Digest of Soya	5.0
Yeast Extract	5.0
Sodium Disulfite Anhydrous	1.0
Iron(III) Ammonium Citrate	1.0
Agar	15.0
Final pH 7.6 ± 0.2 at 25°C	

DESCRIPTION

Clostridium perfringens Agar Base is a basal medium used either on its own or with selective agents for the presumptive identification of *Clostridium perfringens* from clinical specimens, food, water and environmental samples.

D-Cycloserine can be added to this culture medium to comply with the specifications given by ISO 7937, ISO 14189 and APHA.

When supplemented with polymyxin B and kanamycin, the medium conforms to the formulation developed by Shahidi and Ferguson.

If used without any supplement added, this medium is known as Iron Sulfite Agar and recommended by ISO 15213 for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions.

PRINCIPLE

Enzymatic digest of casein and enzymatic digest of soya provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a rich source of vitamins of B-group. Ferric ammonium citrate and sodium metabisulfite are H₂S indicators. Agar is the solidifying agent. Clostridia reduce sulfite to sulfide which reacts with iron to form a black iron sulfide precipitate.

One of the following selective supplements can be added to the medium:

- *Clostridium perfringens* (T.S.C.) Supplement (ref. 81011), containing D-Cycloserine as inhibitor of accompanying flora;
- Kanamycin/Polymyxin B Supplement (ref. 81031);
- D-Cycloserine 4-MUP Supplement (ref. 81098), which contains in addition to D-Cycloserine, 4-Methyl-umbelliferyl-phosphate (MUP) to detect acid phosphatase by its fluorescence under UV light.

PREPARATION

Suspend 42.0 g of powder in 1 liter of distilled or deionized water (*). Heat to boiling until completely dissolved. Autoclave at 121°C for 15 minutes. Cool to 45-50°C. Aseptically, add rehydrated content of 2 vials (10 ml) of:

- *Clostridium perfringens* (T.S.C.) Supplement for TSC (Tryptose Sulfite Cycloserine Agar) Agar or
- Kanamycin/Polymyxin B Supplement for SFP (Shahidi-Ferguson) Agar or
- D-Cycloserine 4-MUP Supplement for TSC Agar with MUP.

Mix well and pour in Petri dishes.

(*) If desired, 100 ml Egg Yolk Emulsion (ref. 80219) can also be added after sterilization to detect lecithinase activity (not indicated in ISO 7937 or ISO 14189 either). Take this into account for calculating the final volume of 1.01 liters. For either TSC Agar or SFP Agar used as an overlay, the egg yolk emulsion is omitted. Its inclusion does not improve the lecithinase reaction and diminishes the visibility of the colonies.

TECHNIQUE

Inoculate the medium by streak/spread plating, pour-plate method or using the membrane filtration technique. Incubate plates anaerobically at 37 ± 1°C (food examination) or 44 ± 1°C (water analysis) for 18-24 hours.

INTERPRETATION OF RESULTS

Count all black colonies on the plates. For confirming presumptive colonies of *Clostridium perfringens* the following tests are recommended: reduction nitrate to nitrite (+), motility test (-), gelatine liquefaction (+).

On TSC Agar with MUP, fluorescence is detected with an UV lamp: light blue fluorescing black colonies indicate *C. perfringens*.

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

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 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.



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2. ISO 14189: 2011. Water quality – Enumeration of *Clostridium perfringens* – Method using membrane filtration.
3. ISO 7937:2004. Microbiology of food and animal feeding stuffs - Horizontal method for the detection of *Clostridium perfringens* - Colony-count technique.
4. ISO 15213:2003. Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions.
5. Rapporti ISTISAN 07/5 ISSA 005B Rev.00. Determinazione di *Clostridium perfringens* (solo su acque provenienti o contaminate da acque superficiali).
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8. Harmon, S.M., O.A. Kautler and J.T. Peeler (1971) Improved medium for enumeration of *Clostridium perfringens*. App. Microbiol. 22:688.
9. Shahidi, SA. and AR Ferguson (1971) App. Microbiol. 21:500-606.



PRODUCT SPECIFICATIONS

NAME

Clostridium perfringens Agar Base

PRESENTATION

Dehydrated medium

STORAGE

10-30°C

PACKAGING

Ref.	Content	Packaging
610207	500 g	500 g of powder in plastic bottle
620207	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM

7.6 ± 0.2

USE

Clostridium perfringens Agar Base is a medium used with supplements for the selective isolation and differentiation of *C. perfringens* from clinical specimens, food, water and environmental samples according to ISO 7937, ISO 14189 and APHA

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Dehydrated medium

Appearance: free-flowing, homogeneous

Colour: beige

Prepared medium

Appearance: clear (opaque if egg yolk emulsion has been added)

Colour: amber

SHELF LIFE











4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Complete medium: TSC Agar
Inoculum for productivity: 50-100 CFU
Inoculum for selectivity: 10⁴-10⁶ CFU
Incubation Conditions: 20 ± 2 h at 37 ± 1°C ^(a) and/or 18-24 at 44 ± 1°C ^(b), in anaerobiosis

Microorganism	WDCM	Growth	Colony Appearance
<i>Clostridium perfringens</i> ^{a,b}	WDCM 00007	Good	Black colonies
<i>Escherichia coli</i> ^a	WDCM 00012	Inhibited	---
<i>Bacillus subtilis</i> ^b	WDCM 00003	Inhibited	---

TABLE OF SYMBOLS

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



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Selective supplement for the identification and enumeration of *Clostridium perfringens*, according to ISO 7937 and ISO 14189.

DESCRIPTION

CLOSTRIDIUM *perfringens* (T.S.C.) Supplement is a selective supplement for the identification and enumeration of *Clostridium perfringens*, according to ISO 7937 and ISO 14189. CLOSTRIDIUM *perfringens* (T.S.C.) Supplement is added to CLOSTRIDIUM *perfringens* (T.S.C.) AGAR BASE, ref. 610207 - 620207.

KIT CONTENTS

Each kit contains:

- 10 bottles of lyophilised CLOSTRIDIUM *perfringens* (T.S.C.) Supplement
- 1 instruction sheet.

PRINCIPLE OF THE METHOD

CLOSTRIDIUM *perfringens* (T.S.C.) Supplement contains the antibiotic D-cycloserine that inhibits the accompanying bacterial flora.

COMPOSITION

CLOSTRIDIUM <i>perfringens</i> (T.S.C.) Supplement		
	Content / bottle	Content / liter of medium
D-cycloserine	200 mg	400 mg

PROCEDURE FOR USE

1. Aseptically reconstitute the content of a bottle of CLOSTRIDIUM *perfringens* (T.S.C.) Supplement with 5 ml of sterile distilled water. Shake until completely dissolved avoiding foam formation.
2. Aseptically add the whole contents of one bottle (5 ml) to 500 ml CLOSTRIDIUM *perfringens* (T.S.C.) AGAR BASE*, (ref. 610207 - 620207), autoclaved and cooled to 45-50°C
3. Mix with care and distribute into final containers as indicated in the instruction sheet of the medium being prepared.

*If desired, 50 ml Egg Yolk Emulsion, ref. 80219 can be added to the medium to detect lecithinase activity (not indicated in ISO 7937 or ISO 14189).

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical sheet of the medium being prepared.

QUALITY CONTROL

1. Visual inspection: white lyophilized, limpid colourless solution once reconstituted.
2. Microbiological control.

Inoculate prepared plates with the strains indicated below. Incubate inverted plates at 35 ± 2°C for 18-24 hours under anaerobic conditions.

Microorganism		Growth	Color
<i>Clostridium perfringens</i>	ATCC® 13124	Good	Black colonies (with a halo if egg yolk emulsion has been added)
<i>Escherichia coli</i>	ATCC® 25922	Inhibited	---

PRECAUTIONS

CLOSTRIDIUM *perfringens* (T.S.C.) Supplement is not classified as dangerous under current legislation. For its use, it is anyway recommended to consult the safety data sheet. This product 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 CLOSTRIDIUM *perfringens* (T.S.C.) Supplement at 2-8°C in its original packaging. In such conditions it 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

- Hauschild, A.H.W., Hilsheimer, R., and Griffith, D.W. 1974. Enumeration of faecal *Clostridium perfringens* spores in egg yolk-free Tryptose – Sulfite – Cycloserine Agar. Appl. Microb., 27:527-530.
- EN ISO 7937: 2004. Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of *Clostridium perfringens* – Colony count technique.
- ISO 14189: 2011. Water quality – Enumeration of *Clostridium perfringens* – Method using membrane filtration.

PRESENTATION

Product	REF	Σ
CLOSTRIDIUM <i>perfringens</i> (T.S.C.) Supplement	81011	10 bottles

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	 Caution, consult accompanying documents	



LISTERIA PALCAM *Supplement*

Selective supplement for the isolation of *Listeria monocytogenes*.

DESCRIPTION

LISTERIA PALCAM *Supplement* is a selective supplement made of a freeze-dried mixture of Polymyxin B, Ceftazidime and Acriflavine to use as supplement of the culture medium LISTERIA PALCAM AGAR code 610168 or 620168 for the isolation of *Listeria monocytogenes*.

KIT CONTENTS

Each kit contains:

- 10 vials of freeze-dried LISTERIA PALCAM *Supplement*
- 1 instructions sheet

PRINCIPLE OF THE METHOD

Polymyxin B, Ceftazidime and Acriflavine contribute to the finale medium selectivity by inhibiting the growth of most of common bacterial species non-*Listeria spp* frequently found in food. Polymyxin B acts against Gram-negative bacteria, Ceftazidime is active against Gram-positive and enterobacteria, Acriflavine inhibits many Gram-positive bacteria.

COMPOSITION

LISTERIA PALCAM <i>Supplement</i>		
	<i>Content / vial</i>	<i>Content / l of medium</i>
Polymyxin B	5.0 mg	10.0 mg
Ceftazidime	10.0 mg	20.0 mg
Acriflavina HCl	2.5 mg	5.0 mg

PROCEDURE FOR USE

1. Reconstitute aseptically the content of one vial of LISTERIA PALCAM *Supplement* with 5 ml of sterile distilled water. Shake until completely dissolved, avoiding foam formation.
2. Add aseptically the entire content of one vial (5 ml) to 500 ml of medium LISTERIA PALCAM AGAR code 610168 or 620168 autoclaved and cooled at 45-50°C.
3. Mix with care.
4. Distribute into Petri dishes.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation for LISTERIA PALCAM AGAR code 610168 or 620168.

QUALITY CONTROL

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

Prepare the plates using as base the medium LISTERIA PALCAM AGAR code 610168 or 620168 added with LISTERIA PALCAM *Supplement* (1 vial in 500 ml of medium). The plates are seeded with the strains indicated in the microbiological control table.

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

Microbiological control:

	Control strains	Growth
<i>Listeria monocytogenes</i>	ATCC 19111	Good
<i>Listeria monocytogenes</i>	ATCC 13932	Good
<i>Escherichia coli</i>	ATCC 25922	Inhibited
<i>Enterococcus faecalis</i>	ATCC 29212	Inhibited

PRECAUTIONS

The product LISTERIA PALCAM *Supplement* is classifiable as hazardous under current legislation; it is recommended that the Safety Data Sheet be consulted on its use.

LISTERIA PALCAM *Supplement* is a selective supplement to be used only for *in vitro* diagnostic use. It is intended for use in a professional environment and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

STORAGE

Store LISTERIA PALCAM *Supplement* at 2-8 °C in its original packaging. In such conditions LISTERIA PALCAM *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

- Van Netten, P. et al.,(1989). J. of Food Microbiol. 8:299-317.
- AFNOR. (1993). Food Microbiology – "Detection of *Listeria monocytogenes*". IDF Provisional International Standard n° 143. International Dairy Federation, Brussels.

PRESENTATION

Product	REF	Σ
LISTERIA PALCAM <i>Supplement</i>	81026	10 vials

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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Rev.0 / 23.10.2005

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LISTERIA PALCAM AGAR

Selective medium for the isolation and enumeration of *Listeria monocytogenes* according to ISO 11290-1.

TYPICAL FORMULA	(g/ l)
Peptone	23.0
Starch	1.0
Sodium Chloride	5.0
Yeast Extract	3.0
Glucose	0.5
Mannitol	10.0
Esculin	0.8
Ferric Ammonium Citrate	0.5
Lithium Chloride	15.0
Phenol Red	0.08
Agar	12.0

Final pH = 7.2 ± 0.2 at 25 °C.

DESCRIPTION

The complete LISTERIA PALCAM AGAR, prepared by adding Listeria Palcam supplement to the medium base, is a selective and differential medium, formulated by Van Netten and other, and according to ISO 11290, for isolation and enumeration of *Listeria monocytogenes* from foods.

The medium is also recommended by:

1. AFNOR for the research of *L. monocytogenes* in foods.
2. IDF as an additional plating medium for the detection of *Listeria spp* in milk and milk products.
3. Health Canada for the detection of *L. monocytogenes* in food and environmental samples.

Aesculin and mannitol, present in the medium, yield a presumptive differentiation of *Listeria* from other aesculin positive bacteria, such as faecal streptococci.

PRINCIPLE

The peptones favour the excellent growth of *Listeria*, glucose and starch are energy sources, esculin is hydrolysed by *Listeria* strains to glucose and esculetin, the latter compound forming a black complex with ferric ions. The competitive flora is inhibited by lithium chloride and by the antimicrobials of the selective supplement: ceftazidim, polymixin B, acriflavine. The fermentation of mannitol by contaminating bacteria that may grow causes phenol red to turn yellow.

PREPARATION

Suspend 35.4 g of powder in 500 ml of distilled or deionized water. Heat until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes. Cool to 45-50°C. Aseptically add 1 vial of Listeria Palcam Supplement (code 81026). Mix well. Dispense into Petri dishes.

TECHNIQUE

Streak a loopful of the suitable enriched broth, inoculated with the sample to analyze, onto the surface of the medium. Incubate at 36±1°C for 24-48 hours.

INTERPRETATION OF RESULTS

Listeria monocytogenes cultivates with grey-green colonies surrounded by a black zone (aesculin hydrolysis) with medium's turning to red for missed mannitol fermentation. Possible contaminants such as staphylococci and enterococci, ferment mannitol and cultivate with yellow colonies surrounded by a yellow zone. The suspected colonies must be submitted to Gram colouring, catalase test, mobility examination and identification biochemical tests (*Listeria* System 18R cod. 71640).

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 media at 2-8°C.

WARNING and PRECAUTIONS

The product is classifiable as hazardous under current legislation; it is recommended that the Safety Data Sheet be consulted on its 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.

REFERENCES

1. ISO 11290- 1/2 Microbiology of food and animal feeding stuffs- Horizontal method for the detection and enumeration of *Listeria monocytogenes*; Part 1 Detection method – Part 2: enumeration method
2. Normalisation Française, AFNOR (1993) V08-55.
3. Manuel suisse des denrées alimentaires, Chapitre 56, E21, juillet 2000,
4. Rapporto ISTISAN 96/35 Istituto Superiore di Sanità; ISSN 1123- 3117
5. Van Netten, P. et al. (1989) Int. J. Food Microbiol. 8, 299-316.



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PRODUCTION SPECIFICATIONS

NAME

LISTERIA PALCAM AGAR

PRESENTATION

Dehydrated culture medium.

STORAGE

10-30°C.

PACKAGING

Code	Content	Packaging
610168	500 g	500 g of powder in plastic bottle
620168	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM

7.2 ± 0.2

USE

The complete LISTERIA PALCAM AGAR, prepared by adding Listeria Palcam supplement to the medium base, is a selective and differential medium, formulated by Van Netten and other, and according to ISO 11290, for isolation and enumeration of *Listeria monocytogenes* from foods.

TECHNIQUE

Refer to technical sheet of the product.

APPEARANCE of the MEDIUM

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: pink.

Prepared medium

Appearance: slightly opalescent.

Color: red.

SHELF LIFE

4 years.

QUALITY CONTROL

- Control of general characteristics, label and print
- Sterility control
 - 7 days at 25 ± 1°C, in aerobiosis
 - 7 days at 36 ± 1°C, in aerobiosis

Microbiological control

Inoculum for productivity: 10-100 UFC/ml







Inoculum for selectivity: 10⁴-10⁵ UFC/ml

Inoculum for specificity: ≤ 10⁴ UFC/ml

Incubation conditions: 37 ± 1°C for 24-48 hours.

Microorganism	ATCC	Growth	Characteristics
<i>Listeria monocytogenes</i>	19111	good	Gray colonies/ black halo
<i>Listeria monocytogenes</i>	13932	good	Gray colonies/ black halo
<i>Escherichia coli</i>	25922	inhibited	
<i>Enterococcus faecalis</i>	29212	inhibited	
<i>Candida albicans</i>	10231	inhibited	

TABLE OF SYMBOLS

LOT Batch code	 Temperature limitation	 Manufacturer	 Contains sufficient for <n> tests	IVD <i>In vitro</i> Diagnostic Medical Device
REF Catalogue number	 Keep away from heat	 Use by	 Caution, consult accompanying documents	



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IODINE MKTT SOLUTION

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

DESCRIZIONE

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

CONTENUTO DELLE CONFEZIONI

Ciascuna confezione contiene:

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

COMPOSIZIONE

IODINE MKTT SOLUTION

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

PROCEDURA DI UTILIZZO

Aggiungere asepticamente 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
<i>Salmonella typhimurium</i>	ATCC 14028	Buona
<i>Escherichia coli</i>	ATCC 25922	Inibita
<i>Salmonella seftenberg</i>	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.

