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
Lattosio	10.0
SodioTiosolfato	8.5
Estratto di Lievito	5.0
Sodio Citrato	1.0
Sali di Bile N.3	1.5
Ammonio Ferrico Citrato	1.5
Verde Brillante	0.33 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 incolori. 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 o deionizzata 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 coperchi parzialmente rimossi.

TECNICA

Inoculare strisciando 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 microorganismi non fermentanti il lattosio possono produrre colonie opache, traluceni o trasparenti, con o senza il centro nero. Le colonie di Shigella sono incolori. I pochi organismi che fermentano il lattosio, che riescono a crescere sul terreno, si differenziano per le colonie rossastre di aspetto mucoide.

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.

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

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 : 10^4-10^5 UFC/ml
   Dimensione dell'inoculo per specificità: $\leq 10^4$ UFC/ml
   Condizioni di incubazione: 18-24 h a 35 ± 2°C in aerobiosi

Microrganismo		Crescita	Caratteristiche
Shigella flexneri	ATCC® 12022	Buona	Colonie incolori
Salmonella typhimurium	ATCC® 14028	Buona	Colonie incolori con o senza centro nero
Enterococcus faecalis	ATCC® 29212	Inibita	—
Staphylococcus aureus	ATCC® 25923	Inibita	—
Escherichia coli	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	Limiti di temperatura	Contenuto sufficiente per <n> test	Attenzione, consultare le istruzioni per l'uso

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

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: microrganism 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

1. Bauer et al. (1966). J. Clin. Pathol. 45:493-496.
2. Mueller, J.H., and Hinton. 1941. Proc. Soc. Exp. Biol. Med. 48: 330-333.
3. NCCLS. Performance standards for susceptibility testing; Twelve Informational Supplement. NCCLS Document M100-S12, January 2002.

Liofilchem s.r.l.
Via Scozia-Zona Industriale - 64026 Roseto degli Abruzzi Tel. +39.085.8930745 - Fax +39.085.8930330
Web site http://www.liofilchem.net E-mail: liofilchem@liofilchem.net

PRODUCT SPECIFICATIONS

NAME
MUELLER HINTON AGAR

PRESENTATION
Dehydrated culture medium

STORAGE
10-30°C

PACKAGING

Code	Content	Packaging
610033	500 g	500 g of powder in plastic bottle
620033	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.

SHELFLIFE
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
Enterococcus faecalis	ATCC 29212	Good	White colonies
Escherichia coli	ATCC 25922	Good	Colorless colonies
Proteus mirabilis	ATCC 25933	Good	Colorless colonies
Staphylococcus aureus	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

CE IVD

Liofilchem s.r.l.
Via Scozia-Zona Industriale - 64026 Roseto degli Abruzzi Tel. +39.085.8930745 - Fax +39.085.8930330
Web site: http://www.liofilchem.net E-mail: liofilchem@liofilchem.net

COLUMBIA AGAR BASE

Medium for fastidious microorganisms isolation from clinical samples.

TYPICAL FORMULA (g/l)

Peptospecial	23.0
Starch	1.0
Sodium Chloride	5.0
Agar	14.0

Final pH = 7.3 ± 0.2 at 25 °C.

DIRECTIONS

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

DESCRIPTION

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

TECHNIQUE

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

QUALITY CONTROL

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

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

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

PERFORMANCE AND LIMITATIONS

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

STORAGE

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

REFERENCES

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

PRESENTATION

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

TABLE OF SYMBOLS

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

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

Instructions For Use
ENGLISH

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

TEST PROCEDURE

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.

© Liofilchem® - Nutrient Agar - Rev.0.1 / 11.05.2015

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		Growth
Pseudomonas aeruginosa	ATCC® 27853	Good
Escherichia coli	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

1. ISO 16266:2008. Water Quality – Detection and enumeration of *Pseudomonas aeruginosa* – Method by membrane filtration.
2. 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	20 plates	10044
Nutrient Agar	90 mm ready-to-use plates	100 plates	10044*
Nutrient Agar	Tubes	20 x 22 ml tubes	31083
Nutrient Agar	Tubes	10 x 22 ml tubes	30083
Nutrient Agar	Bottles	6 x 500 ml bottles	470060
Nutrient Agar	Bottles	6 x 200 ml bottles	412190
Nutrient Agar	Bottles	6 x 100 ml bottles	402190
Nutrient Agar	Dehydrated medium	100 g of powder	620036
Nutrient Agar	Dehydrated medium	500 g of powder	610036
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 <n> tests	Caution, consult Instruction For Use	Do not reuse

LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

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 (H_2S).

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	ATCC	Growth	Slant/butt	Gas	H_2S
Citrobacter freundii	8090	good	acid/acid	+	+
Escherichia coli	25922	good	acid/acid	+	-
Proteus vulgaris	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.

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

PRESENTATION

Product	REF	Σ
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 <n> tests	IVD *In Vitro* Diagnostic Medical Device
REF Catalogue number	Fragile, handle with care	Use by	Temperature limitation	Keep away from heat source

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

Instructions For Use
ENGLISH

Sabouraud Dextrose Broth

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

DESCRIPTION

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

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

TYPICAL FORMULA	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	20.0

Final pH 5.6 ± 0.2 at 25°C

METHOD PRINCIPLE

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

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

PREPARATION

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

TEST PROCEDURE

For use in medical microbiology

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

For use in industrial microbiology

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

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

INTERPRETING RESULTS

Turbidity indicates microbial growth.

