

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)

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**



SGQ N° 049A

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

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**
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"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.

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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.

/

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 xylosus</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	Fosfomycin FOS 100 µg
9121/1	Fosfomycin FOS 100 µg
9109	Fosfomycin FOS 200 µg
9109/1	Fosfomycin FOS 200 µg
9025	Fosfomycin FOS 50 µg
9025/1	Fosfomycin FOS 50 µg
9099	Furazolidon FR 50 µg
9099/1	Furazolidon FR 50 µg
9049	Fusidic acid FC 10 µg
9049/1	Fusidic acid FC 10 µg
9111	Fusidic acid FC 30 µg
9111/1	Fusidic acid FC 30 µg
9169	Gatifloxacin GAT 5 µg
9169/1	Gatifloxacin GAT 5 µg
9026	Gentamicin CN 10 µg
9026/1	Gentamicin CN 10 µg
9124	Gentamicin CN 120 µg
9124/1	Gentamicin CN 120 µg
9125	Gentamicin CN 30 µg
9125/1	Gentamicin CN 30 µg
9074	Griseofulvin AGF 10 µg
9074/1	Griseofulvin AGF 10 µg
9086	Imipenem + Cloxacillin IMI + CL
9183	Imipenem + EDTA IMI + ED 760 (10+750) µg
9183/1	Imipenem + EDTA IMI + ED 760 (10+750) µg
9085	Imipenem + Phenylboronic acid IMI + BO
9085/1	Imipenem + Phenylboronic acid IMI + BO
9079	Imipenem IMI 10 µg
9079/1	Imipenem IMI 10 µg
9107	Itraconazole ITC 50 µg
9107/1	Itraconazole ITC 50 µg
9139	Itraconazole ITC 8 µg
9139/1	Itraconazole ITC 8 µg
9027	Kanamycin K 30 µg

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	Sisomycin SIS 30 µg
9067/2	Spectinomycin SPC 100 µg
9040/2	Streptomycin S 10 µg
9041/2	Sulfafurazole SF 300 µg
9243/2	Tedizolid TZD 2 µg
9050/2	Teicoplanin TEC 30 µg
9043/2	Tetracycline TE 30 µg
9094/2	Tiamulin T 30 µg
9070/2	Ticarillin TC 75 µg
9096/2	Ticarillin-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	805518287TCHR UALV
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	805518287TLYSIAASQ
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



EU Quality Management System Certificate (IVDR)

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

No. V12 071067 0008 Rev. 00

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

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:V12_071067_0008_Rev.00

Report No.: ITA1674857

Valid from: 2022-07-25

Valid until: 2027-07-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-07-25



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: \



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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Sabouraud CAF Agar

Terreno selettivo per la coltivazione e l'isolamento di funghi patogeni a non patogeni.

DESCRIZIONE

Sabouraud CAF Agar è un terreno selettivo utilizzato per la coltivazione e l'isolamento di funghi da campioni clinici e non clinici.

FORMULA TIPICA	(g/l)
Digestione Enzimatica di Caseina	5.0
Digestione Enzimatica di Tessuto Animale	5.0
Glucosio	40.0
Cloramfenicolo	0.5
Agar	15.00
pH Finale 5.6 ± 0.2 a 25°C	

PRINCIPIO DEL METODO

La digestione enzimatica di caseina e la digestione enzimatica di tessuto animale fornisce azoto e vitamine per la crescita dei funghi. L'alta concentrazione di glucosio insieme al pH acido rendono il terreno particolarmente adatto per la coltivazione dei funghi. Il cloramfenicolo è un antibiotico ad ampio spettro con effetto inibitorio su molti batteri sia Gram positivi che Gram negativi. L'agar è l'agente solidificante.

PREPARAZIONE

- Terreno disidratato Sospendere 65.5 g di polvere in 1 litro di acqua distillata o deionizzata sterile. Mescolare bene. Riscaldare agitando di frequente e bollire fino a completa dissoluzione. Sterilizzare in autoclave a 118°C per 15 minuti.
- Terreno in flaconi Sciogliere il contenuto di un flacone in bagnomaria a 100°C (con i tappi leggermente svitati) fino a completa dissoluzione del terreno. Verificare, una volta fuso, la buona omogeneità del terreno capovolgendo il flacone dopo averne avvitato il tappo. Raffreddare a 45-50°C, mescolare bene senza formazione di bolle. Versare in contenitori finali in condizioni di asepsi.

PROCEDURA DEL TEST

Inoculare le piastre o le provette a becco di clarino strisciando direttamente il campione sulla superficie dell'agar. Strisciare il campione clinico il prima possibile dopo il prelievo ed il trasporto nel laboratorio. Incubare in atmosfera aerobica a 30°C per 2-7 giorni.

INTERPRETAZIONE DEI RISULTATI

Osservare le colonie fungine ed esaminare morfologia e colore. L'identificazione finale dovrebbe essere confermata tramite test biochimici e sierologici.

Al fine di ottenere colture fungine pure potrebbe essere necessario trasferire la crescita nella provetta a becco di clarino su terreni in piastra.

ASPETTO

Terreno disidratato: omogeneo, beige chiaro.
Terreno preparato: ambra, leggermente opalescente.

CONSERVAZIONE

La polvere è fortemente igroscopica, conservare a 10-30°C, in ambiente asciutto, nel suo contenitore originale chiuso ermeticamente. Conservare i flaconi, le provette e le piastre pronte a 10-25°C al riparo dalla luce. Non usare il prodotto dopo la sua data di scadenza indicata sull'etichetta o se il prodotto mostra segni di contaminazione o deterioramento.

DURATA

Terreno disidratato: 4 anni.
Terreno in flaconi: 2 anni.
Terreno in provette: 1 anno.
Piastrine pronte all'uso: 6 mesi.

CONTROLLO DI QUALITÀ

Le piastre vengono inoculate con i ceppi microbici indicati nella tabella CQ.

Inoculo per produttività: 10-100 UFC/ml.

Inoculo per selettività: 10⁴-10⁵ UFC/ml.

Condizioni di incubazione: ambiente aerobico a 30±2°C per 2-7 giorni.

Tabella CQ.

Microrganismo		Crescita
<i>Aspergillus niger</i>	ATCC® 16404	Buona
<i>Candida albicans</i>	ATCC® 10231	Buona
<i>Saccharomyces cerevisiae</i>	ATCC® 9763	Buona
<i>Trichophyton mentagrophytes</i>	ATCC® 9533	Buona
<i>Escherichia coli</i>	ATCC® 8739	Inibita

AVVERTENZE E PRECAUZIONI

Il prodotto non contiene sostanza nocive in concentrazioni superiori ai limiti fissati dall'attuale legislazione e perciò non è classificato come pericoloso. Ciononostante si raccomanda di consultare la scheda di sicurezza per il suo corretto uso. Il prodotto è da intendersi per uso diagnostico in vitro e deve essere utilizzato esclusivamente da operatori adeguatamente addestrati.

SMALTIMENTO DEI RIFIUTI








Lo smaltimento dei rifiuti deve essere effettuato in conformità alle normative nazionali e locali in vigore.

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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.

PRESENTAZIONE		Contenuto	Ref.
Sabouraud CAF Agar	Piastre da 90 mm pronte all'uso	20 piastre	11035
Sabouraud CAF Agar	Piastre da 90 mm pronte all'uso	100 piastre	11035*
Sabouraud CAF Agar	Piastre da 140 mm pronte all'uso	10 piastre	10242
Sabouraud CAF Agar	Provette a becco di clarino	10 provette da 10 ml	30023
Sabouraud CAF Agar	Provette a becco di clarino	20 provette da 10 ml	31023
Sabouraud CAF Agar	Flaconi	6 flaconi da 200 ml	412370
Sabouraud CAF Agar	Flaconi	6 flaconi da 100 ml	402370
Sabouraud CAF Agar	Terreno disidratato	500 g di polvere	610203
Sabouraud CAF Agar	Terreno disidratato	100 g di polvere	620203
Sabouraud CAF Agar	Terreno disidratato	5 kg di polvere	6102035

TABELLA DEI SIMBOLI

LOT Codice del lotto	IVD Dispositivo Medico Diagnostico <i>in vitro</i>	 Fabbricante	 Utilizzare entro	 Fragile, maneggiare con cura
REF Numero di catalogo	 Limiti di temperatura	 Contenuto sufficiente per <n> saggi	 Attenzione, Consultare le istruzioni per l'uso	 Non riutilizzare



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STREPTOSYSTEM 12R

System for the identification of Streptococci.

ENGLISH

DESCRIPTION

STREPTOSYSTEM 12R is a 24-well system containing 12 x 2 desiccated biochemical substrata for the identification of streptococci.

Each system allows the performance of two tests and is inoculated with the bacterial suspension of the microorganism to test. Incubation at 36±1°C for 18-24 hours.

The microorganism is identified by assessing the color change of the various wells in order to determine the corresponding numerical code.

CONTENT OF THE PACKAGE

Ref. 72560	Ref. 79560
<ul style="list-style-type: none"> • 20 Systems STREPTOSYSTEM 12R (40 tests) • 40 Vial of Inoculum Strepto Broth (5.0 mL) • 2 Cartridges of PYR-Disc • 1 Vial of PYR Reagent (5.0 mL) • 1 Vial of Ninhydrin Reagent (5.0 mL) 	<ul style="list-style-type: none"> • 4 Systems STREPTOSYSTEM 12R (8 tests) • 8 Vial of Inoculum Strepto Broth (5.0 mL) • 1 Cartridge of PYR-Disc • 1 Vial of PYR Reagent (5.0 mL) • 1 Vial of Ninhydrin Reagent (5.0 mL)

NECESSARY ITEMS NOT CONTAINED IN THE PACKAGE

<ul style="list-style-type: none"> • VP Reagent (ref. 87002). 	<ul style="list-style-type: none"> • Vaseline oil (ref. 87006)
--	---

PRINCIPLE OF THE METHOD

STREPTOSYSTEM 12R allows the identification of streptococci on the basis of biochemical tests performed in the wells containing specific culture media.

