



Italia

CERTIFICATO

Nr. 50 100 11497 - Rev. 003

Si attesta che / This is to certify that

IL SISTEMA QUALITÀ DI
THE QUALITY SYSTEM OF**LIOFILCHEM S.r.l.**SEDE LEGALE E OPERATIVA:
REGISTERED OFFICE AND OPERATIONAL SITE:**VIA SCOZIA SNC - ZONA INDUSTRIALE
I-64026 ROSETO DEGLI ABRUZZI (TE)**SEDE OPERATIVA:
OPERATIONAL SITE:**CONTRADA PIANE VOMANO - TRAVERSA DI VIA GRECIA
I-64026 ROSETO DEGLI ABRUZZI (TE)**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

**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 (IAF 12, 29)**

**Design and development, production and sale of in-vitro diagnostic
medical devices: culture media for bacteriology, identification and
susceptibility testing systems, kits for plasma protein determination
(IAF 12, 29)**



SGQ N° 049A

Membro degli Accordi di Mutuo Riconoscimento
EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual
Recognition AgreementsPer l'Organismo di Certificazione
For the Certification Body
TÜV Italia S.r.l.**Andrea Coscia**

Direttore Divisione Business Assurance

Validità / Validity

Dal / From: 2019-02-11

Al / To: 2022-02-10

Data emissione / Issuing Date

2019-02-11

PRIMA CERTIFICAZIONE / FIRST CERTIFICATION: 2012-09-25

"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"



CERTIFICATO
N° Q5 071067 0006 Rev. 00

Certificate
No. Q5 071067 0006 Rev. 00

Titolare del certificato: Liofilchem S.r.l.

Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALIA

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

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia,
64026 Roseto degli Abruzzi (TE), ITALIA

Holder of Certificate:

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

Stabilimento(i):

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

Liofilchem S.r.l.
Contrada Piane Vomano, Traversa di Via Grecia, 64026 Roseto degli Abruzzi (TE), ITALY

Facility(ies):

Marchio di certificazione:



Certification Mark:



Campo di applicazione:

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. Distribuzione di altri dispositivi medico diagnostici in-vitro

Scope of Certificate:

Design and development, production and sale of in-vitro diagnostic medical devices: culture media for bacteriology, identification and susceptibility testing systems, kits for plasma protein determination. Distribution of other in-vitro diagnostic medical devices

Norma(e) applicata(e):

EN ISO 13485:2016
Dispositivi medici - Sistemi di gestione per la qualità - Requisiti per scopi regolamentari (ISO 13485:2016)
DIN EN ISO 13485:2016

Applied Standard(s):

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

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). Vedere anche note sul retro.

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). See also notes overleaf.

N° del rapporto:

ITA1070742

Valido da:

2018-12-19

Valido fino al:

2021-12-18

Report No.:

ITA1070742

Data, 2018-12-19

Valid from:

2018-12-19

Valid until:

2021-12-18

Pagina 1 di 1

Traduzione per scopi informativi. La sola versione inglese (tedesco) è legalmente impegnativa

I. Pirelli
Stefan Preiß

Date, 2018-12-19

Stefan Preiß



Liofilchem®

DICHIARAZIONE DI CONFORMITÀ CE / EC DECLARATION OF CONFORMITY

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 del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 32.1 del 07.06.2017

dichiara sotto la propria responsabilità

1. che il dispositivo sopra indicato soddisfa 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 il dispositivo in oggetto non è incluso 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 il dispositivo in oggetto è stato messo in commercio munito 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 device listed in the attached table, Revision 32.1 of 07.06.2017

hereby certifies under its own responsibility

1. that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex III) and its relevant transposition into national law;
2. the above mentioned is 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 device in question, was introduced into the market provided with CE mark.

Roseto, 07.06.2017

Direttore Tecnico/ Technical Director
Dott. Silvio Brocco



DICHIARAZIONE DI CONFORMITÀ CE

La società Lipfilchem® S.r.l., con Sede Legale in Via Scizia, 64026 Roseto degli Abruzzi (TE) Italia, in qualità di fabbricante del dispositivo medico-diagnostico *in vitro* elencato nella tabella allegata Revisione 32.1 del 07.06.2017

dichiara sotto la propria responsabilità

- che il dispositivo sopra indicato soddisfa tutte le disposizioni applicabili della Direttiva 98/79/CE (Allegato II) recepita nella Legislazione Italiana dal Decreto Legislativo n° 332 del 8 settembre 2000;
- che il dispositivo in oggetto non è incluso nell'Allegato II, lista A e B della Direttiva 98/79/CE
- 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;
- che il processo di fabbricazione segue adeguati principi di assicurazione della qualità;
- di aver attivato e di mantenere aggiornato un sistema di sorveglianza post-produzione per il monitoraggio dei prodotti;
- che il dispositivo in oggetto è stato messo in commercio munito di marcatura CE.

EC DECLARATION OF CONFORMITY

The company Lipfilchem® S.r.l., registered Office in Via Scizia, 64026 Roseto degli Abruzzi (TE) Italy, as a manufacturer of the *in vitro* medical-diagnostic device listed in the attached table, Revision 32.1 of 07.06.2017

hereby certifies under its own responsibility

- that the above mentioned device complies with all the applicable provisions of Directive 98/79/EC (Annex II) and its relevant transposition into national law;
- that the above mentioned is not included in Annex II, List A and B of Directive 98/79/EC;
- that the technical documentation referred to in 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;
- that the manufacturing process follows suitable principles of quality assurance;
- that, has implemented and keep up to date, a post-production surveillance system for monitoring the products;
- that the device in question, was introduced into the market provided with CE mark.