APPEARANCE

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

STORAGE

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

SHELF LIFE

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

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: ≤100 CFU.
Incubation conditions: 32.5 ± 2.5°C for 48-72 h (*C. albicans*) and at 22.5 ± 2.5°C for up to 5 days (all listed organisms), under aerobic atmosphere.

QC Table.

Microorganism		Growth
Candida albicans	ATCC® 10231	Good
Aspergillus brasiliensis	ATCC® 16404	Good
Saccharomyces cerevisiae	ATCC® 9763	Good

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

1. European Pharmacopoeia 6.5 (2009) 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms.
2. United States Pharmacopoeia 32 NF 27 (2009) <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
3. Japanese Pharmacopoeia 4.05 (2008) Microbiological examination of non-sterile products: Test for specified microorganisms.
4. Sabouraud, R. (1892) Ann. Dermatol. Syphilol. 3:1061.

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

TABLE OF SYMBOLS

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

LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

Istruzioni per l'uso
ITALIANO

Sabouraud Dextrose Broth

Terreno liquido per la coltivazione di lieviti e muffe da diversi materiali, secondo USP/EP/JP.

DESCRIZIONE

Sabouraud Dextrose Broth (SDB) è un terreno liquido raccomandato per l'utilizzo nelle procedure qualitative per l'isolamento di lieviti e muffe e per la coltura e subcoltura dei funghi da campioni clinici e non clinici.

Questo terreno è conforme con i requisiti del metodo armonizzato nelle Farmacopee Statunitense (USP), Europea (EP) e Giapponese (JP) per l'esame microbiologico dei prodotti non sterili.

FORMULA TIPICA

	(g/l)
Digerito Pancreatico di Caseina	5.0
Digerito Peptico di Tessuti Animali	5.0
Destrosio	20.0

pH Finale 5.6 ± 0.2 a 25°C

PRINCIPIO DEL METODO

Digerito pancreatico di caseina e digerito peptico di tessuti animali forniscono aminoacidi, azoto, carbonio, vitamine e minerali che supportano la crescita dei microrganismi. Il destrosio è una fonte di energia. L'alta concentrazione di destrosio ed il pH acido del terreno determinano la selettività per i funghi.

Al terreno può essere aggiunto il cloramfenicolo per incrementare l'inibizione batterica ed il recupero dei dermatofiti.

PREPARAZIONE

Terreno disidratato: Sospendere 30 g di polvere in 1 litro di acqua distillata o deionizzata sterile. Mescolare bene. Riscaldare agitando di frequente e bollire fino a completa dissoluzione. Dispensare in contenitori appropriati. Sterilizzare in autoclave a 121°C per 15 minuti.

PROCEDURA DEL TEST

Per l'uso in microbiologia medica

Inoculare il campione direttamente nel brodo. Incubare a 25°C per 2-7 giorni (le condizioni di incubazione possono variare in funzione della tipologia del campione e del microrganismo testato).

Per l'uso nella microbiologia industriale

Per la preparazione delle sospensioni fungine far crescere *C. albicans* o *A. brasiliensis* nel brodo a 20-25°C per 48-72 ore o per 5-7 giorni, rispettivamente.

Per la ricerca di *C. albicans*, inoculare la preparazione del prodotto da esaminare 1:100 in SDB ed incubare a 30-35°C per 3-5 giorni. Subcoltivare su una piastra di Sabouraud Dextrose Agar (ref. 10035)

INTERPRETAZIONE DEI RISULTATI

La torbidità è indice di crescita microbica.

ASPETTO

Terreno disidratato: omogeneo, fine granulometria, beige chiaro.
Terreno preparato: limpido, ambra chiaro, può presentare un leggero precipitato.

CONSERVAZIONE

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

VALIDITÀ

Terreno disidratato: 4 anni.
Terreno in flaconi/provette: 2 anni.

© Liofilchem® - Sabouraud Dextrose Broth - Rev.0 / 01.02.2016

CONTROLLO DI QUALITÀ

Il terreno viene inoculato con i ceppi microbici indicati nella tabella CQ.
Inoculo per produttività: ≤100 UFC.
Condizioni di incubazione: aerobica, a 32.5 ± 2.5°C per 48-72 ore (*C. albicans*) ed a 22.5 ± 2.5°C fino a 5 giorni (tutti i microrganismi elencati).

Tabella CQ.

Microrganismo		Crescita
Candida albicans	ATCC® 10231	Buona
Aspergillus brasiliensis	ATCC® 16404	Buona
Saccharomyces cerevisiae	ATCC® 9763	Buona

AVVERTENZE E PRECAUZIONI

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

SMALTIMENTO DEI RIFIUTI

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

BIBLIOGRAFIA

1. European Pharmacopoeia 6.5 (2009) 2.6.13. Microbiological examination of non-sterile products: Test for specified microorganisms.
2. United States Pharmacopoeia 32 NF 27 (2009) <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
3. Japanese Pharmacopoeia 4.05 (2008) Microbiological examination of non-sterile products: Test for specified microorganisms.
4. Sabouraud, R. (1892) Ann. Dermatol. Syphilol. 3:1061.