The combination of positive and negative reactions allows to determine a numerical code that in turn permits to identify the examined bacterium by using the Codes table or the Software on-line.

CONFIGURATION

Well		BIOCHEMICAL REACTIONS STREPTOCOCCI IDENTIFICATION
1-VP	*	Production of acetoin (Voges-Proskauer test)
2-IPP	*	Hydrolysis of hippurate
3-ESC		Hydrolysis of esculin
4-PYR	*	Hydrolysis of pirrolidonil-β-naftilammide (PYR test)
5-ONPG		Hydrolysis of ONPG (ortho-nitrophenyl-β-galactoside)
6-ADC	□	Decarboxylation of arginine
7-RIB		Fermentation of ribose
8-ARA		Fermentation of arabinose
9-MAN		Fermentation of mannitol
10-SOR		Fermentation of sorbitol
11-TRE		Fermentation of trehalose
12-RAF		Fermentation of raffinose

□ : after inoculation, overlay the well with vaseline oil

* : after incubation, add the indicated reagent

TEST PROCEDURE**PREPARATION OF THE BACTERIAL SUSPENSION**

1. The microorganism to be identified must be recently isolated (18-24 h); bacteria cultures older than 48 hours can provide not reliable results.
2. Take one or more morphologically similar, well-isolated colonies from the agar culture medium and suspend in Inoculum Strepto Broth contained in the package.

INOCULUM OF THE SYSTEM

1. Take a system from its wrapper and bring it to room temperature.
2. Write down patient's name, date and origin of the microorganism.
3. Transfer 0.2 mL of bacterial suspension into each well of the system.
4. Deposit a **PYR-Disc** into the well **1-PYR**.
5. Overlay with 1 drop of vaseline oil the well **6-ADC**.
6. Cover the system with the lid provided and incubate at $36\pm 1^{\circ}\text{C}$ for 18-24 hours.

INTERPRETATION OF RESULTS

At the end of the incubation period:

1. Add 2 drops of Alpha-naphthol and 1 drop of NaOH 40% (ref. 80252) into the well **1-VP**;
2. Add 2 drops of Ninhydrin Reagent into the well **2-IPP**;
3. Add 2 drops of PYR Reagent into the well **4-PYR**;
4. Wait for 15-20 minutes and watch for the color change in the wells. Interpret the results using the interpretative table.
5. Note the results on the Test Results Form and determine the 4-digit code by following instructions provided in the **NUMERICAL CODE FORMATION** paragraph.
6. Identify the microorganism by using the Codes table or the Software on-line.

Interpretative table.

Well	REACTIONS FOR THE BIOCHEMICAL IDENTIFICATION	Well color	
		Positive reaction	Negative reaction
1-VP	VP test	pink-red	yellow
2-IPP	Hippurate hydrolysis	blue-violet	colorless
3-ESC	Esculin hydrolysis	black-brown	yellow
4-PYR	PYR test	pink-fuchsia disc	light pink disc
5-ONPG	ONPG hydrolysis	yellow	colorless
6-ADC	Arginine decarboxylation	red	yellow-orange
7-RIB	Ribose fermentation	yellow-orange	red
8-ARA	Arabinose fermentation	yellow-orange	red
9-MAN	Mannose fermentation	yellow-orange	red
10-SOR	Sorbitol fermentation	yellow-orange	red
11-TRE	Trehalose fermentation	yellow-orange	red
12-RAF	Raffinose fermentation	yellow-orange	red

NUMERICAL CODE FORMATION

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

- Value 1 : first test positive in each group (**VP, PYR, RIB, SOR**).
- Value 2 : second test positive in each group (**IPP, ONPG, ARA, TRE**).
- Value 4 : third test positive in each group (**ESC, ADC, MAN, RAF**).
- Value 0 : every negative test

A 4-digit code is obtained by adding together the values corresponding to positive reactions within each group. The code allows the identification of the organism under examination by using the Codes Table. The example below shows how a numerical code can be formed.

Example.

	Group 1			Group 2			Group 3			Group 4		
Test	VP	IPP	ESC	PYR	ONPG	ADC	RIB	ARA	MAN	SOR	TRE	RAF
Values	1	2	4	1	2	4	1	2	4	1	2	4
Results	-	-	-	+	-	+	-	-	-	-	+	-
Sum of values	0			5			0			2		
CODE 0502	IDENTIFICATION: <i>Streptococcus pyogenes</i>											

SCHEME OF REACTIONS													
Microorganism	VP	IPP	ESC	PYR	ONPG	ADC	RIB	ARA	MAN	SOR	TRE	RAF	Hemolysis
<i>S. pyogenes</i>	-	-	-	+	-	+	-	-	-	-	+	-	β
<i>S. agalactiae</i>	+	+	-	-	-	+	+	-	-	-	+	-	-/β
<i>S. epidermidis</i>	-	-	±	-	-	+	+	-	-	+	-	-	β
<i>S. dysgalactiae</i>	-	-	-	-	-	+	+	-	-	±	+	-	-/α
<i>S. equi</i>	-	-	-	-	-	+	-	-	-	-	-	-	β
<i>E. faecalis</i>	+	±	+	+	-	+	+	-	+	+	+	-	-/α
<i>E. faecium</i>	+	±	+	+	+	+	+	+	+	-	+	-	-/α
<i>E. casseliflavus</i>	+	±	+	+	+	+	+	+	+	-	+	+	-/α
<i>S. durans</i>	+	±	+	+	±	+	+	-	-	-	±	-	-/α/β
<i>S. bovis</i> I	+	-	+	-	-	-	-	-	+	-	+	+	-/α
<i>S. bovis</i> II	+	-	+	-	-	-	-	-	-	-	±	+	-/α
<i>S. equinus</i>	+	-	+	-	-	-	-	-	-	-	-	-	-/α
<i>E. avium</i>	+	-	+	+	-	-	+	±	+	+	+	-	-/α
<i>S. milleri</i> I	+	-	-	-	-	+	-	-	-	-	-	±	β
<i>S. milleri</i> II	+	-	+	-	-	+	-	-	-	-	+	-	α/β
<i>S. sanguis</i> I	-	-	+	-	-	+	-	-	-	-	+	±	α
<i>S. sanguis</i> II	-	-	-	-	±	±	-	-	-	-	±	+	α
<i>S. salivarius</i>	+	-	+	-	±	-	-	-	-	-	±	+	-
<i>S. mitis</i>	-	-	-	-	±	-	-	-	-	-	-	-	α
<i>S. pneumoniae</i>	-	-	±	-	+	±	-	-	-	-	+	+	α
<i>S. mutans</i>	+	-	+	-	-	-	-	-	+	+	+	+	-/α
<i>S. lactis</i>	+	-	+	±	±	+	+	-	±	-	+	-	-/α
<i>S. suis</i> I	-	-	+	±	±	+	-	-	-	-	+	-	α
<i>S. suis</i> II	-	-	±	±	±	+	-	-	-	-	+	+	α
<i>S. uberis</i>	+	+	+	±	-	+	+	-	+	+	+	-	-/α
<i>S. acidominimus</i>	-	+	±	±	-	-	±	-	±	-	±	-	α
<i>S. viridans</i>	-	+	±	±	-	-	±	-	±	±	+	±	α

+ : positive reaction

- : negative reaction

± : variable reaction

Codes table.