BIBLIOGRAFIA / BIBLIOGRAPHY

1. ISO 6785 Milk and milk products – Detection of *Salmonella* 1^aEd. 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	
IODINE MKTT SOLUTION	80009	10 provette / tubes

TABELLA DEI SIMBOLI / TABLE OF SYMBOLS

Codice del lotto Batch code	Dispositivo medico diagnostico <i>in vitro</i> <i>In Vitro</i> Diagnostic Medical Device	Fabbricante Manufacturer	Contenuto della confezione Kit content	Limiti di temperatura Temperature limitations	Non riutilizzare Do not reuse
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	

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
<i>Salmonella typhimurium</i>	ATCC 14028	Good
<i>Escherichia coli</i>	ATCC 25922	Inhibited
<i>Salmonella seftenberg</i>	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

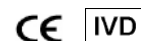
Disposal of waste must be carried out according to national and local regulations in force.



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Rev. 1 / 07.02.2012



Baird Parker Agar Base

Selective medium for detection and enumeration of coagulase-positive staphylococci in food and animal feed, according to ISO 6888.

DESCRIPTION

Baird Parker Agar Base is a selective medium used with supplements for the isolation and enumeration of *Staphylococcus aureus* from food, foodstuffs and water.

This medium complies with the specification given by ISO 6888 (all parts), FDA-BAM and APHA.

TYPICAL FORMULA

	(g/l)
Pancreatic Digest of Casein	10.0
Meat Extract	5.0
Yeast Extract	1.0
Sodium Pyruvate	10.0
L-Glycine	12.0
Lithium Chloride	5.0
Agar	17.0
Final pH 7.2 ± 0.2 at 25°C	

METHOD PRINCIPLE

Pancreatic 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. Sodium pyruvate and glycine are incorporated to stimulate the growth of even damaged *S. aureus* cells without destroying the selectivity. Lithium chloride and the high concentration of glycine inhibit accompanying microflora. Agar is the solidifying agent.

Supplementation with Egg yolk Tellurite Emulsion (ref. 80122, 80123) in addition to being an enrichment, aids in the identification process by demonstrating lecithinase activity (egg yolk reaction). Presence of potassium tellurite confers further selectivity and determines grey or black colouration of colonies.

If *Proteus* spp are suspected in the test sample, Sulfamethazine Supplement (ref. 81095) may be added to suppress growth and swarming.

For foodstuffs likely to be contaminated by staphylococci forming atypical colonies on Baird Parker Medium or by background flora which can obscure the colonies being sought, the RPF Supplement (ref. 81057) should be used: rabbit plasma, fibrinogen and trypsin inhibitor allow the confirmation of staphylococci on the basis of coagulase reaction.

PREPARATION

<u>Dehydrated medium</u>	Suspend 60 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.
<u>Medium in bottles</u>	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.
<u>Supplements</u>	Cool the medium to 45-50°C before adding supplements aseptically. Baird Parker Egg Yolk Tellurite Agar: add 5 ml of Egg yolk Tellurite Emulsion to 100 ml of base. If necessary, add 1 ml of reconstituted Sulfamethazine Supplement when <i>Proteus</i> spp are suspected. Baird Parker RPF Agar: add 10 ml of reconstituted RPF Supplement to 90 ml of base (if the 100 ml bottle is being used, first remove 10 ml of medium from the bottle). Mix well avoiding foam formation and under sterile conditions distribute into Petri dishes.

TEST PROCEDURE

Baird Parker Egg Yolk Tellurite Agar (ISO 6888-1/-3)

- For direct enumeration, spread 0.1 ml of sample, initial suspension or decimal dilutions, over the medium surface (use a suitable diluent such as Buffered Peptone Water, ref. 24099).
- For detection and enumeration by the MPN technique, inoculate by subculturing the selective enrichment in Giolitti Cantoni Broth (ref. 620100).

Baird Parker RPF Agar (ISO 6888-2)

Transfer 1 ml of test sample or its initial suspension to two sterile Petri dishes. Repeat the operation with 1 ml of the first decimal dilution and successive dilution. Into each Petri dish, immediately pour freshly prepared complete medium. Carefully mix the inoculum with the culture medium and leave to solidify.

Incubate at 37 ± 1°C for 24-48 hours.

INTERPRETING RESULTS

Baird Parker Egg Yolk Tellurite Agar

Take for enumeration only those plates containing a maximum of 300 typical and/or atypical colonies, from two successive dilutions (one of the plates shall contain at least 15 colonies):

- Typical colonies of *S. aureus* appear black or gray, shining and convex, surrounded by a zone of clearing of the medium. After incubation for at least 24 h, an opalescent ring immediately in contact with the colonies, may appear in this clear zone.

- Atypical colonies are identical in appearance but not surrounded by a clear zone. They can mainly be observed in dairy products.

Confirm typical and atypical colonies by the Coagulase Test (ref. 88030). The majority of other organisms are inhibited but some may grow sparsely, producing white to brown colonies with no clearing of the egg yolk.

Baird Parker RPF Agar

The medium allows the simultaneous enumeration and confirmation to be performed in a single operation. Coagulase-positive staphylococci colonies appear black or grey with a halo of precipitation, indicating coagulase activity.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, beige.

Prepared medium: opaque, yellow.

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 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.

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: 50-100 CFU.

Inoculum for selectivity: 10⁴-10⁶ CFU.

Inoculum for specificity: 10³-10⁴ CFU.

Incubation conditions: 37 ± 1°C for 24-48 hours.

QC Table.

Microorganism	Specification
<i>Staphylococcus aureus</i>	WDCM 00034 Good growth, black or grey colonies with halo
<i>Escherichia coli</i>	WDCM 00012 Total inhibition
<i>Staphylococcus saprophyticus</i>	WDCM 00159 Black or gray colonies without halo
<i>Staphylococcus epidermidis</i>	WDCM 00009 Black or gray colonies without halo

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 6888-3:2003. Microbiology of food and animal feeding stuffs. Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species). Part 3 : detection and MPN technique for low numbers.
3. ISO 6888-1:1999/Amd 1:2003. Inclusion of precision data.
4. ISO 6888-1:1999. Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species) – Part 1: Technique using Baird-Parker agar medium.
5. ISO 6888-2:1999. Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species) -- Part 2: Technique using rabbit plasma fibrinogen agar medium.
6. Microbiology of food and animal feeding stuffs -- Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species) -- Part 2: Technique using rabbit plasma fibrinogen agar medium
7. D.De Medici, L.Fenicia, L.Orefice and A.Stacchin. Rapporto ISTISAN 96/35. ISSN 1123-3117. Metodi di analisi per il controllo microbiologico degli alimenti.
8. Baird Parker , A.C. (1969) The use of Baird Parker's medium for the isolation and enumeration of *Staphylococcus aureus* in "Isolation methods for microbiologists" Shapton, D.A. & Gould ed. London: Academic Press.
9. Smith, B.A. & Baird Parker, A.C. (1964) - The use of sulphamezathine for inhibiting *Proteus* spp. on Baird- Parker's isolation medium for *Staphylococcus aureus*. J. Appl. Bact. 27:78-82.
10. Baird Parker , A.C. (1962) An improved diagnostic and selective medium for isolating coagulase-positive staphylococci. J. Appl. Bacteriol. 25:12-19.

PRESENTATION	Contents	Ref.
Baird Parker Agar Base	Bottles	6 x 100 ml bottles 420110
Baird Parker Agar Base	Dehydrated medium	500 g of powder 610004
Baird Parker Agar Base	Dehydrated medium	100 g of powder 620004

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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Egg Yolk Tellurite Emulsion

Supplement for detection of coagulase-positive staphylococci, according to ISO 6888.

DESCRIPTION

A sterile, stabilized emulsion of egg yolk containing potassium tellurite for use in Baird Barker Agar Base (ref. 610004, 620004). The complete medium is used for the isolation and enumeration of *Staphylococcus aureus* in food, in accordance with ISO 6888 (part 1 and 3).

COMPOSITION

Chicken egg yolks in an equal volume of saline solution (0.9% NaCl) with potassium tellurite (2 g/l).

METHOD PRINCIPLE

Egg yolk is broken down by staphylococci containing lecithinase to yield clear zones around the colonies. Potassium tellurite is reduced by coagulase-positive staphylococci causing blackening of colonies.

PROCEDURE FOR USE

Aseptically, add 50 ml to 1 litre of Baird Parker Agar Base sterilized in autoclave and cooled to 45-50°C. Final concentration of tellurite in medium is 0.01% w/v.

TECHNIQUE AND INTERPRETATION OF RESULTS

Refer to the technical sheet of the medium being prepared.

APPEARANCE

Yellowish opaque emulsion. May contain a precipitate that can be resuspended.

STORAGE

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

SHELF LIFE

1 year.

QUALITY CONTROL

Cultural response in Baird Parker Agar after 48 hours incubation at $37 \pm 1^\circ\text{C}$:

Microorganism	Specification	
<i>Staphylococcus aureus</i>	WDCM 00034	Good growth, black or grey colonies with clear halo
<i>Escherichia coli</i>	WDCM 00012	Total inhibition
<i>Staphylococcus saprophyticus</i>	WDCM 00159	Black or grey colonies without halo
<i>Staphylococcus epidermidis</i>	WDCM 00036	Black or grey colonies without halo

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 6888-3:2003. Microbiology of food and animal feeding stuffs. Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species). Part 3 : detection and MPN technique for low numbers.
3. ISO 6888-1:1999. Microbiology of food an animal feeding stuffs. Horizontal method for the enumeration of coagulase-positive staphylococci (*Staphylococcus aureus* and other species) - Part 1: Technique using Baird Parker Agar Medium.
4. Baird-Parker A.C. (1962) An improved diagnostic and selective medium for isolating coagulase-positive staphylococci. J. Appl. Bacteriol. 25:12-19.

PRESENTATION	Contents	Ref.
Egg Yolk Tellurite Emulsion	4 x 50 ml bottles	80122
Egg Yolk Tellurite Emulsion	6 x 100 ml bottles	80125

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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NOVOBIOCIN MKTT Supplement

Selective supplement for the detection of *Salmonella spp.*

DESCRIPTION

NOVOBIOCIN MKTT Supplement is a selective supplement for the detection of *Salmonella spp.*, used for enrichment of MULLER KAUFFMANN BROTH BASE cod. 610239 or 620239.

KIT CONTENTS

Each kit contains:

- 10 bottles of NOVOBIOCIN MKTT Supplement freeze-dried
- 1 Instruction sheet

PRINCIPLE OF THE METHOD

Novobiocin is an antibiotic effective against both Gram-negative and Gram-positive bacteria.

COMPOSITION

NOVOBIOCIN MKTT Supplement		
	Contents / bottle	Contents / l of medium
Novobiocin	20.0 mg	40.0 mg

PROCEDURE FOR USE

1. Reconstitute the contents of a bottle of NOVOBIOCIN MKTT Supplement aseptically with 5 ml of sterile distilled water. Shake until completely dissolved, avoiding foam formation.
2. Add the entire contents of a bottle (5 ml) aseptically to 500 ml of MULLER KAUFFMANN BROTH BASE cod. 610239 or 620239, boiled, cooled to 45-50°C and added with IODINE MKTT SOLUTION.
3. Mix with care.
4. Distribute into sterile tubes.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

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

QUALITY CONTROL

1. Control of the appearance: a white freeze-dried product.
2. Microbiological control.

Prepare the tubes using as base MULLER KAUFFMANN BROTH BASE cod. 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

Microbiological control

Control strains		Growth
<i>Salmonella typhimurium</i>	ATCC 14028	Good
<i>Escherichia coli</i>	ATCC 25922	Inhibited
<i>Salmonella seftenberg</i>	ATCC 10384	Good

PRECAUTIONS

The product NOVOBIOCIN MKTT Supplement is classifiable as hazardous under current legislation; it is recommended that the Safety Data Sheet be consulted on its use.

NOVOBIOCIN MKTT Supplement is a selective supplement to be used 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 NOVOBIOCIN MKTT Supplement at 2-8°C in its original packaging. Keep away from sources of heat and avoid excessive changes of temperature. In such conditions NOVOBIOCIN MKTT Supplement maintains its validity until the expiry date indicated on the label. Eliminate without using if there are signs of deterioration.

REFERENCES






- DeSmedt, Bolderdijk, Rappold and Lautenschlaeger. 1986. J. Food Prot. 49:510.
- Dusch and Altwegg. 1995. J. Clin. Microbiol. 33:802.
- Aspinall, Hindle and Hutchinson. 1992. Eur. J. Clin. Microbiol. Infect. Dis. 11:936.

PRESENTATION

Product	REF	Σ
NOVOBIOCIN MKTT Supplement	81073	10 bottles

One bottle is sufficient to prepare 500 ml of medium

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	 Caution, consult accompanying documents	



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Rev.0/ 07.07.2009

Neutralizing Fluid E.P.

Liquid medium for neutralizing antimicrobials, according to the European Pharmacopoeia.

TYPICAL FORMULA (g/l)

Peptone	1.0
Histidine Hydrochloride	1.0
Lecithin	3.0
Potassium Dihydrogen Phosphate	3.6
Disodium Hydrogen Phosphate Dihydrate	7.2
Sodium Chloride	4.3
Final pH 7.0 ± 0.2 at 25°C	

DESCRIPTION

Neutralizing Fluid E.P. is a liquid medium used for neutralizing the activity of antimicrobial agents.

The medium is formulated according to the European Pharmacopoeia specification for the microbiological examination of non-sterile products.

PRINCIPLE

Peptone supplies amino acids, nitrogen, carbon, minerals, vitamins and other nutrients which support the growth of microorganism. Histidine inactivates aldehydes. Lecithin neutralizes quaternary ammonium compounds. Phosphates serve as buffering agents. Sodium chloride maintains the osmotic balance of the medium.

Supplementation with polysorbate (Tween) 80 is effective against phenolic compounds and mercurial derivatives.

PREPARATION

Suspend 20.1 g of powder in 1 liter of deionized or distilled water containing 30 g of polysorbate 80 (ref. 80031). Bring to boil and shake until completely dissolved. Pour into suitable containers. Sterilize at 121°C for 15 minutes.

TECHNIQUE

Neutralizing Fluid E.P. may be incorporated into diluents or media, such as Buffered Peptone Water EP, USP (ref. 400040), preferably before sterilization.

INTERPRETATION OF RESULTS

Refer to technical sheet of the medium being used.

STORAGE AND TRANSPORT CONDITIONS

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

- European Pharmacopoeia (2007) Directorate for the Quality of Medicine of the Council of Europe. 2.6.13. Microbiological examination of non-sterile products: test for specific micro-organisms. Council of Europe Strasbourg.



PRODUCT SPECIFICATIONS

NAME

Neutralizing Fluid E.P.

PRESENTATION

Dehydrated medium

STORAGE

10-30°C

PACKAGING

Ref.	Content	Packaging
610330	500 g	500 g of powder in plastic bottle
620330	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM

7.0 ± 0.2

USE

Neutralizing Fluid E.P. is a liquid medium formulated according to the European Pharmacopoeia specification for the microbiological examination of non-sterile products

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: opalescent

Colour: light amber

SHELF LIFE










4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Cultural response observed when subcultured on Tryptic Soy Agar after an incubation at 30°C for 3 hours in Neutralizing Fluid E.P.
Inoculum for productivity: 50-100 CFU
Incubation Conditions: 18-24 h at 32.5 ± 2.5°C, in aerobiosis

Microorganism		Growth
<i>Staphylococcus aureus</i>	ATCC® 6538	Good
<i>Escherichia coli</i>	ATCC® 8739	Good
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Good
<i>Bacillus subtilis</i>	ATCC® 6633	Good
<i>Salmonella typhimurium</i>	ATCC® 14028	Good
<i>Candida albicans</i>	ATCC® 10231	Good
<i>Aspergillus niger</i>	ATCC® 16404	Good

TABLE OF SYMBOLS

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



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Rapid test for the detection of bacterial β -galactosidase.

DESCRIPTION

O.N.P.G. TEST is a rapid test for the detection of bacterial β -galactosidase.

CONTENT OF THE PACKAGES

Each package contains 5 cartridges with 50 discs in a thermo-sealed container, a desiccant and an instruction sheet.

ITEMS NECESSARY BUT NOT INCLUDED IN THE PACKAGES

Physiological solution, sterile disposable tubes, sundry microbiology laboratory materials.