PRESENTAZIONE

		Contenuto	Ref.
Sabouraud Dextrose Broth	Provette	Provette 20 x 10 ml	24109
Sabouraud Dextrose Broth	Flaconi	Flaconi 6 x 100 ml	402040
Sabouraud Dextrose Broth	Flaconi	Flaconi 25 x 100 ml	452040
Sabouraud Dextrose Broth	Flaconi	Flaconi 6 x 500 ml	471070
Sabouraud Dextrose Broth	Terreno disidratato	500 g di polvere	610104
Sabouraud Dextrose Broth	Terreno disidratato	100 g di polvere	620104

TABELLA DEI SIMBOLI

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

LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858940330 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

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 preenrichment 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
Escherichia coli	25922	good
Staphylococcus aureus	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.

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

PRESENTATION

Product	REF	Σ
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	Σ	Contains sufficient for <n> tests
REF	Catalogue number		Fragile, handle with care		Use by		Temperature limitation

IVD	*In Vitro* Diagnostic Medical Device
	Keep away from heat source

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

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	2.0
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	ATCC	Growth	Characteristics
Escherichia coli	25922	inhibited	
Enterobacter aerogenes	13048	good	blue
Salmonella typhimuriums	14028	good	blue
Salmonella typhi	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.

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

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	Σ
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 <n> tests	IVD *In Vitro* Diagnostic Medical Device
REF Catalogue number	Fragile, handle with care	Use by	Temperature limitation	Keep away from heat source

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

Instructions For Use
ENGLISH

Mannitol Salt Agar

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

DESCRIPTION

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

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

TYPICAL FORMULA

	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Beef Extract	1.0
D-Mannitol	10.0
Sodium Chloride	75.0
Phenol Red	0.025
Agar	15.0

Final pH 7.4 ± 0.2 at 25°C

METHOD PRINCIPLE

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

PREPARATION

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

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

TEST PROCEDURE

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

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

INTERPRETING RESULTS

S. aureus cultivates with yellow or white colonies surrounded by a yellow zone. Confirm by identification tests*. Coagulase-negative Staphylococci form small colorless to red colonies with no color change to the medium

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

APPEARANCE OF THE MEDIUM

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

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and prepared plates at 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: 10^4-10^6 CFU
Incubation conditions: aerobically at 35 ± 2°C for 24-48 hours.
*30-35°C for 18-72 h (USP/EP/JP Growth Promotion Testing).

QC Table.

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

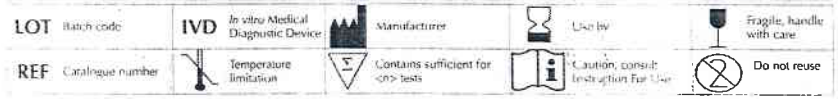
Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

1. European Pharmacopoeia 6.5 (2009). 2.6.13 Microbiological examination of non-sterile products: Test for specified microorganisms.
2. United States Pharmacopoeia 32 NF 27 (2009). <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
3. Japanese Pharmacopoeia 4.05 (2008). Microbiological examination of non-sterile products: Test for specified microorganisms.
4. 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.
5. Kluos, W.E., and T.L. Bannerman (1995) Staphylococcus and Micrococcus. In Manual of clinical microbiology, 6th ed.
6. 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



LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930140 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

Istruzioni per l'uso
ITALIANO

Mannitol Salt Agar

Terreno selettivo per l'isolamento ed il conteggio di stafilococchi da campioni clinici ed altri materiali, in accordo a USP/EP/JP.

DESCRIZIONE

Mannitol Salt Agar è un terreno selettivo utilizzato per l'isolamento di stafilococchi patogeni da campioni clinici, alimenti ed altri materiali di importanza sanitaria.

Il terreno è preparato secondo il metodo armonizzato USP/EP/JP per la ricerca di *S. aureus* nei prodotti farmaceutici non sterili.

FORMULA TIPICA

	(g/l)
Digerito Pancreatico di Caseina	5,0
Digerito Peptico di Tessuto Animale	5,0
Estratto di Carne	1,0
D-Mannitolo	10,0
Sodio Cloruro	75,0
Rosso Fenolo	0,025
Agar	15,0

pH Finale 7.4 ± 0.2 a 25°C

PRINCIPIO DEL METODO

Il digerito pancreatico di caseina, il digerito peptico di tessuto animale e l'estratto di carne forniscono aminoacidi, azoto, carbonio, vitamine e minerali per la crescita dei microrganismi. Il mannitolo è il carboidrato fermentabile. La presenza di cloruro di sodio al 7.5% inibisce la maggior parte dei batteri ad eccezione degli stafilococchi. Il rosso fenolo è l'indicatore di pH. L'agar è l'agente solidificante.

PREPARAZIONE

Terreno disidratato

Sospendere 111 g di polvere in 1 litro di acqua distillata o deionizzata sterile. Mescolare bene. Riscaldare agitando di frequente e bollire per 1 minuto per ottenere la completa dissoluzione. Sterilizzare in autoclave a 121°C per 15 minuti.

Terreno in flaconi

Sciogliere il contenuto di un flacone in bagnomaria a 100°C (con il tappo leggermente svitato) fino a completa dissoluzione del terreno. Verificare, una volta fuso, la buona omogeneità del terreno capovolgendo il flacone dopo averne avvitato il tappo. Raffreddare a 45-50°C, mescolare bene senza formazione di bolle. Versare in piastre Petri in condizioni di asepsi.

PROCEDURA DEL TEST

Inoculare le piastre strisciando il campione da esaminare direttamente sulla superficie dell'agar. Incubare in atmosfera aerobica a 35 ± 2°C per 24-48 ore.