Code	Microorganism	Code	Microorganism
0000	<i>S. mitis</i>	5047	<i>S. mutans</i>
0004	<i>S. sanguis</i> II	5153	<i>E. avium</i>
0006	<i>S. sanguis</i> II	5173	<i>E. avium</i>
0200	<i>S. mitis</i>	5204	<i>S. salivarius</i>
0204	<i>S. sanguis</i> II	5206	<i>S. salivarius</i>
0206	<i>S. sanguis</i> II <i>S. pneumoniae</i>	5402	<i>S. milleri</i> II
0400	<i>S. equi</i>	5412	<i>S. lactis</i>
0406	<i>S. suis</i> II	5452	<i>S. lactis</i>
0411	<i>S. epidermidis</i>	5512	<i>S. durans</i> <i>S. lactis</i>
0412	<i>S. dysgalactiae</i>	5510	<i>S. durans</i>
0413	<i>S. dysgalactiae</i>	5552	<i>S. lactis</i>
0502	<i>S. pyogenes</i>	5553	<i>E. faecalis</i>
0506	<i>S. suis</i> II	5710	<i>S. durans</i>
0604	<i>S. sanguis</i> II	5712	<i>S. durans</i>
0606	<i>S. equi</i>	5752	<i>S. lactis</i>
0706	<i>S. suis</i> II	5772	<i>E. faecium</i>
1400	<i>S. milleri</i> I	5776	<i>E. casseliflavus</i>
1404	<i>S. milleri</i> I	6000	<i>S. acidominimus</i>
2000	<i>S. acidominimus</i>	6002	<i>S. acidominimus</i> <i>S. viridans</i>
2002	<i>S. acidominimus</i> <i>S. viridans</i>	6003	<i>S. viridans</i>
2003	<i>S. viridans</i>	6007	<i>S. viridans</i>
2007	<i>S. viridans</i>	6010	<i>S. acidominimus</i>
2010	<i>S. acidominimus</i>	6012	<i>S. viridans</i>
2012	<i>S. viridans</i>	6013	<i>S. viridans</i>
2013	<i>S. viridans</i>	6017	<i>S. viridans</i>
2017	<i>S. viridans</i>	6050	<i>S. acidominimus</i>
2050	<i>S. acidominimus</i>	6052	<i>S. acidominimus</i> <i>S. viridans</i>
2052	<i>S. acidominimus</i> <i>S. viridans</i>	6053	<i>S. viridans</i>
2053	<i>S. viridans</i>	6010	<i>S. acidominimus</i>
2057	<i>S. viridans</i>	6012	<i>S. viridans</i>
2100	<i>S. acidominimus</i>	6013	<i>S. viridans</i>
2102	<i>S. acidominimus</i> <i>S. viridans</i>	6017	<i>S. viridans</i>
2103	<i>S. viridans</i>	6050	<i>S. acidominimus</i>
2107	<i>S. viridans</i>	6052	<i>S. acidominimus</i> <i>S. viridans</i>
2110	<i>S. acidominimus</i>	6053	<i>S. viridans</i>
2112	<i>S. acidominimus</i> <i>S. viridans</i>	6057	<i>S. viridans</i>
2113	<i>S. viridans</i>	6100	<i>S. acidominimus</i>
2117	<i>S. viridans</i>	6103	<i>S. viridans</i>
2150	<i>S. acidominimus</i>	6107	<i>S. viridans</i>
2152	<i>S. acidominimus</i> <i>S. viridans</i>	6110	<i>S. acidominimus</i>
2153	<i>S. viridans</i>	6112	<i>S. acidominimus</i> <i>S. viridans</i>
2157	<i>S. viridans</i>	6113	<i>S. viridans</i>
3412	<i>S. agalactiae</i>	6117	<i>S. viridans</i>
4402	<i>S. sanguis</i> I <i>S. suis</i> I	6150	<i>S. acidominimus</i>
4206	<i>S. pneumoniae</i>	6152	<i>S. acidominimus</i> <i>S. viridans</i>
4406	<i>S. sanguis</i> I <i>S. suis</i> II	6153	<i>S. viridans</i>
4411	<i>S. epidermidis</i>	6157	<i>S. viridans</i>
4502	<i>S. suis</i> I	7453	<i>S. uberis</i>
4602	<i>S. suis</i> I	7473	<i>S. uberis</i>
4606	<i>S. pneumoniae</i>	7510	<i>S. durans</i>
4702	<i>S. suis</i> I	7512	<i>S. durans</i>
4706	<i>S. suis</i> II	7553	<i>E. faecalis</i> <i>S. uberis</i>
5000	<i>S. equinus</i>	7573	<i>S. uberis</i>
5004	<i>S. bovis</i> II <i>S. salivarius</i>	7772	<i>E. faecium</i>
5006	<i>S. bovis</i> II <i>S. salivarius</i>	7776	<i>E. casseliflavus</i>
5046	<i>S. bovis</i> I		

QUALITY CONTROL

Every batch of STREPTOSYSTEM 12R is subjected to the quality control using reference microbial strains:

Streptococcus pyogenes ATCC® 19615, *Streptococcus pneumoniae* ATCC® 6303,
Enterococcus faecalis ATCC® 19433, *Streptococcus agalactiae* ATCC® 13813.

FACTORS THAT MAY INVALIDATE THE RESULTS

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

CAUTIONS

The product, STREPTOSYSTEM 12R, is classified as hazardous under current legislation, refer to the safety data sheet for a correct use. STREPTOSYSTEM 12R 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 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, STREPTOSYSTEM 12R 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.








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PRESENTATION

Product	Ref.	Packaging
STREPTOSYSTEM 12R	72560	40 Test
STREPTOSYSTEM 12R	79560	8 Test

TABLE OF SYMBOLS

IVD <i>In Vitro</i> 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





VP (NaOH) Reagent Droppers

Reagents for performing the Voges-Proskauer test,
in dropper bottles.

INTENDED PURPOSE

Kit of reagents for the execution of Voges-Proskauer test used as qualitative test to distinguish between members of Enterobacteriaceae on the basis of the capability to produce acetylmethylcarbinol (acetoin) as a fermentation product from glucose. This test is intended as an aid in the diagnosis, requiring further tests to complete the diagnostic results.

DESCRIPTION

VP (NaOH) Reagent Droppers is used for the identification of bacteria, particularly in the Enterobacteriaceae family, based on production of acetylmethylcarbinol (acetoin) from glucose metabolism.

KIT CONTENT

- 10 dropper bottles of sodium alpha naphthol (2,5 ml).
- 10 dropper bottles of sodium hydroxide (2,5 ml).

METHOD PRINCIPLE

Certain bacteria metabolize glucose to produce acetylmethylcarbinol when cultivated in specific media such as MR-VP broth. Upon addition of Voges-Proskauer reagents, acetylmethylcarbinol is oxidized to diacetylmethylcarbinol, which in turn reacts with creatine (from the broth) to form a red-colored compound.

MATERIALS REQUIRED BUT NOT PROVIDED

Standard microbiological supplies and equipment such as: inoculating loop, pipettes, culture media, quality control organisms.

REAGENTS

- 5% (w/v) solution of Sodium Alpha naphthol in ethyl alcohol
- 40% (w/v) solution of potassium hydroxide in distilled water

SPECIMEN

Collect specimens in sterile containers or with sterile swabs and transport to the laboratory. Process each specimen using procedures appropriate for that sample. This product is recommended for use only with pure cultures.

Refer to specific guidelines for more detailed information.

TEST PROCEDURE

1. Inoculate a tube of MR-VP broth with a pure culture of the test organism and incubate at $35 \pm 2^\circ\text{C}$ for 24-72 hours.
2. Following incubation, aseptically transfer 1-2 ml of the broth culture to a separate test tube.
3. Add 0.6 ml (12 drops) of alpha-naphthol and 0.2 ml (4 drops) of NaOH 40% and shake well to expose the medium to atmospheric oxygen (necessary for oxidation of acetoin to obtain a colour reaction).

INTERPRETING RESULTS

A positive test is given by the development of a pink to bright red colour within 20 minutes after addition of reagents. No color development indicates a negative reaction.

Notes: Development of a copper colour should be considered negative. Positive and negative controls should be run simultaneously with the organism to be tested (see QUALITY CONTROL)

STORAGE

Store at 2-8°C away from light in its original package, until the expiry date shown on the label. Eliminate if signs of deterioration or contamination are evident.

SHELF LIFE

2 years.

QUALITY CONTROL

Appearance control: The alpha-naphthol solution appears limpid and beige; the potassium hydroxide solution appears clear limpid colourless.

Control strain		Characteristic reactions
<i>Listeria monocytogenes</i> 4b	WDCM 00021 ATCC® 13932 NCTC 10527	Positive reaction: Formation of a pink to bright red colour
<i>Enterobacter cloacae</i>	WDCM 00083 ATCC® 13047 NCTC 10005	
<i>Escherichia coli</i>	WDCM 00013 ATCC® 25922 NCTC 12241	Negative reaction: No colour change

PERFORMANCE CHARACTERISTICS

Performance testing of VP (NaOH) Reagent Droppers was carried out using the QC strains listed above. The results obtained met the established criteria.

LIMITATIONS

One should at least 20 min for color to develop before considering the Voges-Proskauer test negative.

WARNING AND PRECAUTIONS

- 1) **For *in vitro* diagnostic use (IVD).**
- 2) **For laboratory professional use only.**
- 3) Operators must be trained and have certain experience. Please read the instructions carefully before using the product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.
- 4) Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.
- 5) Do not use if the product or packaging appears to be damaged.
- 6) Follow standard precautions. All patient specimens should be considered potentially infectious and handled accordingly.
- 7) Handle all specimens as if infectious using safe laboratory procedures. Dispose of hazardous or biologically contaminated materials according to the practices of your institution.
- 8) Avoid cross-contamination of samples by using disposable tips and changing them after each sample.
- 9) Do not mix reagents of different batches. Please use the product within the validity period.
- 10) Do not eat, drink, smoke, apply cosmetics or handle contact lenses in areas where reagents and human specimens are handled.
- 11) Results should be interpreted by a trained professional in conjunction with the patient's history and clinical signs and symptoms, and epidemiological risk factors.
- 12) Ensure laboratory equipment is calibrated and maintained in accordance with the laboratory's procedure.
- 13) When test results are transmitted from the laboratory to an informatics centre, attention has to be done to avoid erroneous data transfer.

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.

ORDER INFORMATION

Product	Packaging	Ref.
VP (NaOH) Reagent Droppers	10 x 2.5 ml 10 x 2.5 ml	87002

Revision History

Revision	Release Date	Change Summary
4	2023-05-15	Updated layout and content in compliance with IVDR 2017/746
3	2022-05-25	Updated: Kit Content, Table of Symbols

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

liofilchem.com/ifu-sds



VASELINE OIL

Vaseline oil for microbiological use,
in dropper bottles.

DESCRIPTION

VASELINE OIL is a material used to keep an anaerobic environment for the microbial growth and for the performance of some biochemical tests suitable for microbial identification. The product use is recommended specially for Liofilchem microbial identification systems, when specified in test procedure of the system.

CONTENT OF THE PACKAGES

Each package contains 10 dropper bottles of 10 ml and 1 instruction sheet.

PRINCIPLE OF THE METHOD

VASELINE OIL, due to its physical-chemical properties, prevents environmental oxygen from coming into contact with medium and microorganism, assuring therefore the keeping of an anaerobiosis level sufficient to the aim the product is set for.

COMPOSITION

Each bottle of VASELINE OIL contains 10 ml of vaseline oil for microbiological use.

TEST PROCEDURE AND INTERPRETATION OF RESULTS

For the product use and interpretation of results refer to the instruction sheet of the relevant identification systems and to the laboratory procedures.

QUALITY CONTROL FOR THE USER

Appearance: limpid colourless solution.