PRINCIPLE OF THE METHOD

The ortho-nitrophenyl-galactopyranoside (O.N.P.G.), contained in the medium, is hydrolyzed by microorganisms able to produce the enzyme β -galactosidase with the formation of a yellow colour orthonitrophenolic compound. Some *Enterobacteriaceae* as for example *E.coli*, *Klebsiella* spp., *Enterobacter* spp. produce both β -galactosidase and permease and so they are lactose fermenter, others as *Citrobacter* spp. and *Arizona* spp. produce only β -galactosidase and so they slowly ferment lactose, others as *Salmonella* spp., *Shigella* spp., *Proteus* spp., *Providencia* spp. and *Morganella* spp. do not produce β -galactosidase therefore they are not lactose fermenter. The presence of β -galactosidase enzyme is important for the taxonomy of *Enterobacteriaceae*.

COMPOSITION

Each disc is impregnated with ortho-nitrophenyl-galactopyranoside (O.N.P.G.), which is a specific substratum for the β -galactosidase.

TEST PROCEDURE

1. Take the package from the fridge, take a cartridge and leave it for a few minutes on the bench until it has reached room temperature.
2. Insert a **O.N.P.G. TEST** disc into a sterile tube.
3. Add 0.2 mL of physiological solution to the tube.
4. With a sterile loop suspend in the culture medium of the tube a well isolated bacterial colony of 24 hours incubation chosen from a selective or not selective medium containing lactose.
5. Take a second tube, insert a **O.N.P.G. TEST** disc and add 0.2 mL of physiological solution. Do not to inoculate this tube and use it as negative control.
6. Put the top to the tubes and incubate them at 36 ± 1 °C for a minimum of 4 hours till a maximum of 24 hours.

INTERPRETATION OF THE RESULTS

Interpret the results according to the table 1:

Table 1

Colour of the medium	O.N.P.G TEST
Yellow	Positive
Colourless	Negative

QUALITY CONTROL FOR THE USER

Appearance: white discs.

Microbiological control:

Each batch of **O.N.P.G. TEST** is subjected to the quality control, using one bacterial culture of *Citrobacter freundii* ATCC® 8090 as positive control and one of *Proteus mirabilis* ATCC® 25923 as negative control.

PRECAUTIONS

The product, **O.N.P.G. TEST**, is not classified as hazardous under current legislation, neither does it contain noxious substances in concentrations $\geq 1\%$. **O.N.P.G. TEST** is a disposable device to be used only for diagnostic use *in vitro*. 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 **O.N.P.G. TEST** at 2-8 °C in its original package. In such conditions the product is valid until the expiry date shown on the label. Do not use them beyond that date. Dispose of them if they show signs of deterioration.

DISPOSAL OF USED MATERIAL

After the use, **O.N.P.G. TEST** and the material that has come into contact with the sample must be decontaminated and disposed of in accordance with the laboratory procedures for the decontamination and disposal of potentially infected material.







REFERENCES

1. Edwin H.Lenette: Manual of Clinical Microbiology (1995).
2. BLAZEVIC, D.J., and EDERER, G.M.: Principles of biochemical tests in diagnostic microbiology. 63-67. New York, John Wiley & Sons, 1975.
3. S.P. Lapage and M.S. Jayaraman. Beta-galactosidase and lactose fermentation in the identification of enterobacteria including salmonellae.J.Clin.Path. (1964), 17,117.
4. J.Lederberg, The β -galactosidase of *escherichia coli*, strain K-12., *J. Bact.*, 60, 381 (1950).

PRESENTATION

Product	Ref.	Tests
O.N.P.G. TEST	88105	250 discs

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



Peptone Bacteriological

Peptone obtained by enzymatic hydrolysis of animal tissue

PHYSIC-CHEMICAL CHARACTERISTIC

Solubility in water at 5%	Complete
Loss on drying	≤ 6.0%
Total nitrogen	≤ 12.5%
α-amino nitrogen AN	3-4.5%
Ash	5%

DESCRIPTION

Peptone Bacteriological is an enzymatic hydrolysate of meat that supplies a limpid, colorless and very stable watery solution. It is used in the preparation of culture media as a nitrogen source readily available for bacterial growth. It is a general use very nutritive peptone, with neutral pH. Peptone Bacteriological 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 signs of deterioration or contamination are evident.

DISPOSAL OF WASTE

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

PACKAGE

Code	Content	Packaging
611701	500 g	500 g of product in plastic bottle
621701	100 g	100 g of product in plastic bottle
6117015	5000 g	5000 g of product in plastic bottle

pH of THE MEDIUM

7.0 ± 0.5 (5% solution)

SHELF LIFE

4 years









QUALITY CONTROL

Dehydrated powder

Appearance: free-flowing, homogeneous.

Colour: white.

TABLE OF SYMBOLS

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

PHENYLALANINE AGAR

Medium for enterobacteria differentiation.

TYPICAL FORMULA (g/l)

Yeast Extract	3.0
Disodium Phosphate	1.0
Sodium Chloride	5.0
DL-Phenylalanine	2.0
Agar	15.0

Final pH = 7.3 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 26.0 g of powder in 1 liter of distilled or deionized water. Heat until completely dissolved. Distribute into final tubes. Sterilize in autoclave at 121°C for 15 minutes. Allow the medium to solidify in a slanted position.

DESCRIPTION

PHENYLALANINE AGAR is a medium recommended for the differentiation of members of the *Proteus* and *Providencia* groups from other enterobacteria.

TECHNIQUE

Inoculate the slant with test organisms and incubate at 36 ± 1 °C for 18-24 hours. Add 3-5 drops of Ferric Chloride 10% (code 80272) and 3-5 drops of a 0.1 N HCl solution to a 24 hours culture. Rotate the tubes to wet and loosen the growth.

A positive test is indicated by the formation of a characteristic green color. *Proteus* and *Providencia* groups give a positive reaction in 1-5 minutes. Other members of *Enterobacteriaceae* give negative reactions.

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: light tan.

Prepared medium

Appearance: slightly opalescent without precipitate.

Color: light amber.

Incubation conditions: 36 ± 1 °C for 18-24 hours.

Microorganism	ATCC	Growth	Reaction
<i>Escherichia coli</i>	25922	good	-
<i>Enterobacter aerogenes</i>	13048	good	-
<i>Proteus mirabilis</i>	25933	good	+
<i>Proteus vulgaris</i>	13315	good	+

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 tubes at 2-8 °C.








REFERENCES

- Ann. Inst. Pasteur. (1954) **87**: 375-386.
- Pub. Hlth Lab. (1957) **15**: 153.

PRESENTATION

Product	REF	Σ
PHENYLALANINE AGAR (19.2 l)	610039	500 g
PHENYLALANINE AGAR (3.8 l)	620039	100 g

TABLE OF SYMBOLS

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



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PSEUDOMONAS (CETRIMIDE) AGAR

Selective medium for *Pseudomonas aeruginosa* isolation, according to European Pharmacopoeia.

TYPICAL FORMULA (g/l)

Pancreatic digest of gelatin	20.0
Magnesium Chloride	1.4
Dipotassium Sulphate	10.0
Cetrimide	0.3
Agar	15.0

Final pH = 7.2 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 46.7 g of powder in 990 ml of distilled or deionized water.
Add 10 ml of Glycerol supplement (code 80021).
Heat until completely dissolved.
Sterilize in autoclave at 121 °C for 15 minutes.
Dispense in petri dishes.

DESCRIPTION

PSEUDOMONAS (CETRIMIDE) AGAR is recommended by the European Pharmacopoeia for the isolation and identification of *Pseudomonas* strains.

The medium promotes the production of fluorescein (pyoverdin), a green-yellow fluorescent pigment that oxidizes to yellow. It is water-soluble and, unlike pyocyanin (blue-green pigment), is not soluble in chloroform. The pigment diffuses throughout the medium and the fluorescent yellow-green color is observed.

Gelatin pancreatic digest provide the nutrient growth factors: nitrogen, vitamins, minerals and amino acids. Glycerol is the carbon source. Magnesium chloride and dipotassium sulfate enhance the production of pyocyanin, pyoverdin and fluorescein. Cetrimide is the selective agent as it inhibits the growth of the accompanying microbial flora.

TECHNIQUE

Inoculate the medium using the streak plate method to obtain isolated colonies.
Incubate for 18-48 hours at 36 ± 1 °C.

Examine for the presence of a good growth and pigment production.

Pseudomonas aeruginosa colonies will be green to blue-green with pigment that diffuses into the medium.

The identification of *Pseudomonas aeruginosa* is completed by performing oxidase test and the differential tests for the production of fluorescein and pyocyanin on, respectively, Pseudomonas Agar F (code 610309) and Pseudomonas Agar P (code 610310).

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: very light beige.

Prepared medium

Appearance: slightly opalescent, firm.

Color: light amber.

Incubation conditions: 36 ± 1 °C for 18-48 hours.

Microorganism	ATCC	Growth	Appearance
<i>Pseudomonas aeruginosa</i>	9027	good	green to blue-green
<i>Pseudomonas aeruginosa</i>	27853	good	green to blue-green
<i>Escherichia coli</i>	25922	poor	



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PERFORMANCE AND LIMITATIONS

The quaternary ammonium compound "Cetrimide" inhibits the growth of Gram positive and Gram negative bacteria, except *Pseudomonas spp.*

The particular formulation stimulates production of fluorescein and pyocyanin, though some strains of *Pseudomonas aeruginosa* may fail to produce pyocyanin.

Non-*Pseudomonas aeruginosa* strains that are not completely inhibited on this medium may be encountered and must be differentiated from *Pseudomonas aeruginosa*.

Consult appropriate references.

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. King, E.O., and D.E. Raney (1954). Two simple media for the demonstration of pyocyanin and fluorescein. J. Lab. Clin. **44**, 301.
2. Gilligan, P.H. (1995). *Pseudomonas* and *Burkholderia*, p.509-519. In Manual of Clinical Microbiology, 6th ed. American Society for microbiology, Washington, D.C.
3. European Pharmacopoeia, 3rd ed.2001. Supplement.

PRESENTATION








Product	REF	
PSEUDOMONAS (CETRIMIDE) AGAR (10.7 l)	610041	500 g
PSEUDOMONAS (CETRIMIDE) AGAR (2.1 l)	620041	100 g
PSEUDOMONAS (CETRIMIDE) AGAR (107.0 l)	6100415	5 Kg

TABLE OF SYMBOLS

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



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Phenol Red Broth Base

Liquid medium for carbohydrate fermentation studies.

DESCRIPTION

Phenol Red Broth Base is a liquid medium used with an appropriate carbohydrate for the differentiation of microorganisms on the basis of fermentation reactions.

TYPICAL FORMULA

	(g/l)
Casein Peptone	10.0
Meat Extract	3.0
Sodium Chloride	5.0
Phenol Red	0.018
Final pH 7.4 ± 0.2 at 25°C	

METHOD PRINCIPLE

Casein peptone and meat extract provide nitrogen, vitamins, minerals and amino acids essential for growth. Sodium chloride maintains the osmotic balance of the medium. Phenol red is the pH indicator. Various fermentable substances may be added in any desired concentration. The concentration of carbohydrate generally employed for testing fermentation reactions of bacteria is 0.5 to 1%.

PREPARATION

Dehydrated medium

Suspend 18 g of the powder in 1 liter of distilled or deionized water. Heat until completely dissolved. If desired, add 5 to 10 g of the specified carbohydrate(*). Mix well. Dispense into test tubes. If necessary, insert Durham tubes. Sterilize in autoclave at 121°C for 15 minutes.

*Alternatively, filtered sterilized carbohydrate solutions may be added to the cooled sterilized broth.

Medium in tubes

Under aseptic conditions, add a specific carbohydrate (final concentration 5-10 g/l) as filter-sterilized solution. If necessary, insert Durham tubes.

NOTE: Without the addition of carbohydrates, the medium can be used as negative control for fermentation studies.

TEST PROCEDURE

Inoculate tubes with isolated colonies. Tubes without carbohydrates added should also be inoculated to serve as growth controls. Incubate at 35 ± 2°C for 18-48 h with loose caps.

INTERPRETING RESULTS

Examine tubes for growth, acid production, and gas production (if Durham tube is used).

A yellow color in the medium indicates a positive reaction for carbohydrate fermentation. If a Durham tube is used, bubbles in the inverted tube is an indication of gas production. The presence of a single bubble is recorded as positive for the production of gas.

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, pinkish-beige.

Prepared medium: clear, bright red to red-orange.

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 year.

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.

Inoculum for productivity: ≤ 100 CFU.

Incubation conditions: 18-48 h / $35 \pm 2^\circ\text{C}$.

QC Table.

Microorganism		Specification with Glucose		
		Growth	Acid reaction	Gas formation
<i>Escherichia coli</i>	ATCC® 25922	Good	+ (color change to yellow)	+
<i>Shigella flexneri</i>	ATCC® 12022	Good	+ (color change to yellow)	-
<i>Pseudomonas aeruginosa</i>	ATCC® 27853	Good	- (red medium)	-

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 by properly trained operators.

DISPOSAL OF WASTE









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

BIBLIOGRAPHY

1. Isenberg, H.D. (ed.). 2004. Clinical microbiology procedures handbook, vol. 1, 2 and 3, 2nd ed. American Society for Microbiology, Washington, D.C.
2. Murray, P.R., E.J. Baron, J.H. Jorgensen, M.A. Tenover, and R.H. Tenover (ed.). 2003. Manual of clinical microbiology, 8th ed. American Society for Microbiology, Washington, D.C.
3. Forbes, B.A., D.F. Sahm, and A.S. Weissfeld. 2002. Bailey & Scott's diagnostic microbiology, 11th ed. Mosby, Inc., St. Louis.
4. MacFaddin, J.F. 2000. Biochemical tests for identification of medical bacteria, 3rd ed., Lippincott Williams & Wilkins, Baltimore.
5. Holt, J.G., N.R. Krieg, P.H.A. Sneath, J.T. Staley, and S.T. Williams (ed.). 1994. Bergey's Manual™ of determinative bacteriology, 9th ed. Williams & Wilkins, Baltimore.
6. Ewing, W.H. 1986. Edwards and Ewing's identification of *Enterobacteriaceae*. 4th ed. Elsevier Science Publishing Co., New York.
7. Vera, H.D. 1950. Relation of peptones and other culture media ingredients to accuracy of fermentation tests. *Am.J.PublicHealth*, 40:1267-1272.

PRESENTATION	Category	Packaging	Ref.
Phenol Red Broth	Tubes	20 x 10 ml	24446
Phenol Red Broth Base	Dehydrated media	500 g	610174
Phenol Red Broth Base	Dehydrated media	100 g	620174

TABLE OF SYMBOLS

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



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Rappaport Vassiliadis Soy (RVS) Broth

Instructions For Use
ENGLISH

Selective liquid medium for detection of *Salmonella* according to ISO 6579-1.

DESCRIPTION

Rappaport Vassiliadis Soy (RVS) Broth is a culture medium used for the selective enrichment of *Salmonella* spp. from food, animal feed, environmental and clinical samples.

This medium conforms to the requirements of ISO 6579-1.

TYPICAL FORMULA*

	(g/litre)
Enzymatic Digest of Soya	4.5
Sodium Chloride	7.2
Potassium Dihydrogen Phosphate (KH ₂ PO ₄)	1.26
Dipotassium Hydrogen Phosphate (K ₂ HPO ₄)	0.18
Magnesium Chloride Anhydrous	13.4
Malachite Green	0.036

Final pH 5.2 ± 0.2 at 25°C

*Formula may be adjusted and/or supplemented as required to meet performance specifications.

METHOD PRINCIPLE

Enzymatic digest of soya provides amino acids, nitrogen, carbon, minerals and vitamins for organisms growth. Sodium chloride maintains the osmotic balance of the medium. Potassium phosphates act as a buffer. Magnesium chloride and malachite green are the selective agents. The low pH helps inhibit non-target organisms.

PREPARATION

Dehydrated medium Suspend 26.6 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into final containers. Sterilize in autoclave at 115°C for 15 minutes.

TEST PROCEDURE

Following the method described in the ISO 6579-1, transfer 0.1 ml of the culture obtained in the pre-enrichment (Buffered Peptone Water, ref. 24099) to a tube containing 10 ml of the RVS Broth.

Incubate at 41.5 ± 1°C for 24 ± 3 hours.

Use the culture obtained to inoculate the selective solid media, i.e. XLD agar (ref. 10056) and a second isolation agar.

For more information, see the ISO document.

Notes:

Before use, allow RVS broth to equilibrate at room temperature if it was stored at a lower temperature.

For some products, like dried milk products and cheese, it may be necessary to incubate the selective enrichment medium for an additional 24 h.

After incubation, the selective enrichment can be stored refrigerated at 5 ± 3°C for up to 72 h.

INTERPRETING RESULTS

Turbidity in the RVS broth indicates microbial growth.

Refer to the technical sheets of the solid media.

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: 3 years.

Medium in tubes: 2 years.

QUALITY CONTROL

Appearance of Dehydrated Medium: Free-flowing, homogeneous, green.

Appearance of Prepared Medium: Clear, blue.