Per l'esame microbiologico dei prodotti non sterili, il metodo armonizzato USP/EP/JP raccomanda di inoculare il campione in Tryptic Soy Broth (ref. 24444). Subcoltivare su una piastra di Mannitol Salt Agar ed incubare a 30-35°C per 18-72 ore.

INTERPRETAZIONE DEI RISULTATI

S. aureus coltiva con colonie gialle o bianche circondate da un alone giallo .Confermare con test identificativi*. Gli stafilococchi coagulasi negativi formano piccole colonie da incolore a rosse con nessun cambiamento di colore del terreno.

*Le colonie sospette possono essere subcoltivate su un terreno moderatamente selettivo come Baird Parker RPF Agar (ref. 10521, 402210) per la determinazione dell'attività della coagulasi (ISO 6888-2).

ASPETTO

Terreno disidratato: omogeneo, fine granulometria, beige-rosa.
Terreno preparato: rosastro-rosso, leggermente opalescente.

CONSERVAZIONE

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

© Liofilchem® -Mannitol Salt Agar - Rev.0.1 / 11.05.2015

VALIDITÀ

Terreno disidratato: 4 anni.
Terreno in flaconi: 2 anni.
Piastre pronte all'uso: 6 mesi.

CONTROLLO DI QUALITÀ

Le piastre vengono inoculate con i ceppi microbici indicati nella tabella CQ.
Inoculo per produttività: 10-100 UFC.
Inoculo per selettività: 10^4-10^6 UFC.
Condizioni di incubazione: ambiente aerobico a 35 ± 2°C per 24-48 ore.
*30-35°C per 18-72 ore (USP/EP/JP Growth Promotion Testing).

Tabella CQ.

Microrganismo		Crescita	Specifiche
Staphylococcus aureus	ATCC® 25923	Buona	Colonie gialle con alone giallo
*Staphylococcus aureus**	ATCC® 6538	Buona	Colonie gialle con alone giallo
Staphylococcus epidermidis	ATCC® 12228	Buona	Colonie rosse
Escherichia coli	ATCC® 25922	Inibita	---
*Escherichia coli**	ATCC® 8739	Inibita	---

AVVERTENZE E PRECAUZIONI

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

SMALTIMENTO DEI RIFIUTI

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

BIBLIOGRAFIA

1. European Pharmacopoeia 6.5 (2009). 2.6.13 Microbiological examination of non-sterile products: Test for specified microorganisms.
2. United States Pharmacopoeia 32 NF 27 (2009). <62> Microbiological examination of non-sterile products: Test for specified microorganisms.
3. Japanese Pharmacopoeia 4.05 (2008). Microbiological examination of non-sterile products: Test for specified microorganisms.
4. 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.
5. Kloos, W.E., and T.L. Bannerman (1995) Staphylococcus and Micrococcus. In Manual of clinical microbiology, 6th ed.
6. Chapman, G.H. (1945) The significance of sodium chloride in studies of staphylococci. J. Bacteriol. 50:201-203.

PRESENTAZIONE		Contenuto	Ref.
Mannitol Salt Agar	Piastre da 90 mm pronte all'uso	20 piastre	10030
Mannitol Salt Agar	Piastre da 90 mm pronte all'uso	100 piastre	10030*
Mannitol Salt Agar	Flaconi	Flaconi 6 x 500 ml	470080
Mannitol Salt Agar	Flaconi	Flaconi 6 x 200 ml	412290
Mannitol Salt Agar	Flaconi	Flaconi 6 x 100 ml	402290
Mannitol Salt Agar	Terreno disidratato	500 g di polvere	610029
Mannitol Salt Agar	Terreno disidratato	100 g di polvere	620029
Mannitol Salt Agar	Terreno disidratato	5 kg di polvere	6100295

TABELLA DEI SIMBOLI

LOT Codice del lotto	IVD *In vitro* Diagnostic Medical Device	Fabbricante	Utilizzare entro	Fragile, maneggiare con cura	
REF Numero di catalogo	Limiti di temperatura	Contenuto sufficiente per <n> saggi	Attenzione, Consultare le istruzioni per l'uso	Non riutilizzare	

LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930340 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

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 (H_2S).

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	ATCC	Growth	Slant/butt	Gas	H_2S
Citrobacter freundii	8090	good	acid/acid	+	+
Escherichia coli	25922	good	acid/acid	+	-
Proteus vulgaris	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.

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

PRESENTATION

Product	REF	Σ
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 <n> tests	IVD *In Vitro* Diagnostic Medical Device
REF Catalogue number	Fragile, handle with care	Use by	Temperature limitation	Keep away from heat source

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

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	Characteristics
Staphylococcus aureus	25923	markedly to completely inhibited	
Escherichia coli □□	25922	good	red colonies w / green metallic sheen
Salmonella typhimurium	14028	good	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

1. Endo, S. (1904). Uber ein Verfahrenzum Nachweis der Typhusbacillen. Centr. Bakt., Abt 1, Orig. **35**:109-110.
2. 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	

LIOFILCHEM s.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto D.A. (TE) - ITALY
Phone +390858930745 Fax +390858930330
Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

Instructions For Use
ENGLISH

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		Growth
Salmonella Typhimurium	ATCC® 14028	Good
Shigella sonnei	ATCC® 25931	Good
Escherichia coli	ATCC® 25922	Partially to completely inhibited

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

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

PRESENTATION

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

TABLE OF SYMBOLS

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

LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel. +39 0858930745 Fax +39 0858930330 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

Istruzioni per l'uso
ITALIANO

Selenite Broth

Terreno liquido per l'arricchimento selettivo di *Salmonella* spp, da campioni clinici e non clinici, secondo APHA.