Roseto, 07.06.2017

Direttore Tecnico/ Technical Director
Dott. Silvio Drocco

1.0.24

PRODOTTI CE DI LIBERA VENDITA / FREE SALE CE PRODUCTS

Rev. 32.1 del 07.06.2017

10002	DNA AGAR - BLU DI TOLUIDINA	10046	SEPIRIA TELLOURE AGAR
10004	CLEB AGAR (BLOOD 5%)	10047	SEPIRIA TELLOURE AGAR
10005	CLEB AGAR (BLOOD 5%)	10048	SEPIRIA TELLOURE AGAR
10006	MAG CONKEY SODIUM AGAR	10049	SEPIRIA TELLOURE AGAR
10007	MAG CONKEY SODIUM AGAR	10050	SEPIRIA TELLOURE AGAR
10008	TRYPTIC SOY AGAR (BLOOD 5%)	10051	SEPIRIA TELLOURE AGAR
10009	TRYPTIC SOY AGAR (BLOOD 5%)	10052	SEPIRIA TELLOURE AGAR
10010	TRYPTIC SOY AGAR (BLOOD 5%)	10053	SEPIRIA TELLOURE AGAR
10011	TRYPTIC SOY AGAR (BLOOD 5%)	10054	SEPIRIA TELLOURE AGAR
10012	TRYPTIC SOY AGAR (BLOOD 5%)	10055	SEPIRIA TELLOURE AGAR
10013	TRYPTIC SOY AGAR (BLOOD 5%)	10056	SEPIRIA TELLOURE AGAR
10014	TRYPTIC SOY AGAR (BLOOD 5%)	10057	SEPIRIA TELLOURE AGAR
10015	TRYPTIC SOY AGAR (BLOOD 5%)	10058	SEPIRIA TELLOURE AGAR
10016	TRYPTIC SOY AGAR (BLOOD 5%)	10059	SEPIRIA TELLOURE AGAR
10017	TRYPTIC SOY AGAR (BLOOD 5%)	10060	SEPIRIA TELLOURE AGAR
10018	TRYPTIC SOY AGAR (BLOOD 5%)	10061	SEPIRIA TELLOURE AGAR
10019	TRYPTIC SOY AGAR (BLOOD 5%)	10062	SEPIRIA TELLOURE AGAR
10020	TRYPTIC SOY AGAR (BLOOD 5%)	10063	SEPIRIA TELLOURE AGAR
10021	TRYPTIC SOY AGAR (BLOOD 5%)	10064	SEPIRIA TELLOURE AGAR
10022	TRYPTIC SOY AGAR (BLOOD 5%)	10065	SEPIRIA TELLOURE AGAR
10023	TRYPTIC SOY AGAR (BLOOD 5%)	10066	SEPIRIA TELLOURE AGAR
10024	TRYPTIC SOY AGAR (BLOOD 5%)	10067	SEPIRIA TELLOURE AGAR
10025	TRYPTIC SOY AGAR (BLOOD 5%)	10068	SEPIRIA TELLOURE AGAR
10026	TRYPTIC SOY AGAR (BLOOD 5%)	10069	SEPIRIA TELLOURE AGAR
10027	TRYPTIC SOY AGAR (BLOOD 5%)	10070	SEPIRIA TELLOURE AGAR
10028	TRYPTIC SOY AGAR (BLOOD 5%)	10071	SEPIRIA TELLOURE AGAR
10029	TRYPTIC SOY AGAR (BLOOD 5%)	10072	SEPIRIA TELLOURE AGAR
10030	TRYPTIC SOY AGAR (BLOOD 5%)	10073	SEPIRIA TELLOURE AGAR
10031	TRYPTIC SOY AGAR (BLOOD 5%)	10074	SEPIRIA TELLOURE AGAR
10032	TRYPTIC SOY AGAR (BLOOD 5%)	10075	SEPIRIA TELLOURE AGAR
10033	TRYPTIC SOY AGAR (BLOOD 5%)	10076	SEPIRIA TELLOURE AGAR
10034	TRYPTIC SOY AGAR (BLOOD 5%)	10077	SEPIRIA TELLOURE AGAR
10035	TRYPTIC SOY AGAR (BLOOD 5%)	10078	SEPIRIA TELLOURE AGAR
10036	TRYPTIC SOY AGAR (BLOOD 5%)	10079	SEPIRIA TELLOURE AGAR
10037	TRYPTIC SOY AGAR (BLOOD 5%)	10080	SEPIRIA TELLOURE AGAR
10038	TRYPTIC SOY AGAR (BLOOD 5%)	10081	SEPIRIA TELLOURE AGAR
10039	TRYPTIC SOY AGAR (BLOOD 5%)	10082	SEPIRIA TELLOURE AGAR
10040	TRYPTIC SOY AGAR (BLOOD 5%)	10083	SEPIRIA TELLOURE AGAR
10041	TRYPTIC SOY AGAR (BLOOD 5%)	10084	SEPIRIA TELLOURE AGAR
10042	TRYPTIC SOY AGAR (BLOOD 5%)	10085	SEPIRIA TELLOURE AGAR
10043	TRYPTIC SOY AGAR (BLOOD 5%)	10086	SEPIRIA TELLOURE AGAR
10044	TRYPTIC SOY AGAR (BLOOD 5%)	10087	SEPIRIA TELLOURE AGAR
10045	TRYPTIC SOY AGAR (BLOOD 5%)	10088	SEPIRIA TELLOURE AGAR
10046	TRYPTIC SOY AGAR (BLOOD 5%)	10089	SEPIRIA TELLOURE AGAR
10047	TRYPTIC SOY AGAR (BLOOD 5%)	10090	SEPIRIA TELLOURE AGAR
10048	TRYPTIC SOY AGAR (BLOOD 5%)	10091	SEPIRIA TELLOURE AGAR
10049	TRYPTIC SOY AGAR (BLOOD 5%)	10092	SEPIRIA TELLOURE AGAR
10050	TRYPTIC SOY AGAR (BLOOD 5%)	10093	SEPIRIA TELLOURE AGAR
10051	TRYPTIC SOY AGAR (BLOOD 5%)	10094	SEPIRIA TELLOURE AGAR
10052	TRYPTIC SOY AGAR (BLOOD 5%)	10095	SEPIRIA TELLOURE AGAR
10053	TRYPTIC SOY AGAR (BLOOD 5%)	10096	SEPIRIA TELLOURE AGAR
10054	TRYPTIC SOY AGAR (BLOOD 5%)	10097	SEPIRIA TELLOURE AGAR
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10056	TRYPTIC SOY AGAR (BLOOD 5%)	10099	SEPIRIA TELLOURE AGAR
10057	TRYPTIC SOY AGAR (BLOOD 5%)	10100	SEPIRIA TELLOURE AGAR
10058	TRYPTIC SOY AGAR (BLOOD 5%)	10101	SEPIRIA TELLOURE AGAR
10059	TRYPTIC SOY AGAR (BLOOD 5%)	10102	SEPIRIA TELLOURE AGAR
10060	TRYPTIC SOY AGAR (BLOOD 5%)	10103	SEPIRIA TELLOURE AGAR
10061	TRYPTIC SOY AGAR (BLOOD 5%)	10104	SEPIRIA TELLOURE AGAR
10062	TRYPTIC SOY AGAR (BLOOD 5%)	10105	SEPIRIA TELLOURE AGAR
10063	TRYPTIC SOY AGAR (BLOOD 5%)	10106	SEPIRIA TELLOURE AGAR
10064	TRYPTIC SOY AGAR (BLOOD 5%)	10107	SEPIRIA TELLOURE AGAR
10065	TRYPTIC SOY AGAR (BLOOD 5%)	10108	SEPIRIA TELLOURE AGAR
10066	TRYPTIC SOY AGAR (BLOOD 5%)	10109	SEPIRIA TELLOURE AGAR
10067	TRYPTIC SOY AGAR (BLOOD 5%)	10110	SEPIRIA TELLOURE AGAR
10068	TRYPTIC SOY AGAR (BLOOD 5%)	10111	SEPIRIA TELLOURE AGAR
10069	TRYPTIC SOY AGAR (BLOOD 5%)	10112	SEPIRIA TELLOURE AGAR
10070	TRYPTIC SOY AGAR (BLOOD 5%)	10113	SEPIRIA TELLOURE AGAR
10071	TRYPTIC SOY AGAR (BLOOD 5%)	10114	SEPIRIA TELLOURE AGAR
10072	TRYPTIC SOY AGAR (BLOOD 5%)	10115	SEPIRIA TELLOURE AGAR
10073	TRYPTIC SOY AGAR (BLOOD 5%)	10116	SEPIRIA TELLOURE AGAR
10074	TRYPTIC SOY AGAR (BLOOD 5%)	10117	SEPIRIA TELLOURE AGAR
10075	TRYPTIC SOY AGAR (BLOOD 5%)	10118	SEPIRIA TELLOURE AGAR
10076	TRYPTIC SOY AGAR (BLOOD 5%)	10119	SEPIRIA TELLOURE AGAR
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10079	TRYPTIC SOY AGAR (BLOOD 5%)	10122	SEPIRIA TELLOURE AGAR
10080	TRYPTIC SOY AGAR (BLOOD 5%)	10123	SEPIRIA TELLOURE AGAR
10081	TRYPTIC SOY AGAR (BLOOD 5%)	10124	SEPIRIA TELLOURE AGAR
10082	TRYPTIC SOY AGAR (BLOOD 5%)	10125	SEPIRIA TELLOURE AGAR
10083	TRYPTIC SOY AGAR (BLOOD 5%)	10126	SEPIRIA TELLOURE AGAR
10084	TRYPTIC SOY AGAR (BLOOD 5%)	10127	SEPIRIA TELLOURE AGAR
10085	TRYPTIC SOY AGAR (BLOOD 5%)	10128	SEPIRIA TELLOURE AGAR
10086	TRYPTIC SOY AGAR (BLOOD 5%)	10129	SEPIRIA TELLOURE AGAR
10087	TRYPTIC SOY AGAR (BLOOD 5%)	10130	SEPIRIA TELLOURE AGAR
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10091	TRYPTIC SOY AGAR (BLOOD 5%)	10134	SEPIRIA TELLOURE AGAR
10092	TRYPTIC SOY AGAR (BLOOD 5%)	10135	SEPIRIA TELLOURE AGAR
10093	TRYPTIC SOY AGAR (BLOOD 5%)	10136	SEPIRIA TELLOURE AGAR
10094	TRYPTIC SOY AGAR (BLOOD 5%)	10137	SEPIRIA TELLOURE AGAR
10095	TRYPTIC SOY AGAR (BLOOD 5%)	10138	SEPIRIA TELLOURE AGAR
10096	TRYPTIC SOY AGAR (BLOOD 5%)	10139	SEPIRIA TELLOURE AGAR
10097	TRYPTIC SOY AGAR (BLOOD 5%)	10140	SEPIRIA TELLOURE AGAR
10098	TRYPTIC SOY AGAR (BLOOD 5%)	10141	SEPIRIA TELLOURE AGAR
10099	TRYPTIC SOY AGAR (BLOOD 5%)	10142	SEPIRIA TELLOURE AGAR
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10102	TRYPTIC SOY AGAR (BLOOD 5%)	10145	SEPIRIA TELLOURE AGAR
10103	TRYPTIC SOY AGAR (BLOOD 5%)	10146	SEPIRIA TELLOURE AGAR
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10108	TRYPTIC SOY AGAR (BLOOD 5%)	10151	SEPIRIA TELLOURE AGAR
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10147	TRYPTIC SOY AGAR (BLOOD 5%)	10190	SEPIRIA TELLOURE AGAR
10148	TRYPTIC SOY AGAR (BLOOD 5%)	10191	SEPIRIA TELLOURE AGAR
10149	TRYPTIC SOY AGAR (BLOOD 5%)	10192	SEPIRIA TELLOURE AGAR
10150	TRYPTIC SOY AGAR (BLOOD 5%)	10193	SEPIRIA TELLOURE AGAR
10151	TRYPTIC SOY AGAR (BLOOD 5%)	10194	SEPIRIA TELLOURE AGAR
10152	TRYPTIC SOY AGAR (BLOOD 5%)	10195	SEPIRIA TELLOURE AGAR
10153	TRYPTIC SOY AGAR (BLOOD 5%)	10196	SEPIRIA TELLOURE AGAR
10154	TRYPTIC SOY AGAR (BLOOD 5%)	10197	SEPIRIA TELLOURE AGAR
10155	TRYPTIC SOY AGAR (BLOOD 5%)	10198	SEPIRIA TELLOURE AGAR
10156	TRYPTIC SOY AGAR (BLOOD 5%)	10199	SEPIRIA TELLOURE AGAR
10157	TRYPTIC SOY AGAR (BLOOD 5%)	10200	SEPIRIA TELLOURE AGAR
10158	TRYPTIC SOY AGAR (BLOOD 5%)	10201	SEPIRIA TELLOURE AGAR
10159	TRYPTIC SOY AGAR (BLOOD 5%)	10202	SEPIRIA TELLOURE AGAR
10160	TRYPTIC SOY AGAR (BLOOD 5%)	10203	SEPIRIA TELLOURE AGAR
10161	TRYPTIC SOY AGAR (BLOOD 5%)	10204	SEPIRIA TELLOURE AGAR
10162	TRYPTIC SOY AGAR (BLOOD 5%)	10205	SEPIRIA TELLOURE AGAR
10163	TRYPTIC SOY AGAR (BLOOD 5%)	10206	SEPIRIA TELLOURE AGAR
10164	TRYPTIC SOY AGAR (BLOOD 5%)	10207	SEPIRIA TELLOURE AGAR
10165	TRYPTIC SOY AGAR (BLOOD 5%)	10208	SEPIRIA TELLOURE AGAR
10166	TRYPTIC SOY AGAR (BLOOD 5%)	10209	SEPIRIA TELLOURE AGAR
10167	TRYPTIC SOY AGAR (BLOOD 5%)	10210	SEPIRIA TELLOURE AGAR
10168	TRYPTIC SOY AGAR (BLOOD 5%)	10211	SEPIRIA TELLOURE AGAR
10169	TRYPTIC SOY AGAR (BLOOD 5%)	10212	SEPIRIA TELLOURE AGAR
10170	TRYPTIC SOY AGAR (BLOOD 5%)	10213	SEPIRIA TELLOURE AGAR
10171	TRYPTIC SOY AGAR (BLOOD 5%)	10214	SEPIRIA TELLOURE AGAR
10172	TRYPTIC SOY AGAR (BLOOD 5%)	10215	SEPIRIA TELLOURE AGAR
10173	TRYPTIC SOY AGAR (BLOOD 5%)	10216	SEPIRIA TELLOURE AGAR
10174	TRYPTIC SOY AGAR (BLOOD 5%)	10217	SEPIRIA TELLOURE AGAR
10175	TRYPTIC SOY AGAR (BLOOD 5%)	10218	SEPIRIA TELLOURE AGAR
10176	TRYPTIC SOY AGAR (BLOOD 5%)	10219	SEPIRIA TELLOURE AGAR
10177	TRYPTIC SOY AGAR (BLOOD 5%)	10220	SEPIRIA TELLOURE AGAR
10178	TRYPTIC SOY AGAR (BLOOD 5%)	10221	SEPIRIA TELLOURE AGAR
10179	TRYPTIC SOY AGAR (BLOOD 5%)	10222	SEPIRIA TELLOURE AGAR
10180	TRYPTIC SOY AGAR (BLOOD 5%)	10223	SEPIRIA TELLOURE AGAR
10181	TRYPTIC SOY AGAR (BLOOD 5%)	10224	SEPIRIA TELLOURE AGAR
10182	TRYPTIC SOY AGAR (BLOOD 5%)	10225	SEPIRIA TELLOURE AGAR
10183	TRYPTIC SOY AGAR (BLOOD 5%)	10226	SEPIRIA TELLOURE AGAR
10184	TRYPTIC SOY AGAR (BLOOD 5%)	10227	SEPIRIA TELLOURE AGAR
10185	TRYPTIC SOY AGAR (BLOOD 5%)	10228	SEPIRIA TELLOURE AGAR
10186	TRYPTIC SOY AGAR (BLOOD 5%)	10229	SEPIRIA TELLOURE AGAR
10187	TRYPTIC SOY AGAR (BLOOD 5%)	10230	SEPIRIA TELLOURE AGAR
10188	TRYPTIC SOY AGAR (BLOOD 5%)	10231	SEPIRIA TELLOURE AGAR
10189	TRYPTIC SOY AGAR (BLOOD 5%)	10232	SEPIRIA TELLOURE AGAR
10190	TRYPTIC SOY AGAR (BLOOD 5%)	10233	SEPIRIA TELLOURE AGAR
10191	TRYPTIC SOY AGAR (BLOOD 5%)	10234	SEPIRIA TELLOURE AGAR
10192	TRYPTIC SOY AGAR (BLOOD 5%)	10235	SEPIRIA TELLOURE AGAR
10193	TRYPTIC SOY AGAR (BLOOD 5%)	10236	SEPIRIA TELLOURE AGAR
10194	TRYPTIC SOY AGAR (BLOOD 5%)	10237	SEPIRIA TELLOURE AGAR
10195	TRYPTIC SOY AGAR (BLOOD 5%)	10238	SEPIRIA TELLOURE AGAR
10196	TRYPTIC SOY AGAR (BLOOD 5%)	10239	SEPIRIA TELLOURE AGAR
10197	TRYPTIC SOY AGAR (BLOOD 5%)	10240	SEPIRIA TELLOURE AGAR
10198	TRYPTIC SOY AGAR (BLOOD 5%)	10241	SEPIRIA TELLOURE AGAR
10199	TRYPTIC SOY AGAR (BLOOD 5%)	10242	SEPIRIA TELLOURE AGAR
10200	TRYPTIC SOY AGAR (BLOOD 5%)	10243	SEPIRIA TELLOURE AGAR
10201	TRYPTIC SOY AGAR (BLOOD 5%)	10244	SEPIRIA TELLOURE AGAR
10202	TRYPTIC SOY AGAR (BLOOD 5%)	10245	SEPIRIA TELLOURE AGAR
10203	TRYPTIC SOY AGAR (BLOOD 5%)	10246	SEPIRIA TELLOURE AGAR
10204	TRYPTIC SOY AGAR (BLOOD 5%)	10247	SEPIRIA TELLOURE AGAR
10205	TRYPTIC SOY AGAR (BLOOD 5%)	10248	SEPIRIA TELLOURE AGAR
10206	TRYPTIC SOY AGAR (BLOOD 5%)	10249	SEPIRIA TELLOURE AGAR
10207	TRYPTIC SOY AGAR (BLOOD 5%)	10250	SEPIRIA TELLOURE AGAR
10208	TRYPTIC SOY AGAR (BLOOD 5%)	10251	SEPIRIA TELLOURE AGAR
10209	TRYPTIC SOY AGAR (BLOOD 5%)	10252	SEPIRIA TELLOURE AGAR
10210	TRYPTIC SOY AGAR (BLOOD 5%)	10253	SEPIRIA TELLOURE AGAR
10211	TRYPTIC SOY AGAR (BLOOD 5%)	10254	SEPIRIA TELLOURE AGAR
10212	TRYPTIC SOY AGAR (BLOOD 5%)	10255	SEPIRIA TELLOURE AGAR
10213	TRYPTIC SOY AGAR (BLOOD 5%)	10256	SEPIRIA TELLOURE AGAR
10214	TRYPTIC SOY AGAR (BLOOD 5%)	10257	SEPIRIA TELLOURE AGAR
10215	TRYPTIC SOY AGAR (BLOOD 5%)	10258	SEPIRIA TELLOURE AGAR
10216	TRYPTIC SOY AGAR (BLOOD 5%)	10259	SEPIRIA TELLOURE AGAR
10217	TRYPTIC SOY AGAR (BLOOD 5%)	10260	SEPIRIA TELLOURE AGAR
10218	TRYPTIC SOY AGAR (BLOOD 5%)	10261	SEPIRIA TELLOURE AGAR
10219	TRYPTIC SOY AGAR (BLOOD 5%)	10262	SEPIRIA TELLOURE AGAR
10220	TRYPTIC SOY AGAR (BLOOD 5%)	10263	SEPIRIA TELLOURE AGAR
10221	TRYPTIC SOY AGAR (BLOOD 5%)	10264	SEPIRIA TELLOURE AGAR
10222	TRYPTIC SOY AGAR (BLOOD 5%)	10265	SEPIRIA TELLOURE AGAR
10223	TRYPTIC SOY AGAR (BLOOD 5%)	10266	SEPIRIA TELLOURE AGAR
10224	TRYPTIC SOY AGAR (BLOOD 5%)	10267	SEPIRIA TELLOURE AGAR
10225	TRYPTIC SOY AGAR (BLOOD 5%)	10268	SEPIRIA TELLOURE AGAR
10226	TRYPTIC SOY AGAR (BLOOD 5%)	10269	SEPIRIA TELLOURE AGAR
10227	TRYPTIC SOY AGAR (BLOOD 5%)	10270	SEPIRIA TELLOURE AGAR
10228	TRYPTIC SOY AGAR (B		



Chromogenic selective medium for the isolation and differentiation of *Candida* spp directly from clinical and nonclinical specimens.

Chromatic™ Candida is a chromogenic selective medium used for the isolation and differentiation of *Candida* species directly from clinical and nonclinical specimens permitting to distinguish among *C.albicans*, *C.tropicalis*, *C.krusei*, *C.glabrata*, *C.dubliniensis* and *C.parapsilosis*.

TYPICAL FORMULA	(g/l)
Peptone	10.0
Chloramphenicol	0.5
Chromogenic Mix	25.2
Agar	15.0
Final pH 6.1 ± 0.2 at 25°C	

Peptone provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Chloramphenicol is the selective agent inhibiting most of the bacteria. Chromogenic mix allows to identify the *Candida* genus on the basis of the color and morphology of the colonies. Agar is the solidifying agent.

<u>Dehydrated medium</u>	Suspend 50.7 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. DO NOT AUTOCLAVE.
<u>Medium in bottles</u>	Melt the content of the bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

Inoculate the medium by direct streaking, spread plating or membrane filtration method. Incubate aerobically at 30-37°C for 24-48 hours.

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

Microorganism	Typical colony color
<i>Candida albicans</i>	Green
<i>Candida dubliniensis</i>	Yellow-green
<i>Candida glabrata</i>	Beige
<i>Candida krusei</i>	Pink, pale edges
<i>Candida parapsilosis</i>	Pale pink-white
<i>Candida tropicalis</i>	Blue

See pictures in Appendix I.

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



STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

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

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU
Inoculum for selectivity: 10⁴-10⁶ CFU.
Incubation conditions: aerobically at 35 ± 2°C for 24-48 hours.

QC Table.