Expected Cultural Response:

Control strains	WDCM	Inoculum	Incubation	Criteria
<i>Salmonella</i> Typhimurium + <i>Escherichia coli</i> + <i>Pseudomonas aeruginosa</i>	00031 00012 or 00013 00025	≤100 CFU	24 ± 3 h / 41.5 ± 1°C	>10 characteristic colonies on XLD agar or other medium of choice
<i>Salmonella</i> Enteritidis + <i>Escherichia coli</i> + <i>Pseudomonas aeruginosa</i>	00030 00012 or 00013 00025			
<i>Escherichia coli</i>	00012 or 00013	>10 ³ CFU		Partial inhibition ≤100 colonies on TSA
<i>Enterococcus faecalis</i>	00009 or 00087			<10 colonies on TSA

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

WARNING AND PRECAUTIONS

For *in vitro* diagnostic use. 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 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.
Rappaport Vassiliadis Soy (RVS) Broth	Tube	20 x 10 ml	24400
Rappaport Vassiliadis Soy (RVS) Broth	Tube	100 x 10 ml	26400
Rappaport Vassiliadis Soy (RVS) Broth	Bottle	6 x 100 ml	402550 •
Rappaport Vassiliadis Soy (RVS) Broth	Dehydrated medium	500 g	610175
Rappaport Vassiliadis Soy (RVS) Broth	Dehydrated medium	100 g	620175

• Not CE-marked

This document is available from the online Support Center:

liofilchem.com/ifu-sds



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

<u>Dehydrated medium</u>	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.
<u>Medium in bottles</u>	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:

- 10¹ CFU: maximum acceptable count = 20;
- 10² CFU: maximum acceptable count = 200;
- 10³ 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
<i>Candida albicans</i>	WDCM 00054	Good
<i>Aspergillus brasiliensis</i>	WDCM 00053	Good
<i>Saccharomyces cerevisiae</i>	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

- EN ISO 11133:2014+Amd1:2018. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
- European Pharmacopoeia 6.5 (2009) 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms.
- United States Pharmacopoeia 32 NF 27 (2009) <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
- Japanese Pharmacopoeia 4.05 (2008) Microbiological examination of non-sterile products: Test for specified microorganisms.
- 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 f
Sabouraud Dextrose Agar	90 mm plates (triple-wrapped and gamma-irradiated, 30 ml filling volume)	20 plates	10114S f
Sabouraud Dextrose Agar	60 mm plates	20 plates	163402 f
Sabouraud Dextrose Agar	60 mm plates	450 plates	173402 f
Sabouraud Dextrose Agar	55 mm contact plates	20 plates	15327 f
Sabouraud Dextrose Agar	55 mm contact plates irradiated	20 plates	15327S f
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

f: Not CE Marked

SLANETZ BARTLEY AGAR + TTC

Selective medium for fecal streptococci enumeration and isolation, according to the formulation reported by ISO 7899-2:2000.

TYPICAL FORMULA (g/l)

Tryptose	20.0
Glucose	2.0
Yeast Extract	5.0
Dipotassium Hydrogen Phosphate	4.0
Sodium Azide	0.4
Triphenyl Tetrazolium Chloride	0.1
Agar	13.0
Final pH 7.2 ± 0.2	

DESCRIPTION

SLANETZ BARTLEY AGAR + TTC is a selective medium for fecal streptococci enumeration and isolation in water and foods by membrane filtration or pour plate technique prepared according to the formulation reported by ISO 7899-2:2000.

PRINCIPLE

Tryptose is a peptone obtained by the enzymatic hydrolysis of a mix containing meat, yeast and casein. It is utilized for the growth and isolation of fastidious microorganisms. Glucose is a source of energy. Yeast extract is a source of aminoacids and vitamins of group B. Dipotassium hydrogen phosphate allows to maintain the osmotic balance of the medium. Sodium azide inhibits the growth of Gram-negative and staphylococci. TTC is a redox indicator and it is colorless in the oxidized form and is reduced in the insoluble red triphenyl formazan. Agar is the solidifying agent.

PREPARATION

Suspend 44.5 g in 1 litre of distilled or deionized water. Heat until completely dissolved. Autoclave at 98°C for 2 minutes. Cool to 45-50°C. Mix well, dispense into Petri dishes and allow to solidify.

TECHNIQUE

Inoculate the plates by streaking the sample onto the agar surface. Incubate at 36±1 for 18-24 hours.

INTERPRETATION of RESULTS

Observe the colonies on the agar surface: all the colonies which cultivate with the typical red or reddish-brown color can be considered enterococci.

STORAGE

10-30°C away from light, until the expiry date on the label or until signs of deterioration or contamination are evident.

WARNING and PRECAUTIONS

The product is not classified as hazardous by current legislation and does not contain harmful substances in concentrations of ≥1%. 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.

REFERENCES

1. Burkwal, M.K., and P.A. Hartman. (1964). *App. Microbiol.* 12,18.
2. Slanetz, L.W., and C.H. Bartley (1957). *J. Bact.*, 74,591.
3. ISO 7899-2: 2000 Recherche et dénombrement des streptocoques fécaux. Partie 2: methode par filtration sur membrane.



PRODUCT SPECIFICATIONS

NAME

SLANETZ BARTLEY AGAR + TTC

PRESENTATION

Dehydrated culture medium.

STORAGE

10-30°C

PACKAGING

Code	Content	Packaging
610147	500 g	500 g of powder in plastic bottle
620147	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM

7.2 ± 0.2

USE

SLANETZ BARTLEY AGAR + TTC is a selective medium for fecal streptococci enumeration and isolation in water and foods by membrane filtration or pour plate technique prepared according to the formulation reported by ISO 7899-2:2000.

TECHNIQUE

Refer to technical sheet of the product.

APPEARANCE of the MEDIUM

Dehydrated medium

Appearance: free-flowing, homogeneous.

Colour: light beige

Prepared medium

Appearance: slightly opalescent

Colour: light to medium amber

SHELF LIFE








4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
 Inoculum for productivity: 10-100 UFC/ml
 Inoculum for selectivity: 10⁴-10⁵ UFC/ml.
 Inoculum for specificity: ≤ 10⁴ UFC/ml
 Incubation conditions: 18-24 h at 36 ± 1°C, in aerobiosis

Microorganism		Growth	Characteristics
<i>Enterococcus faecalis</i>	ATCC 19433	Good	Red colonies
<i>Enterococcus faecalis</i>	ATCC 29212	Good	Red colonies
<i>Streptococcus pyogenes</i>	ATCC 19615	Inhibited	
<i>Escherichia coli</i>	ATCC 25922	Inhibited	

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



S.S. AGAR (MODIFIED)

Selective medium for the isolation of *Salmonella* spp. and *Shigella* spp.

TYPICAL FORMULA	(g/l)
Peptone	5.5
Meat Extract	5.0
Lactose	10.0
Sodium Tiosulfate	8.5
Yeast Extract	5.0
Sodium Citrate	1.0
Bile Salts N.3	1.5
Ferric Ammonium Citrate	1.5
Brilliant Green	0.33 mg
Neutral Red	0.025
Agar	14.0
Final pH 7.0 ± 0.2	

DESCRIPTION

S.S. AGAR (MODIFIED) is a highly selective medium for the isolation of *Salmonella* spp. and some species of *Shigella* from clinical specimens and food.

PRINCIPLE

Gram-positive microorganisms and coliforms are inhibited by selective components: brilliant green, bile salts n.3, sodium tiosulfate and citrate. The differentiations of microorganisms is obtained through the introduction of lactose in the medium. Lactose fermented bacteria cause acidification, thus formation of red colonies for the presence of neutral red. Not-fermented microorganisms form instead colourless colonies. Sodium tiosulfate in combination with iron acts as indicator for sulphur production causing the blackening of the colony center.

PREPARATION

Suspend 52.0 g of the powder in 1 litre of distilled or deionized water. Mix well. Heat to boil shaking frequently until dissolved completely. DO NOT AUTOCLAVE. Cool to 45-50°C. In aseptic conditions dispense in Petri dishes and let solidify the medium with the lids of the plates partially removed.

TECHNIQUE

Inoculate the plate streaking the sample onto the agar surface to isolate pure colonies from samples containing a mixed flora. Incubate at 36±1°C for 18-24 hours.

INTERPRETATION OF RESULTS

Salmonella spp. and other lactose not-fermented microorganisms can produce opaque, translucent or transparent colonies, with or without black center. *Shigella* colonies are colourless. The few lactose fermented microorganisms, that are able to growth on the medium, show reddish mucoid colonies.

STORAGE

10-30°C away from light, until the expiry date on the label. Eliminate if signs 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. The product is designed for *in vitro* diagnostic use only and must be used by properly trained operators.

DISPOSAL OF WASTE

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

REFERENCES

1. Gray L.D. (1995). *Escherichia, Salmonella, Shigella and Yersinia*, p. 450-456. In *Manual of clinical microbiology*, 6th ed. American society of microbiology.
2. Leifson E. (1935). *J. Pathol. Bacteriol.* 40: 581.
3. Rose, H.M., and M.H. Kolodny (1942). *J. Lab. Clin. Med.* 27: 1081-1083.



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PRODUCT SPECIFICATIONS

NAME

S.S. AGAR (MODIFIED)

PRESENTATION

Dehydrated medium

STORAGE

10-30°C

PACKAGING

Ref.	Content	Packaging
610042	500 g	500 g of powder in plastic bottle
620042	100 g	100 g of powder in plastic bottle
6100425	5 kg	5 kg of powder in plastic container

pH OF THE MEDIUM

7.0 ± 0.2

USE

S.S. AGAR (MODIFIED) is a highly selective medium for the isolation of *Salmonella* spp. and some species of *Shigella* from clinical specimens and foods

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Dehydrated medium

Appearance: free-flowing, homogeneous

Colour: light-pink

Prepared medium

Appearance: opalescent

Colour: purple

SHELF LIFE









4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Inoculum for productivity: 10-100 UFC/ml
Inoculum for selectivity: 10⁴-10⁵ UFC/ml
Inoculum for specificity: ≤10⁴ UFC/ml
Incubation Conditions: 18-24 h at 35 ± 2°C, in aerobiosis

Microorganism		Growth	Features
<i>Shigella flexneri</i>	ATCC® 12022	Good	Colourless colonies
<i>Salmonella typhimurium</i>	ATCC® 14028	Good	Colourless colonies with or without black center
<i>Enterococcus faecalis</i>	ATCC® 29212	Inhibited	---
<i>Staphylococcus aureus</i>	ATCC® 25923	Inhibited	---
<i>Escherichia coli</i>	ATCC® 25922	Partially Inhibited	Pink or red colonies

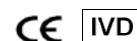
TABLE OF SYMBOLS

 LOT	Batch code	 IVD	<i>In vitro</i> Diagnostic Medical Device		Manufacturer		Use by
 REF	Catalogue number		Temperature limitation		Contains sufficient for <n> tests		Caution, consult instructions for use



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Enterosystem 24R

System for the identification of Gram-negative, oxidase negative enterobacteria.

Ref. 71619 - 79619

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Enterosystem 24R

System for the identification of Gram-negative, oxidase negative enterobacteria.

DESCRIPTION

Enterosystem 24R is a 24-well system containing desiccated biochemical substrates for the identification of Gram-negative bacteria that belong to the family of Enterobacteriaceae. The system is inoculated with the suspension of the organism to be examined and incubated in thermostat. The wells are examined for color changes and the resulting pattern of positive and negative reactions determines the numerical profile used for identification. The complete list of those organisms that is possible to identify with this system is provided in the Identification Table at the end of this document.

CONTENT OF THE PACKAGE

Ref. 71619	Ref. 79619
<ul style="list-style-type: none"> • 20 Enterosystem 24R • 20 Vials of Physiological Solution (7.0 mL) • 1 Cartridge of Xylose Disc (20 discs) • 1 Cartridge of Arabinose Disc (20 discs) • Instructions sheet and Data chart 	<ul style="list-style-type: none"> • 4 Enterosystem 24R • 4 Vials of Physiological Solution (7.0 mL) • 1 Cartridge of Xylose Disc (20 discs) • 1 Cartridge of Arabinose Disc (20 discs) • Instructions sheet and Data chart

ITEMS NECESSARY BUT NOT INCLUDED IN THE PACKAGE

- Enterosystem 18R Reagent (ref. 80252): Vaseline Oil, Indole Test Reagent, VP Test Reagents
- Gram Color Kit (ref. 80293)
- Oxidase Test Stick (ref. 88029)
- McFarland 0.5 Barium Sulphate Standard (ref. 80400)
- Identification Software online (free-access)

PRINCIPLE OF THE METHOD

Enterosystem 24R allows the identification of Gram-negative, oxidase negative enterobacteria of clinical significance. 24 different tests are carried out, each in every single well of the system. These wells are inoculated with a bacterial suspension that reconstitutes the dehydrated media contained in. The reactions occurring in the wells during incubation produce color changes which are read according to the Interpretive Table. The organism numerical profile is determined and the identification is obtained by using the Identification Software on Liofilchem website.

CONFIGURATION

Well	Test	Well	Test
1-ONPG	Hydrolysis of ONPG (Ortho-nitrophenyl- β -galactoside)	13-MAN	Utilization of mannitol
2-LDC □	Decarboxylation of lysine	14-INO	Utilization of inositol
3-ODC □	Decarboxylation of ornithine	15-SOR	Utilization of sorbitol
4-ADC □	Decarboxylation of arginine	16-SAC	Utilization of saccharose
5-PD	Deamination of phenylalanine	17-ARA	Utilization of arabinose
6-CIT	Utilization of citrate	18-RAF	Utilization of raffinose
7-UR □	Hydrolysis of urea	19-RAM	Utilization of rhamnose
8-H₂S □	Production of hydrogen sulphide	20-MEL	Utilization of melibiose
9-MLN	Utilization of malonate	21-LAC	Utilization of lactose
10-VP *	Production of acetoin (Voges-Proskauer test)	22-TRE	Utilization of trehalose
11-IND *	Production of indole (Kovac's test)	23-XYL	Utilization of xylose
12-GLU	Utilization of glucose	24-DUL	Utilization of dulcitol

□ : overlay the well with vaseline oil

* : after incubation, add the indicated reagent to perform the test

COLLECTION OF THE SAMPLE

Enterosystem 24R is not for use directly with clinical or other specimens. The microorganism to be identified must first be isolated on a culture medium suitable for growth of enterobacteria such as MacConkey Agar (ref. 10029), Eosin Methylene Blue Agar (ref. 10048), Salmonella and Shigella Agar (ref. 10036), Hektoen Enteric Agar (ref. 10043) as well as a non selective blood agar (e.g. Tryptic Soy Agar with 5% Sheep Blood, ref. 11037).

TEST PROCEDURE

PREPARATION OF BACTERIAL SUSPENSION

- The microorganism to be identified must be recently isolated (18-24 h); bacterial cultures older than 48 hours can provide not reliable results.
- Before inoculating the microorganism to be examined, Gram staining and oxidase testing are required. Use Enterosystem 24R with Gram-negative, oxidase negative bacteria only.
- Take one or more morphologically similar well isolated colonies from the agar culture medium and suspend in physiological solution. The final turbidity should be equal to 0.5 McFarland. This suspension must be used immediately after preparation.

Note: A drop from the inoculum tube, either before or after inoculating the system, can be spread onto an agar slant or plate (any appropriate media) for purity check.

INOCULATION OF THE SYSTEM

1. Take a system from its wrapper and bring it to room temperature.
2. Write down the name of the patient and the date of the start of the examination.
3. Transfer a disc of Arabinose Disc into the well **17-ARA** and a disc of Xylose Disc into the well **23-XYL**.
4. Dispense 0.2 mL of bacterial suspension into each well of the system and overlay with 1 drop of vaseline oil the wells **2-LDC**, **3-ODC**, **4-ADC**, **7-UR** and **8-H₂S**.
5. Cover the system with the lid provided and incubate at 36±1°C for 18-24 hours.

INTERPRETATION OF THE RESULTS

At the end of the incubation period:

1. Add 2 drops of Alpha-naphthol and 1 drop of NaOH 40% to the well **10-VP** (wait 15-20 min for reading after adding the reagents).
2. Add 2 drops of Kovac's reagent to the well **11-IND** (wait 1-2 min for reading after adding the reagent).
3. Watch for the color change in the wells and interpret the results by referring to the Interpretive Table.
4. Note the results on the test results form and determine the 8-digit code following instructions provided as outlined under NUMERICAL CODE FORMATION.
5. Identify the organism by using the Identification Software.

Interpretive table.