DESCRIZIONE

Selenite Broth è un terreno di arricchimento utilizzato per l'isolamento selettivo di *Salmonella* ed alcune specie di *Shigella*.

Questo terreno è preparato secondo la formula originale descritta da Leifson come Selenite F Broth e [illegible] raccomandata da American Public Health Association per l'esame degli alimenti.

FORMULA TIPICA	(g/l)
Digerito Enzimatico di Caseina	5.0
Lattosio	4.0
Sodio Fosfato	10.0
Sodio Selenite	4.0

pH Finale 7.0 ± 0.2 a 25°C

PRINCIPIO DEL METODO

Il digerito enzimatico di caseina fornisce aminoacidi, azoto, carbonio, vitamine e minerali per la crescita dei microrganismi. Il lattosio è il carboidrato fermentabile. Il sodio fosfato è il tampone. Il sodio selenite è l'agente selettivo che inibisce molte specie di batteri Gram-positivi e Gram-negativi incluso enterococchi e coliformi.

PREPARAZIONE

Terreno disidratato: Sospendere 23 g di polvere in 1 litro di acqua distillata o deionizzata sterile. Mescolare bene. Riscaldare agitando di frequente e bollire fino a completa dissoluzione. Distribuire in contenitori adeguati (flaconi o provette). Si raccomanda di utilizzare contenitori alti almeno 5 cm in quanto la sopravvivenza delle salmonelle è favorita da basse tensioni di ossigeno. NON AUTOCLAVARE.

PROCEDURA DEL TEST

Inoculare le provette con 1-2 g di campione fecale o altro materiale solido (approssimativamente 10-15% in volume) ed emulsionare nel brodo. Per le urine, si dovrebbe utilizzare il terreno a doppia concentrazione da inoculare con un ugual volume di campione. Incubare a 35 ± 2°C per 12-24 ore (la crescita dei coliformi può sopraffare quella dei patogeni se l'incubazione viene prolungata oltre le 24 ore).

INTERPRETAZIONE DEI RISULTATI

La torbidità è indice di crescita microbica.

Subcoltivare su terreni in piastra selettivi come XLD Agar (ref. 10056), Hektoen Enteric Agar (ref. 10043) o MacConkey Agar (ref. 10029), cercando di ottenere colonie ben isolate. Esaminare le colonie con morfologia tipica. Confermare con ulteriori test biochimici.

ASPETTO

Terreno disidratato: omogeneo, fine granulometria, da bianco a beige chiaro.
Terreno preparato: chiaro, giallo pallido.

CONSERVAZIONE

La polvere è fortemente igroscopica, conservare a 10-30°C, in ambiente asciutto, nel suo contenitore originale chiuso ermeticamente. Conservare i flaconi e le provette a 2-8°C al riparo dalla luce. Non usare il prodotto dopo la sua data di scadenza indicata sull'etichetta o se il prodotto mostra segni di contaminazione o deterioramento.

VALIDITÀ

Terreno disidratato: 4 anni.
Terreno in provette/flaconi: 1 anno.

CONTROLLO DI QUALITÀ

Il terreno viene inoculato con i ceppi microbici indicati nella tabella CQ.
Inoculo per produttività: ≤100 UFC.
Inoculo per selettività: >10^3 UFC.
Condizioni di incubazione: ambiente aerobico a 35 ± 2°C per 18-24 ore.

Tabella CQ.

Microrganismo		Crescita
Salmonella Typhimurium	ATCC® 14028	Buona
Shigella sonnei	ATCC® 25931	Buona
Escherichia coli	ATCC® 25922	Da parzialmente a completamente a inibita

AVVERTENZE E PRECAUZIONI

Il prodotto contiene sostanze nocive ed è classificato come pericoloso. Si raccomanda di consultare la scheda di sicurezza per il suo corretto uso. Il prodotto è da intendersi per uso diagnostico *in vitro* e deve essere utilizzato esclusivamente da operatori adeguatamente addestrati.

SMALTIMENTO DEI RIFIUTI

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

BIBLIOGRAFIA

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

PRESENTAZIONE		Contenuto	Ref.
Selenite Broth	Provette	Provette 20 x 10 ml	24110
Selenite Broth	Provette	Provette 20 x 5 ml	24143
Selenite Broth	Flaconi	Flaconi 6 x 100 ml	402050
Selenite Broth	Flaconi	Flaconi 6 x 200 ml	412050
Selenite Broth (Double Concentration)	Flaconi	Flaconi 6 x 200 ml	432050
Selenite Broth	Flaconi	Flaconi 6 x 500 ml	470020
Selenite Broth	Flaconi	Flaconi 6 x 1000 ml	463130
Selenite Broth	Terreno disidratato	500 g di polvere	610145
Selenite Broth	Terreno disidratato	100 g di polvere	620145
Selenite Broth	Terreno disidratato	5 kg di polvere	6101455

TABELLA DEI SIMBOLI

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

LIOFILCHEM® s.r.l.
Via Scozia zona ind.le, 64026 Roseto degli Abruzzi (Te) Italy
Tel +39 0858930745 Fax +39 0858930310 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

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
Ferric Ammonium Citrate	0.5
Sodium Azide	0.15
Agar	15.0

Final pH 7.1 ± 0.1 at 25°C

DESCRIPTION

Bile Aesculin Azide Agar is a selective medium used for isolating and enumerating enterococci from environmental samples of sanitary importance and clinical specimens.