Microorganism		Growth	Specification
<i>Candida albicans</i>	ATCC® 10231	Good	Green colonies
<i>Candida krusei</i>	ATCC® 14243	Good	Pink colonies
<i>Candida parapsilosis</i>	ATCC® 22019	Good	Pale pink-white colonies
<i>Candida tropicalis</i>	ATCC® 750	Good	Blue colonies
<i>Escherichia coli</i>	ATCC® 25922	Inhibited	---
<i>Staphylococcus aureus</i>	ATCC® 25923	Inhibited	---

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

1. Odds, F.C. And Bernaerts. 1994. CHROMagar Candida, a new differential medium for presumptive identification of clinically important *Candida* species. J. Clin. Microbiol. 32: 1923-1929.
2. Wingard, JR. Importance of *Candida* species other than *C. albicans* as pathogens in oncology patients. Clin Infect Dis. 1995; 20: 115-25.
3. Pfaller, Huston and Coffman. 1996. J. Clin. Microbiol. 32: 1923-1929.
4. Maertens JA. History of the development of azole derivatives. J Clin Microbiol Infect. 2004; 10: 1-10.

PRESENTATION		Contents	Ref.
Chromatic™ Candida	90 mm ready-to-use plates	20 plates	11612
Chromatic™ Candida	60 mm ready-to-use plates	20 plates	163692
Chromatic™ Candida	Bottles	6 x 100 ml bottles	481110
Chromatic™ Candida	Dehydrated medium	500 g of powder	610613
Chromatic™ Candida	Dehydrated medium	100 g of powder	620613

TABLE OF SYMBOLS

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

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IRON SULPHITE AGAR

Medium for the detection and enumeration of sulphite-reducing bacteria in food and other samples.

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Casein	10.0
Sodium Sulphite	0.5
Ferric Citrate	0.5
Agar	15.0
Final pH 7.1 ± 0.2	

DESCRIPTION

IRON SULPHITE AGAR is a medium used for the detection and enumeration of sulphite-reducing bacteria in food and other samples.

PRINCIPLE

Enzymatic digest of casein provides nitrogen, vitamins, minerals and amino acids essential for growth. Sodium sulphite and ferric citrate are H₂S indicators: Sulphite-reducing bacteria reduce sulphite to sulphide which react with iron of ferric citrate to form a black precipitate of iron sulphide turning the colonies black. Agar is the solidifying agent.

PREPARATION

Suspend 25 g of powder in 1 liter of distilled water. Heat until completely dissolved. Autoclave at 121°C for 15 minutes. Dispense aseptically into final containers.

TECHNIQUE

Dispense the medium in 10 ml amount in tubes. Inoculate the sample when the medium is at about 50°C. Allow to solidify before incubating. Alternatively, filter diluted samples through membrane filters. Then, place each one of these filters either in tube (rolled up filter and medium at 50°C) or onto Petri dish containing IRON SULPHITE AGAR. Incubate anaerobically at 35±2°C for 24-48 hours. If thermophilic bacteria are suspected, incubate at 55°C.

INTERPRETATION OF RESULTS

Sulphite-reducing bacteria cultivate with black colonies. Confirmation tests should be further carried out to identify the organism growing in the medium. There are many gram-negative bacteria that are able to reduce sulphite to sulphide with iron sulphide production in this medium, but in these cases the enzymes are extracellular and the entire medium becomes dark, rendering their enumeration impossible.

STORAGE

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

REFERENCES

- Mossel, D.A.A., Golstein Brouwers G.W.M.V. and De Bruijn A.S. (1959) J. Path. Bact. 78: 290-291.
- Tanner, F.W. (1944) The Microbiology of Foods, 2nd ed, p. 1127.



PRODUCT SPECIFICATIONS

NAME
IRON SULPHITE AGAR

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

Ref.	Content	Packaging
611401	500 g	500 g of powder in plastic bottle
621401	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
7.1 ± 0.2

USE
IRON SULPHITE AGAR is a medium used for the detection and enumeration of sulphite-reducing bacteria in food and other samples

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Dehydrated medium

Appearance: free-flowing, homogeneous

Colour: beige

Prepared medium

Appearance: slightly opalescent

Colour: light amber

SHELF LIFE

4 years

QUALITY CONTROL

1. Control of general characteristics, label and print

2. Microbiological control

Inoculum for productivity: 10-100 CFU/ml

Inoculum for specificity: ≤10⁴ CFU/ml

Incubation Conditions: 24-48 hours at 55°C, in anaerobic atmosphere

Microorganism

Microorganism	ATCC®	Colour
<i>Clostridium sporogenes</i>	ATCC® 19404	Good
<i>Clostridium perfringens</i>	ATCC® 11437	Good
<i>Escherichia coli</i>	ATCC® 25922	Good

TABLE OF SYMBOLS

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

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MUELLER HINTON AGAR

Medium for susceptibility test (Kirby-Bauer method).

TYPICAL FORMULA (g/L)	
Meat Extract	2.0
Casamino Acids, Technical	17.5
Starch	1.5
Agar	15.0
Final pH 7.3 ± 0.1	

DESCRIPTION

MUELLER HINTON AGAR is used for antimicrobial susceptibility testing of rapidly growing aerobic microorganisms by the disk diffusion technique.

PRINCIPLE

Casamino acids and meat extract are a source of amino acids, nitrogen, minerals, vitamins, carbon and other factors which increase the growth of microorganisms. Starch acts as a protective substance against toxic molecules which can be present in the medium. Hydrolysis of starch during sterilization supplies a little amount of glucose which represents a source of energy. Agar is the solidifying agent. Kirby-Bauer method is based on the diffusion, through the agar, of antimicrobial substances which soaks paper disks: microorganism growth shows an inhibition halo around the disk and the diameter of the halo is correlated to the Minimal Inhibiting Concentration (MIC).

PREPARATION

Suspend 36.0 g of powder in 1 litre of distilled or deionized water. Heat to boiling and shake until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes. Dispense in final containers.

TECHNIQUE

Transfer 4-5 colonies in an appropriate broth. Place it in a 37°C incubator until an opacity is obtained equivalent to the standard opacity of 0.5 on the MacFarland scale. Introduce a sterile swab into the inoculum and inoculate the agar passing 2 or 3 times onto the entire surface. Press the disk containing the antimicrobial on the agar surface. Incubate at 36±1°C for 18 hours, measure the inhibition zone with a compass and compare to the NCCLS recommended zone ranges.

INTERPRETATION OF RESULTS

Compare obtained values of inhibition halo diameter with the values reported on NCCLS M100(M2) document.

STORAGE

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

WARNING and PRECAUTIONS

The product is not classified as hazardous by current legislation and does not contain harmful substances in concentrations of ≥1%. The product is designed for *In Vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL of WASTE

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

REFERENCES

- Bauer et al. (1996). J. Clin. Pathol. 49:493-496.
- Mueller, J.H. and Hinton, 1941. Proc. Soc. Exp. Biol. Med. 48: 330-333.
- NCCLS. Performance standards for susceptibility testing; Twelve International Supplement. NCCLS Document M100-S12, January 2002.



PRODUCT SPECIFICATIONS

NAME
MUELLER HINTON AGAR

PRESENTATION
Dehydrated culture medium

STORAGE
10-30°C

PACKAGING

Code	Content	Packaging
6100333	500 g	500 g of powder in plastic bottle
6200333	100 g	100 g of powder in plastic bottle
6100335	5 kg	5 kg of powder in plastic container

pH OF THE MEDIUM
7.3 ± 0.1

USE

MUELLER HINTON AGAR is used for antimicrobial susceptibility testing of rapidly growing aerobic microorganisms by the disk diffusion technique.

TECHNIQUE

Refer to technical sheet of the product.

APPEARANCE OF THE MEDIUM

Amber medium, slightly opalescent.

SHELF LIFE

4 years

QUALITY CONTROL

1. Control of general characteristics, label and print

2. Sterility control

7 days at 25 ± 1°C, in aerobiosis
7 days at 36 ± 1°C, in aerobiosis

3. Microbiological control

Incubation conditions: 18-24 h at 36 ± 1°C

Microorganism	Growth	Characteristics
<i>Enterococcus faecalis</i>	ATCC 29212	Good White colonies
<i>Escherichia coli</i>	ATCC 25922	Good Colorless colonies
<i>Proteus mirabilis</i>	ATCC 25933	Good Colorless colonies
<i>Staphylococcus aureus</i>	ATCC 25923	Good White colonies

TABLE of SYMBOLS

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



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KLIGLER IRON AGAR

Differential medium for enterobacteria identification.

TYPICAL FORMULA (g/l)

Proteose Peptone	20.0
Sodium Chloride	5.0
Yeast Extract	3.0
Meat Extract	3.0
Ferrous Sulfate	0.2
Sodium Thiosulphate	0.3
Lactose	10.0
Glucose	1.0
Phenol Red	0.024
Agar	11.0
Final pH = 7.4 ± 0.2 at 25 °C.	

DIRECTIONS

Suspend 53.5 g of powder in 1 liter of distilled or deionized water. Heat to boiling until completely dissolved. Dispense into final tubes. Sterilize in autoclave at 121°C for 15 minutes. Cool in a slanting position.

DESCRIPTION

KLIGLER IRON AGAR is a solid medium used to distinguish between *Enterobacteriaceae* on the basis of their ability to ferment lactose and / or glucose and to produce hydrogen sulphide.

TECHNIQUE

Inoculate by stabbing the butt and abundantly streaking the slope. Incubate at 36 ± 1°C for 18-24 hours and check the color of the medium both in the butt and at the slope. Also check for the presence of gas in the butt and the presence of the black precipitate (H₂S).

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: pinkish beige.

Prepared medium

Appearance: slightly opalescent, slight precipitate.

Color: slightly orange-red.

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

Microorganism

Microorganism	ATCC	Growth	Slant/butt acid/acid	Gas	H ₂ S
<i>Citrobacter freundii</i>	8090	good	acid/acid	+	+
<i>Escherichia coli</i>	25922	good	acid/acid	+	+
<i>Proteus vulgaris</i>	6380	good	alkaline/acid	-	+

PERFORMANCE AND LIMITATIONS

A pure culture is essential when inoculating Kligler Iron Agar. If inoculated with a mixed culture, irregular observations may occur.

STORAGE

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

REFERENCES

1. MacFaddin, J.F. (1976). Biochemical tests for identification of medical bacteria.
2. Kligler, I.J. (1918). J. Exp. Med. 28: 319-322.

PRESENTATION

Product	REF	
KLIGLER IRON AGAR (9.3 l)	610023	500 g
KLIGLER IRON AGAR (1.8 l)	620023	100 g

TABLE OF SYMBOLS

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



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SIMMONS CITRATE AGAR

Differential medium for enterobacteria identification.

TYPICAL FORMULA

	(g/l)
Magnesium Sulfate	0.2
Ammonium Dihydrogen Phosphate	1.0
Dipotassium Phosphate	1.0
Sodium Citrate	2-3
Sodium Chloride	5.0
Brom Thymol Blue	0.08
Agar	15.0

Final pH = 6.8 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 24.3 g of powder in 1 liter of distilled or deionized water. Heat to boiling until completely dissolved. Dispense into final tubes and sterilize in the autoclave at 121°C for 15 minutes. Allow the medium to solidify in a slant position.

DESCRIPTION

SIMMONS CITRATE AGAR is recommended for the differentiation and identification of Enterobacteriaceae on the basis of citrate utilization.

TECHNIQUE

Inoculate the medium with the specimen by stabbing the butt and streaking the slope. Incubate at 36 ± 1 °C for 24-48 hours. Organisms able to utilize ammonium dihydrogen phosphate and sodium citrate as the sole sources of nitrogen and carbon respectively will grow on this medium and produce an alkaline reaction as evidenced by a change in the color of the bromthymol blue indicator from green (neutral) to blue (alkaline).

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: yellow, may have green tinge.

Prepared medium

Appearance: slightly opalescent, may have a slight precipitate.

Color: forest green.

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

Microorganism

Microorganism	ATCC	Growth	Characteristics
<i>Escherichia coli</i> □ □ □	25922	inhibited	
<i>Enterobacter aerogenes</i>	13048	good	blue
<i>Salmonella typhimurium</i>	14028	good	blue
<i>Salmonella typhi</i>	19430	good	green

STORAGE

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



REFERENCES

1. Ewig W.H. and Edwards P.R. (1960). Bull. Bact. Nomen. And Taxon. 10:1-12.
2. American Public Health Association (1981). Standard Methods for the Examination of Water and Wastewater, 15th ed. APHA Inc, Washington DC.
3. Matsen J.M., and Sherris J.C. (1969) Appl. Microbiol. 18: 452-454.

PRESENTATION

Product	REF	
SIMMONS CITRATE AGAR (20.5 l)	610046	500 g
SIMMONS CITRATE AGAR (4.1 l)	620046	100 g

TABLE OF SYMBOLS

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

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ENDO AGAR

Medium for coliforms confirmatory test.

TYPICAL FORMULA (g/l)

Peptone	10.0
Lactose	10.0
Dipotassium Phosphate	3.5
Agar	15.0
Sodium Sulphite	2.5
Basic Fuchsin	0.5
Final pH = 7.5 ± 0.2 at 25 °C.	

DIRECTIONS

Suspend 41.5 g of powder in 1 liter of distilled or deionized water. Heat to boiling with frequent and careful overturnings until complete dissolution. Autoclave at 121 °C for 15 minutes. Evenly disperse the precipitate when dispensing. Use immediately.

DESCRIPTION

ENDO AGAR is used for confirming the presence of coliforms organisms.

TECHNIQUE

For the confirmation of presumptive tests with liquid media, subculture tubes showing gas, or acid and gas formation, onto an Endo Agar plate. Incubate at 36 ± 1 °C for 24 hours. Lactose fermenting coliforms (e.g. *E. coli*) give rise to deep red colonies which color the surrounding medium and possess a golden metallic sheen. Non-lactose fermenters form colorless translucent colonies, against the pink to colorless medium.

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: medium purple.

Prepared medium

Appearance: opalescent with precipitates.

Color: pink.

Incubation conditions: 36 ± 1 °C for 24 ± 2 hours.

Microorganism

ATCC	Growth
<i>Staphylococcus aureus</i> 25923	markedly to completely inhibited
<i>Escherichia coli</i> □□ 25922	good
<i>Salmonella typhimurium</i> 14028	good

Characteristics

red colonies w / green metallic sheen
colorless to pink colonies



PERFORMANCE AND LIMITATIONS

If the medium is to be used the same day it is rehydrated, it does not need to be autoclaved. Boil to dissolve completely before dispensing into plates.

STORAGE

The powder is very hygroscopic: store the powder at 10-30 °C, in a dry environment, in its original container tightly closed and use it before the expiry date on the label or until signs of deterioration or contamination are evident. The medium should be used the day it is prepared: if it is necessary store in the dark at 2-8 °C for no more than 3 days.