Well	Test	Well color	
		Positive reaction	Negative reaction
1-ONPG	ONPG hydrolysis	yellow	colorless
2-LDC	Lysine decarboxylation	red	yellow-orange
3-ODC	Ornithine decarboxylation	red	yellow-orange
4-ADC	Arginine decarboxylation	red	yellow-orange
5-PD	Phenylalanine deamination	black-brown	yellow
6-CIT	Citrate utilization	blue-dark green	light green
7-UR	Urea hydrolysis	red-fuchsia	yellow-orange
8-H₂S	Hydrogen sulphide production	black	yellow
9-MLN	Malonate utilization	blue-green	yellow
10-VP	Voges-Proskauer (add reagents)	pink-red	yellow
11-IND	Indole (add Kovac's Reagent)	red ring	yellow
12-GLU	Glucose	yellow	blue-green
13-MAN	Mannitol	yellow	blue-green
14-INO	Inositol	yellow	blue-green
15-SOR	Sorbitol	yellow	blue-green
16-SAC	Saccharose	yellow	blue-green
17-ARA	Arabinose	yellow	blue-green
18-RAF	Raffinose	yellow	blue-green
19-RAM	Rhamnose	yellow	blue-green
20-MEL	Melibiose	yellow	blue-green
21-LAC	Lactose	yellow	blue-green
22-TRE	Trehalose	yellow	blue-green
23-XYL	Xylose	yellow	blue-green
24-DUL	Dulcitol	yellow	blue-green

NUMERICAL CODE FORMATION

The biochemical tests are separated into 8 groups of 3 and a value of 1, 2 or 4 is indicated for each:

- Value 1 : first test positive in each group (**ONPG, ADC, UR, VP, MAN, SAC, RAM, TRE**);
- Value 2 : second test positive in each group (**LDC, PD, H₂S, IND, INO, ARA, MEL, XYL**);
- Value 4 : third test positive in each group (**ODC, CIT, MLN, GLU, SOR, RAF, LAC, DUL**);
- Value 0 : every negative test.

A 8-digit code is obtained by adding together the values corresponding to positive reactions within each group.

The example below shows how a numerical code is formed.

	Group 1			Group 2			Group 3			Group 4			Group 5			Group 6			Group 7			Group 8		
Test	ONPG	LDC	ODC	ADC	PD	CIT	UR	H ₂ S	MLN	VP	IND	GLU	MAN	INO	SOR	SAC	ARA	RAF	RAM	MEL	LAC	TRE	XYL	DUL
Value	1	2	4	1	2	4	1	2	4	1	2	4	1	2	4	1	2	4	1	2	4	1	2	4
Result	+	-	+	+	-	+	-	-	+	+	-	+	+	+	+	+	+	+	+	+	+	+	-	-
Sum of values	5			5			4			5			7			7			7			1		
NUMERICAL CODE: 55457771 IDENTIFICATION: <i>Enterobacter cloacae</i>																								

QUALITY CONTROL

Each batch of Enterosystem 24R is subjected to the quality control using the following reference strains: *Escherichia coli* ATCC® 25922, *Salmonella* Typhimurium ATCC® 14028, *Proteus mirabilis* ATCC® 25933, *Klebsiella pneumoniae* ATCC® 13883, *Enterobacter cloacae* ATCC® 13047.

PERFORMANCE

The results obtained with the Enterosystem 24R agree with those obtained using other microbiological and biochemical tests for microbial identification.

FACTORS THAT MAY INVALIDATE THE RESULTS

Contaminated culture; Poor standardization of the inoculum; clinical material unsuitable; use of expired systems or expired supplementary reagents; non compliance with temperatures and times of incubation.

PRECAUTIONS

The product Enterosystem 24R 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. Enterosystem 24R is a disposable device to be used only for diagnostic use *in vitro*. The product must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

Store Enterosystem 24R at 2-8°C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions the product 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.








DISPOSAL OF USED MATERIAL

After use, Enterosystem 24R and 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.

PRESENTATION

Product	Ref.	Package
Enterosystem 24R	71619	20 tests
Enterosystem 24R	79619	4 tests

TABLE OF SYMBOLS

IVD for <i>in vitro</i> diagnostic use	 Do not reuse	 Manufacturer	 Contains sufficient for <n> test	 Temperature limits
REF Catalogue number	 Fragile, handle with care	 Use by	 Caution, consult accompanying documents	LOT Batch number



Enterosystem 18R Reagent

Reagents for indole and Voges-Proskauer tests for use with Enterosystem 18R.

DESCRIPTION

Enterosystem 18R Reagent is a kit containing the reagents Alpha Naphtol, NaOH 40%, Kovac's Reagent and Vaseline Oil necessary for the proper use of Enterosystem 18R (ref. 71618), a system for the identification of Gram-negative, oxidase negative, enterobacteria.

KIT CONTENTS

- 1 x 10 ml vial of Alpha Naphtol.
- 1 x 10 ml vial of NaOH 40%.
- 1 x 10 ml vial of Kovac's Reagent.
- 2 x 40 ml bottles of Vaseline Oil.
- 1 instruction sheet.

METHOD PRINCIPLE

Alpha Naphtol and NaOH 40% are used to carry out the Voges-Proskauer test into the well 10-VP.

Kovac's Reagent is used to carry out the indole test into the well 11-IND.

Vaseline Oil is used for the maintenance of a sufficiently anaerobic environment into the wells 2-LDC, 3-ODC, 4-ADC, 7-UR and 8-H₂S.

REAGENTS

- Alpha Naphtol: 6% (w/v) alpha naphtol dissolved in ethyl alcohol.
- NaOH 40%: 40% (w/v) sodium hydroxide in aqueous solution.
- Kovac's Reagent: 5% (w/v) *p*-dimethylaminobenzaldehyde dissolved in a solution of 25% hydrochloridric acid and 75% isobutyl alcohol.
- Vaseline Oil.

TEST PROCEDURE AND RESULTS INTERPRETATION

Refer to the package insert provided with Enterosystem 18R.

QUALITY CONTROL FOR THE USER

For each reagent, check positive and negative results by using suitable organisms, according to bibliographics references.

PPRECAUTIONS

Enterosystem 18R Reagent is classifiable as hazardous under current legislation; it is recommended that the Safety Data Sheet be consulted on its use. The product is intended for *in vitro* diagnostic use only and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

STORAGE AND TRANSPORT CONDITIONS

Store at 2-8°C away from light in its original package, until the expiry date shown 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.

ELIMINATING USED MATERIAL

After use, used Enterosystem 18R Reagent and the material that has come into contact with the sample must be decontaminated and disposed of in accordance with the laboratory procedures for the decontamination and disposal of potentially infected material.











BIBLIOGRAPHY

1. Murray, Baron, Pfaller, Tenorev and Tenover: Manual of Clinical Microbiology (1995).
2. Bayley and Scott's: Diagnostic Microbiology (1986).
3. Edwin H.Lenette: Manual of Clinical Microbiology (1995).

PRESENTATION

Product	Ref.	Content
Enterosystem 18R Reagent	80252	100-200 tests

TABLE OF SYMBOLS

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



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Rev.3 / 19.09.2014



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	
<i>Contents / bottle</i>	
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
<i>Staphylococcus aureus</i>	Good	Black
<i>Escherichia coli</i>	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	
POTASSIUM TELLURITE 1% Supplement	80022	5 bottles x 10 ml
POTASSIUM TELLURITE 1% Supplement	80422	10 bottles x 10 ml

TABLE OF SYMBOLS

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



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Rev.1 / 12.01.2012

POTASSIUM TELLURITE 3.5% Supplement

Selective supplement for the isolation of Staphylococci

DESCRIPTION

POTASSIUM TELLURITE 3.5% Supplement is a supplement consisting of a 3.5% potassium tellurite aqueous solution for microbiological use, used in culture medium Giolitti Cantoni Broth Base code 610100 or 620100, for isolation of staphylococci and in other media the composition of which provides for the inclusion of potassium tellurite.

KIT CONTENTS

Each kit contains:

- Bottles containing POTASSIUM TELLURITE 3.5% Supplement
- 1 Instruction sheet

PRINCIPLE OF THE METHOD

POTASSIUM TELLURITE 3.5% Supplement is a selective supplement used chiefly in the 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 3.5% Supplement	
Contents / ml	
Potassium tellurite	35.0 mg
Distilled water	1.0 ml

PROCEDURE FOR USE

1. Aseptically add 2.9 ml of POTASSIUM TELLURITE 3.5% Supplement to 500 ml of Vogel Johnson Agar medium code 610186 or 620186, or 0.3 ml (0.03 ml for analysis of meat-based products) to 19 ml of Giolitti Cantoni Broth Base code 610100 or 620100, 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 3.5% Supplement that should be added to it.
2. Mix with care.
3. Distribute into the final containers.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation for Vogel Johnson Agar code 610186 or 620186 or Giolitti Cantoni Broth Base code 610100 or 620100, 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 code 610186 or 620186 supplemented with POTASSIUM TELLURITE 3.5% Supplement (2.9 ml 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
<i>Staphylococcus aureus</i>	Good	Black
<i>Escherichia coli</i>	Inhibited	-----

PRECAUTIONS

The product POTASSIUM TELLURITE 3.5% 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 3.5% 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 3.5% Supplement at 2-8 °C in its original packaging. In such conditions POTASSIUM TELLURITE 3.5% 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.
- Giolitti C. and Cantoni C. (1966) J. Appl. Bact. **29**: 395.

PRESENTATION

product	REF	Σ
POTASSIUM TELLURITE 3.5% Supplement	80291	5 bottles X 10 ml
POTASSIUM TELLURITE 3.5% Supplement	80491	10 bottles X 10 ml
POTASSIUM TELLURITE 3.5% Supplement	80492	10 bottles X 1 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



Violet Red Bile Lactose Agar

Selective medium for the enumeration of coliforms
in food, water and other materials, according to APHA and ISO 4832.

DESCRIPTION

Violet Red Bile Lactose Agar is a selective medium used for the isolation and enumeration of coliform bacteria in food, water and other materials of sanitary importance, according to APHA and ISO 4832.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Animal Tissues	7.0
Yeast Extract	3.0
Lactose	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

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. Lactose 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

<u>Dehydrated medium</u>	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.
<u>Medium in tubes/bottles</u>	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 10 and 150 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. Incubate aerobically at 30°C or 37°C, depending on the organisms under study, for 24 ± 2 hours.

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, RODAC plates can be directly used for surface sampling by firmly pressing the agar medium against the test area for a few seconds.

INTERPRETING RESULTS

Select plates containing 10-150 colonies. Count the purplish-red colonies with a diameter of at least 0.5 mm.

Atypical colonies (e.g. smaller size) and all colonies derived from milk products should be confirmed by using Brilliant Green Lactose Bile Broth 2% (ref. 20102).

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 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.

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.

Inoculum for selectivity: 10^4 - 10^6 CFU.

Inoculum for specificity: 10^3 - 10^4 CFU.

Incubation conditions: aerobically at $30 \pm 1^\circ\text{C}$ for 24 ± 2 hours.

QC Table.

Microorganism	Specification	
<i>Escherichia coli</i>	WDCM 00012	Good growth, purplish-red colonies with or without precipitation halo
<i>Enterococcus faecalis</i>	WDCM 00009	Inhibition
<i>Pseudomonas aeruginosa</i>	WDCM 00025	Colorless to beige 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

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2. ISO 4832:2006. Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of coliforms – Colony count technique.
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.

PRESENTATION

		Contents	Ref.
Violet Red Bile Lactose Agar	90 mm ready-to-use plates	20 plates	11183
Violet Red Bile Lactose Agar	90 mm ready-to-use plates	100 plates	11183*
Violet Red Bile Lactose Agar	55 mm ready-to-use RODAC plates (in blister packs)	20 plates	15326
Violet Red Bile Lactose Agar	55 mm ready-to-use RODAC plates	20 plates	15326L
Violet Red Bile Lactose Agar	Tubes	20 x 22 ml tubes	31076
Violet Red Bile Lactose Agar	Tubes	10 x 22 ml tubes	34076
Violet Red Bile Lactose Agar	Bottles	6 x 100 ml bottles	402460
Violet Red Bile Lactose Agar	Dehydrated medium	500 g of powder	610058
Violet Red Bile Lactose Agar	Dehydrated medium	100 g of powder	620058
Violet Red Bile Lactose Agar	Dehydrated medium	5 kg of powder	6100585

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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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

<u>Dehydrated medium</u>	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.
<u>Medium in bottles</u>	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

- 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).
- Inoculate Violet Red Bile Glucose Agar by pour plating or spread plating method.
- 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
<i>Escherichia coli</i>	WDCM 00012 or WDCM 00013	50-100 CFU	24 ± 2 h / 37 ± 1°C	P _R ≥ 0.5	Pink to red colonies with or without precipitation halo
<i>Salmonella</i> Typhimurium	WDCM 00031				
<i>Salmonella</i> Enteritidis	WDCM 00030				
<i>Enterococcus faecalis</i>	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
<i>Escherichia coli</i>	ATCC® 8739 (WDCM 00012)	≤ 100 CFU	18-24 h / 30-35°C	Recovery ≥ 50%, pink to red colonies with precipitation halo
<i>Pseudomonas aeruginosa</i>	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

This document is available from the online Support Center:

liofilchem.com/ifu-sds



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UREA 40% Supplement

Supplement for the detection of urease activity of bacteria

DESCRIPTION

UREA 40% Supplement is a supplement per la detection of urease activity of bacteria and it is made of a 40% urea aqueous solution for microbiological use. UREA 40% Supplement is used for the enrichment of medium Urea Agar Base cod. 610107 or 620107.

KIT CONTENTS

Each kit contains:

- 10 bottles each containing 5 ml of UREA 40% Supplement.
- 1 Instruction sheet

PRINCIPLE OF THE METHOD

The utilization of urea by microorganisms provided of urease causes the alkalization of medium and consequently the colour turning of indicator red phenol from amber to pink colour.

COMPOSITION

UREA 40% Supplement		
	<i>Contents / bottle</i>	<i>Contents / l of medium</i>
Urea	2.0 g	20.0 g

PROCEDURE FOR USE

1. Aseptically take the content of one bottle of UREA 40% Supplement and add it to 95 ml of Urea Agar Base cod. 610107 or 620107 autoclaved and cooled to 45-50 °C.
2. Mix with care avoiding the formation of foam.
3. Distribute into the final containers.

TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation for medium Urea Agar Base cod. 610107 or 620107.

QUALITY CONTROL

1. Control of the appearance: clear, colourless solution.

2. Microbiological control:

prepare the plates using as base the medium Urea Agar Base cod. 610107 or 620107 added with UREA 40% Supplement.

The plates are inoculated with the strains indicated in the table of microbiological control.

Conditions of incubation: 6-24 h at 36 ± 1 °C.

Microbiological control:

Control strains		Ureasic activity
<i>Proteus vulgaris</i>	ATCC 13315	Positive / pink medium
<i>Escherichia coli</i>	ATCC 25922	Negative / no change in colour

PRECAUTIONS

The product UREA 40% Supplement is classified as irritant under current legislation;; it is recommended that the Safety Data Sheet be consulted on its correct use.

UREA 40% 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 UREA 40% Supplement at 2-8°C in its original packaging. In such conditions UREA 40% Supplement maintains its validity until the expiry date indicated on the label. Non utilizzare oltre questa data. Eliminate without using if there are signs of deterioration.

REFERENCES











- Christensen, W.B. (1946). J. Bact. **52**: 461-466.
- Maslen, L.G.C. (1952). Brit. Med. J. **2**: 545-546.

PRESENTATION

product	REF	
UREA 40% Supplement	80292	10 bottles

One bottle is sufficient to prepare 100 ml of medium

TABLE OF SYMBOLS

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



LIOFILCHEM Bacteriology Products

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Rev.0 / 06.04.2005



XLD Agar

Selective medium for detection of *Salmonella* and *Shigella* spp in food, environmental samples and other materials, according to ISO 6579 and ISO 21567.

DESCRIPTION

XLD (Xylose Lysine Deoxycholate) Agar is a selective medium used for the isolation and differentiation of pathogen Enterobacteriaceae, especially *salmonellae* and *shigellae* from food, environmental samples and clinical specimens.

XLD Agar is formulated according to ISO 6579 and ISO 21567 for the detection of *Salmonella* and *Shigella* spp, respectively.

TYPICAL FORMULA

	(g/l)
Yeast Extract	3.0
Sodium Chloride	5.0
Xylose	3.75
Lactose	7.5
Sucrose	7.5
L-Lysine	5.0
Sodium Thiosulfate	6.8
Iron(III) Ammonium Citrate	0.8
Phenol Red	0.08
Sodium Deoxycholate	1.0
Agar	15.0
Final pH 7.4 ± 0.2 at 25°C	

METHOD PRINCIPLE

Yeast extract is a source of vitamins, particularly of B-group. Sodium chloride maintains the osmotic balance of the medium. Xylose, lactose and sucrose are the fermentable carbohydrates. Lysine is the decarboxylase substrate. Sodium thiosulfate and ferric ammonium serve as indicators of hydrogen sulphide production under alkaline conditions. Phenol red is the pH indicator. Sodium deoxycholate is the selective agent inhibiting most Gram-positive bacteria. Agar is the solidifying agent.

PREPARATION

<u>Dehydrated medium</u>	Suspend 55.4 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.
<u>Medium in bottles</u>	Melt the content of the bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Immediately cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Inoculate the plates by spread method. Incubate aerobically at 37 ± 1°C for up to 48 hours.

INTERPRETING RESULTS

After incubation observe the color of the colonies and interpret the results as indicated in the ID Table.

ID Table.