PRECAUTIONS

The product, VASELINE OIL, does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is designed for *In vitro* diagnostic use and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

CONSERVAZIONE

Store VASELINE OIL at 10-25°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, VASELINE OIL 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

- Murray, Baron, Pfaller, Tenover, Tenover. Manual of Clinical Microbiology. 7th Edition.
- BLAZEVIC, D.J., and EDERER, G.M.: Principles of biochemical tests in diagnostic microbiology. 63-67. New York, John Wiley & Sons, 1975.

PRESENTATION

Product	REF	
VASELINE OIL	87006	10 bottles x 10 ml

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	



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Rev.1 / 02.09.2013



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 <input type="checkbox"/>	Decarboxylation of lysine	14-INO	Utilization of inositol
3-ODC <input type="checkbox"/>	Decarboxylation of ornithine	15-SOR	Utilization of sorbitol
4-ADC <input type="checkbox"/>	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 <input type="checkbox"/>	Hydrolysis of urea	19-RAM	Utilization of rhamnose
8-H₂S <input type="checkbox"/>	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 inculum 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



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

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

La sottoscritta, fabbricante
We, the undersigned manufacturer

Biolife Italiana S.r.l.

Con Sede Legale in
With Registered Office in

Viale Monza 272, 2018 - Milano

SRN: IT-MF-000018174

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

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

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

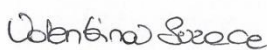
Regolamento (UE) 2017/746 del parlamento Europeo e del consiglio del 5 Aprile 2017, pubblicato su GU L 117 del 5.5.2017, pag. 176
Regulation (UE) 2017/746 of the European Parliament and of the Council of 27th October 1998 of In Vitro Diagnostic Medical Device, published in the Official Journal L117 on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

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

Norme Armonizzate/ Harmonized Standards

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

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


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

TERRENI DI COLTURA PRONTI IN FLACONE / READY-TO USE CULTURE MEDIA IN FLASK

REF.	PRODUCT NAME	UDI-DI	BASIC UDI-DI
5115412	HEKTOEN ENTERIC AGAR - 6 x 100 mL	08054187137266	805418713MEDI AFLASK0051E4
5115413	HEKTOEN ENTERIC AGAR - 6 x 200 mL	08054187137273	805418713MEDI AFLASK0051E4
5115824	LEGIONELLA AGAR BASE (BCYE) - 6 X 180 mL	08054187137280	805418713MEDI AFLASK0051E4
5116702	MAC CONKEY AGAR - 6 x 100 mL	08054187137419	805418713MEDI AFLASK0051E4
5116703	MAC CONKEY AGAR (EP, USP, JP) - 6 x 200 mL	08054187137426	805418713MEDI AFLASK0051E4
5118102	NUTRIENT AGAR (ISO 8523/6579/10273) - 6 x 100 mL	08054187137501	805418713MEDI AFLASK0051E4
5119632	PSEUDOMONAS SELECTIVE AGAR (CETRIMIDE) (EP, USP, JP) - 6 x 100 mL	08054187137655	805418713MEDI AFLASK0051E4
5120002	SABOURAUD BROTH - 6 x 100 mL	08054187137730	805418713MEDI AFLASK0051E4
5120052	SABOURAUD DEXTROSE AGAR (EP, USP, JP) - 6 x 100 mL	08054187137747	805418713MEDI AFLASK0051E4
5120053	SABOURAUD DEXTROSE AGAR (EP, USP, JP) - 6 x 200 mL	08054187137754	805418713MEDI AFLASK0051E4
5120062	SABOURAUD DEXTROSE AGAR W/CAF 50 - 6 x 100 mL	08054187137761	805418713MEDI AFLASK0051E4
5120063	SABOURAUD DEXTR.AG+CAF - 6 x 200 mL	08054187138973	805418713MEDI AFLASK0051E4
5120252	SELENITE BROTH - 6 x 100 mL	08054187137778	805418713MEDI AFLASK0051E4
5121372	THIOGLYCOLLATE MEDIUM - 6 x 100 mL	08054187137013	805418713MEDI AFLASK0051E4
5121502	TRYPTIC SOY AGAR (EP, USP, JP) - 6 x 100 mL	08054187137853	805418713MEDI AFLASK0051E4
5121503	TRYPTIC SOY AGAR (EP, USP, JP) - 6 x 200 mL	08054187137860	805418713MEDI AFLASK0051E4
5121552	TRYPTIC SOY BROTH (EP, USP, JP) - 6 x 100 mL	08054187137877	805418713MEDI AFLASK0051E4
5121553	TRYPTIC SOY BROTH (EP, USP, JP) - 6 x 200 mL	08056450500012	805645050MEDI AFLASK0051E8

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

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



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

TERRENI DI COLTURA PRONTI IN PIASTRA - linea COLOREX / READY-TO USE CULTURE MEDIA IN PLATES - COLOREX			
REF.	PRODUCT NAME	UDI-DI	BASIC UDI-DI
54AC09	COLOREXTM ACINETOBACTER - 20 piastre	08056450505925	805645050COLOREXPLATE54RE
54AC09R	COLOREXTM ACINETOBACTER MDR - 20 piastre	08056450505956	805645050COLOREXPLATE54RE
54CD12	COLOREXTM CLOSTRIDIUM DIFFICILE - 20 piastre	08056450505901	805645050COLOREXPLATE54RE
54CQ26	COLOREXTM COLISTIN RESISTANCE - 20 piastre	08056450505932	805645050COLOREXPLATE54RE
54CP57	COLOREXTM CAMPYLOBACTER - 20 piastre	08056450505963	805645050COLOREXPLATE54RE
54CS17	COLOREXTM SUPERCARBA - 20 piastre	08056450505918	805645050COLOREXPLATE54RE
54LN76	COLOREXTM LINEZOLID RESISTANCE - 20 piastre	08056450506069	805645050COLOREXPLATE54RE
54MR50	COLOREXTM MRSA - 20 piastre	08056450505949	805645050COLOREXPLATE54RE
54SP37	COLOREXTM STREP A - 20 piastre	08056450506052	805645050COLOREXPLATE54RE
54TA67	COLOREXTM STAPHYLOCOCCUS AUREUS - 20 piastre	08056450505994	805645050COLOREXPLATE54RE
54VRE95	COLOREXTM VRE - 20 piastre	08056450505895	805645050COLOREXPLATE54RE
54ST16	COLOREX TM STEC - 20 piastre	08056450506502	805645050COLOREXPLATE54RE



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54CA24	COLOREX TM CANDIDA PLUS - 20 piastre	08056450506571	805645050COLOREXPLATE54RE
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TERRENI DI COLTURA PRONTI IN PROVETTA / READY-TO USE CULTURE MEDIA IN TUBES			
REF.	PRODUCT NAME	UDI-DI	BASIC UDI-DI
551146	BIOTONE BROTH (TRYPTOSE) - 20 x 9 mL	08054187132216	805418713MEDIATUBES0055TC
551230	BRAIN HEART INFUSION BROTH - 20 x 9 mL	08054187131592	805418713MEDIATUBES0055TC
551524	GN BROTH HAJNA (ISTISAN 07/05) - 20 x 9 mL	08054187134746	805418713MEDIATUBES0055TC
551560	KLIGLER IRON AGAR (ISO 6579) - 20 pv incl.	08054187134753	805418713MEDIATUBES0055TC
551634	IUT MEDIUM - 20 pv incl.	08054187131615	805418713MEDIATUBES0055TC
551635	LOWENSTEIN-JENSEN MEDIUM - 20 pv incl.	08054187131622	805418713MEDIATUBES0055TC
551636	LYSINE IRON AGAR - 20 pv incl.	08054187132988	805418713MEDIATUBES0055TC
551743	MULLER KAUFFMANN TETRATHIONATE BROTH - 20 x 10 mL	08054187131646	805418713MEDIATUBES0055TC
551810	NUTRIENT AGAR (ISO 8523/6579/10273) - 20 pv incl.	08054187134791	805418713MEDIATUBES0055TC
551815	NUTRIENT BROTH - 20 x 9 mL	08054187133015	805418713MEDIATUBES0055TC
551980	RAPPAPORT VASSILIADIS BROTH (ISTISAN 96/35) - 20 x 10 mL	08054187131660	805418713MEDIATUBES0055TC
552000	SABOURAUD BROTH (EP, USP, JP) - 20 x 9 mL	08054187131462	805418713MEDIATUBES0055TC
552006	SABOURAUD DEXTROSE AGAR W/CAF 50 - 20 pv incl.	08054187132537	805418713MEDIATUBES0055TC
552008	SABOURAUD DEXTROSE AGAR WITH CAF CEX - 20 pv incl.	08054187132551	805418713MEDIATUBES0055TC
552025	SELENITE BROTH - 20 x 9 mL	08054187131387	805418713MEDIATUBES0055TC
552134	TODD-HEWITT BROTH - 20 x 9 mL	08054187133800	805418713MEDIATUBES0055TC
552137	THIOGLYCOLLATE MEDIUM (EP, USP, JP) - 20 x 10 mL	08054187131400	805418713MEDIATUBES0055TC
552141	TRIPLE SUGAR IRON AGAR USP - 20 pv incl.	08054187132995	805418713MEDIATUBES0055TC
552150	TRYPTIC SOY AGAR (EP, USP, JP) - 20 pv incl.	08054187134852	805418713MEDIATUBES0055TC
552155	TRYPTIC SOY BROTH (EP, USP, JP) - 20 x 9 mL	08054187132513	805418713MEDIATUBES0055TC
552175	UREA AGAR (ISO 6579) - 20 pv incl.	08054187134876	805418713MEDIATUBES0055TC
554002	PERGOLA MEDIUM - 20 pv incl.	08054187134982	805418713MEDIATUBES0055TC
5513311	TRICHOMONAS CPLM SELECTIVE BROTH - 20 x 9 mL	08054187131608	805418713MEDIATUBES0055TC
552134B	TODD-HEWITT CNA BROTH (LIM BROTH) - 20 x 9 mL	08054187133817	805418713MEDIATUBES0055TC