REFERENCES

- Endo, S. (1904). Über ein Verfahren zum Nachweis der Typhusbacillen. Centr. Bakt., Abt 1, Orig. 35:109-110.
- American Public Health Association. (1975). Standard methods for the examination of water and wastewater, 14th ed.

PRESENTATION

Product	REF	Σ
ENDO AGAR (12.0 l)	610020	500 g
ENDO AGAR (2.4 l)	620020	100 g

TABLE OF SYMBOLS

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

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ФЕДЕРАЛЬНАЯ СЛУЖБА ПО НАДЗОРУ В СФЕРЕ ЗАРОВООХРАНЕНИЯ
(РОСЗДРАВНАДЗОР)

РЕГИСТРАЦИОННОЕ УДОСТОВЕРЕНИЕ НА МЕДИЦИНСКОЕ ИЗДЕЛИЕ

от 17 октября 2011 года № ФСР 2008/03236

На медицинское изделие

Набор реагентов для бактериологических исследований "Питательная среда для культивирования и выделения бифидобактерий сухая (Бифидум-среда)"
по ТУ 9398-041-78095326-2008

Настоящее регистрационное удостоверение выдано

Федеральное бюджетное учреждение науки "Государственный научный центр прикладной микробиологии и биотехнологии" Федеральной службы по надзору в сфере защиты прав потребителей и благополучия человека (ФБУН ГНЦ ПМБ)
Россия, 142279, Московская область, Серпуховский район, п. Оболенск

Производитель

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Место производства медицинского изделия

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Номер регистрационного досье № 35007 от 31.08.2011

Вид медицинского изделия -

Класс потенциального риска применения медицинского изделия 1

Код Общероссийского классификатора продукции для медицинского изделия 93 9816

приказом Росздравнадзора от 17 октября 2011 года № 6730-Пр/11
и приказом от 15 июля 2016 года № 6982 о замене
допущено к обращению на территории Российской Федерации.

Врио руководителя Федеральной службы
по надзору в сфере здравоохранения

Д.В. Пархоменко

0018548



Mannitol Salt Agar

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



DESCRIPTION

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

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

TYPICAL FORMULA (g/l)

Pancreatic Digest of Casein	5.0
Beef Digest of Animal Tissue	5.0
Beef Extract	1.0
D-Mannitol	10.0
Sodium Chloride	75.0
Phenol Red	0.025
Agar	15.0
Final pH 7.4 ± 0.2 at 25°C	

METHOD PRINCIPLE

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

PREPARATION

Dehydrated medium
Suspend 111 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil for 1 minute shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

Medium in bottles

Melt the content of the bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

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

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

INTERPRETING RESULTS

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

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

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

APPEARANCE OF THE MEDIUM

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

Prepared medium: slightly opalescent, pinkish-red.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.

Medium in bottles: 2 years.

Ready-to-use plates: 6 months.

QUALITY CONTROL

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

Inoculum for productivity: 10-100 CFU

Inoculum for selectivity: 10⁵-10⁶ CFU

Incubation conditions: aerobically at 35 ± 2°C for 24-48 hours.

*30-35°C for 18-72 h (USP/EP/IP Growth Promotion Testing).

QC Table.

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

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

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

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Medical Diagnostic Device	Manufacturer	Use by	Fragile, handle with care
REF	Catalogue number	Temperature limitation	Contains sufficient for <10 ³ tests		Caution, consult instruction for use	Do not reuse

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Fluid Thioglycollate Medium

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



DESCRIPTION

Fluid Thioglycollate Medium is a general purpose liquid enrichment medium used for sterility control of pharmaceutical products and for cultivation and isolation of fastidious anaerobic and aerobic microorganisms. The composition is in accordance with the requirements of the Harmonized US, European and Japanese Pharmacopoeia as well as with ISO 7937 for isolation of *Clostridium perfringens*.

TYPICAL FORMULA

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

Final pH 7.1 ± 0.2 at 25°C

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Glucose is a source of energy. Sodium chloride maintains the osmotic balance of the medium. Sodium thioglycollate and L-cysteine are included to reduce the redox potential of the medium and create an anaerobic atmosphere. These reducing agents also neutralize the bacteriostatic effects of mercury and other heavy metal compounds in the preparation to be tested for sterility. Resazurin is an oxidation-reduction indicator being pink when oxidized and colorless when reduced. The small amount of agar assists in the maintenance of a low redox potential by stabilizing the medium against convection currents, thereby maintaining anaerobiosis in the lower depths of the medium.

PREPARATION

Dehydrated medium Suspend 29.8 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into appropriate containers. Sterilize in autoclave at 121°C for 15 minutes.

Medium in tubes/bottles If the medium exhibits more than 20% pink color (due to oxidation), the medium may be reheated once for 5 minutes with cap slightly loosened in steam or boiling water in order to expel the oxygen.

TEST PROCEDURE

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

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

INTERPRETING RESULTS

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

APPEARANCE

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

Prepared medium: slightly opalescent, light amber (20% or less of upper layer may be pink).

STORAGE

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

SHELF LIFE

Dehydrated medium: 4 years.

Medium in bottles: 2 years.

Medium in tubes: 1 year.

QUALITY CONTROL

Fluid Thioglycollate Medium is inoculated with the microbial strains indicated in the QC table. Inoculum for productivity: ≤ 100 CFU.

Incubation conditions: 24 h at 30-35°C for bacteria, 48 h at 20-25°C for yeasts, 72 h at 20-25°C for moulds (Pharmacopoeia growth promotion):

18-24 at 37 ± 1°C for *Clostridium perfringens* (ISO 11133).

QC Table.

Microorganism	ATCC®	Specification
<i>Bacillus subtilis</i>	ATCC® 6633	Visible turbidity
<i>Clostridium sporogenes</i>	ATCC® 19404	Visible turbidity
<i>Escherichia coli</i>	ATCC® 8739	Visible turbidity
<i>Pseudomonas aeruginosa</i>	ATCC® 9027	Visible turbidity
<i>Staphylococcus aureus</i>	ATCC® 6538	Visible turbidity
<i>Candida albicans</i>	ATCC® 10231	Visible turbidity
<i>Aspergillus brasiliensis</i>	ATCC® 16404	Visible turbidity
<i>Clostridium perfringens</i>	WDCM 00007	Slight to good turbidity

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

- ISO 11133:2014, Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media
- ISO 7937:2004, Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of *Clostridium perfringens* – Colony count technique.
- United States Pharmacopoeial Convention (2008). The United States Pharmacopoeia, 31/the National formulary 26, Supp. 1, 8-1-08, online.
- European Directorate for the Quality of Medicines and Healthcare. 2008.The European pharmacopoeia, 6th ed., Supp. 1, 4-1-08, online.
- Japanese Ministry of Health, Labour and Welfare. 2006. The Japanese pharmacopoeia, 15th ed., online.
- Brewer J.H. (1940) Clear liquid medium for the aerobic "cultivation" of anaerobes. J. Am. Med. Assoc. 115:598-600.

PRESENTATION

	Contents	Ref.
Fluid Thioglycollate Medium	Tubes	20 x 10 ml tubes
Fluid Thioglycollate Medium	Tubes	100 x 10 ml tubes
Fluid Thioglycollate Medium	Tubes	10 x 20 ml tubes
Fluid Thioglycollate Medium	Tubes	20 x 20 ml tubes
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (flip-off cap)
Fluid Thioglycollate Medium	Bottles	6 x 300 ml bottles (flip-off cap)
Fluid Thioglycollate Medium	Bottles	6 x 1000 ml bottles (flip-off cap)
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (screw cap)
Fluid Thioglycollate Medium	Bottles	25 x 100 ml bottles (screw cap)
Fluid Thioglycollate Medium	Bottles	6 x 900 ml bottles (screw cap)
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (crimp cap)
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (perforable cap)
Fluid Thioglycollate Medium	Bottles	6 x 500 ml bottles (wide neck)
Fluid Thioglycollate Medium	Dehydrated medium	500 g of powder
Fluid Thioglycollate Medium	Dehydrated medium	100 g of powder
Fluid Thioglycollate Medium	Dehydrated medium	5 kg of powder

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Diagnostic Medical Device	Use by	Fragile, handle with care	Keep away from sunlight
REF	Catalogue number	Temperature limitation	Contains sufficient for <20 tests	Caution, consult instruction for use	Do not reuse	

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Chromatic™ Detection

Chromogenic medium for the enumeration and identification of microorganisms directly from clinical and nonclinical specimens.

DESCRIPTION

Chromatic™ Detection is a chromogenic medium used for the enumeration and identification of microorganisms directly from clinical and nonclinical specimens.

The medium allows to carry out indole test for confirmation of *Escherichia coli*.

TECHNICAL DATA

Peptone	14.0
Tryptone	6.0
Yeast Extract	3.0
Sodium Chloride	5.0
Chromogenic Mix	13.1
Agar	15.0
Final pH 7.2 ± 0.2 at 25°C	

METHOD PRINCIPLE

Peptone and tryptone provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Sodium chloride maintains the osmotic balance of the medium. Chromogenic mix allows to identify microorganisms on the basis of the color and morphology of the colonies. Agar is the solidifying agent.

PREPARATION

Dehydrated medium
Suspend 56.1 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

Medium in bottles
Melt the content of the bottle in a water bath at 100°C (loosening the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

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

INTERPRETING RESULTS

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

ID Table	Microorganism	Typical colony color
<i>E. coli</i>		Pink-reddish-mauve
<i>Klebsiella</i> spp.	<i>Enterobacter</i> spp., <i>Serratia</i> spp.	Green-blue
<i>Proteus</i> spp.		Brown
<i>Pseudomonas</i> spp.		Yellowish-green
<i>S. aureus</i>		Cream
<i>E. faecalis</i>		Green-turquoise
<i>S. saprophyticus</i>		Light pink

See pictures in Appendix 1.

APPEARANCE

Dehydrated medium: fine, dry, homogeneous, free of extraneous material, beige.
Prepared medium: slightly opalescent, amber.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 2-8°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

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

QUALITY CONTROL

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

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

QC Table.

Microorganism	Growth	Specification
<i>Escherichia coli</i>	ATCC® 25922	Good
<i>Klebsiella pneumoniae</i>	ATCC® 13883	Good
<i>Proteus mirabilis</i>	ATCC® 12453	Good
<i>Pseudomonas aeruginosa</i>	ATCC® 27853	Good
<i>Staphylococcus aureus</i>	ATCC® 25923	Good
<i>Enterococcus faecalis</i>	ATCC® 29212	Good
<i>Staphylococcus saprophyticus</i>	ATCC® 15305	Good

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

- Medino J., S. Siarakas, G.J. Robertson, G.R. Funnel, T. Gottlieb, and R. Bradbury (1996) Evaluation of Colorex Orientation for differentiation and presumptive identification of Gram-negative bacilli and Enterococcus species. J. Clin. Microbiol. 34: 1788-1793.
- Samia Z., et al. (1998) Evaluation of use of a new chromogenic Agar in detection of urinary tract pathogens. J. Clin. Microbiol. 36: 990-994.

PRESENTATION

Chromatic™ Detection	90 mm ready-to-use plates	20 plates	Ref.
Chromatic™ Detection	Bottles	6 x 100 ml bottles	481130
Chromatic™ Detection	Dehydrated medium	500 g of powder	610612
Chromatic™ Detection	Dehydrated medium	100 g of powder	620612
Chromatic™ Detection	Dehydrated medium	5 kg of powder	6106125

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF	Catalogue number	Temperature limitation	Contains sufficient for <20 tests	Caution, consult instruction for Use	Do not reuse	

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CE IVD

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XLD Agar

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

DESCRIPTION

XLD (Xylose lysine Deoxycholate) Agar is a selective medium used for the isolation and differentiation of pathogen Enterobacteriaceae, especially *Salmonella* and *Shigella* from food, environmental samples and clinical specimens. XLD Agar is formulated according to ISO 6579 and ISO 21567 for the detection of *Salmonella* and *Shigella* spp, respectively.

TYPICAL FORMULA

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

METHOD PRINCIPLE

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

PREPARATION

Dehydrated medium
Suspend 55.4 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. DO NOT AUTOCLAVE.
Medium in bottles
Melt the content of the bottle in a water bath at 100°C (loosening the cap partially removed) until completely dissolved. Immediately cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

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

INTERPRETING RESULTS

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

ID Table.

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

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, pink.
Prepared medium: slightly opalescent, red.

STORAGE

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

SHELF LIFE

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

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: ≤100 CFU
Inoculum for selectivity: >10⁷ CFU
Incubation conditions: aerobically at 37 ± 1°C for 24 ± 3 hours.

QC Table.

Microorganism	Growth	Specification
<i>Salmonella Typhimurium</i>	WDCM 00031	Good
<i>Salmonella Enteritidis</i>	WDCM 00030	Good
<i>Shigella flexneri</i>	ATCC® 12022	Good
<i>Escherichia coli</i>	WDCM 00013	Poor
<i>Enterococcus faecalis</i>	WDCM 00087	Inhibited

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

- EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
- EN ISO 21567:2004 Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Shigella* spp.
- ISO 6579:2002. Microbiology of food and animal feeding stuffs – Horizontal method for the detection of *Salmonella* spp.
- Vanderzant C. and D.F. Splittstoesser (1992) Compendium of methods for the microbiological examination of foods, 3rd ed. American Public Health Association, Washington D.C.
- Rollender W. et al. (1969) Comparison of xylose lysine deoxycholate agar and MacConkey Agar for the isolation of *Salmonella* and *Shigella* from clinical specimens. Am J Clin Pathol; 31:284-386
- Taylor WJ. (1965) Isolation of *Shigella* I. Xylose lysine agars: new media for isolation of enteric pathogens. Am J Clin Pathol; 44:471-475.
- Taylor WJ. and Harris B (1965) Isolation of *Shigella* II. Comparison of plating media and enrichment broths. Am J Clin Pathol; 44:476-479.

PRESENTATION

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

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF	Catalogue number		Temperature limitation	Contains sufficient for <10 tests	Caution, consult instruction for use	Do not reuse



LIOFILCHEM® s.r.l.

CE IVD

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PEPTONE BACTERIOLOGICAL

Peptone obtained by enzymatic hydrolysis of animal tissue.