Microorganism	Appearance of colonies
<i>Salmonella</i> , <i>Edwardsiella</i> spp	Red with black center
<i>Shigella</i> , <i>Providencia</i> , <i>Pseudomonas</i> spp, <i>Salmonella paratyphi</i> (H ₂ S-negative strains)	Red
<i>Salmonella typhosa</i> (xylose-positive strains)	Orange
<i>Escherichia coli</i> , <i>Enterobacter</i> , <i>Aeromonas</i> , <i>Klebsiella</i> , <i>Serratia</i> spp	Yellow with yellow zone
<i>Citrobacter</i> spp (lactose-positive strains)	Yellow with yellow zone, sometimes with black center
<i>Proteus</i> spp	Yellow with yellow zone and black center

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, pink.

Prepared medium: slightly opalescent, red.

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: 2 years.

Medium in bottles: 1 year.

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

Inoculum for selectivity: $> 10^3$ CFU

Incubation conditions: aerobically at $37 \pm 1^\circ\text{C}$ for 24 ± 3 hours.

QC Table.

Microorganismo		Growth	Specification
<i>Salmonella</i> Typhimurium	WDCM 00031	Good	Red colonies with black center
<i>Salmonella</i> Enteritidis	WDCM 00030	Good	Red colonies with black center
<i>Shigella flexneri</i>	ATCC® 12022	Good	Red colonies
<i>Escherichia coli</i>	WDCM 00013	Poor	Yellow colonies
<i>Enterococcus faecalis</i>	WDCM 00087	Inhibited	---

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

- EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
- EN ISO 21567:2004 Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Shigella* spp.
- ISO 6579:2002 Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Salmonella* spp.
- 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.
- Rollender W. et al. (1969) Comparison of xylose lysine deoxycholate agar and MacConkey Agar for the isolation of *Salmonella* and *Shigella* from clinical specimens. Am J Clin Pathol; 51/2:284-386
- Taylor W.J. (1965) Isolation of Shigellae I. Xylose lysine agars: new media for isolation of enteric pathogens. Am J Clin Pathol; 44:471-475.
- Taylor W.J. and Harris B (1965) Isolation of Shigellae II. Comparison of plating media and enrichment broths. Am J Clin Pathol; 44X:476-479.

PRESENTATION

		Contents	Ref.
XLD Agar	90 mm ready-to-use plates	20 plates	10056
XLD Agar	90 mm ready-to-use plates	100 plates	10056*
XLD Agar	Bottles	6 x 100 ml bottles	402570
XLD Agar	Dehydrated medium	500 g of powder	610060
XLD Agar	Dehydrated medium	100 g of powder	620060
XLD Agar	Dehydrated medium	5 kg of powder	6100605

TABLE OF SYMBOLS

LOT Batch code	IVD <i>In vitro</i> 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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CERTIFIED COMPANY UNI EN ISO 9001 & UNI EN ISO 13485

DICHIARAZIONE DI CONFORMITA' CE CE DECLARATION OF CONFORMITY

La sottoscritta Nuova Aptaca s.r.l.
The undersigned Nuova Aptaca s.r.l.

DICHIARA
DECLARES

Che i Dispositivi Medici di seguito descritti:
That Medical Devices described as follows:



**TAMPONI PER LA RACCOLTA E LA CONSERVAZIONE DI CAMPIONI BIOLOGICI,
ANCHE IN AMBITO CHIRURGICO, CON O SENZA TERRENO DI TRASPORTO**
**MEDICAL SWABS AND APPLICATORS FOR BIOLOGICAL SAMPLE COLLECTION
AND PRESERVATION, ALSO FOR SURGERY USE, WITH OR WITHOUT
TRANSPORT MEDIUM**

PRODOTTI STERILI – STERILE PRODUCTS

(i cui codici di dettaglio sono riportati nell'allegato 1)
(which detailed codes are reported in Annex 1)

- Sono conformi ai requisiti essenziali di cui all'allegato I della Direttiva 93/42/CE così come integrata e modificata dalla Direttiva 2007/47/CE recepita con D.lgs n° 46 del 24/02/1997 emendato con D.lgs n° 37 del 25/01/2010 e s.m.i.
They are conform to the essential requirements of Annex I of Directive 93/42/EC as amended and integrated by Directive 2007/47/EC, put into force by D.Lgs n° 46 dated 24/02/1997 and as amended by D.lgs n° 37 dated 25/01/2010.
- Sono classificati di Classe IIa sterile in base all'Allegato IX - regola 6 - p.to 2.2. della Direttiva 93/42/CE così come integrata e modificata dalla Direttiva 2007/47/CE.
They are classified as Class IIa sterile according to Annex IX - Rule 6 - p.t 2.2. of Directive 93/42/EC as amended and integrated by Directive 2007/47/EC
- Sono soggetti a marcatura CE rilasciata dall'Organismo Notificato n° 0426 Italcert Srl
They are subject to CE mark issued by the Notified Body n° 0426 Italcert Srl
- Sono prodotti con un Sistema Qualità della produzione conforme all'Allegato V della Direttiva 93/42/CE
They are manufactured with a production quality system in accordance with Annex V of Directive 93/42/EC

Tale dichiarazione è supportata dalla certificazione del Sistema Qualità Nuova Aptaca secondo gli standard UNI EN ISO 9001 e UNI EN ISO 13485

This statement is supported by the New Aptaca Quality System Certification according to UNI EN ISO 9001 and UNI EN ISO 13485

Rilasciato / Released
Canelli, 08.06.2017

Duilio BUONO
Quality Assurance Manager

ALLEGATO 1 alla Dichiarazione di Conformità Tamponi sterili Annex 1 to Declaration of Conformity Sterile Swabs

CLINISWAB ^{TS} Tamponi Con Terreno Trasporto Agar Gel / Agar Gel Transport Swabs		
REF	DESCRIZIONE	DESCRIPTION
301/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto AMIES senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with AMIES clear, with label, sterile individually wrapped
301/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto AMIES senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs alluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with AMIES clear, with label, sterile individually wrapped
301/SG/XL	Tampone asta Plastica puntale Viscosa, con terreno di trasporto AMIES MAGGIORATO (6ml) senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with DOUBLE AMIES clear, with label, sterile individually wrapped
303/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto AMIES con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with AMIES with Charcoal, with label, sterile individually wrapped
303/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto AMIES con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs alluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with AMIES with Charcoal, with label, sterile individually wrapped
303/SG/XL	Tampone asta Plastica puntale Viscosa, con terreno di trasporto AMIES MAGGIORATO (6ml) con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with DOUBLE AMIES with Charcoal, with label, sterile individually wrapped
305/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto STUART senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with STUART clear, with label, sterile individually wrapped
305/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto STUART senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs alluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with STUART clear, with label, sterile individually wrapped
307/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto STUART con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with STUART with Charcoal, with label, sterile individually wrapped
307/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto STUART con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs alluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with STUART with Charcoal, with label, sterile individually wrapped
309/SG	Tampone asta Plastica puntale Viscosa, con terreno di trasporto CARY BLAIR senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with CARY BLAIR, with label, sterile individually wrapped
309/AL/SG	Tampone asta Alluminio puntale Viscosa, con terreno di trasporto CARY BLAIR senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs alluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with CARY BLAIR, with label, sterile individually wrapped
CLINISWAB ^{TS} Tamponi Con Terreno Trasporto Liquido In Spugna / Transport Swabs with liquid medium in sponge		
REF	DESCRIZIONE	DESCRIPTION
311/SG	Tamponi asta Plastica e puntale in Viscosa, con provetta in PP Ø12x150 con spugna contenente terreno VIRUS, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with soaked sponge of Virus medium, with label, sterile individually wrapped
313/SG	Tamponi asta Alluminio e puntale in Viscosa, con provetta in PP Ø12x150 con spugna contenente terreno VIRUS, sterile confezione singola	Swabs alluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with soaked sponge of Virus medium, with label, sterile individually wrapped
321/SG	Tamponi asta Plastica e puntale in Viscosa, con provetta in PP Ø12x150 con spugna contenente terreno CLAMIDIA, sterile confezione singola	Swabs plastic stick and Rayon tip, test tubes in PP Ø12x150 mm with soaked sponge of Chlamydia medium, with label, sterile individually wrapped
323/SG	Tamponi asta Alluminio e puntale in Viscosa, con provetta in PP Ø12x150 con spugna contenente terreno CLAMIDIA, sterile confezione singola	Swabs alluminum stick and Rayon tip, test tubes in PP Ø12x150 mm with soaked sponge of Chlamydia medium, with label, sterile individually wrapped
CLINISWAB ^{LTS} Tamponi Foam Con Terreno Trasporto Liquido / Foam Liquid Transport Swabs		
REF	DESCRIZIONE	DESCRIPTION
430/SG/ST/F	Tampone tipo STANDARD FOAM, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
430/SG/FT/F	Tampone tipo FINE FOAM, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
435/SG/ST/F	Tampone tipo STANDARD FOAM, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
435/SG/FT/F	Tampone tipo FINE FOAM, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped

440/SG/ST/F	Tampone tipo STANDARD FOAM, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
440/SG/FT/F	Tampone tipo FINE FOAM, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
445/SG/ST/F	Tampone tipo STANDARD FOAM, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
445/SG/FT/F	Tampone tipo FINE FOAM, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
450/SG/ST/F	Tampone tipo STANDARD FOAM, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and STANDARD FOAM tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
450/SG/FT/F	Tampone tipo FINE FOAM, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and FINE FOAM tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped

CLINISWAB^{LTS}

Tamponi Poliestere Con Terreno Trasporto Liquido / Polyester Liquid Transport Swabs

REF	DESCRIZIONE	DESCRIPTION
430/SG/ST/D	Tampone tipo STANDARD POLIESTERE, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
430/SG/FT/D	Tampone tipo FINE POLIESTERE, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
435/SG/ST/D	Tampone tipo STANDARD POLIESTERE, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
435/SG/FT/D	Tampone tipo FINE POLIESTERE, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
440/SG/ST/D	Tampone tipo STANDARD POLIESTERE, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
440/SG/FT/D	Tampone tipo FINE POLIESTERE, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
445/SG/ST/D	Tampone tipo STANDARD POLIESTERE, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
445/SG/FT/D	Tampone tipo FINE POLIESTERE, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
450/SG/ST/D	Tampone tipo STANDARD POLIESTERE, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and STANDARD POLYESTER tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
450/SG/FT/D	Tampone tipo FINE POLIESTERE, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and FINE POLYESTER tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped

CLINISWAB^{LTS}

Tamponi Viscosa Con Terreno Trasporto Liquido / Rayon Liquid Transport Swabs

REF	DESCRIZIONE	DESCRIPTION
430/SG/ST/R	Tampone tipo STANDARD VISCOSA, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
430/SG/FT/R	Tampone tipo FINE VISCOSA, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped
435/SG/ST/R	Tampone tipo STANDARD VISCOSA, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
435/SG/FT/R	Tampone tipo FINE VISCOSA, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
440/SG/ST/R	Tampone tipo STANDARD VISCOSA, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
440/SG/FT/R	Tampone tipo FINE VISCOSA, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
445/SG/ST/R	Tampone tipo STANDARD VISCOSA, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
445/SG/FT/R	Tampone tipo FINE VISCOSA, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
450/SG/ST/R	Tampone tipo STANDARD VISCOSA, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and STANDARD RAYON tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped
450/SG/FT/R	Tampone tipo FINE VISCOSA, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs plastic stick and FINE RAYON tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped

CLINISWAB^{LTS}

Tamponi Alluminio Con Terreno Trasporto Liquido / Alluminum Liquid Transport Swabs

REF	DESCRIZIONE	DESCRIPTION
430/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 1ml di terreno liquido AMIES, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 1 ml AMIES liquid medium, sterile individually wrapped

435/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 1ml di terreno liquido STUART, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 1 ml STUART liquid medium, sterile individually wrapped
440/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 2ml di terreno liquido CARY BLAIR, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 2 ml CARY BLAIR liquid medium, sterile individually wrapped
445/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 2ml di terreno liquido SELENITE, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 2 ml SELENITE liquid medium, sterile individually wrapped
450/SG/AL	Tampone asta ALLUMINIO, puntale in VISCOSA, con provetta 2ml di terreno liquido SALINE, sterile confezione singola	Swabs aluminum stick and STANDARD RAYON tip, with test tubes 2 ml SALINE liquid solution, sterile individually wrapped

CLINISWAB^{DS}

Tamponi Secchi In Provetta / Dry Swabs In Test Tubes

REF	DESCRIZIONE	DESCRIPTION
2150/SG	Tampone Legno, puntale in Cotone, in provetta PP Ø12x150, con etichetta, sterile	Swabs Wooden stick and Cotton tip, in PP test tubes Ø12x150 mm, with label, sterile
2150/SG/CS	Tampone Legno, puntale in Cotone, in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs Wooden stick and Cotton tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2160/SG	Tampone Plastica, puntale in Viscosa, in provetta PP Ø12x150, con etichetta, sterile	Swabs Plastic stick and Rayon tip, in PP test tubes Ø12x150 mm, with label, sterile
2160/SG/CS	Tampone Plastica, puntale in Viscosa, in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs Plastic stick and Rayon tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2170/SG	Tampone Alluminio, puntale in Viscosa, in provetta PP Ø12x150, con etichetta, sterile	Swabs Alluminum stick and Rayon tip, in PP test tubes Ø12x150 mm, with label, sterile
2170/SG/CS	Tampone Alluminio, puntale in Viscosa, in provetta PP Ø12x150, con etichetta, sterile confezione singola	Swabs Alluminum stick and Rayon tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2190/SG	Tamponi asta Plastica, puntale in FOAM standard, in provetta Ø12x150, con etichetta, sterile	Swabs Plastic stick and Standard FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile
2190/SG/CS	Tamponi asta Plastica, puntale in FOAM standard, in provetta Ø12x150, con etichetta, sterile in confezione singola	Swabs Plastic stick and Standard FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped
2191/SG	Tamponi asta Plastica, puntale in FOAM fine/pediatrico, in provetta Ø12x150, con etichetta, sterile	Swabs Plastic stick and Fine FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile
2191/SG/CS	Tamponi asta Plastica, puntale in FOAM fine/pediatrico, in provetta Ø12x150, con etichetta, sterile in confezione singola	Swabs Plastic stick and Fine FOAM tip, in PP test tubes Ø12x150 mm, with label, sterile individually wrapped

CLINISWAB^{DS}

TAMPONI SECCHI IN BLISTER / Dry Swabs In Blister

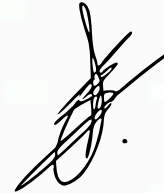
REF	DESCRIZIONE	DESCRIPTION
5100/SG/CS	Tampone Legno, puntale in Cotone, sterile confezione singola	Swabs Wooden stick and Cotton tip, sterile individually wrapped
5100/SG/2	Tampone Legno, puntale in Cotone, sterile confezione da 2 pezzi	Swabs Wooden stick and Cotton tip, sterile in peel-pack of 2 pieces
5100/SG/10	Tampone Legno, puntale in Cotone, sterile confezione da 10 pezzi	Swabs Wooden stick and Cotton tip, sterile in peel-pack of 10 pieces
6100/SG/CS	Tampone Plastica, puntale in Viscosa, sterile confezione singola	Swabs Plastic stick and Rayon tip, sterile individually wrapped
7100/SG/CS	Tampone Alluminio, puntale in Viscosa, sterile confezione singola	Swabs Alluminum stick and Rayon tip, sterile individually wrapped
6200/SG/CS	Tampone Plastica, puntale in FOAM standard, sterile confezione singola	Swabs Plastic stick and Standard Foam tip, sterile individually wrapped
6300/SG/CS	Tampone Plastica, puntale in FOAM pediatrico, sterile confezione singola	Swabs Plastic stick and Fine Foam tip, sterile individually wrapped

CLINISWAB^{STS}

Tamponi Stantuffo Con Terreno Di Trasporto Agar Gel / Sliding Transport Agar Gel Swabs

REF	DESCRIZIONE	DESCRIPTION
201/SG	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno AMIES senza carbone in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Clear, with label, sterile
201/SG/CS	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno AMIES senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Clear, with label, sterile individually wrapped
203/SG	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno AMIES con carbone in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES with Charcoal, with label, sterile
203/SG/CS	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno AMIES con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with AMIES Charcoal, with label, sterile individually wrapped
205/SG	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno STUART senza carbone in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Clear, with label, sterile
205/SG/CS	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno STUART senza carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Clear, with label, sterile individually wrapped
207/SG	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno STUART con carbone in provetta PP Ø12x150, con etichetta, sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART with Charcoal, with label, sterile

207/SG/CS	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno STUART con carbone in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with STUART Charcoal, with label, sterile individually wrapped
209/SG	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno CARY BLAIR in provetta PP Ø12x150, con etichetta., sterile	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with CARY BLAIR, with label, sterile
209/SG/CS	Tampone "stantuffo" Plastica puntale in Viscosa, con terreno CARY BLAIR in provetta PP Ø12x150, con etichetta, sterile confezione singola	Sliding Swabs plastic stick and Rayon tip, in PP test tubes Ø12x150 mm with CARY BLAIR, with label, sterile individually wrapped



CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

SCHEDA TECNICA PRODOTTO TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
 16.03.2020



TRANSPORT SWABS WITH AGAR GEL MEDIUM TAMPONI CON TERRENO DI TRASPORTO AGAR GEL

DESCRIZIONE / DESCRIPTION



A complete range of swabs for the collection and transport of bacteriological samples, with transport medium agar gel to grant the survival of specimens during their transportation to clinical laboratory. The transport

swabs are composed of a soft rayon tip with plastic or aluminum applicator stick, atoxic and resistant to sudden changes of temperature, and a labelled cylindrical test tube Ø12x155 mm, in unbreakable medical PP, to preserve sample and users safety. supplied with label on test tube and cap for patient and sample identification and as a seal indicating that the product has not been previously used. Cap has same diameter than test tube.