This medium complies with ISO 7899-2 for rapid confirmation of typical colonies on the primary isolation Slanetz Bartley Agar.

PRINCIPLE

Tryptone and peptone provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Ox-bile inhibits the growth of numerous accompanying bacteria. Sodium chloride maintains the osmotic balance of the medium. The glycoside aesculin is hydrolyzed from enterococci to aesculetin and glucose. The aesculetin reacts with iron ions forming a dark brown or black complex. Sodium azide suppress the growth of Gram-negative bacteria. Agar is the solidifying agent.

PREPARATION

Suspend 56.7 g of powder in 1 liter of deionized or distilled water. Bring to boil and shake until completely dissolved. Mix well. Sterilize in autoclave at 121°C for 15 minutes. Cool up to 45-50°C. Pour in Petri dishes.

TECHNIQUE

ISO 7899-2 recommends to filter the water sample trough a filter membrane (0.45 µm pore diameter), transfer the membrane onto a Slanetz Bartley Agar plate (ref. 163462) and incubate aerobically at 36 ± 2°C for 40-48 h.
Confirm red-maroon-pink colonies by transferring the membrane and the colonies onto a plate of Aesculin Azide Bile Agar which as been preheated to 44°C. Incubate at 44 ± 0.5°C for 2 h.

Alternatively, sample can be inoculated by spread plating, pour plating or by direct streaking on the medium surface. Incubate at 35 ± 2°C for 18-24 h.

INTERPRETATION OF RESULTS

Enterococci typically produce colonies showing a tan-black color in the surrounding medium.

STORAGE

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

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 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

- ISO 7899-2:2000. Water quality – Detection and enumeration of intestinal enterococci – Part 2: Membrane filtration method.
- Facklam R.R. and M. Moody (1970) Presumptive identification of group D streptococci: the bile-aesculin test. App. Microbiol. 20:245-250.
- Isenberg H.D. and D. Goldber (1970) Laboratory studies with a selective Enterococcus medium. Appl. Microbiol 20:433-436
- Slanetz L.W. and C.H. Bartley (1957) Numbers of enterococci in water, sewage and faeces determined by the membrane filtration technique with an improved medium. J. Bact. 74:591-595.

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

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

SHELFLIFE
4 years

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Microbiological control
   Inoculum for productivity: 50-100 CFU
   Inoculum for selectivity: 10^4-10^6 CFU
   Incubation Conditions: 18-24 h at 35 ± 2°C, in aerobiosis

Microorganism		Growth	Specification
Enterococcus faecalis	ATCC® 19433	Good	Blackening
Enterococcus faecium	ATCC® 19434	Good	Blackening
Escherichia coli	ATCC® 25922	Inhibited	—
Streptococcus pyogenes	ATCC® 19615	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

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

Bile Aesculin Azide Agar

Terreno selettivo per la ricerca ed il conteggio degli enterococchi nelle acque ed in altri materiali, secondo ISO 7899-2.

FORMULA TIPICA

	(g/l)
Triptone	17.0
Peptone	3.0
Estratto di Lievito	5.0
Bile di Bue	10.0
Sodio Cloruro	5.0
Esculina	1.0
Ferro Ammonio Citrato	0.5
Sodio Azide	0.15
Agar	15.0

pH Finale 7.1 ± 0.1 a 25°C

DESCRIZIONE

Bile Aesculin Azide Agar è un terreno selettivo utilizzato per l'isolamento ed il conteggio di enterococchi da campioni ambientali di importanza sanitaria e campioni clinici

Questo terreno è conforme ad ISO 7899-2 per la conferma rapida degli enterococchi intestinali dopo l'isolamento su Slanetz Bartley Agar.

PRINCIPIO

Triptone e peptone forniscono aminoacidi, azoto, carbonio, vitamine e minerali per la crescita dei microrganismi. L'estratto di lievito è una fonte di vitamine, soprattutto del gruppo-B. La bile di bue inibisce la crescita della flora batterica contaminante. Il sodio cloruro mantiene il bilancio osmotico del terreno. Il glicoside esculina è idrolizzato dagli enterococchi a esculetina e glucosio. L'esculetina reagisce con gli ioni ferro formando un complesso marrone scuro o nero. Il sodio azide sopprime la crescita dei batteri Gram negativi. L'agar è l'agente solidificante.

PREPARAZIONE

Sospendere 56.7 g di polvere in 1 litro di acqua deionizzata o distillata. Portare ad ebollizione ed agitare fino a completa dissoluzione. Miscelare bene. Sterilizzare a 121°C per 15 minuti. Raffreddare a 45-50°C. Versare in piastre Petri.

TECNICA

ISO 7899-2 raccomanda di filtrare il campione d'acqua attraverso una membrana (pori con diametro di 0.45 µm), trasferire la membrana su una piastra di Slanetz Bartley Agar (ref. 163462) ed incubare a 36 ± 2°C per 40-48 ore in atmosfera aerobica. Confermare le colonie di colore rosso-marrone-rosa trasferendo la membrana e le colonie su una piastra di Aesculin Azide Bile Aga che è stata preriscaldata a 44°C. Incubare a 44 ± 0.5°C per 2 ore.