USE

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

PHYSICO-CHEMICAL CHARACTERISTICS

	Standard
Solubility in water at 2%	Complete
pH of 2% solution	7.0+/-0.5
Loss on drying	≤ 6.0%
Total nitrogen	>12.5%
α-amino nitrogen AN	3-4.5%
Ash	5.0%

TECHNIQUE

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

QUALITY CONTROL

Dehydrated powder

Appearance: free-flowing, homogeneous.

Color: cream.

STORAGE

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

REFERENCES

- Standard Methods for Examination of Water and Sewage, 15th ed., (1980).
- J. Dairy Science, **16**: 277: (1933).

PRESENTATION

Product	REF	Σ
PEPTONE BACTERIOLOGICAL	611701	500 g
PEPTONE BACTERIOLOGICAL	621701	100 g
PEPTONE BACTERIOLOGICAL	6117015	5 Kg

TABLE OF SYMBOLS

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



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NUTRIENT BROTH

Medium for non fastidious bacteria growth.

TYPICAL FORMULA (g/l)

Beef Extract	1.0
Yeast Extract	2.0
Peptone	5.0
Sodium Chloride	5.0

Final pH = 6.8 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 13.0 g of powder in 1 liter of distilled or deionized water. Dissolve completely. Dispense into final tubes. Sterilize in autoclave at 121 °C for 15 minutes.

DESCRIPTION

NUTRIENT BROTH is a general purpose medium used for the cultivation of those microorganisms that are not exacting on their food requirements. It is the formula as specified by the American Public Health Association in Standard Methods for the Examination of Water and Sewage and Standard Methods for the Examination of Dairy Products.

TECHNIQUE

Inoculate the broth with specimen on a swab. Incubate for 18-24 hours at 36 ± 1 °C. Turbidity indicates growth. As a pre-enrichment medium when testing certain foods and dairy products for *Salmonella*, consult appropriate references for specific recommendations:

- Mix 25 g of sample with 225 ml of Nutrient Broth.
- Incubate for 18-24 hours at 36 ± 1 °C.
- Transfer a portion to a selective enrichment broth.

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: medium tan.

Prepared medium

Appearance: clear with no precipitate.

Color: light to medium amber.

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

Microorganism

	ATCC	Growth
<i>Escherichia coli</i> □	25922	good
<i>Staphylococcus aureus</i>	25923	good

STORAGE

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

REFERENCES

1. American Public Health Association. 1923. Standard methods of water analysis, 5th ed.
2. Association of Official Analytical Chemists. 1995. Official methods of analysis of AOAC International, 16th ed.
3. Marshall, R.T. (ed.). 1993. Standard methods for the microbiological examination of dairy products, 16th ed.

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PRESENTATION

Product	REF	
NUTRIENT BROTH (38.4 l)	610037	500 g
NUTRIENT BROTH (7.6 l)	620037	100 g
NUTRIENT BROTH (384.6 l)	6100375	100 g

TABLE OF SYMBOLS

LOT	Batch code	Caution, consult accompanying documents	Manufacturer	Contains sufficient for <2> tests	IVD	In Vitro Diagnostic Medical Device
REF	Catalogue number	Fragile, handle with care	Use by	Temperature limitation		Keep away from heat source



MRS Agar

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

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

DESCRIPTION

MRS Agar is a medium used with supplements for the cultivation of *Lactobacillus* spp from all types of materials. It may also support the growth of *Pedococcus* and *Leuconostoc* species as well as other secondary bacteria.
The complete medium complies with the recommendations of ISO 15214 and APHA.

PRINCIPLE

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

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

PREPARATION

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

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

TECHNIQUE

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

INTERPRETATION OF RESULTS

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

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

STORAGE AND TRANSPORT CONDITIONS

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

REFERENCES

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

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IVD



PRODUCT SPECIFICATIONS

NAME
MRS Agar

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

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

pH OF THE MEDIUM
5.7 ± 0.1

USE

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

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Powder medium

Appearance: free-flowing, homogeneous

Colour: beige

Ready-to-use medium

Appearance: slightly opalescent

Colour: amber

SHELF LIFE

4 years

QUALITY CONTROL

1. Control of general characteristics, label and print

2. Microbiological control

Inoculum for productivity: 50-100 CFU

Inoculum for selectivity: 10⁴-10⁷ CFU

Incubation Conditions: 72 ± 3 h at 30 ± 1°C, in microaerobiosis

Microorganism

	Growth
<i>Lactobacillus sakei</i>	WDCM 00015 Good
<i>Lactobacillus lactis</i>	WDCM 00016 Good
<i>Escherichia coli</i>	WDCM 00012 Inhibited
<i>Bacillus cereus</i>	WDCM 00001 Inhibited

TABLE OF SYMBOLS

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



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IVD



S.S. AGAR (MODIFIED)

Terreno selettivo per l'isolamento di *Salmonella* spp. e *Shigella* spp.

FORMULA TIPICA	(g/l)
Peptone	5,5
Estratto di Carne	5,0
Latissio	10,0
Sodio Tiosolfato	8,5
Estratto di Lievito	5,0
Sodio Citrato	1,0
Sali di Bile N.3	1,5
Animento Feritico Citrato	1,5
Verde Brillante	0,23 mg
Rosso Neutro	0,025
Agar	14,0
pH Finale	7,0 ± 0,2

DESCRIZIONE

S.S. AGAR (MODIFIED) è un terreno altamente selettivo per l'isolamento di *Salmonella* spp ed alcune specie di *Shigella* da materiale clinico, alimenti ed altri campioni.

PRINCIPIO

I microrganismi Gram-positivi ed i coliformi sono inibiti dai componenti selettivi: verde brillante, sali di bile, tiosolfato e citrato. La differenziazione dei microrganismi è ottenuta attraverso l'introduzione del lattosio nel terreno: gli organismi che fermentano il lattosio producono acidificazione che, in presenza del rosso neutro, determina la formazione di colonie rosse. I lattosio non-fermentanti producono colonie incolore. Il tiosolfato, in combinazione con il ferro, agisce come un indicatore per la produzione di solfuro che è indicata da un annerimento del centro delle colonie.

PREPARAZIONE

Sospendere 52,0 g di polvere in 1 litro di acqua distillata sterile. Mescolare bene. Riscaldare agitando di frequente e bollire fino a completa dissoluzione. NON AUTOCLAVARE. Raffreddare il terreno a 45-50°C. In condizioni di asepsi dispensare in piastre Petri e lasciar solidificare il terreno mantenendo i coperti parzialmente rimossi.

TECNICA

Inoculare sfidando il campione da analizzare sulla superficie del terreno al fine di isolare colonie pure da campioni contenenti una flora mista. Incubare a 36±1°C per 18-24 ore.

INTERPRETAZIONE DEI RISULTATI

Salmonella spp ed altri microrganismi non fermentanti il lattosio possono produrre colonie opache, traslucanti o trasparenti, con o senza il centro nero. Le colonie di *Shigella* sono incolore. I pochi organismi che fermentano il lattosio, che riescono a crescere sul terreno, si differenziano per le colonie rossastre di aspetto mucoso.

CONSERVAZIONE

Il prodotto può essere conservato a 10-30°C al riparo dalla luce, fino alla data di scadenza indicata in etichetta. Eliminare se vi sono segni evidenti di deterioramento o contaminazione.

AVVERTENZE E PRECAUZIONI

Il prodotto non contiene sostanze nocive in concentrazioni superiori ai limiti fissati dalla normativa vigente, perciò non è classificato come pericoloso; per il suo impiego si consiglia comunque di consultare la scheda di sicurezza. Il prodotto è destinato esclusivamente per Uso Diagnostico *in vitro* e deve essere utilizzato da parte di personale qualificato.

SMALTIMENTO DEI RIFIUTI

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

RIFERIMENTI BIBLIOGRAFICI

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

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SPECIFICHE DI PRODOTTO

DENOMINAZIONE
S.S. AGAR (MODIFIED)

PRESENTAZIONE
Terreno disidratato

CONSERVAZIONE
10-30°C

CONFEZIONAMENTO

Ref.	Contenuto	Modalità di confezionamento
610042	500 g	500 g di polvere in flacone in plastica
620042	100 g	100 g di polvere in flacone in plastica
6100425	5 kg	5 kg di polvere in contenitore in plastica

pH DEL TERRENO
7,0 ± 0,2

IMPIEGO

S.S. AGAR è un terreno altamente selettivo per l'isolamento di *Salmonella* spp ed alcune specie di *Shigella* da materiale clinico, alimenti ed altri campioni.

TECNICA

Fare riferimento alla scheda tecnica del prodotto

ASPETTO DEL TERRENO

Terreno disidratato
Aspetto: omogeneo
Colore: rosa chiaro
Terreno preparato
Aspetto: opaco
Colore: viola

VALIDITÀ DALLA DATA DI PRODUZIONE

4 anni

CONTROLLO DI QUALITÀ

1. Controllo caratteristiche generali, etichettatura e stampa
2. Controllo microbiologico
Dimensione dell'inoculo per produttività: 10-100 UFC/ml
Dimensione dell'inoculo per selettività: 10⁴-10⁶ UFC/ml
Dimensione dell'inoculo per specificità: 510⁴ UFC/ml
Condizioni di incubazione: 18-24 h a 35 ± 2°C in aerobiosi

Microorganismo

Microorganismo	ATCC®	Crescita	Caratteristiche
<i>Shigella flexneri</i>	ATCC® 12022	Buona	Colonie incolore
<i>Salmonella typhimurium</i>	ATCC® 14028	Buona	Colonie incolore con o senza centro nero
<i>Enterococcus faecalis</i>	ATCC® 29212	Inibita	—
<i>Staphylococcus aureus</i>	ATCC® 25923	Inibita	—
<i>Escherichia coli</i>	ATCC® 25922	Parzialmente inibita	Colonie rosa o rosse

TABELLA DEI SIMBOLI

LOT	Numero di lotto	IVD	Per uso diagnostico in vitro	Fabbricante	Data di scadenza
REF	Numero di catalogo	IVD	Limiti di temperatura	Contenuto sufficiente per <n> test	Attenzione, consultare le istruzioni per l'uso

PHENYLALANINE AGAR

Medium for enterobacteria differentiation.

TYPICAL FORMULA (g/l)

Yeast Extract	3.0
Disodium Phosphate	1.0
Sodium Chloride	5.0
DL-Phenylalanine	2.0
Agar	15.0
Final pH = 7.3 ± 0.2 at 25 °C.	

DIRECTIONS

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

DESCRIPTION

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

TECHNIQUE

Inoculate the slant with test organisms and incubate at 36 ± 1°C for 18-24 hours. Add 3-5 drops of Ferric Chloride 10% (code 80272) and 3-5 drops of a 0.1 N HCl solution to a 24 hours culture. Rotate the tubes to wet and loosen the growth. A positive test is indicated by the formation of a characteristic green color. *Proteus* and *Providencia* groups give a positive reaction in 1-5 minutes. Other members of *Enterobacteriaceae* give negative reactions.

QUALITY CONTROL

Dehydrated medium

Appearance: free-flowing, homogeneous.

Color: light tan.

Prepared medium

Appearance: slightly opalescent without precipitate.

Color: light amber.

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

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

STORAGE

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

Store prepared tubes at 2-8 °C.

REFERENCES

1. Ann. Inst. Pasteur. (1954) **87**: 375-386.
2. Pub. Hlth Lab. (1957) **5**: 153.

PRESENTATION

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

TABLE OF SYMBOLS

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



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Nutrient Agar

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

DESCRIPTION

Nutrient Agar is a medium used for the cultivation of non-fastidious organisms from clinical specimens and environmental samples.

Nutrient Agar is formulated according to ISO 16266 for the detection and enumeration of *Pseudomonas aeruginosa* in water by the membrane filtration technique.

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

METHOD PRINCIPLE

Peptone and meat extract provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Sodium chloride maintains the osmotic balance of the medium. Agar is the solidifying agent.

PREPARATION

Dehydrated medium
Suspend 28 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

Medium in tubes/bottles
Melt the content of the tube/bottle in a water bath at 100°C (loosening the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the tube/bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

According to ISO 16266, transfer the membrane and presumptive *Pseudomonas aeruginosa* to a plate of Nutrient Agar. Incubate aerobically at 36 ± 2°C for 20-24 hours.

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

INTERPRETING RESULTS

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

APPEARANCE

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

STORAGE

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

SHELF LIFE

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



QUALITY CONTROL

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

Inoculum for productivity: 50-100 CFU

Incubation conditions: aerobically at 36 ± 1°C for 20-24 hours.

QC Table.

Microorganism	ATCC®	Growth
<i>Pseudomonas aeruginosa</i>	ATCC® 27853	Good
<i>Escherichia coli</i>	ATCC® 25922	Good

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

- ISO 16266:2008. Water Quality – Detection and enumeration of *Pseudomonas aeruginosa* – Method by membrane filtration.
- Marshall, R.T. (1993) Standard methods for the microbiological examination of dairy products, 16th ed.

PRESENTATION

	Contents	Ref.
Nutrient Agar	90 mm ready-to-use plates	10044
Nutrient Agar	90 mm ready-to-use plates	10044*
Nutrient Agar	Tubes	20 x 22 ml tubes
Nutrient Agar	Tubes	10 x 22 ml tubes
Nutrient Agar	Bottles	6 x 500 ml bottles
Nutrient Agar	Bottles	6 x 200 ml bottles
Nutrient Agar	Bottles	6 x 100 ml bottles
Nutrient Agar	Dehydrated medium	100 g of powder
Nutrient Agar	Dehydrated medium	500 g of powder
Nutrient Agar	Dehydrated medium	5 kg of powder
		6100365

TABLE OF SYMBOLS

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

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Sabouraud Dextrose Agar

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



DESCRIPTION

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

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

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

TYPICAL FORMULA

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

Final pH 5.6 ± 0.2 at 25°C

METHOD PRINCIPLE

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

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

PREPARATION

Dehydrated medium Suspend 65 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

Medium in bottles Melt the content of the bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

For use in medical microbiology

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

For use in food, animal feed and water testing

Refer to EN ISO 11133 for specific instructions.

For use in industrial microbiology

Control of non-sterile products

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

Passive Air Monitoring

Take the lid off the settle plate and leave the medium exposed to the air for a period of time no longer than 4 hours. Plates can be placed according to the 1/1/1 scheme (for 1 h, about 1 m above the floor, at least 1 m from the walls or any obstacle).