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



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4015204	GC MEDIUM BASE - 5 Kg	08054187139437	805418713MEDIAPOWDER040ZN
4015242	GN BROTH HAJNA - 500 g	08054187137365	805418713MEDIAPOWDER040ZN
4015412	HEKTOEN ENTERIC AGAR - 500 g	08054187134081	805418713MEDIAPOWDER040ZN
4015414	HEKTOEN ENTERIC AGAR - 5 Kg	08054187134074	805418713MEDIAPOWDER040ZN
4015432	HERELLEA AGAR - 500 g	08054187139482	805418713MEDIAPOWDER040ZN
4015602	KLIGLER IRON AGAR - 500 g	08054187138836	805418713MEDIAPOWDER040ZN
4015822	LEGIONELLA BCYE AGAR BASE - 500 g	08054187131271	805418713MEDIAPOWDER040ZN
4015824	LEGIONELLA BCYE AGAR B - 5 Kg	08054187131240	805418713MEDIAPOWDER040ZN
4015952	LEVINE EMB BLUE AGAR - 500 g	08054187139581	805418713MEDIAPOWDER040ZN
4015954	LEVINE EMB BLUE AGAR - 5 Kg	08054187139604	805418713MEDIAPOWDER040ZN
4016352	LOWENSTEIN JENSEN MEDIUM BASE - 500 g	08054187133046	805418713MEDIAPOWDER040ZN
4016354	LOWENSTEIN JENSEN MEDIUM BASE - 5 Kg	08054187133053	805418713MEDIAPOWDER040ZN
4016362	LYSINE IRON AGAR - 500 g	08054187139000	805418713MEDIAPOWDER040ZN
4016652	MANNITOL SALT AGAR - 500 g	08054187133534	805418713MEDIAPOWDER040ZN
4016654	MANNITOL SALT AGAR - 5 Kg	08054187133541	805418713MEDIAPOWDER040ZN
4016702	MAC CONKEY AGAR - 500 g	08054187132254	805418713MEDIAPOWDER040ZN
4016704	MAC CONKEY AGAR - 5 Kg	08054187132247	805418713MEDIAPOWDER040ZN
4016722	MAC CONKEY AGAR MUG - 500 g	08054187139741	805418713MEDIAPOWDER040ZN
4016724	MAC CONKEY AGAR MUG - 5 Kg	08054187139758	805418713MEDIAPOWDER040ZN
4016852	MALONATE BROTH - 500 g	08054187139772	805418713MEDIAPOWDER040ZN
4017352	MRVP MEDIUM - 500 g	08054187133176	805418713MEDIAPOWDER040ZN
4017402	MUELLER HINTON AGAR II - 500 g	08054187136245	805418713MEDIAPOWDER040ZN
4017404	MUELLER HINTON AGAR II - 5 Kg	08054187136238	805418713MEDIAPOWDER040ZN
4017412	MUELLER HINTON BROTH - 500 g	08054187139871	805418713MEDIAPOWDER040ZN
4017432	MULLER KAUFFMANN TETRATHIONATE BROTH BASE - 500 g	08054187139888	805418713MEDIAPOWDER040ZN
4017434	MULLER KAUFFMAN TET.BROTH - 5 Kg	08054187139895	805418713MEDIAPOWDER040ZN
4018102	NUTRIENT AGAR - 500 g	08054187133206	805418713MEDIAPOWDER040ZN
4018104	NUTRIENT AGAR - 5 Kg	08054187133213	805418713MEDIAPOWDER040ZN
4018152	NUTRIENT BROTH - 500 g	08054187137105	805418713MEDIAPOWDER040ZN
4018154	NUTRIENT BROTH - 5 Kg	08054187137112	805418713MEDIAPOWDER040ZN
4018362	O/F HUGH LEIFSON BASE - 500 g	08056450500050	805645050MEDIAPOWDER040TY
4019162	PHENYLALANINE AGAR - 500 g	08054187135712	805418713MEDIAPOWDER040ZN
4019632	PSEUDOMONAS SELECTIVE AGAR - 500 g	08054187133978	805418713MEDIAPOWDER040ZN
4019802	RAPPAPORT VASSILIADIS (RV) BROTH - 500 g	08054187132612	805418713MEDIAPOWDER040ZN
4019804	RAPPAP.VASSILIAD(RV)BROTH - 5 Kg	08054187132629	805418713MEDIAPOWDER040ZN
4019852	ROGOSA BIOS AGAR - 500 g	08054187134678	805418713MEDIAPOWDER040ZN
4020002	SABOURAUD BROTH - 500 g	08054187131431	805418713MEDIAPOWDER040ZN
4020004	SABOURAUD BROTH - 5 Kg	08054187131455	805418713MEDIAPOWDER040ZN
4020052	SABOURAUD DEXTROSE AGAR - 500 g	08054187131257	805418713MEDIAPOWDER040ZN
4020054	SABOURAUD DEXTROSE AGAR - 5 Kg	08054187131264	805418713MEDIAPOWDER040ZN
4020062	SABOURAUD DEXTROSE AGAR W/ CAF 50 mg - 500 g	08054187131936	805418713MEDIAPOWDER040ZN
4020064	SABOURAUD DEXTROSE AGAR W/ CAF 50 mg - 5 Kg	08054187131943	805418713MEDIAPOWDER040ZN
4020072	SABOURAUD DEXTROSE AGAR W/ CAF 500 mg - 500 g	080564505000180	805645050MEDIAPOWDER040TY
4020252	SELENITE BROTH - 500 g	08054187136153	805418713MEDIAPOWDER040ZN
4020254	SELENITE BROTH - 5 Kg	08054187136160	805418713MEDIAPOWDER040ZN
4020362	SIM BIOS MEDIUM - 500 g	080564505000289	805645050MEDIAPOWDER040TY
4020452	SIMMONS CITRATE AGAR - 500 g	08054187132179	805418713MEDIAPOWDER040ZN
4020752	SS AGAR - 500 g	08054187138393	805418713MEDIAPOWDER040ZN
4020754	SS AGAR - 5 Kg	08054187138409	805418713MEDIAPOWDER040ZN
4021062	TCBS KOBAYASHI AGAR - 500 g	08054187134562	805418713MEDIAPOWDER040ZN
4021064	TCBS KOBAYASHI AGAR - 5 Kg	08054187134579	805418713MEDIAPOWDER040ZN
4021342	TODD-HEWITT BROTH - 500 g	080564505000456	805645050MEDIAPOWDER040TY
4021372	THIOGLYCOLLATE MEDIUM - 500 g	08054187133282	805418713MEDIAPOWDER040ZN



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4021374	THIOGLYCOLLATE MEDIUM - 5 Kg	08054187133299	805418713MEDIAPOWDER040Z
4021412	TRIPLE SUGAR IRON AGAR U.S.P. - 500 g	08054187134029	805418713MEDIAPOWDER040Z
4021502	TRYPTIC SOY AGAR - 500 g	08054187131356	805418713MEDIAPOWDER040Z
4021504	TRYPTIC SOY AGAR - 5 Kg	08054187131370	805418713MEDIAPOWDER040Z
4021512	TRYPTIC SOY BLOOD AGAR BASE - 500 g	08054187134197	805418713MEDIAPOWDER040Z
4021514	TRYPTIC SOY BLOOD AGAR BASE - 5 Kg	08054187134203	805418713MEDIAPOWDER040Z
4021552	TRYPTIC SOY BROTH - 500 g	08054187133725	805418713MEDIAPOWDER040Z
4021554	TRYPTIC SOY BROTH - 5 Kg	08054187133732	805418713MEDIAPOWDER040Z
4021752	UREA AGAR BASE-CHRISTENSEN - 500 g	08056450500470	805645050MEDIAPOWDER040TY
4021802	UREA BROTH BASE - STUART - 500 g	08054187135729	805418713MEDIAPOWDER040Z
4022062	XLD AGAR - 500 g	08054187131547	805418713MEDIAPOWDER040Z
4022064	XLD AGAR - 5 Kg	08054187131554	805418713MEDIAPOWDER040Z
4053502	CHROMOGENIC SALMONELLA AGAR BASE - 500 g	08054187139079	805418713MEDIAPOWDER040Z
4080002	CHROMALBICANS AGAR - 500 g	08054187133893	805418713MEDIAPOWDER040Z
4080052	CHROMOGENIC CANDIDA AGAR - 500 g	08054187137556	805418713MEDIAPOWDER040Z
4080102	CHROMOGENIC STREPTO B AGAR BASE - 500 g	08054187138225	805418713MEDIAPOWDER040Z
4080252	CHROMART CRE-ESBL AGAR BASE - 500 g	08056450503587	805645050MEDIAPOWDER040TY
40113612	COLUMBIA CNA AGAR BASE - 500 g	08056450500388	805645050MEDIAPOWDER040TY
40113614	COLUMBIA CNA AGAR BASE - 5 Kg	08056450500395	805645050MEDIAPOWDER040TY
40121022	BISMUTH SULPHITE AGAR - 500 g	08054187138621	805418713MEDIAPOWDER040Z
40129012	CLED MEDIUM - 500 g	08054187139116	805418713MEDIAPOWDER040Z
40129014	CLED MEDIUM - 5 kg	08056450501545	805645050MEDIAPOWDER040TY
40136912	DERMATOPHYTE SELECTIVE MEDIUM - DTM - (TAPLIN) - 500 g	08056450501002	805645050MEDIAPOWDER040TY
402025B2	SELENITE BROTH BASE - 500 g	08056450501682	805645050MEDIAPOWDER040TY
409810G2	CHROMOGENIC URINE AGAR IV - 500 g	08054187137358	805418713MEDIAPOWDER040Z
4011534	BCSA BURKHOL.CEP.SEL.AGAR BASE - 5 kg	08056450505321	805645050MEDIAPOWDER040TY
4019634	PSEUDOMONAS SELECTIVE AG. - 5 kg	08054187133961	805418713MEDIAPOWDER040Z
4053504	CHROMOGENIC SALMO.AG.BASE - 5 kg	08056450503037	805645050MEDIAPOWDER040TY
4080004	CHROMALBICANS AGAR - 5 kg	08054187133909	805418713MEDIAPOWDER040Z
4080054	CHROMOGENIC CANDIDA AGAR - 5 kg	08056450503181	805645050MEDIAPOWDER040TY