In alternativa, il campione può essere inoculato per spatolamento, inclusione o per striscio diretto sulla superficie del terreno. Incubare a 35 ± 2°C per 18-24 ore.

INTERPRETAZIONE DEI RISULTATI

Tipicamente gli enterococchi producono colonie con alone marrone-nero.

CONSERVAZIONE

La polvere è fortemente igroscopica, conservare a 10-30°C, in ambiente asciutto, nel suo contenitore originale chiuso ermeticamente.. Non usare il prodotto dopo la sua data di scadenza indicata sull'etichetta o se il prodotto mostra segni di contaminazione o deterioramento. Conservare le piastre preparate a 2-8°C al riparo dalla luce.

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 ad 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. ISO 7899-2:2000. Water quality – Detection and enumeration of intestinal enterococci – Part 2: Membrane filtration method.
2. Facklam R.R. and M. Moody (1970) Presumptive identification of group D streptococci: the bile-aesculin test. App. Microbiol. 20:245-250.
3. Isenberg H.D. and D. Goldber (1970) Laboratory studies with a selective Enterococcus medium. Appl. Microbiol.20:433-436
4. Slanetz L.W. and C.H. Bartley (1957) Numbers of enterococci in water, sewage and faeces determined by the membrane filtration technique with an improved medium. J. Bact. 74:591-595.

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

SPECIFICHE DI PRODOTTO

DENOMINAZIONE
Bile Aesculin Azide Agar

PRESENTAZIONE
Terreno disidratato

CONSERVAZIONE
10-30°C

CONFEZIONAMENTO

Ref.	Contenuto	Confezionamento
610001	500 g	500 g in flacone di plastica
620001	100 g	100 g in flacone di plastica
6100015	5 Kg	5 kg in flacone di plastica

pH DEL TERRENO
7.1 ± 0.1

IMPIEGO
Bile Aesculin Azide Agar è un terreno selettivo utilizzato per la conferma ed il conteggio di enterococchi nelle acque ed in altri campioni secondo ISO 7899-2

TECNICA
Fare riferimento alla scheda tecnica del prodotto

ASPETTO DEL TERRENO
Terreno in polvere
Aspetto: omogeneo, fine granulometria
Colore: beige
Terreno pronto all'uso
Aspetto: leggermente opalescente
Colore: da ambra scuro a verde oliva

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: 50-100 UFC
   Dimensione dell'inoculo per selettività: 10^4-10^6 UFC
   Condizioni di incubazione: 18-24 h a 35 ± 2°C, in aerobiosi

Microrganismo		Crescita	Specifiche
Enterococcus faecalis	ATCC® 19433	Buona	Annerimento
Enterococcus faecium	ATCC® 19434	Buona	Annerimento
Escherichia coli	ATCC® 25922	Inibita	—
Streptococcus pyogenes	ATCC® 19615	Inibita	—

TABELLA DEI SIMBOLI

LOT	Numero di lotto	IVD	Per uso diagnostico *in vitro*		Fabbricante		Data di scadenza		Fragile, maneggiare con cura
REF	Numero di catalogo		Limiti di temperatura	Σ	Contenuto sufficiente per <n> test		Attenzione, consultare le istruzioni per l'uso		Non riutilizzare

LIOFILCHEM® S.r.l.
Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.net E-mail: liofilchem@liofilchem.net

CE IVD

CISQ is a member of

IQNet

THE INTERNATIONAL CERTIFICATION NETWORK

www.iqnet-certification.com

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.

ICIM

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	Emissione corrente	Data di scadenza
First issue	*Current issue*	*Expiring date*
18/01/2007	18/01/2019	17/01/2022

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

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. IGBG-MD Nr.6 IDNO 1003... REPUBLICA MOLDOVA, MUN.

FEDERAZIONE CISQ

www.cisq.com

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

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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

0449CIM_03_IT

CISQ is a member of

IQNet
THE INTERNATIONAL CERTIFICATION NETWORK
www.iqnet-certification.com

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.

ICIM

CERTIFICATO n. / *CERTIFICATE No.* 4265/4/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 CEI EN ISO 13485:2016

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.

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*	Emissione corrente *Current Issue*	Data di scadenza *Expiring date*
18/01/2007	18/01/2019	17/01/2022

ICIM S.p.A.
Piazza Don Enrico Mapelli, 75 – 20099 Sesto San Giovanni (MI)
www.icim.it

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. IGEG-NLD1 Nr.4 IDNO 1003600117582 REPUBLICA MOLDOVA

FEDERAZIONE CISQ

www.cisq.com

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

ACCREDIA L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 004 A

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

0860CM_02_IT

ITALCERT

CERTIFICATO N° 505SGQ03

CERTIFICATE N° 505SGQ03

Si certifica che il
this is to certify that

Sistema di Gestione per la Qualità

Quality Management System

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

L'AMMINISTRATORE DELEGATO
MANAGING DIRECTOR
Dr. Ing. Roberto Cusolito

Data di Prima Emissione *First Issue Date*	Data di Prima Emissione ITALCERT *First Issue Date ITALCERT*	Data di Rinnovo *Renewal Date*	Data di Scadenza *Expiration Date*
1998-07-23	2011-10-30	2017-10-30	2020-10-29

Settore IAF 14 - 29

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 023A PRD N° 122D
SGA N° 020D ISP N° 075E
PRS N° 097C
Membro degli Accordi di Mutuo Riconoscimento EA, IAF e ILAC
Signatory of EA, IAF and ILAC Mutual Recognition Agreements

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

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Сертификат №:
59878-2009-AQ-MCW-FINAS

Дата начальной сертификации:
20 декабря 2000

Действителен:
21 июня 2018 - 31 августа 2021

Настоящим удостоверяется, что система менеджмента организации:

АО «ТЕРМО ФИШЕР САЙЕНТИФИК»

Кубинская, д.73, литер А, корпус 1, Санкт-Петербург, Российская Федерация, 196240

была признана соответствующей стандарту:
ISO 9001:2015

Настоящий сертификат действителен для следующей области:
ПРОИЗВОДСТВО ДОЗАТОРОВ ПИПЕТОЧНЫХ И СПЕЦИАЛЬНОГО ДИАГНОСТИЧЕСКОГО ПЛАСТИКА.