Surfaces and Personnel Hygiene Monitoring

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

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

INTERPRETING RESULTS

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

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

- 10¹ CFU: maximum acceptable count = 20;
- 10² CFU: maximum acceptable count = 200;
- 10³ CFU: maximum acceptable count = 2000, and so forth.

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

APPEARANCE

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

STORAGE

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

SHELF LIFE

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

QUALITY CONTROL

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

Inoculum for productivity: 50-100 CFU.

Incubation conditions: 32.5 ± 2.5°C for 24-48 h (*C. albicans*) and at 22.5 ± 2.5°C for up to 5 days (all listed organisms), under aerobic atmosphere.

QC Table.

Microorganism	WDCM	Growth
<i>Candida albicans</i>	WDCM 00054	Good
<i>Aspergillus brasiliensis</i>	WDCM 00053	Good
<i>Saccharomyces cerevisiae</i>	WDCM 00058	Good

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

1. EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. European Pharmacopoeia 6.5 (2009) 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms.
3. United States Pharmacopoeia 32 NF 27 (2009) <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
4. Japanese Pharmacopoeia 4.05 (2008) Microbiological examination of non-sterile products: Test for specified microorganisms.
5. Sabouraud, R. (1892) Ann. Dermatol. Syphilid. 3:1061.

PRESENTATION

	Contents	Ref.
Sabouraud Dextrose Agar	90 mm ready-to-use plates	20 plates 10035
Sabouraud Dextrose Agar	90 mm ready-to-use plates	100 plates 10035*
Sabouraud Dextrose Agar	90 mm ready-to-use plates (triple-wrapped and gamma-irradiated)	20 plates 10035S
Sabouraud Dextrose Agar	Slant tubes	10 x 9 ml tubes 30093
Sabouraud Dextrose Agar	Slant tubes	20 x 9 ml tubes 31093
Sabouraud Dextrose Agar	Bottles	6 x 500 ml bottles 470040
Sabouraud Dextrose Agar	Bottles	6 x 200 ml bottles 412280
Sabouraud Dextrose Agar	Bottles	6 x 100 ml bottles 402280
Sabouraud Dextrose Agar	Dehydrated medium	500 g of powder 610103
Sabouraud Dextrose Agar	Dehydrated medium	100 g of powder 620103
Sabouraud Dextrose Agar	Dehydrated medium	5 kg of powder 610103S

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF	Catalogue number	Temperature limitation	Contains sufficient for <= 5 tests		Caution, consult Instruction for Use	Do not reuse

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CE

IVD

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Selenite Broth

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

DESCRIPTION

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

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

TYPICAL FORMULA

	(g/l)
Enzymatic Digest of Casein	5.0
Lactose	4.0
Sodium Phosphate	10.0
Sodium Selenite	4.0
Final pH 7.0 ± 0.2 at 25°C	

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Lactose is the fermentable carbohydrate. Sodium phosphate is the buffer. Sodium selenite is the selective agent inhibiting many species of Gram-positive and Gram-negative bacteria including enterococci and coliforms.

PREPARATION

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

TEST PROCEDURE

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

INTERPRETING RESULTS

Turbidity indicates microbial growth.

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

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, white to light beige.
Prepared medium: clear, very pale yellow.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and tubes at 2-8°C, away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.
Medium in tubes/bottles: 1 year.



QUALITY CONTROL

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

Inoculum for productivity: ≤100 CFU.

Inoculum for selectivity: >10³ CFU.

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

QC Table.

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

WARNING AND PRECAUTIONS

The product contains hazardous substances and is classified as dangerous. It is recommended to consult the safety data sheet for its correct use. The product is intended for *In vitro* diagnostic use and must be used only by properly trained operators.

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

- Versalovic, J., K.C. Carroll, G. Funke, J.H. Jorgensen, M.L. Landry, and D.W. Warnock (2011) Manual of Clinical Microbiology. 10th ed. ASM Press, Washington, D.C.
- Quality Control for Commercially Prepared Microbiological Media (2004) - 3rd ed. M22-A3. Clinical and Laboratory Standards Institute - CLSI (NCCLS), Wayne, PA.
- Vanderzant, C., and D.F. Splittstoesser (eds.). Compendium of methods for the microbiological examination of foods, 3rd ed. American Public Health Association, Washington, D.C.
- Leifson, E. (1939) New selenite selective enrichment medium for the isolation of typhoid and paratyphoid bacilli. Am. J. Hyg. 24:423-432.

PRESENTATION

	Contents	Ref.
Selenite Broth	20 x 10 ml tubes	24110
Selenite Broth	20 x 5 ml tubes	24143
Selenite Broth	Bottles	402050
Selenite Broth	Bottles	412050
Selenite Broth (Double Concentration)	Bottles	432050
Selenite Broth	Bottles	470020
Selenite Broth	Bottles	463130
Selenite Broth	Dehydrated medium	610145
Selenite Broth	Dehydrated medium	620145
Selenite Broth	Dehydrated medium	6101455

TABLE OF SYMBOLS

LOT	Batch code	IVD	In vitro Diagnostic Medical Device	Manufacturer	Contains sufficient for <10 tests	Use by	Fragile, handle with care
REF	Catalogue number		Temperature limitation		Caution, consult instruction for use		Do not reuse

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Bile Aesculin Azide Agar

Selective medium for detection and enumeration of enterococci in water and other materials, according to ISO 7899-2.

TYPICAL FORMULA	(g/l)
Tryptone	17.0
Peptone	3.0
Yeast Extract	5.0
Ox-bile	10.0
Sodium Chloride	5.0
Aesculin	1.0

Final pH 7.1 ± 0.1 at 25°C

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Final pH 7.1 ± 0.1 at 25°C



PRODUCT SPECIFICATIONS

NAME
Bile Aesculin Azide Agar

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

Ref	Content	Packaging
610001	500 g	500 g of powder in plastic bottle
620001	100 g	100 g of powder in plastic bottle
6100015	5 Kg	5 kg of powder in plastic bottle

pH OF THE MEDIUM
7.1 ± 0.1

USE
Bile Aesculin Azide Agar is a selective medium used for confirmation and enumeration of enterococci from water and other samples according to ISO 7899-2

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Powder medium
Appearance: free-flowing, homogeneous
Colour: beige
Ready-to-use medium
Appearance: slightly opalescent
Colour: dark amber to olive green

SHELF LIFE
4 years

QUALITY CONTROL

- Control of general characteristics, label and print
- Microbiological control
Inoculum for productivity: 50-100 CFU
Inoculum for selectivity: 10⁶-10⁸ CFU
Incubation Conditions: 18-24 h at 35 ± 2°C, in aerobiosis

Microorganism	Growth	Specification
Enterococcus faecalis	Good	Blackening
Enterococcus faecium	Good	Blackening
Escherichia coli	Inhibited	—
Staphylococcus pyogenes	Inhibited	—

TABLE OF SYMBOLS

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

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CE IVD

MacConkey Agar

Selective and differential medium for detection of Enterobacteriaceae from clinical samples and other materials, according to USP/EP/JP.

**DESCRIPTION**

MacConkey Agar is a slightly selective medium giving excellent differentiation between lactose-fermenting and lactose-nonfermenting Gram-negative enteric bacilli, from faeces, urine, foodstuffs, waste water and other materials of sanitary importance.

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

TYPICAL FORMULA

	(g/l)
Pancreatic Digest of Gelatin	17.0
Peptone from Meat	1.5
Peptone from Casein	1.5
Lactose	10.0
Sodium Chloride	5.0
Bile Salts	1.5
Agar	15.0*
Neutral Red	0.03
Crystal Violet	0.001
Final pH 7.1 ± 0.2 at 25°C	

* Adjusted according to gel strength to meet performance specifications.

METHOD PRINCIPLE

Pancreatic digest of gelatin and peptones from meat and casein provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Lactose is the fermentable carbohydrate. Sodium Chloride maintains the osmotic balance of the medium. Bile salts and crystal violet are the selective agents, inhibiting Gram-positive organisms and allowing Gram-negative bacteria to grow. Agar is the solidifying agent. Neutral red is the pH indicator.

PREPARATION

Dehydrated medium
Suspend 51.5 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil for 1 minute shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

Medium in bottles

Melt the content of the bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Inoculate the plates by directly streaking the specimen on the agar surface or spread the sample from an enrichment culture. Incubate aerobically at 35 ± 2°C for 18-24 h.

To isolate *E. coli* in pharmaceutical products, the Harmonized USP/EP/JP method recommends to carry out a two steps enrichment procedure by inoculating the sample in Tryptic Soy Broth (ref. 452080) and afterwards in MacConkey Broth (ref. 494000). Subculture on a plate of MacConkey Agar and incubate aerobically at 30-35°C for 18-72 hours.

INTERPRETING RESULTS

Lactose-nonfermenting organisms, such as *Salmonella*, *Shigella* and *Proteus* spp, form colorless or clear colonies.

Lactose-fermenting organisms, such as *E. coli* and *Klebsiella* spp, grow as pink to red colonies with or without a zone of precipitated bile.

Enterococci, *Staphylococci* and other Gram-positive bacteria are partially or completely inhibited.

APPEARANCE OF THE MEDIUM

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

Prepared medium: slightly opalescent, pinkish-red.

STORAGE

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

SHELF LIFE

Dehydrated medium: 4 years.

Medium in bottles: 2 years.

Ready-to-use plates: 6 months.

QUALITY CONTROL

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

Inoculum for productivity: 50-100 CFU.

Inoculum for selectivity: 10¹-10⁶ CFU.

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

18-72 h at 30-35°C for *E. coli* (Pharmacopoeia growth promotion).

QC Table.

Microorganism	Growth	Specification
<i>Salmonella</i> Typhimurium	Good	Colorless colonies
<i>Shigella flexneri</i>	ATCC® 12022	Colorless colonies
<i>Proteus mirabilis</i>	ATCC® 12453	Colorless colonies
<i>Escherichia coli</i>	ATCC® 8739	Pink colonies with bile ppt
<i>Klebsiella pneumoniae</i>	ATCC® 13883	Pink colonies
<i>Enterococcus faecalis</i>	ATCC® 29212	Very small, opaque colonies
<i>Staphylococcus aureus</i>	ATCC® 25923	Inhibited

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

- European Pharmacopoeia 6.5 (2009), 2.6.13 Microbiological examination of non-sterile products: Test for specified microorganisms.
- United States Pharmacopoeia 32 NF 27 (2009), <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
- Japanese Pharmacopoeia 4.05 (2008), Microbiological examination of non-sterile products: Test for specified microorganisms.
- Murray Baron, Jorgensen, Landry and Pfaller ed. (2007) Manual of clinical microbiology, 9th ed. American Society for Microbiology, Washington, D.C.
- MacConkey A. (1905) Lactose-fermenting bacteria in faeces. J. Hygiene 8:333-379.

PRESENTATION

	Contents	Ref.
MacConkey Agar	90 mm ready-to-use plates	10029
MacConkey Agar	90 mm ready-to-use plates	10029*
MacConkey Agar	Bottles	470090
MacConkey Agar	Bottles	412240
MacConkey Agar	Bottles	402240
MacConkey Agar	Dehydrated medium	610028
MacConkey Agar	Dehydrated medium	620028
MacConkey Agar	Dehydrated medium	6100285

TABLE OF SYMBOLS

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

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CE IVD



Urea/Indole Test

Rapid test for detection of urease and indole production.

ENGLISH

DESCRIPTION

Urea/Indole Test is used for the rapid qualitative determination of urease activity and indole production as a first-step in screening non-lactose fermenting colonies from agar plates.

KIT CONTENTS

- Each kit contains:
- 30 tubes with desiccated biochemical substrate
- 1 tube of Kovac's Reagent
- 1 instruction sheet

PRINCIPLE OF THE METHOD

Enteric pathogens such as *Salmonellae* and *Shigellae* are urease negative whilst organisms such as *Proteus*, *Morganella*, *Klebsiella* spp. and some species of *Citrobacter* are strongly urease positive. The production of indole from tryptophan is a characteristic absent in *Salmonella* but present in *E. coli*, *Morganella* and some species of *Klebsiella*, *Aerobacter* and *Citrobacter*.

COMPOSITION

Desiccated substrata consist of peptones rich in tryptophan, urea, buffering agents and phenol red as pH indicator.

PROCEDURE FOR USE

1. Take the number of Urea/Indole Test tubes needed from the fridge and allow them to reach room temperature.
2. Add 0.3 mL of Physiological Solution (ref. 20095) to each tube.
3. Inoculate heavily with the test organism from a fresh overnight culture.
4. Add 2 drops of Vaseline Oil (ref. 80278)
5. Incubate at 35 ± 2°C for 1-4 hours and up to 24 h.
6. Add 2-3 drops of Kovac's Reagent to perform the Indole Test.

INTERPRETATION OF THE RESULTS

A positive result for the Urease Test is indicated by a colour change from yellow to red-fuchsia. A positive result for the Indole Test is indicated by the development of a red ring.

If the organism is urease negative and indole negative it is possibly *Salmonella*. Further tests are required for confirmation.

QUALITY CONTROL

Control strains	Urease	Indole
<i>Escherichia coli</i>	Negative	Positive
<i>Proteus mirabilis</i>	Positive	Negative
<i>Salmonella</i> Thyphimurium	Negative	Negative

PRECAUTIONS

Urea/Indole Test is not classifiable as hazardous under current legislation; However 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 by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

2-8°C in its original packaging. Keep away from sources of heat and avoid excessive changes of temperature. Use until the expiry date indicated on the label. Eliminate without using if there are signs of deterioration.

REFERENCES

- Blazevic D.J. and Ederer, G.M.(1975) Principles of biochemical tests in diagnostic microbiology. 63-67. New York, John Wiley & Sons.
- Isenberg H.D. and Sundheim L.H.(1980) Indole reactions in bacteria. J. Bacteriol. 75:682-690. Baltimore, Williams & Wilkins.
- MacFaddin J.F. (1980) Biochemical tests for identification for medical bacteria. 2nd ed. 173-183. Baltimore, Williams & Wilkins.

PRESENTATION

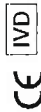
Product	Ref.	Contents
Urea/Indole Test	8802.4	30 tests

TABLE OF SYMBOLS

	In Vitro Diagnostic Medical Device		Do not reuse		Manufacturer		Contains sufficient for <=10 tests		Temperature limitation
	Catalogue number		Fragile, handle with care		Use by		Caution, consult accompanying documents		Batch code

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IVD

Row L 2/2008



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IVD

Row L 2/2008



Urea/Indole Test

Test rapido per la ricerca di ureasi e produzione di indolo.