ADDITIVI PER TERRENI DI COLTURA / ADDITIVES FOR CULTURE MEDIA

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



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

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

IVD PER L'IDENTIFICAZIONE MICROBICA / IVD FOR MICROBIAL IDENTIFICATION

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

SISTEMI DI RACCOLTA - TRATTAMENTO / COLLECTION - TREATMENT SYSTEMS

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

KIT PER PARASSITOLOGIA / PARASITOLOGY KIT

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



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Certified Quality System
ISO 13485:2021
Cert. n° D1016000050
ISO 9001:2015
Cert. n° D1016000051
ISO 14001:2015
Cert. n° AQS/A/104412023

DICHIARAZIONE CE DI CONFORMITA'

In accordo all' allegato III della Direttiva 98/79/EC
dispositivi medico-diagnostici in vitro

Si certifica che i prodotti IVD presenti nell'elenco allegato sono fabbricati da Mascia Brunelli SpA.

1. Rispettare i requisiti essenziali (Allegato I) della Direttiva IVD 98/79 / CE. Questa conformità è adeguatamente documentata e rispetta tutti i requisiti elencati nell'Allegato I della suddetta Direttiva.
2. Il sottoscritto dichiara che sono adempiuti gli obblighi imposti dall'Allegato III commi da 2 a 5:
 - La disponibilità della documentazione tecnica di cui all'allegato III (sezione 3), che consente la valutazione della conformità dei prodotti ai requisiti della direttiva.
 - Il produttore adotta tutte le misure necessarie per garantire che il processo di fabbricazione segua il principio di garanzia della qualità appropriato per i prodotti fabbricati (allegato III sezione 4).
 - Il produttore ha istituito e mantenuto aggiornata una procedura sistematica per il riesame post-produzione dei dispositivi in vitro e si impegna ad applicare le azioni correttive (Allegato II sezione 5).
3. Mascia Brunelli SpA dispone di un Sistema di Qualità certificato secondo le norme EN ISO 9001 e EN ISO 13485.
4. La presente dichiarazione di conformità certifica che i requisiti dell'allegato I e dell'allegato III sono rispettati e documentati.
5. Mascia Brunelli SpA dichiara che la documentazione tecnica di cui all'allegato III della suddetta Direttiva è disponibile presso i nostri uffici e da noi conservata per cinque anni dall'ultimo lotto di produzione.
6. Validità: il presente documento è valido per cinque anni e sarà aggiornato su base annuale
7. Questi prodotti (vedere allegato) sono stati marcati CE come altro dispositivo medico IVD nell'Allegato II in quanto non rientrano né nell'elenco A e B dell'allegato II della Direttiva 98/79 / CE, né nei prodotti di classe A in accordo al Regolamento Europeo 746/2017 (IVDR).

Mascia Brunelli SpA conferma che nessun farmaco o medicinale è incluso nei prodotti elencati.

Dr.ssa Beatrice Brunelli
MASCIA BRUNELLI Spa

Milano, 30/11/2023

Dichiarazione CE rev. 31 30/11/2023

All: 1



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ISO 13485:2021
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Cert. n° D1016000051
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Cert. n° AQS/A/104412023

DECLARATION OF CONFORMITY

According to Annex III of the IVD Medical Device Directive 98/79/EC

This is to certify the IVD products in the attached list are manufactured by Mascia Brunelli SpA.

1. Comply with the essential requirements (Annex I) of the IVD Directive 98/79/EC. This compliance has been properly documented and covers the items listed in Annex I of the above Directive.
2. The undersigned declares that the obligations imposed by Annex III sections 2 to 5 are fulfilled:
 - The availability of the technical documentation as set out in Annex III (section 3), allowing the assessment of conformity of the products with the requirements of the directive.
 - The manufacturer takes all necessary measures to ensure that the manufacturing process follows the principle of quality assurance as appropriate for the products manufactured (Annex III section 4).
 - The manufacturer has instituted and kept up to date a systematic procedure to review experience gained from devices in the post-production phase and implements appropriate means to apply corrective actions (Annex II section 5).
3. Mascia Brunelli SpA has certified Quality System in place to the EN ISO 9001 and EN ISO 13485 standard.
4. This Declaration of Conformity certifies that the requirements of Annex I and Annex III have been met and documented.
5. Mascia Brunelli SpA declares that the technical documentation as for Annex III of the above mentioned Directive is available in our offices and we be kept for five years since last production batch
6. Validity: this document is valid for five years and will be revised yearly basis
7. These products (please see attachment) have been CE Marked as other IVD Medical Device to Annex II as they neither be part of the products in List A or B of the Annex II of the Directive 98/79/EC neither in class A according to European Regulation 746/2017 (IVDR).

Mascia Brunelli SpA confirms that no drug or medicine is included in the listed products.

Dr.ssa Beatrice Brunelli
MASCIA BRUNELLI Spa

Milano, 30/11/2023

CE-Declaration Rev. 31
30rd November 2023

Annex: 1

Allegato / Annex 1**Mascia Brunelli Catalogo Generale/General Catalog - 2021-2022**

Prodotto/Product	Codice/Ref
DIAGNOSTICA RAPIDA: TEST IMMUNOCROMATOGRAFICI	
RAPID DIAGNOSTIC TESTS: LATERAL FLOW TESTS	
ADENO+ROTA COMBI DIPSTICK	VC1004
ADENO RESPI CARD	VC1014
ADENO RESPI CARD PLUS	VC1014P
ADENO+ROTA CARD	VC194025
ADENO+ROTA CARD PLUS	VC194025P
ADENOVIRUS CARD	VC194020
ADENOVIRUS CARD PLUS	VC194020P
ASTROVIRUS - DIPSTICK	VC1020
ASTROVIRUS - DIPSTICK PLUS	VC1020P
β-HCG MONOSTEP TEST	VP80417
β-HCG MONOSTEP TEST PLUS	VP80417P
BENCE JONES KAPPA & LAMBDA FREE DIPSTICK	VT83000
BUPRENORFINA CARD	VU86101
BUPRENORFINA CARD	VU86110
CALPROTECTIN CARD	VT81610
CALPROTECTIN 50-200 CARD	VT81615
CAMPYLOBACTER SPECIES Ag CARD	VC1007
CAMPYLOBACTER SPECIES Ag CARD PLUS	VC1007P
CLOSTRIDIUM DIFFICILE GDH	VC194065
CLOSTRIDIUM DIFFICILE GDH CARD PLUS	VC194065P
CLOSTRIDIUM DIFFICILE TOXIN A + B	VC194055
CLOSTRIDIUM DIFFICILE TOXIN A + B PLUS	VC194055P
COCAINA CARD	VU85401
COCAINA CARD	VU85410
COMBI GDH-TOX A+B	VC194070P
CRYPTO+GIARDIA CARD	VC1023P
CRYPTO-DIPSTICK	VC1005
CRYPTO-DIPSTICK PLUS	VC1005P
COMBI GASTROENTEROVIRUS CARD	VC194026
COMBI GASTROENTEROVIRUS CARD PLUS	VC194026P
CRYPTO+GIARDIA+ENTAMEBA CARD	VC1032
DENGUE COMBO NS1+ IgG/IgM	VQ84006
DROGHE MULTI TEST CARD 7 parametri	VU85007
DROGHE MULTI TEST CARD 10 parametri	VU85010
E.COLI O157 CARD	VC1010
E.COLI O157 CARD PLUS	VC1010P
ENTAMOEBIA Ag CARD	VC1030
ENTEROVIRUS	VC1026
ENTEROVIRUS PLUS	VC1026P

Prodotto/Product	Codice/Ref
GARDNERELLA VAGINALIS	VQ81601
GIARDIA CARD	VC1016
GIARDIA CARD PLUS	VC1016P
GONORREA Ag CARD	VQ81602
HANTAAN IgG / IgM CARD	VQ84008
HAV IgM/IgG CARD	VR82006
Hb FECALE	VT81510
Hb FECALE PLUS	VT81520
Hb-FECAL-TRANSFERRIN COMBI	VT81650
HELICOBACTER PYLORI CARD Ab	VQ81650
HEPY STOOL CARD	VT82000
HEPY STOOL CARD	VT82001
HEPY STOOL CARD PLUS	VT82001P
HEPY STOOL CARD PLUS	VT82003P
HEPYLORI	VC1150
HEPYLORI PLUS	VC1150P
iGFBP-1 RAPID TEST KIT	VP86000
INFLUENZA A+B-RESPI-DIPSTICK	VC1012
INFLUENZA A+B-RESPI-DIPSTICK PLUS	VC1012P
LACTOFERRIN CARD	VT81600
LEGIONELLA PNEUMOPHILA CARD	VQ84100
LEGIONELLA PNEUMOPHILA CARD PLUS	VQ84100P
LEISHMANIA Ab CARD	VQ85210
LEPTOSPIRA CARD	VQ85100
MALARIA MBPan	VQ81706
MALARIA MBPan PLUS	VQ81706P
MICROALBUMINA MONOSTEP	VT81802
MONONUCLEOSI CARD IgM	VQ82705
MONONUCLEOSI CARD PLUS IgM	VQ82705P
NOROVIRUS	VC1027
NOROVIRUS CARD PLUS	VC1027P
OPPIACEI (EROINA-MORFIN-CODEINA) CARD	VU85301
OPPIACEI (EROINA-MORFIN-CODEINA) CARD	VU85310
ROTA DIPSTICK	VC1001
ROTAVIRUS CARD	VC194022
ROTAVIRUS CARD PLUS	VC194022P
RSV+ADENO-RESPI-DIPSTICK	VC1019
RSV-RESPI-CARD	VC1015
RSV-RESPI-CARD PLUS	VC1015P
SALMONELLA Ag	VQ84060
STREP B CARD	VQ81305
STREP B CARD	VQ81310
STREP B CARD PLUS	VQ81310P
STREP A CARD	VQ81209
STREP A CARD	VQ81210
STREP A CARD PLUS	VQ81210P