All the Devices are produced according to GMP (Good Manufacturing Practice) and are classified and certified as Medical Devices

Class IIa sterile (invasive surgery for temporary use). The swabs are sterile irradiated (SAL 10⁻⁶), in medical easy opening peel-pack, Pyrogen free.

Una gamma completa di tamponi per la raccolta e il trasporto di campioni batteriologici, con terreno di trasporto agar gel per garantire la sopravvivenza dei campioni durante il trasporto al laboratorio.

I tamponi sono composti di un puntale in soffice viscosa con asta in plastica o in alluminio, non tossico e resistente agli sbalzi termici, corredati di provetta cilindrica Ø12x155 mm, prodotta in polipropilene medicale infrangibile al fine di preservare il campione e la sicurezza degli operatori. L'etichetta pre-applicata sulla provetta e sul tappo serve sia per l'identificazione del paziente e del campione sia come garanzia che il prodotto non sia stato in precedenza utilizzato. Il tappo è del medesimo diametro della provetta.

Tutti i Dispositivi sono prodotti in accordo alle GMP (Good Manufacturing Practice) e sono classificati e certificati come Dispositivi Medici di Classe IIa sterile (invasivi chirurgici per uso temporaneo).

I tamponi sono sterili per irraggiamento (SAL 10⁻⁶), in peel-pack medicale di facile apertura, garantiti Apirogeni.

CE 0426 MD marked sterile Swab - manufactured in compliance with 93/42/EC Directive (Italian D.lgs 46 del 24/02/1997) + 2007/47/EC - Class IIa sterile

CE IVD marked sterile Test Tube with medium - manufactured in compliance with 98/79/EC Directive (Italian D.lgs 332 del 08/09/2000)

Tampone DM con marchio CE 0426 - conforme alla Direttiva 93/42/CE (D.lgs 46 del 24/02/1997) + 2007/47/CE - Classe IIa sterile

Provetta sterile con terreno di trasporto con marchio CE IVD conforme alla Direttiva 98/79/CE (D.lgs 332 del 08/09/2000)

INTENDED PURPOSE / DESTINAZIONE D'USO

Swab Intended purpose is "MEDICAL DEVICE" CLASS IIA STERILE. Swabs are sterile and ready-for-use systems intended for clinical samples drawing, transport and maintenance for cultural exam. The swab is suitable for short contact with the human body including surgical wounds. Test Tubes are classified as IVD and are intended only for the preservation of samples. Product must be used as directed, Aptaca is not responsible for any unauthorized use.

For professional use only.

National classification of medical devices (CND - For Italian law) > V901302 (Transport swabs for collection sample)

La destinazione d'uso del tampone è quella di "DISPOSITIVO MEDICO" DI CLASSE IIA STERILE. I tamponi sono dei sistemi sterili e pronti all'uso, previsti per il prelievo, il trasporto e il mantenimento di campioni clinici per l'esame culturale. Il tampone è un dispositivo indicato per prelievi che prevedono brevi contatti col corpo umano anche in ambito chirurgico. Le provette sono classificate come IVD e sono destinate unicamente alla conservazione dei campioni prelevati. Si declina ogni responsabilità per utilizzi diversi da quello specificato.

Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.

Classificazione Nazionale dei Dispositivi Medici (CND) > V901302 (Tamponi con terreno di trasporto per prelievo di campioni)

APPLICATOR / TAMPONE



The applicator shaft of the swab is mounted on the tube plug which serves as an optimal grip for an efficient swab handling.

Available in two versions on sampling site base:



- **Aluminum shaft, rayon tip:** atoxic shaft, with rayon tip, ideal for arduous or delicate sampling. The narrow dimension of the swabs shaft (only 0.9 mm), the high flexibility and strength, the small fiber tip, make it particularly suitable for urogenital, urethral, ocular, nasopharyngeal and paediatric uses.

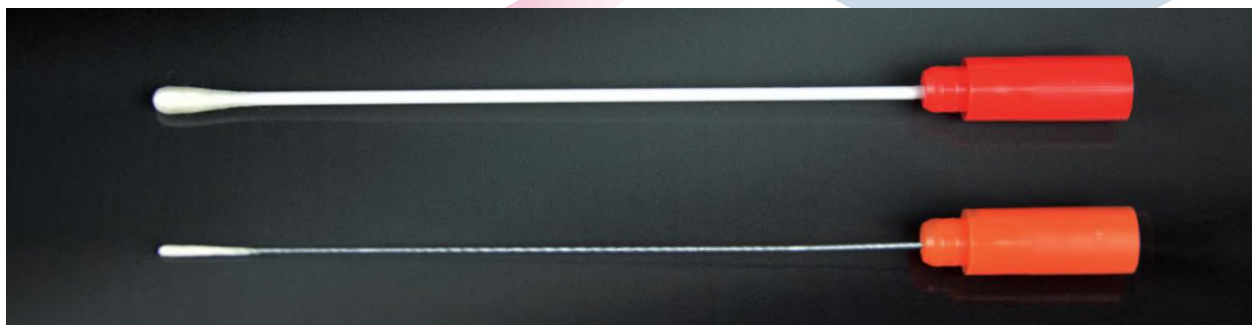
- **Plastic shaft, Rayon tip:** made in anti-shock polystyrene, very flexible but easily breakable as needed,

with rayon tip, atoxic. Particularly suitable for mouth, throat, vagina, urogenital apparatus, skin, wounds and surgical wounds.

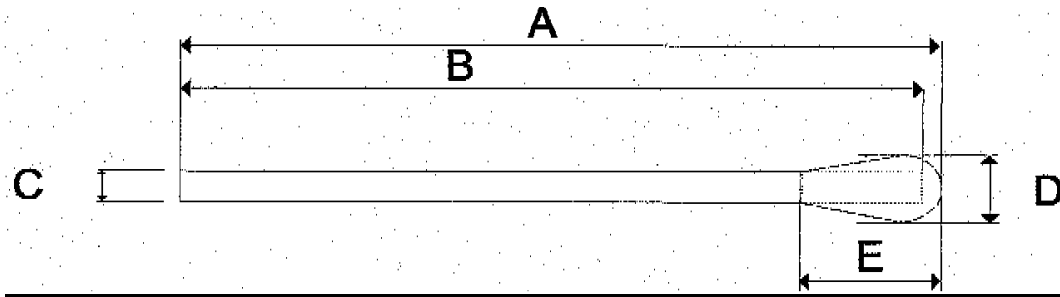
L'asta del tampone è montata sul tappo della provetta per una presa ottimale ed una efficace direzionalità.

Disponibili in due varianti in base al sito di prelievo:

- **Asta alluminio, puntale in viscosa:** asta con puntale in viscosa, atossico, ideale per prelievi difficoltosi o delicati. Il diametro dell'asta di soli 0,9 mm, l'alta flessibilità e resistenza e le ridotte dimensioni del puntale in fibra la rendono particolarmente idonea per prelievi urogenitali, uretrali, oculari, nasofaringei e pediatrici.
- **Asta plastica, puntale in viscosa:** prodotta in polistirolo antiurto, molto flessibile ma facilmente spezzabile in base alle necessità, puntale in viscosa, atossico. Tampone particolarmente idoneo per bocca, gola, vagina, apparato urogenitale, pelle, ferite e incisioni chirurgiche.



PLASTIC STICK, RAYON TIP / ASTA PLASTICA, PUNTALE IN VISCOSA



This specialty swab is made with rayon fiber. It is bonded securely to a rigid white birch polystyrene handle by an aqueous based adhesive.

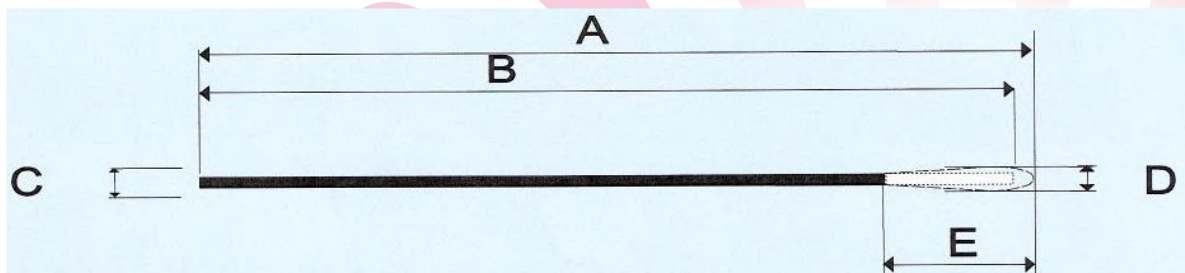
Tampone prodotto con fibre di rayon. Il puntale in rayon è saldamente fissato all'asta semirigida in polistirolo mediante un adesivo a base acquosa.

Absorbance / Assorbenza: 100 μ L \pm 10% in 10 sec. (acqua + TSB) / (water + TSB)

Dimensions / Dimensioni

A: 150 \pm 2 mm / **B:** 146 \pm 1 mm / **C:** \varnothing 2,5 \pm 0,1 mm / **D:** 5 - 6 mm / **E:** 15 mm \pm 2 mm

ALUMINUM STICK, RAYON TIP / ASTA ALLUMINIO, PUNTALE IN VISCOSA



Swabs with viscose (rayon) tip, aluminium stick, atoxic, resistant to sudden changes of temperature. Atoxic glue to fix viscose tip. Very thin shaft and small tip for paediatric, urethral, urogenital and nasopharyngeal sampling. Without break point.

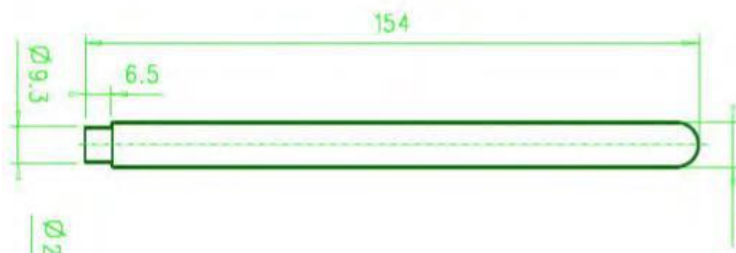
Tamponi in viscosa con stelo in alluminio, non tossico e resistente agli sbalzi termici. La colla utilizzata per il fissaggio della viscosa è atossica. Asta e puntale particolarmente sottili per un utilizzo pediatrico, uretrale, urogenitale e nasofaringeo. Senza punto di rottura "break-point"

Absorbance / Assorbenza: 20 μ L \pm 10% in 10 sec. (acqua + TSB) / (water + TSB)

Dimensions / Dimensioni

A: 147 \pm 2 mm / **B:** 145 \pm 1 mm / **C:** \varnothing 0,9 \pm 0,1 mm / **D:** 2,2 \pm 0,5 mm / **E:** 12 \pm 2 mm

TEST TUBE / PROVETTA



Transport Medium is contained in a cylindrical test tube \varnothing 12 x 155 mm, in transparent, unbreakable medical polypropylene (PP), to preserve sample and user's safety. With pressure cap in polyethylene (HDPE) with specific colour according to medium type. Pre-labelled on test tube to allow a correct sample identification. Item code, lot number and expiry date printed on each label for a full traceability.

Il terreno di trasporto è contenuto in una provetta cilindrica \varnothing 12 x 155 mm, prodotta in polipropilene (PP) medicale e trasparente, al fine di preservare il campione e la sicurezza degli operatori. Con tappo a pressione in polietilene (HDPE) di colore specifico in base al terreno contenuto. Ogni provetta è etichettata per consentire una sicura identificazione del campione. Su ogni etichetta sono stampati il codice articolo, lotto e scadenza per una tracciabilità completa.

Clear AMIES / AMIES chiaro



Sterile swabs with clear Amies agar gel medium. Amies transport medium allows the survival of many microorganisms, such as *Shigella flexneri*, *Neisseria*, *Trichomonas vaginalis*, *Enterobacterias*, *Haemophilus*, *Corynebacterium*, *Streptococcus pneumonie*, *Streptococcus pyrogenes*, *Salmonella typhi*, *Brucella abortus*.

Available with double Amies agar gel medium (6 ml) which allows a better bacteriological sample inoculation inside the medium, ensuring a safer anaerobic bacteria viability. Furthermore it allows to dilute the samples in a medium greater quantity.

Tamponi sterili con terreno di trasporto Amies agar gel chiaro. Il terreno Amies è particolarmente idoneo per garantire la sopravvivenza di molti microrganismi come per esempio

Shigella flexneri, Neisseria, Trichomonas vaginalis, Enterobacterias, Haemophilus, Corynebacterium, Streptococcus pneumonie, Streptococcus pyrogenes, Salmonella typhi, Brucella abortus.

Disponibili anche nella versione con terreno di trasporto Amies maggiorato che consente un'immersione migliore del campione batteriologico nel terreno garantendo una più sicura sopravvivenza dei batteri anaerobici. Consente altresì di avere il campione stemperato in una quantità maggiore di terreno.

Item code Codice articolo	Swabs type / Tipo tampone		R.D.M. ¹
301/SG	Plastic stick, Rayon tip / Asta Plastica, puntale in Viscosa		1901073/R
301/AL/SG	Aluminum stick, Rayon tip / Asta Alluminio, puntale in Viscosa		1901386/R
301/SG/XL	Double AMIES / AMIES Maggiorato Plastic stick, Rayon tip / Asta Plastica, puntale in Viscosa		1901387/R
SHELF LIFE / SCADENZA			
24 months / mesi			
pH			
7.2 ± 0.2 at/a 25°C			
Composizione Terreno		Medium Composition	
Cloruro di Sodio	3,0 g	Sodium Chloride	
Potassio Cloruro	0,2 g	Potassium Chloride	
Calcio Cloruro	0,1 g	Calcium Chloride	
Magnesio Cloruro	0,1 g	Magnesium Chloride	
Fosfato monopotassio	0,2 g	Monopotassium Phosphate	
Disodio Fosfato	1,15 g	Disodium Phosphatate	
Sodio Tioglicolato	1 g	Sodium Thyoglicollate	
Bacto Agar	7,5 g	Bacto Agar	
Acqua Distillata	1 litro / liter	Distilled Water	
Microrganismo Micro-organism	Limite Limit	Tempo 0 Time 0	Tempo 24 ore Time 24 hours
Neisseria gonorrhoeae ATCC 43069	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	++
Haemophilus influenzae ATCC 10211 or 19418	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	+++
Bacteroides fragilis ATCC 25285	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	+++
++++	Tutte le colonie vive, colonie confluenti	All alive colonies, confluent colonies	
+++	Limite tra le colonie visibile, colonie semi confluenti	Visible limit between colonies, semi-confluent colonies	
++	da 4.000 a 2.000 colonie	From 4,000 to 2,000 colonies	
+	da 2.000 a 200 colonie	From 2,000 to 200 colonies	

¹ Repertorio Nazionale dei Dispositivi Medici
 Mod ST-059/11.19/2

AMIES with CHARCOAL / AMIES con CARBONE



Sterile swabs with Amies with charcoal agar gel medium. The Amies formula with charcoal has been shown to improve the recovery of *Neisseria gonorrhoeae*, *Vibrio cholerae* and is often moreover recommended for *Bordetella pertussis*.

Available with double Amies agar gel medium (6 ml) which allows a better bacteriological sample inoculation inside the medium, ensuring a safer anaerobic bacteria viability. Furthermore it allows to dilute the samples in a medium greater quantity.

Tamponi sterili con terreno agar gel di trasporto Amies con carbone. La formula Amies con carbone ha dimostrato una migliore sopravvivenza della Neisseria gonorrhoeae, Vibrio cholerae ed è spesso maggiormente raccomandato per la Bordetella pertussis.

Disponibili anche nella versione con terreno di trasporto Amies maggiorato che consente un'immersione migliore del campione batteriologico nel terreno garantendo una più sicura sopravvivenza dei batteri anaerobici. Consente altresì di avere il campione stemperato in una quantità maggiore di terreno.