ITALIANO

DESCRIZIONE

Urea/Indole Test è utilizzato per la determinazione veloce e qualitativa dell'attività ureasica e della produzione di indolo come primo step nello screening di colonie non fermentanti il lattosio da piastre agar.

CONTENUTO DELLE CONFEZIONI

- Ciascuna confezione contiene:
- 10 provette con substrati biochimici essiccati
- 1 provetta di Kovac's Reagent
- 1 foglio istruzioni

PRINCIPIO DEL METODO

I patogeni enterici come ad esempio *Salmonellae* e *Shigellae* sono ureasi negativi mentre i microrganismi come *Proteus*, *Morganella*, *Klebsiella* spp. ed alcune specie di *Citrobacter* sono fortemente ureasi positivi. La produzione di indolo dal triptofano è una caratteristica assente nella *Salmonella* ma presente in *E. coli*, *Morganella* ed alcune specie di *Klebsiella*, *Aerobacter* e *Citrobacter*.

COMPOSIZIONE

I substrati essiccati consistono di peptoni ricchi in triptofano, urea, agenti tampone e rosso fenolo come indicatore di pH.

PROCEDURA DI UTILIZZO

1. Prelevare dal frigorifero il numero necessario di provette di Urea/Indole Test ed aspettare che raggiungano la temperatura ambiente.
2. Aggiungere 0.3 mL di Physiological Solution (ref. 20095) in ciascuna provetta.
3. Inoculare con il microrganismo da esaminare proveniente da una coltura recente incubata over night.
4. Aggiungere 2 gocce di Vaseline Oil (ref. 80278)
5. Incubare a 35 ± 2°C per 1-4 ore, fino ad un massimo di 24 ore.
6. Aggiungere 2-3 gocce di Kovac's Reagent per eseguire il Test Indolo.

INTERPRETAZIONE DEI RISULTATI

Un risultato positivo per il Test Ureasi è indicato da un viraggio di colore da giallo a rosso-fucsia. Un risultato positivo per il Test Indolo è indicato dallo sviluppo di un anello rosso.

Se il microrganismo è ureasi negativo ed indolo negativo potrebbe trattarsi di *Salmonella*. Ulteriori test sono necessari per la conferma.

CONTROLLO QUALITÀ

Cepi di controllo	Ureasi	Indolo
<i>Escherichia coli</i>	ATCC® 25922	Positivo
<i>Proteus mirabilis</i>	ATCC® 25933	Positivo
<i>Salmonella</i> Thyphimurium	ATCC® 14028	Negativo

PRECAUZIONI

Urea/Indole Test non è classificabile come pericoloso ai sensi della legislazione vigente; per il suo impiego si consiglia comunque di consultare la scheda di sicurezza. Il prodotto è destinato esclusivamente ad uso diagnostico *in vitro* e deve essere usato in laboratorio da operatori adeguatamente addestrati, con metodi approvati di asepsi e di sicurezza nei confronti degli agenti patogeni.

CONSERVAZIONE

Conservare a 2-8°C nella sua confezione originale. Tenere lontano da fonti di calore ed evitare eccessivi cambiamenti di temperatura. Utilizzare entro la data di scadenza indicata in etichetta. Eliminare se vi sono segni di deterioramento.

BIBLIOGRAFIA

- Blazevic D.J. and Ederer, G.M.(1975) Principles of biochemical tests in diagnostic microbiology. 63-67. New York, John Wiley & Sons.
- Isenberg H.D. and Sundheim L.H.(1980) Indole reactions in bacteria. J. Bacteriol. 75:682-690. Baltimore, Williams & Wilkins.
- MacFaddin J.F. (1980) Biochemical tests for identification for medical bacteria. 2nd ed. 173-183. Baltimore, Williams & Wilkins.

PRESENTAZIONE

Prodotto	Ref.	Contenuto
Urea/Indole Test	8802.4	30 test

TABELLA DEI SIMBOLI

	In Vitro Diagnostic Medical Device		Do not reuse		Manufacturer		Contains sufficient for <=10 tests		Temperature limitation
	Catalogue number		Fragile, handle with care		Use by		Caution, consult accompanying documents		Batch code



Optochine Test

Diagnostic discs for pneumococci identification.

DESCRIPTION

Optochine Test is constituted by paper discs, each one containing 5 µg of Optochin (Ethylhydrocupreine hydrochloride), used for differentiating *Streptococcus pneumoniae* from the other alpha-haemolytic streptococci.

CONTENT OF THE PACKAGES

Each package contains:

- 2 cartridges with 50 discs each, packaged in a heat-sealed container.
- Dryer.

PRINCIPLE OF THE METHOD

Optochin is an agent specifically active against *Streptococcus pneumoniae*, the other alpha-haemolytic streptococci are resistant. The disc is placed onto the surface of a culture medium that is suitable for the growth of streptococci, inoculated with a pure liquid culture of the microorganism under examination. After the incubation all the plates are examined for the presence or absence of an inhibition halo around the disc of Optochin.

COMPOSITION

Each disc contains 5 µg of Optochin.

PREPARATION OF THE SPECIMEN

1. Mixed cultures or clinical specimens must not be used to determine susceptibility to Optochin.
2. Inoculate a tube of Brain Heart Infusion Broth (ref. 20104) with pure colonies of the microorganism under examination.
3. Incubate at $36 \pm 1^\circ\text{C}$ overnight.

TEST PROCEDURE

1. Take the cartridges container from the refrigerator and leave it on the test bench until it reaches room temperature (about 30 minutes). This will prevent humidity being deposited on the discs when the package is opened, which could prejudice their long-term stability.
2. Using a sterile swab, evenly inoculate the surface of a plate of blood agar such as Tryptic Soy Blood Agar (ref. 11037), Columbia Blood Agar (ref. 11025) or other blood medium, with the suspension of the streptococcus under examination.
3. Using sterile tools, gently press one disc of Optochin on the inoculated surface.
4. Turn the plate upside down and incubate at $36 \pm 1^\circ\text{C}$ for 18-24 hours in atmosphere containing 5% of CO_2 .
5. Check for presence or absence of an inhibition halo around the disc of Optochin.

INTERPRETATION OF THE RESULTS

The test organism is considered sensitive to Optochin and presumptively *Streptococcus pneumoniae* if the inhibition zone is ≥ 14 mm diameter. The presumptive identification must be confirmed by serological tests.

QUALITY CONTROL

Each batch of Optochine Test is tested for susceptibility to Optochin by using *Streptococcus pneumoniae* ATCC® 6305 for positive control, and *Streptococcus pyogenes* ATCC® 19615 for negative control, inoculated on Columbia Blood Agar with 5% of defibrinated sheep blood.

PRECAUTIONS

Optochine Test cannot be classified as being hazardous according to the current legislation. Optochine Test is a disposable device to be used only for diagnostic use *in vitro*. It must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

STORAGE

Store Optochine Test at $-20^\circ\text{C}/+8^\circ\text{C}$ 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, Optochine Test and material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

BIBLIOGRAPHY

- https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/394193/TP_25i3.pdf
- J. Lab. Clin. Med., 49: 641, 1957.
- J. Clin. Path., 8: 58, 1955.
- Serological Studies on Pneumococci, Munksgaard, Copenhagen, Oxford University Press, London, 1943.
- J. Exp. Med. 22: 269, 1915.

PRESENTATION

Product	Ref.	Test
Optochine Test	9501	100

TABLE OF SYMBOLS

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



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F00010



Oxidase Test Stick

Rapid test for detection of cytochrome oxidase enzymatic activity.

DESCRIPTION

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

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

CONTENTS OF THE PACKAGES

Each package contains 50 Oxidase Test Stick.

METHOD PRINCIPLE

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

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

COMPOSITION

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

TEST PROCEDURE

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

INTERPRETING RESULTS

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

LIMITATIONS

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

STORAGE

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

SHELF LIFE

2 years.

QUALITY CONTROL

Control strains are indicated in the QC table.

QC Table.

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

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

PRESENTATION	Contents	Ref.
Oxidase Test Stick	50 sticks	88029

TABLE OF SYMBOLS

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



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CE IVD

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Bacitracin Test

DESCRIZIONE

Bacitracin Test sono dischi di carta, impregnati con 0,04 unità di Bacitracina, utilizzati per la differenziazione degli streptococchi del Gruppo A di Lancefield dagli altri streptococchi beta emolitici appartenenti a Gruppi diversi.

CONTENUTO DELLE CONFEZIONI

Ciascuna confezione contiene 2 cartucce con 50 dischi ciascuna, confezionate in un contenitore termosaldato, in presenza di un essiccatore e un foglio istruzioni.

PRINCIPIO DEL METODO

La Bacitracina, antibiotico polipeptidico, è attiva nei confronti degli streptococchi beta emolitici di Gruppo A. Gli streptococchi di Gruppo C e G sono meno sensibili e quelli di Gruppo B sono resistenti. Il disco viene applicato sulla superficie di un terreno di coltura, idoneo per la crescita degli streptococchi, inoculato con una brodcultura allestita con colonie pure del microrganismo in esame. Dopo l'incubazione, vengono esaminate le piastre e verificata la presenza o l'assenza di un alone di inibizione intorno al disco di Bacitracina.

COMPOSIZIONE

Ciascun disco è impregnato con 0,04 UI di Bacitracina.

PROCEDURA DEL TEST

1. Prelevare il contenitore delle cartucce dal frigorifero e lasciarlo sul banco di lavoro fino al raggiungimento della temperatura ambiente (circa 30 minuti). In tal modo si evita che all'apertura della confezione si depositi umidità di condensa sui dischi, pregiudicandone la stabilità nel tempo.
2. Inoculare uniformemente la superficie di una piastra di agar-sangue quali Tryptic Soy Blood Agar, Columbia Blood Agar o altro terreno al sangue, con una coltura dello streptococco beta-emolitico da saggiare. Bacitracin Test può essere effettuato anche inoculando il materiale clinico in esame, come per esempio l'essudato rinofaringeo prelevato con un tampone, su una piastra di agar-sangue.
3. Depositare il disco di Bacitracina sulla superficie inoculata.
4. Incubare 18-24 ore a $36 \pm 1^\circ\text{C}$.
5. Verificare la presenza o l'assenza di un alone di inibizione intorno al disco di Bacitracina.

INTERPRETAZIONE DEI RISULTATI

Semina del ceppo precedentemente isolato

La presenza di un alone di inibizione di 10-18 mm, intorno al disco di Bacitracina, indica che lo streptococco è presumibilmente di Gruppo A. Altri streptococchi beta emolitici, non di Gruppo A, crescono fino ai bordi del disco.

I risultati del test della Bacitracina vanno confermati con l'identificazione sierologica di Gruppo.

Semina del materiale clinico

La presenza di un alone di inibizione intorno al disco di Bacitracina, se confermati dai dati della morfologia delle colonie e dell'emolisi, depongono a favore della presenza di Streptococchi di Gruppo A, da confermare mediante l'identificazione sierologica di Gruppo.

CONTROLLO QUALITÀ

Ogni lotto di Bacitracin Test viene sottoposto al test di sensibilità alla Bacitracina, utilizzando una coltura di *Streptococcus pyogenes* ATCC® 19615 per il controllo positivo e di *Streptococcus agalactiae* ATCC® 13813 per il controllo negativo, seminati su Columbia Blood Agar con 5% di sangue defibrinato di montone.

PRECAUZIONI

Il prodotto Bacitracin Test non è classificabile come pericoloso ai sensi della legislazione vigente, ma rientra nello specifico campo di applicazione della normativa relativa all'obbligo di fornitura di scheda di sicurezza, perché può causare fenomeni di allergia in soggetti sensibili, in caso di contatto con la pelle. Bacitracin Test è un dispositivo monouso, da usare solo per uso diagnostico *in vitro*, è destinato ad un ambito professionale e deve essere usato in laboratorio da operatori adeguatamente addestrati, con metodi approvati di asepsi e di sicurezza nei confronti degli agenti patogeni.

CONSERVAZIONE

Conservare Bacitracin Test a $2-8^\circ\text{C}$ nella sua confezione originale. Non conservare vicino a fonti di calore ed evitare eccessive variazioni di temperatura. In queste condizioni Bacitracin Test è valido fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento quali tracce di umidità.

ELIMINAZIONE DEL MATERIALE USATO

Dopo l'utilizzazione Bacitracin Test ed il materiale venuto a contatto con il campione devono essere decontaminati e smaltiti in accordo con le tecniche in uso in laboratorio per la decontaminazione e lo smaltimento di materiale potenzialmente infetto.

BIBLIOGRAFIA

- K.L. Ruoff, R.A. Wiley and D. Beighton. 1999. *Streptococcus*. In P.R. Murray, E.J. Baron, M.A. Pfaller, F.C. Tenover, R.H. Tenover (ed) *Manual of Clinical Microbiology* 7th ed. American Society for Microbiology, Washington, D.C.
- W.R. Maxted. 1953 *The use of bacitracin for identifying Group A haemolytic Streptococci*. J.Clin.Path. 6 (3), 224-226.

PRESENTAZIONE

Prodotto	REF	Σ
Bacitracin Test	9502	100

TABELLA DEI SIMBOLI

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



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F13113
Rev.2 / 12.11.2015



GRAM COLOR KIT

DESCRIZIONE

GRAM COLOR KIT è un kit per la colorazione dei microrganismi, che ne permette la differenziazione in due categorie: Gram-positivi (Gram+) che si colorano in blu e Gram-negativi (Gram-), che si colorano in rosso. Tale colorazione costituisce, insieme con l'osservazione diretta della morfologia cellulare, il primo livello di classificazione tassonomica dei procarioti.

CONTENUTO DELLE CONFEZIONI

I reagenti sono contenuti in flaconi di plastica, chiusi in termoisolamento e forniti di tappo gocciolatoio. Ciascuna confezione contiene:

- 1 flacone contenente 250 ml di Soluzione Cristal Violetto
- 1 flacone contenente 250 ml di Soluzione Lugol-PVP
- 1 flacone contenente 250 ml di Soluzione Decolorante
- 1 flacone contenente 250 ml di Soluzione Safranina

PRINCIPIO DEL METODO

La colorazione di Gram è basata sulla proprietà che ha il Cristal Violetto di combinarsi con lo Iodio, formando composti non decolorabili con l'alcool o con la miscela alcool-acetone. Alcuni batteri hanno una speciale affinità per questa reazione e, una volta colorati con il cristal violetto, non perdono il colore, se trattati con l'alcool o con la miscela alcool-acetone, restando colorati in blu (batteri Gram-positivi). Altri perdono il colore blu e si colorano con la Safranina assumendo una colorazione rossa (batteri Gram-negativi).