Prodotto/Product	Codice/Ref
STREP PNEUMONIAE	VQ84070P
SYPHILIS Ab	VQ83000
TRICHOMONAS VAGINALIS	VQ81604
TUBERCULOSI	VQ81800
DIAGNOSTICA RAPIDA: TEST IN AGGLUTINAZIONE	
RAPID TESTS: AGGLUTINATION TESTS	
ASO LATEX	UA80300
ASO LATEX	UA80315
CAMPYLOBACTER RAPID LATEX TEST KIT	271020
E. COLI O157 RAPID LATEX TEST KIT	271080
LEGIONELLA RAPID LATEX TEST KIT - KIT COMPLETO	271050
LEGIONELLA LATEX TEST 01	271051
LEGIONELLA LATEX TEST 2-15	271052
LEGIONELLA LATEX SPP TEST	271053
LEGIONELLA LATEX TEST KIT PLUS	271054
LUPUS ERYTEMATOSUS SISTEMICO (L.E.S.) LATEX	UB80800
MONONUCLEOSI LATEX	UB80710
MONONUCLEOSI LATEX	UB80720
PCR LATEX	UA80100
PCR LATEX	UA80110
RF LATEX	UA80200
RF LATEX	UA80210
RPR TEST	UC80600
RPR TEST	UC80610A
SALMONELLA RAPID LATEX TEST KIT	271030
STAPH RAPID LATEX TEST KIT	271060
STREP GROUPING RAPID LATEX TEST KIT	271070
STREP GROUPING RAPID LATEX TEST KIT	271071
STREP GROUPING RAPID LATEX TEST KIT	271072
TPHA TEST	UC80500
TPHA TEST	UC80515
WAALER-ROSE TEST	UA80255
CONTROLLI PER TEST RAPIDI	
LATERAL FLOW and AGGLUTINATION CONTROLS	
ADENOVIRUS CONTROLLI	UD80015
ASO CONTROLLI	UD80320
BENCE JONES CONTROLLI	QA20100B
Calprotectin CONTROLLI	UD80050
CLOSTRIDIUM DIFFICILE Tox. A+B CONTROLLI	UD80360
CRYPTOSPORIDIUM CONTROLLI	UD80360
GIARDIA CONTROLLI	UD80041

Prodotto/Product	Codice/Ref
EMOGLOBINA (Hb FECALE) CONTROLLI	UD80010
HELICOBACTER PYLORI CONTROLLI	UD80005
LEGIONELLA PNEUMOPHILA CONTROLLI	UD80035
LUPUS ERYTEMATOSUS SISTEMIC (L.E.S.) CONTROLLI LATEX	UD80802
MONONUCLEOSI CONTROLLI	UD80700
PCR CONTROLLI	UD80120
RF CONTROLLI	UD80220
ROTAVIRUS CONTROLLI	UD80020
RSV CONTROLLI	UD80040
STREP A CONTROLLI	UD80025
STREP B CONTROLLI	UD80030
TPHA CONTROLLI	UD80502
WAALER-ROSE CONTROLLI	UD80252
CHIMICA CLINICA	
CLINICAL CHEMISTRY	
ACE (Angiotensin Converting Enzyme)	NACE8865
ACE CALIBRATORE	ACECAL8865
ACIDI BILIARI	NABIL8903
ACIDI BILIARI CONTROLLI	NABIL8901
ACIDO CITRICO	NCI8822
ADA (Adenosine Deaminase)	NCADA016
ADA CONTROLLO	NCADAC01
ALDOLASE	ZZALD100
AMMONIA	NAAM8870
CALCULUS ANALYSIS III	3914003
CI+OX CALIBRATORE ACIDO CITRICO e OSSALATI	CTOG111
FRUTTOSIO-GLUCOSIO	NCGF8815
G6PDH CONTROL SET	NAG6CON
G6PDH-CALIBRATOR	NAG6CAL3
G6PDH-GLUCOSE 6 PHOSPHATE DEHYDROGENASE	NAGP68905
G6PDH-RED CELL LYSING REAGENT	NAGB1129
G6PDH-GLUCOSE 6 PHOSPHATE DEHYDROGENASE SET	NAG6P8910
L- LACTIC ACID	NALA8810
OSSALATI	NAOX8850
OXALATE PURIFIER	NAOXA75
OXALATE CONTROLLO ALTO	OG6502
OXALATE CONTROLLO BASSO	OG6627
PYRUVATE	NAPY8825
PYRUVATE KINASE	NCPK8831
PYRUVATE KINASE (PK) CONTROL 4X1mL	OGPKC032
RAME	NB12000
SUBSTRATE ELEVATED CONTROL	OG3005
SUBSTRATE LOW CONTROL	OG3006

Prodotto/Product	Codice/Ref
TOTAL HEMOGLOBIN	NATHEMO395
UREA INSTANT TEST	NCURE900
VMA	340249000
ZINCO	NB12100
<i>TURBIDIMETRIA: PROTEINE URINARIE</i>	
<i>TURBIDIMETRY: URINARY PROTEINS</i>	
PROTEINURIA DI BENCE JONES (BENCE JONES PROTEINS	QA20100
BENCE JONES CONTROLLI	QA20100B
<i>SIEROLOGIA BATTERICA</i>	
<i>FEBRILE ANTIGENS</i>	
<i>FEVER MACROTEST (3 x 20 ml = 120 TEST)</i>	
SALMONELLA TYPHI H	XA100000
SALMONELLA TYPHI O	XA100100
SALMONELLA TYPHI TOTALE	XA100050
SALMONELLA PARATYPHI AH	XA100200
SALMONELLA PARATYPHI AO	XA100300
SALMONELLA PARATYPHI A TOTAL	XA100250
SALMONELLA PARATYPHI BH	XA100400
SALMONELLA PARATYPHI BO	XA100500
SALMONELLA PARATYPHI B TOTAL	XA100450
SALMONELLA PARATYPHI CH	XA100600
SALMONELLA PARATYPHI CO	XA100700
SALMONELLA PARATYPHI C TOTAL	XA100650
BRUCELLA (TOTAL)	XA100800
BRUCELLA ABORTUS	XA100850
BRUCELLA MELITENSIS	XA100860
BRUCELLA SUIS	XA100870
PROTEUS OX 19	XA100900
PROTEUS OX 2	XA101000
PROTEUS OX K	XA101100
SALMONELLA ENTERITIDIS TOTAL	XA101250
LISTERIA KIT TUBE TEST	XA87249
LISTERIA CONTROLLI POSITIVO E NEGATIVO	XE105050
<i>FEVER MICROTEST (3 x 10 ml = 300 TEST)</i>	
SALMONELLA TYPHI H	XB100001
SALMONELLA TYPHI O	XB100101
SALMONELLA TYPHI TOTAL	XB100051
SALMONELLA PARATYPHI AH	XB100201
SALMONELLA PARATYPHI AO	XB100301
SALMONELLA PARATYPHI A TOTAL	XB100251

Prodotto/Product	Codice/Ref
SALMONELLA PARATYPHI BH	XB100401
SALMONELLA PARATYPHI BO	XB100501
SALMONELLA PARATYPHI B TOTAL	XB100451
SALMONELLA PARATYPHI CH	XB100601
SALMONELLA PARATYPHI CO	XB100701
SALMONELLA PARATYPHI C TOTAL	XB100651
BRUCELLA (TOTAL)	XB100801
BRUCELLA ABORTUS	XB100851
BRUCELLA MELITENSIS	XB100861
BRUCELLA SUIS	XB100871
PROTEUS OX 19	XB100901
PROTEUS OX 2	XB101001
PROTEUS OX K	XB101101
SALMONELLA ENTERITIDIS TOTAL	XB101211
FEVER KIT	XB105000
FEVER KIT MINOR	XB105550
<i>FEVER SLIDE TEST (1 x 5 ml = 125 TEST)</i>	
SALMONELLA TYPHI H	XC100002
SALMONELLA TYPHI O	XC100102
SALMONELLA TYPHI TOTAL	XC100052
SALMONELLA PARATYPHI AH	XC100202
SALMONELLA PARATYPHI AO	XC100302
SALMONELLA PARATYPHI A TOTAL	XC101252
SALMONELLA PARATYPHI BH	XC100402
SALMONELLA PARATYPHI BO	XC100502
SALMONELLA PARATYPHI B TOTAL	XC101452
SALMONELLA PARATYPHI CH	XC100602
SALMONELLA PARATYPHI CO	XC100702
SALMONELLA PARATYPHI C TOTAL	XC101652
BRUCELLA (TOTAL)	XC100802
BRUCELLA "BENGAL ROSE"	XC100852
BRUCELLA ABORTUS	XC100842
BRUCELLA MELITENSIS	XC100862
PROTEUS OX 19	XC100902
PROTEUS OX 2	XC101002
PROTEUS OX K	XC101102
MULTIBACTERIAL KIT	XC105100
SALMONELLA TYPHI H	XC100002B
SALMONELLA TYPHI O	XC100102B
SALMONELLA PARATYPHI AH	XC100202B
SALMONELLA PARATYPHI AO	XC100302B
SALMONELLA PARATYPHI A TOTAL	XC101252B
SALMONELLA PARATYPHI BH	XC100402B
SALMONELLA PARATYPHI BO	XC100502B
SALMONELLA PARATYPHI B TOTAL	XC101452B