Item code Codice articolo	Swabs type / Tipo tampone		R.D.M. ¹
303/SG	Plastic stick, Rayon tip / Asta Plastica, puntale in Viscosa		1901235/R
303/AL/SG	Aluminum stick, Rayon tip / Asta Alluminio, puntale in Viscosa		1901388/R
303/SG/XL	Double AMIES / AMIES Maggiorato Plastic stick, Rayon tip / Asta Plastica, puntale in Viscosa		1901389/R
SHELF LIFE / SCADENZA			
24 months / mesi			
pH			
7.2 ± 0.2 at/a 25°C			
Composizione Terreno		Medium Composition	
Cloruro di Sodio	3,0 gr.	Sodium Chloride	
Potassio Cloruro	0,2 gr.	Potassium Chloride	
Calcio Cloruro	0,1 gr.	Calcium Chloride	
Magnesio Cloruro	0,1 gr.	Magnesium Chloride	
Fosfato monopotassio	0,2 gr.	Monopotassium Phosphate	
Disodio Fosfato	1,15 gr.	Disodium Phosphatate	
Sodio Tioglicolato	1 gr.	Sodium Thyoglicollate	
Bacto Agar	7,5 gr.	Bacto Agar	
Acqua Distillata	1 litro / liter	Distilled Water	
Carbone	10 gr.	Charcoal	
Microrganismo Micro-organism	Limite Limit	Tempo 0 Time 0	Tempo 24 ore Time 24 hours
Neisseria gonorrhoeae ATCC 43069	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	++
Haemophilus influenzae ATCC 10211 or 19418	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	++++
Bacteroides fragilis ATCC 25285	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	++++
++++	Tutte le colonie vive, colonie confluenti	All alive colonies, confluent colonies	
+++	Limite tra le colonie visibile, colonie semi confluenti	Visible limit between colonies, semi-confluent colonies	
++	da 4.000 a 2.000 colonie	From 4,000 to 2,000 colonies	
+	da 2.000 a 200 colonie	From 2,000 to 200 colonies	

¹ Repertorio Nazionale dei Dispositivi Medici
 Mod ST-059/11.19/2

Clear STUART / STUART chiaro



Sterile swabs with clear Stuart agar gel medium. Stuart transport medium allows the survival of many microorganisms, such as *Trichomonas vaginalis*, *Haemophilus influenzae*, *Streptococcus pneumoniae*, *Streptococcus pyogenes*, *Corynebacterium diphtheria* and *Neisseria gonorrhoeae*.

Tamponi sterili con terreno agar gel di trasporto Stuart chiaro. Il terreno Stuart è particolarmente idoneo per garantire la sopravvivenza di microrganismi come per esempio Trichomonas vaginalis, Haemophilus influenzae, Streptococcus pneumoniae, Streptococcus pyogenes, Corynebacterium diphtheria and Neisseria gonorrhoeae.

Item code Codice articolo	Swabs type / Tipo tampone		R.D.M. ¹
305/SG	Plastic stick, Rayon tip / Asta Plastica, puntale in Viscosa		1901242/R
305/AL/SG	Aluminum stick, Rayon tip / Asta Alluminio, puntale in Viscosa		1901390/R
SHELF LIFE / SCADENZA			
24 months / mesi			
pH			
7.2 ± 0.2 at/a 25°C			
Composizione Terreno		Medium Composition	
Sodio glicerofosfato	10,0 gr.	Sodium Glycerophosphate	
Calcio cloruro	0,1 gr.	Calcium Chloride	
Acido mercaptoacetico	1,0 ml	Mercaptoacetic Acid	
Bacto Agar	7,5 gr.	Bacto Agar	
Acqua distillata	1 litro/liter	Distilled Water	
Microrganismo Micro-organism	Limite Limit	Tempo 0 Time 0	Tempo 24 ore Time 24 hours
Neisseria gonorrhoeae ATCC 43069	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	++
Haemophilus influenzae ATCC 10211 or 19418	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	+++
Bacteroides fragilis ATCC 25285	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	+++
++++	Tutte le colonie vive, colonie confluenti	All alive colonies, confluent colonies	
+++	Limite tra le colonie visibile, colonie semi confluenti	Visible limit between colonies, semi-confluent colonies	
++	da 4.000 a 2.000 colonie	From 4,000 to 2,000 colonies	
+	da 2.000 a 200 colonie	From 2,000 to 200 colonies	

¹ Repertorio Nazionale dei Dispositivi Medici
 Mod ST-059/11.19/2

STUART with CHARCOAL / STUART con CARBONE



Sterile swabs with Stuart with charcoal agar gel medium. The Stuart formula with charcoal has been shown to improve the recovery of *Neisseria gonorrhoeae*.

Tamponi sterili con terreno agar gel di trasporto Stuart con carbone. La formula Stuart con carbone ha dimostrato una migliore sopravvivenza della Neisseria gonorrhoeae..

Item code Codice articolo	Swabs type / Tipo tampone		R.D.M. ¹
307/SG	Plastic stick, Rayon tip / Asta Plastica, puntale in Viscosa		1901391/R
307/AL/SG	Aluminum stick, Rayon tip / Asta Alluminio, puntale in Viscosa		1901392/R
SHELF LIFE / SCADENZA			
24 months / mesi			
pH			
7.2 ± 0.2 at/a 25°C			
Composizione Terreno		Medium Composition	
Sodio glicerofosfato	10,0 gr.	Sodium Glycerophosphate	
Calcio cloruro	0,1 gr.	Calcium Chloride	
Acido mercaptoacetico	1,0 ml	Mercaptoacetic Acid	
Bacto Agar	7,5 gr.	Bacto Agar	
Carbone	10,0 gr.	Charcol	
Acqua distillata	1 litro/liter	Distilled Water	
Microrganismo Micro-organism	Limite Limit	Tempo 0 Time 0	Tempo 24 ore Time 24 hours
Neisseria gonorrhoeae ATCC 43069	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	++
Haemophilus influenzae ATCC 10211 or 19418	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	++++
Bacteroides fragilis ATCC 25285	≥ 50 UFC/piastra ≥ 50 UFC/plate	++++	++++
+++ + +++ ++ +	Tutte le colonie vive, colonie confluenti Limite tra le colonie visibile, colonie semi confluenti da 4.000 a 2.000 colonie da 2.000 a 200 colonie	All alive colonies, confluent colonies Visible limit between colonies, semi-confluent colonies From 4,000 to 2,000 colonies From 2,000 to 200 colonies	

¹ Repertorio Nazionale dei Dispositivi Medici
 Mod ST-059/11.19/2

CARY BLAIR



Sterile swabs with Cary Blair agar gel medium. Particularly suitable for rectal swabs and faecal specimens. It is suitable for the transport of Salmonella, Shigella, Campylobacter and Vibrio. Sodium glycerophosphate presents in Stuart medium, is replaced by buffer phosphate to avoid, in the medium, the growth of bacteria that have glycerophosphate reductase. The medium is particularly suitable for the transport of Salmonella and Shigella: furthermore its high pH relatively alkaline minimize the bacterial destruction due to formation of acid. Viability of Vibrio cultures for up to four weeks.

Tamponi sterili con terreno agar gel di trasporto Cary Blair. Particolarmente adatto per prelievi rettali e per campioni fecali. È idoneo per il trasporto e la conservazione di Salmonella, Shigella, Campylobacter e Vibrio. Il sodio glicerofosfato, presente nel terreno di Stuart, è stato sostituito da un tampone

fosfato per evitare la crescita nel terreno dei batteri che possiedono l'enzima glicerofosfato reductasi. Il terreno è particolarmente indicato per il trasporto di Salmonella e Shigella; inoltre l'elevato valore di pH mantiene la vitalità delle colture di Vibrio Colerae, Vibrio Parahaemoliticus fino a 4 settimane minimizzando la distruzione batterica a causa di acidi.

Item code Codice articolo	Swabs type / Tipo tampone	R.D.M. ¹
309/SG	Plastic stick, Rayon tip / Asta Plastica, puntale in Viscosa	1901393/R
309/AL/SG	Aluminum stick, Rayon tip / Asta Alluminio, puntale in Viscosa	1901394/R

SHELF LIFE / SCADENZA

24 months / mesi

pH

8.4 ± 0.2 at/a 25°C

Composizione Terreno		Medium Composition	
Sodio Tioglicollato	1,5 g.	Sodium Thyoglicollate	
Sodio Fosfato Dibasico	1,1 g.	Disodium Phosphate	
Cloruro di Sodio	5,0 g.	Sodium Chloride	
Calcio Cloruro	0,09 g.	Calcium Chloride	
Bacto Agar	5 g.	Bacto Agar	
Acqua Distillata	1 litro/liter	Distilled Water	

Cultural characteristics after 24-48 hours of storage at 25°C and subculture on medium
Caratteristiche colturali dopo 24-48 ore di conservazione a 25°C e subcoltura su terreno

Microorganismo / Micro-organism		Terreno / Medium	Crescita Growth
Salmonella enteritidis	ATCC 13076	TSA + 5% Sheep Blood	buona / good
Shigella dysenteriae	ATCC 13316	TSA + 5% Sheep Blood	buona / good
Vibrio cholerae bitype El Tor	ATCC 15748	TSA + 5% Sheep Blood	buona / good
Vibrio parahaemolyticus	ATCC EB101	TSA + 5% Sheep Blood	buona / good

¹ Repertorio Nazionale dei Dispositivi Medici
 Mod ST-059/11.19/2

RESULTS / RISULTATI

La sopravvivenza dei batteri nel terreno di trasporto dipende da molti fattori, tra cui il tipo di batteri, la durata del trasporto, la temperatura di conservazione, la concentrazione di batteri nel campione e la formulazione del terreno di trasporto. I dispositivi assicurano la sopravvivenza di molti microrganismi per 24-48 ore. Nel caso di batteri esigenti come *Neisseria Gonorrhoeae* e *Streptococcus pneumoniae*, i campioni sul tampone devono essere seminati direttamente su piastra con terreno di coltura o trasportati immediatamente in laboratorio e messi in coltura entro 24 ore.

Use of the Cliniswab^{TS} in conjunction with rapid diagnostic kits and instruments must be validated prior to use by the user.

Bacteria survival in the transport media depends upon a series of factors such as bacteria type, transport time, preservation temperature, bacteria concentration in the sample and transport medium formula.

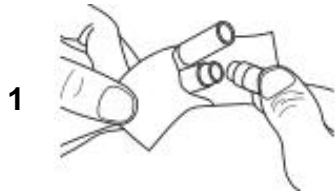
*Devices ensure the survival of several micro-organisms for 24-48 hours. In the case of fastidious bacteria such as *Neisseria Gonorrhoeae* and *Streptococcus pneumoniae*, the samples on the swab shall directly be put on a plate with culture medium or immediately transported to the laboratory and cultivated within 24 hours.*

L'uso dei tamponi Cliniswab^{TS} in combinazione con kit diagnostici rapidi e con strumenti deve essere preventivamente validato dall'utilizzatore.

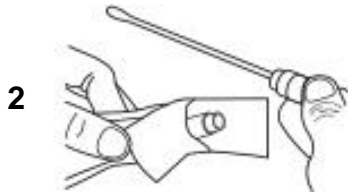
PRECAUTIONAL MEASURES / PRECAUZIONI D'USO

- The device must be suitable for both the selected transport medium (if present) and the defined sampling site;
- Use only for the collection and transport of human biological samples for the detection of potential pathogens such as aerobic, anaerobic and facultative anaerobic bacteria, compatible with the type of device selected;
- Do not deviate from the intended use;
- Do not use the product if it is expired or the package is opened/damaged. Sterility guaranteed if unopened;
- Use the device following aseptic procedures;
- Single-use device; do not reuse. Reusing the device could contaminate the sample and/or the patient;
- Keep the device away from flames and heat sources;
- The fiber is only guaranteed to adhere to the shaft for instant sampling;
- The shaft is breakable, exert moderate pressure during sample collection;
- Store in a cool, dry place at a temperature between +2°C (35.6°F) and +30°C (86°F). Do not freeze;
- After use, the device may contain infectious microorganisms. Use appropriate PPE and dispose of the test tube and swab according to current regulations for medical waste.
- Keep out of flame or heat sources which might damage the product.
- Keep out of reach of children.
- Strictly follow the user's instructions.
- *Utilizzare il Dispositivo solo per la tipologia di campione idonea al terreno di trasporto scelto (se presente) e al sito di prelievo definito;*
- *Utilizzare esclusivamente per la raccolta e il trasporto di campioni biologici umani per la ricerca di eventuali organismi patogeni come batteri aerobi, anaerobi, anaerobici facoltativi compatibilmente con la tipologia di Dispositivo scelta;*
- *Non variare la destinazione d'uso;*
- *Non utilizzare il prodotto scaduto o con la confezione aperta/danneggiata. Sterilità garantita a confezione integra;*
- *Utilizzare il Dispositivo con procedure asettiche;*
- *Non riutilizzare, dispositivo monouso. Il riutilizzo del Dispositivo potrebbe causare la contaminazione del campione prelevato e/o del paziente;*
- *Non avvicinare il dispositivo alla fiamma o a fonti di calore;*
- *L'adesione della fibra all'asta è garantita unicamente per prelievi istantanei;*
- *Il materiale dell'asta è frangibile, esercitare una pressione moderata durante il prelievo;*
- *Conservare in luogo fresco ed asciutto, temperatura min +2°C (35,6 °F) / max +30°C (86 °F). Non congelare;*
- *Ogni dispositivo, dopo l'utilizzo, può contenere microrganismi infettivi, utilizzare appositi D.P.I. e smaltire provetta e tampone secondo le normative vigenti per i rifiuti sanitari*
- *Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.*
- *Prodotto non adatto ai bambini.*
- *Le istruzioni d'uso vanno seguite attentamente.*

HOW TO USE / MODALITÀ D'USO



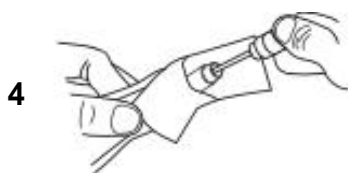
- Open the blister pack from the “peel here” indication and remove the cap of the test tube containing the transport medium;
- Aprire il blister dove vi è l'indicazione “Peel here” e togliere il tappo dalla provetta contenete il terreno di trasporto;



- Remove the applicator from the blister pack;
- Estrarre il tampone applicatore dal blister;



- Collect the sample from the concerned site;
- Effettuare il prelievo dal sito interessato;



- Put the applicator into the test tube containing the transport medium and seal tightly with the cap on the applicator. Write the patient's data on the label;
- Porre il tampone applicatore nella provetta contenete il terreno di trasporto e richiudere bene con il tappo presente sul tampone applicatore. Annotare i dati del paziente sull'etichetta;

SPECIMEN CULTURES IN THE LABORATORY / MODALITÀ D'USO IN LABORATORIO

Manual Processing / Procedura manual

1. Remove the cap with swab applicator;
Rimuovere il tappo con il tampone applicatore;
2. Using the swab applicator, Streak the agar plate while rolling the swab tip.
Utilizzando il tampone applicatore effettuare l'inoculazione sulla piastra strisciando e ruotando il puntale dell'applicatore.



QUALITY ASSURANCE

Tutte le materie prime, componenti e ogni lotto di prodotto finito vengono sottoposti a severi controlli di qualità effettuati dalla ditta allo scopo di verificare che le specifiche siano soddisfatte.

All raw materials, components and every lot of finished product undergo strict quality inspections carried out by N.A. in order to check conformance to specifications.

PRODUCT DETERIORATION / DETERIORAMENTO DEL PRODOTTO

The content of the unopened and undamaged units is guaranteed to be sterile. Do not use the units in case of damage, dehydration or contamination. The Devices must be stored at +2°C (35.6°F) / +30°C (86°F) until used. Improper storage will result in a loss of efficacy. Do not use after expiration date indicated on label.

Il contenuto delle unità non ancora aperte e non danneggiate è garantito sterile. Non utilizzarle se presentano tracce di danneggiamento, disidratazione o contaminazione. Il Dispositivo deve essere conservato a +2°C (35.6°F) / +30°C (86°F) fino ad utilizzo. Conservazione impropria può risultare in perdita di efficacia. Non usare dopo la data di scadenza indicata sull'etichetta.

IMBALLO / PACKING

Confezione interna (pz): 150 pcs
 Internal packing (pcs):

Dimensions: 340 X 225 X 175 mm
 Dimensioni:

Peso: 2,0 Kg.
 Weight:

Confezione esterna (pz): 900 pcs (6 x 150 pcs)
 External packing (pcs):

Dimensions: 540 X 360 X 460 mm
 Dimensioni:

Peso: 12,8 Kg.
 Weight:

SIMBOLI SULL'IMBALLO / PACKAGING SYMBOLS



Data di fabbricazione
 Date of manufacture



Data di scadenza
 Expiry date



Numero di lotto
 Lot number



Fabbricante
 Manufacturer



Monouso
 Do not reuse
 (Disposable)



Codice articolo
 Catalogue number



Non usare se la confezione è danneggiata
 Do not use if package is damaged



Non esporre all'umidità
 Keep dry



Latex free



Non esporre ai raggi solari
 Keep away from sunlight



Limite temperatura
 Temperature limitation



Consultare le istruzioni d'uso
 Consult instructions for use



Sterilizzazione con radiazioni ionizzanti
 Sterilized using irradiation

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