RACCOLTA DEI CAMPIONI

I campioni da sottoporre alla colorazione di Gram sono costituiti principalmente da materiale clinico e da colture microbiche. Le colonie da sottoporre alla colorazione di Gram devono essere prelevate da colture giovani (18-24 ore) preferibilmente da terreni agarizzati.

PROCEDURA DEL TEST

Preparazione e fissazione

Utilizzando vetrini puliti, eseguire uno striscio della coltura o del materiale patologico. Lasciare essiccare all'aria e fissare al calore con passaggi rapidi sulla fiamma. Eseguire la fissazione del campione evitando un eccesso di riscaldamento. Si possono adottare anche altri metodi di fissazione.

Colorazione

1. Ricoprire il vetrino con la Soluzione Cristal Violetto. Attendere 1 minuto, quindi lavare delicatamente con acqua.
2. Ricoprire il vetrino con la Soluzione Lugol-PVP. Attendere 1 minuto, quindi lavare delicatamente con acqua.
3. Decolorare con la Soluzione Decolorante finché il preparato libera colorante (circa 30-60 secondi), quindi lavare delicatamente con acqua.
4. Ricoprire il vetrino con la Soluzione Safranina. Attendere 30-60 secondi, quindi lavare delicatamente con acqua.
5. Asciugare.
6. Osservare il preparato al microscopio con obiettivo per immersione.

INTERPRETAZIONE DEI RISULTATI

I microrganismi Gram-negativi appaiono di colore rosso.

I microrganismi Gram-positivi appaiono di colore blu.

La colorazione di Gram permette di differenziare:

- I bacilli Gram-negativi da quelli Gram-positivi;
- I cocci Gram-negativi da quelli Gram-positivi;
- I coccobacilli Gram-negativi da quelli Gram-positivi; I diplococchi Gram-negativi da quelli Gram-positivi.

CONTROLLO QUALITÀ

Ogni lotto di GRAM COLOR KIT viene sottoposto al controllo di qualità utilizzando una coltura di *Escherichia coli* ATCC 25922 per il controllo dei batteri Gram-negativi (colore rosso) ed una coltura di *Staphylococcus aureus* ATCC 25923 per il controllo dei batteri Gram-positivi (colore blu).

LIMITI

- La colorazione di Gram fornisce una preliminare identificazione ma non sostituisce i normali studi culturali del campione.
- Terapie antibiotiche possono rendere i batteri gram-positivi più sensibili alla decolorazione ed apparire di colore rosa-rosso invece di blu.
- Le cellule prelevate da colture giovani di 18-24 ore hanno una maggiore affinità per i coloranti rispetto alle cellule prelevate da colture vecchie.
- La colorazione di Gram viene alterata dalla distruzione fisica della parete cellulare o del protoplasma; infatti la parete cellulare

dei batteri Gram-positivi interpone una barriera che impedisce il rilascio del complesso Cristal Violetto-Iodio dal citoplasma e la parete cellulare dei batteri Gram-negativi contiene lipidi solubili in solventi organici che permettono la decolorazione del citoplasma. Pertanto i microrganismi distrutti fisicamente da un eccesso di calore non reagiscono alla colorazione di Gram come atteso.

PRECAUZIONI

La confezione di GRAM COLOR KIT contiene sostanze classificate come pericolose ai sensi della legislazione vigente; per il suo impiego si consiglia di consultare la scheda di sicurezza.

GRAM COLOR KIT è un kit per la colorazione batterica, da usare solo per uso diagnostico *in vitro*, è destinato ad un ambito professionale e deve essere usato in laboratorio da operatori adeguatamente addestrati, con metodi approvati di asepsi e di sicurezza nei confronti degli agenti patogeni.

CONSERVAZIONE

Conservare GRAM COLOR KIT a 10-25°C nella sua confezione originale. Non conservare vicino a fonti di calore ed evitare eccessive variazioni di temperatura. In queste condizioni il prodotto GRAM COLOR KIT è valido fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento (cambiamenti di colore delle soluzioni o presenza di precipitati grossolani).

ELIMINAZIONE DEL MATERIALE USATO

Dopo l'utilizzazione, i vetrini colorati con il GRAM COLOR KIT ed il materiale venuto a contatto con il campione devono essere decontaminati e smaltiti in accordo con le tecniche in uso in laboratorio per la decontaminazione e lo smaltimento di materiale potenzialmente infetto.

BIBLIOGRAFIA

- Kruczak-Filipov, P., and R.G. Shively. 1992. Gram stain procedure, p.1.5.1-1.5.18. In H.D. Isenberg (ed.) Clinical Microbiology Procedures Handbook, vol. 1. American Society for Microbiology, Washington, D.C.
- Murray, P.R. (ed.) 1999. Manual of Clinical Microbiology, 7th ed. American Society of Microbiology, Washington, D.C.

PRESENTAZIONE

Prodotto	Ref	Contenuto
GRAM COLOR KIT	80293	4 x 250 ml

TABELLA DEI SIMBOLI

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



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F00411

Rev.3 / 09.05.2017

Certificate

mdc medical device certification GmbH
certifies that

sifin

sifin diagnostics gmbh
Berliner Allee 317-321
13088 Berlin
Germany

for the scope

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

has introduced and applies a

Quality Management System

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

EN ISO 13485

Medical devices – Quality management systems –
Requirements for regulatory purposes

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

Valid from	2018-10-23
Valid until	2021-10-22
Registration no.	D1058700042
Report no.	P18-00745-121758
Stuttgart	2018-07-16


Head of Certification Body



mdc medical device certification GmbH
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sifin

EG-Konformitätserklärung CE-Declaration de Conformité / EC-Declaration of Conformity

CE
Nr./No. 145

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

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

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Salmonella OMA
Anti-Salmonella OMB
Anti-Salmonella OMC
Anti-Salmonella OMD
Anti-Salmonella OME
Anti-Salmonella OMF
Anti-Salmonella OMG

Sonstiges Produkt
Other device/Autre dispositif

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

Angewandte harmonisierte Normen:
Normes harmonisés appliqués:
Applied harmonized standards:

DIN EN ISO 18113, DIN EN 13641,
DIN EN 13640, DIN EN 13612, DIN EN ISO 14971,
DIN EN ISO 13485

Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformité:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2016-12

Berlin, 10.04.2014

Dr. H.-J. Rüger

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer



EG-Konformitätserklärung CE-Declaration de Conformité / EC-Declaration of Conformity

CE
Nr./No. 111

Wir / Nous / We

sifin diagnostics gmbh,
Berliner Allee 317-321, 13088 Berlin, Germany

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

das Medizinprodukt (IVD):
le dispositif médical (IVD):
the medical device (IVD):

Anti-Shigella dysenteriae type 1
Anti-Shigella dysenteriae type 2
Anti-Shigella flexneri type 1
Anti-Shigella flexneri type 2
Anti-Shigella flexneri type 3
Anti-Shigella flexneri type 4
Anti-Shigella flexneri type 5
Anti-Shigella flexneri type 6
Anti-Shigella flexneri group 3,4 (y)
Anti-Shigella flexneri group 6
Anti-Shigella flexneri group 7,8 (x)
Anti-Shigella sonnei S-form (phase I)
Anti-Shigella sonnei F-form (phase II)
Anti-Shigella sonnei S- and F-form (phase I and II)

Sonstiges Produkt
Other device/Autre dispositif

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

Angewandte harmonisierte Normen:
Normes harmonisées appliquées:
Applied harmonized standards:

DIN EN ISO 13485:2016, DIN EN 13612:2002,
DIN EN 13641:2002, DIN EN ISO 14971:2013,
DIN EN ISO 15223-1:2017, DIN EN ISO 18113-1:2013,
DIN EN ISO 18113-2:2013, DIN EN ISO 23640:2015

Konformitätsbewertungsverfahren:
Procédure d'évaluation de la conformité:
Conformity assessment procedure:

Anhang III
Annexe III
Annex III

Gültig bis:
Valable jusqu'au:
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz

Sicherheitsbeauftragter für Medizinprodukte
Agent de sécurité /Safety Officer



CERTIFICATO N° 505SGQ03

CERTIFICATE N° 505SGQ03

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

messso in atto da
implemented by

NUOVA APTACA S.r.l.

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

nella Sede Operativa di
Operative Unit

Regione Monforte, 30 – IT 14053 CANELLI (AT)

è conforme alla norma
is in compliance with the standard

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

per i seguenti Processi
concerning the following kinds of Processes

Gestione della fabbricazione ed immissione in commercio di tamponi sterili
per il prelievo di campioni biologici in orifizi naturali e in ambito chirurgico.
Progettazione e fabbricazione di dispositivi medico diagnostici per laboratori di analisi.
Commercializzazione di dispositivi medici e diagnostici in vitro.
Commercializzazione di articoli da laboratorio

*Management of the manufacturing and placing on the market of sterile tampons for sampling of biological specimens
in natural orifice and in surgical field. Design and manufacturing of diagnostic medical devices for laboratories
of analysis. Marketing of medical and diagnostic devices in vitro. Marketing of laboratory articles.*

Il presente Certificato è soggetto al rispetto delle condizioni stabilite dal Regolamento per la certificazione in vigore applicabili.

This Certificate shall satisfy the requirements established in the Rules for the certification in force applicable.

In caso di discordanza tra le lingue utilizzate nella traduzione del contenuto del presente certificato, fare riferimento alla lingua italiana.

In cases of discrepancy between the languages used in the translation of the content of this certificate, please refer to the Italian language.

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR

Dr. Ing. Roberto Cusolito

Data di Prima Emissione
First Issue Date

1998-07-23

Settore IAF 14 - 29

Data di Prima Emissione ITALCERT
First Issue Date ITALCERT

2011-10-30

Data di Rinnovo
Renewal Date

2017-10-30

Data di Scadenza
Expiration Date

2020-10-29



SGQ N° 023A PRD N° 122B
SGA N° 020D ISP N° 075E
PAS N° 097C

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



CISQ is a member of



IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world. IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO n.
CERTIFICATE No.

4264/4/C

SI CERTIFICA CHE IL SISTEMA DI GESTIONE PER LA QUALITÀ DI
WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

KIMA S.R.L.

UNITÀ OPERATIVE / OPERATIVE UNITS

Via Leonardo Da Vinci 22 - Zona Industriale Tognana - 35028 Piove di Sacco (PD)
Italia

È CONFORME ALLA NORMA / IS IN COMPLIANCE WITH THE STANDARD

UNI EN ISO 9001:2015

Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 29

Commercializzazione di prodotti del Gruppo: kit diagnostici,
terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi,
provette con vuoto predeterminato e aghi sterili.

*Trading of the products of the Group: diagnostic kits, culture media for microbiology,
plastic disposable labware, test tubes with predetermined vacuum and sterile needles.*

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento.
Refer to the documentation of the Quality Management System for details of application to reference standard requirements.

Il presente certificato è soggetto al rispetto del documento ICIM "Regolamento per la certificazione dei sistemi di gestione" e al relativo Schema specifico.
The use and the validity of this certificate shall satisfy the requirements of the ICIM document "Rules for the certification of company management systems" and specific Scheme.

Per informazioni puntuali e aggiornate circa eventuali variazioni intervenute nello stato della certificazione di cui al presente certificato,
si prega di contattare il n° telefonico +39 02 725341 o indirizzo e-mail info@icim.it.

For timely and updated information about any changes in the certification status referred to in this certificate,
please contact the number +39 02 725341 or email address info@icim.it.

Data emissione
First issue
18/01/2007

Emissione corrente
Current issue
18/01/2019

Data di scadenza
Expiring date
17/01/2022


ICIM S.p.A.

Piazza Don Enrico Mapelli, 75 - 20099 Sesto San Giovanni (MI)
www.icim.it



SGQ N° 004 A

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



CISQ è la Federazione Italiana di Organismi di
Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management
system Certification Bodies.



ООО "МиниМед", 241526, Российская Федерация, Брянская область,
Брянский район, с. Супоняно, ул. Шоссейная, 17 А.

Тел. (4832) 92-97-97, 92-24-52, -53, -55, -56, -57, -58, -60, -61, -62
Многоканальный номер - 8-800-100-48-32
Факс (4832) 92-24-54, 92-24-59, 92-24-61

ИНН 3234007127

www.minimed.ru

e-mail: info@minimed.ru

Регистрационное удостоверение № ФСР 2009/05559 от 04.12.2015 г.

Паспорт

Набор реагентов «Масло иммерсионное» по ТУ 9398-011-29508133-2009

Серия	31-19	Дата изготовления	22.10.2019
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1. Назначение

Используется для ахроматических и ахроматических объективов микроскопов всех видов, кроме люминесцентных, предназначенных для работы в видимой области спектра.

2. Технические требования

Наименование показателей	Характеристика и норма по ТУ	Результаты анализа
Внешний вид	Прозрачная бесцветная жидкость со слабым желтоватым оттенком	соответствует
Вязкость кинематическая при температуре 20°C, мм²/с	От 220	1317
Показатель преломления при температуре 20°C	От 1,5150 до 1,5180	1,5155
Коэффициент пропускания масла, %	Не менее 70	440 нм – 98,2 540 нм – 100,0

Иммерсионное масло легко удаляется с поверхности препарата, фронтальной линзы и оправы объектива; инертно к окрашенным и неокрашенным препаратам.

Упаковка – флакон-капельница вместимостью 100,0 мл обеспечивает аккуратное и экономичное нанесение масла на препарат.

Срок годности – 1,5 года с даты изготовления.

3. Транспортирование и хранение

Транспортирование должно проводиться всеми видами крытого транспорта в соответствии с правилами перевозки грузов, действующими на данном виде транспорта. Хранение – в упаковке предприятия-изготовителя в прохладном месте при относительной влажности воздуха не более 80% в местах, защищенных от воздействия прямых солнечных лучей, атмосферных осадков и агрессивных сред в течение всего срока годности.

4. Гарантии изготовителя

Изготовитель гарантирует соответствие качества набора реагентов «Масло иммерсионное» требованиям ТУ 9398-011-29508133-2009 при соблюдении потребителем условий транспортирования, хранения и применения в течение всего срока годности.

Начальник ПТО



Бабич В.А.