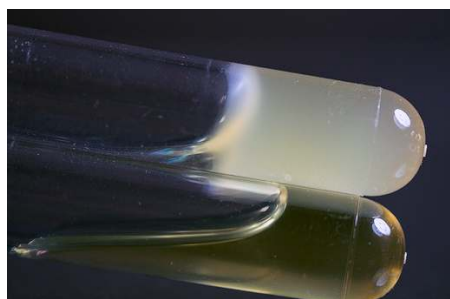
Prodotto/Product	Codice/Ref
SALMONELLA PARATYPHI CH	XC100602B
SALMONELLA PARATYPHI CO	XC100702B
SALMONELLA PARATYPHI C TOTAL	XC101652B
BRUCELLA ABORTUS	XC100842B
BRUCELLA MELITENSIS	XC100862B
<i>FEVER QUICK TEST (1 x 5 ml = 125 TEST)</i>	
SALMONELLA TYPHI H	XD100003
SALMONELLA TYPHI O	XD100103
SALMONELLA PARATYPHI AH	XD100203
SALMONELLA PARATYPHI AO	XD100303
SALMONELLA PARATYPHI A TOTAL	XD100253
SALMONELLA PARATYPHI BH	XD100403
SALMONELLA PARATYPHI BO	XD100503
SALMONELLA PARATYPHI B TOTAL	XD100453
SALMONELLA PARATYPHI CH	XD100603
SALMONELLA PARATYPHI CO	XD100703
SALMONELLA PARATYPHI C TOTAL	XD101653
BRUCELLA (TOTAL)	XD100803
BRUCELLA ABORTUS	XD100843
BRUCELLA MELITENSIS	XD100863
BRUCELLA SUIS	XD100873
PROTEUS OX 19	XD100903
PROTEUS OX 2	XD101003
PROTEUS OX K	XD101103
MULTIBACTERIAL QUICK TEST KIT	XD105003
<i>SIERI DI CONTROLLO</i>	
<i>CONTROL SERA</i>	
CONTROLLO NEGATIVO	XE105030
CONTROLLO POSITIVO POLIVALENTE	XE105040
<i>REAGENTI PER AGGREGAZIONE PIASTRINICA</i>	
<i>PLATELET AGGREGATION</i>	
AGP TEST	3115001
ADP 0,1 mM	311501A
ADENOSIN DIFOSFATO (ADP) 0,1 mM	311500AC
ADP 1 mM	311500WA
ADRENALINE 5mM (Epinephrin) LIO	311501BL
ADRENALINA 5 mM	311500BLC
ARACHIDONIC ACID (25 mM)	311501WB
ARACHIDONIC ACID (25 mM)	311501WBC
COLLAGEN 1 mg/ml	311502C
COLLAGENE 1 g/l	311501CC
RISTOCETIN 25 mg	311502D

Prodotto/Product	Codice/Ref
RISTOCETINA 25 mg	311500DC
TRAP-6 1 mM	311500T

INSTRUCTIONS FOR USE

COAGULASE PLASMA EDTA

Biochemical identification reagent



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

1 - INTENDED USE

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

2 – TYPICAL COMPOSITION – VIAL CONTENT *

REF 429936: Rabbit Plasma EDTA, 5.0 mL (lyophilized)

REF 429937: Rabbit Plasma EDTA, 2.5 mL (lyophilized)

REF 429938: Rabbit Plasma EDTA, 1.0 mL (lyophilized)

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

3 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

The coagulase test was developed from observations, in the early 1900s, that certain staphylococci clotted plasma from the goose,¹ man, horse, and sheep². Today, the widely used and generally accepted method of differentiating staphylococci associated with acute infection or food poisoning is the identification of extracellular coagulase production using a tube coagulase test.^{3,4} Based on their ability to clot plasma, staphylococci may be divided into coagulase-positive or coagulase-negative ones.

The enzyme coagulase acts on a “coagulase reacting factor” present in rabbit plasma, producing a thrombin-like substance which activates fibrinogen to form fibrin, causing the plasma to clot. Coagulase exists in two forms: “bound coagulase” (or clumping factor) which is bound to the cell wall and “free coagulase” which is liberated by the cell wall. Bound coagulase is detected by the slide coagulase test, whereas both free and bound coagulase are detected by the tube coagulase test.⁵

Coagulase Plasma EDTA, in the different proposed formats, is recommended for performing the tube test. Typically, rabbit plasma is inoculated with growth from isolated colonies and examined for the presence of a gel or clot at 4 hours and, if negative, examined again at 24 hours. In addition to *Staphylococcus aureus* also other species, including *Staphylococcus schleiferi* and *Staphylococcus intermedius* may give positive results in the tube coagulase test but are not common isolates from human infections.^{3,5}

For the tube coagulase test, EDTA plasma is superior to citrated plasma because citrate-utilizing organisms such as *Pseudomonas* species, *Serratia marcescens*, *Enterococcus faecalis* and strains of *Streptococcus* will clot citrated plasma.⁵

4 - METHOD OF PREPARATION

REF 429936: reconstitute the content of one vial with 15 mL of sterile distilled water under aseptic conditions.

REF 429937: reconstitute the content of one vial with 7.5 mL of sterile distilled water under aseptic conditions.

REF 429938: reconstitute the content of one vial with 3 mL of sterile distilled water under aseptic conditions.

Stir for 30 seconds by means of a vortex to dissolve completely. The rabbit plasma results to be diluted 1:3.

5 - PHYSICAL CHARACTERISTICS

Appearance of lyophilized pellet

dense pastille

Appearance of coagulase plasma after reconstitution

yellowish to pink opalescent solution

6 - MATERIALS PROVIDED - PACKAGING

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

7 - MATERIALS REQUIRED BUT NOT PROVIDED

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

8 - SPECIMENS

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

9 - TEST PROCEDURE

From the surface of each selected colony, remove an inoculum with a sterile loop and transfer it to a tube of Brain Heart Infusion Broth. Incubate the broth at 35-37°C for 18-24 hours.

Aseptically add 0.5 mL of each culture to 0.5 mL of Coagulase Plasma EDTA in small sterile tubes, and incubate at 35-37°C.

10- READING AND INTERPRETATION

Observe every 60 minutes in the first 4 hours of incubation for clotting by gently slanting the tube. Do not shake.

If no clot is observed by 4 hours, the tube should be read again after 18-24 h of incubation at 35-37°C.





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

11 - USER QUALITY CONTROL

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

Positive control: *S.aureus* ATCC 25923

Negative control: *S.epidermidis* ATCC 12228

ATCC is a trademark of American Type Culture Collection

12 - PERFORMANCES CHARACTERISTICS

Prior to release for sale a representative sample of all lots of Coagulase Plasma EDTA is tested with positive and negative strains.

Coagulase positive strains (reading after 2, 4, 24 hours of incubation at 35-37°C): *S.aureus* ATCC 25923, *S.aureus* ATCC 6538, *S.aureus* ATCC 33862, *S.aureus* MR ATCC 33592.

Coagulase negative strains (reading after 24 hours of incubation at 35-37°C): *S.epidermidis* ATCC 12228, *S.xyloso* ATCC 35033, *S.saprophyticus* ATCC 15305, *S.sciuri* CB-BX 16.1, *E.faecalis* ATCC 19433

All the tested strains give a coagulase reaction according to the specifications.

13 - LIMITATIONS OF THE METHOD

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

14 - PRECAUTIONS AND WARNINGS

- This product is a qualitative *in vitro* diagnostic, for professional use only; it is to be used by adequately trained and qualified laboratory personnel, observing approved biohazard precautions and aseptic techniques.
- This product is not classified as dangerous according to current European legislation
- This product contains raw materials of animal origin. The *ante* and *post mortem* controls of the animals and those during the production and distribution cycle of the raw materials, cannot completely guarantee that this product doesn't contain any transmissible pathogen. Therefore, it is recommended that the product be treated as potentially infectious, and handled observing the usual specific precautions: do not ingest, inhale, or allow to come into contact with skin, eyes, mucous membranes. Download the TSE Statement from the website www.biolifeitaliana.it, describing the measures implemented by Biolife Italiana for the risk reduction linked to infectious animal diseases.
- All laboratory specimens should be considered infectious.
- The laboratory area must be controlled to avoid contaminants such as the reagent, the culture media or the microbial agents.
- Sterilize all biohazard waste before disposal. Dispose the unused reagent and the tubes inoculated with microbial strains in accordance with current local legislation.
- Do not use this product as active ingredient for pharmaceutical preparations or as production material intended for human and animal consumption.
- The Certificates of Analysis and the Safety Data Sheet are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases, existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.

15 - STORAGE CONDITIONS AND SHELF LIFE

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

16 - REFERENCES

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8. McDonald CL, Chapin K. Rapid identification of *Staphylococcus aureus* from blood culture bottles by a classic 2-hour tube coagulase test. *J Clin Microbiol* 1995; 33:50-2. B, II
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TABLE OF APPLICABLE SYMBOLS

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

REVISION HISTORY

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

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