Место и дата:
Москва, 21 июня 2018

FINAS
Finnish Accreditation Service
S001 (EN ISO/IEC 17021)

От выпускающего офиса:
DNV GL – Business Assurance
Трехпрудный переулок 9, стр. 2, Москва, Российская Федерация

S. Grou...

Сергей Грубин
Представитель руководства

Невыполнение условий Договора на сертификацию делает данный Сертификат недействительным.
Аккредитованный офис: DNV GL BUSINESS ASSURANCE FINLAND OY AB, Keilasatama 5, 02150 Espoo, Finland. TEL +358 10 292 4700
assurance.dnvgl.com

Сертификат

mdc medical device certification GmbH
удостоверяет, что на предприятии

ВЕКТОР БЕСТ

АО «Вектор-Бест»
630559, Новосибирская область, р.п. Кольцово,
Научно-производственная зона, корпус 36, к. 211,
Российская Федерация

с производственными площадками согласно приложению к Сертификату

применительно к областям

проектирование и разработка, производство и реализация медицинских изделий in-vitro диагностики (ПЦР, ИФА, биохимия)

была введена и применяется

СИСТЕМА УПРАВЛЕНИЯ КАЧЕСТВОМ

Проведенная проверка системы управления качеством показала, что данная система соответствует требованиям стандарта:

EN ISO 13485

Изделия медицинские – Системы менеджмента качества – Регулирующие системные требования

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

Дата выдачи	2018-07-13
Срок действия до	2020-07-03
Регистрационный №	D1213100017
Отчет №	P18-00489-117996
Штутгарт, Германия	2018-07-13

Руководитель сертификационного органа

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

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

Приложение к Сертификату

№ D1213100017 от 2018-07-13 Стр. 1 из 1

Месторасположение	Область действия
АО «Вектор-Бест», ул. Арбузова, 1/1, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство и реализация медицинских изделий in vitro диагностики
АО «Вектор-Бест», 630559, Новосибирская область, р.п. Кольцово, Научно-производственная зона, корпус 36, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики
АО «Вектор-Бест», ул. Пасечная, 3, 630117, г. Новосибирск, Российская Федерация	проектирование и разработка, производство медицинских изделий in vitro диагностики

Руководитель сертификационного органа

mdc medical device certification GmbH
Kriegerstraße 6
D-70191 Stuttgart, Germany
Phone: +49-(0)711-253597-0
Fax: +49-(0)711-253597-10
Internet: http://www.mdc-ce.de

EC DECLARATION OF CONFORMITY

AO Vector-Best hereby ensures under own responsibility and declares that the products listed on pages 2-3 are in conformity with applicable provisions and fulfill the essential requirements of Annex I Directive 98/79/EC of 27 October 1998 regarding in vitro diagnostic medical devices.

Classification of products:

Other devices (all devices except Annex II and self-testing devices)

Harmonized standards applied:

EN ISO 18113-1:2011; EN ISO 18113-2:2011 (In vitro diagnostic medical devices. Information supplied by the manufacturer (labelling). Terms, definitions and general requirements. In vitro diagnostic reagents for professional use); EN ISO 15223-1:2012 (Symbols to be used with medical device labels, labelling and information to be supplied); EN ISO 13485:2012+AC:2012 (Medical devices. Quality management systems. Requirements for regulatory purposes); EN 13612:2002 (Performance evaluation of in vitro diagnostic medical devices); EN 23640:2013 (In vitro diagnostic medical devices. Evaluation of stability of in vitro diagnostic reagents); EN 13641:2002 (Elimination or reduction of risk of infection related to in vitro diagnostic reagents); EN ISO 14971:2012 (Medical devices. Application of risk management to medical devices).

Conformity assessment procedure:

Annex III (not including section 6).

Manufacturer:

AO Vector-Best
Address: 630559, Koltsovo, Novosibirsk Region, Research and Production area, building 36, office 211, Russian Federation, tel. +7 (383) 336-73-46, tel./fax +7 (383) 332-67-49

European authorized representative:

Bioron GmbH
Address: Rheinhorststr. 18, D-67071 Ludwigshafen, Germany, tel.: +49 (0) 621 5720 915, fax: +49 (0) 621 5720 916

Date: 2017/10/16

Murat Khusainov
General Director AO Vector-Best

Valid until: 2022/07/03

No.	Product name	Identification data	REF
1.	Vectohep A-IgM	ELISA kit for determination of IgM to hepatitis A virus	D-0352
2.	Vectohep A-IgG	ELISA kit for quantitative and qualitative determination of IgG to hepatitis A virus	D-0362
3.	Vectohep TTV-IgG	ELISA kit for determination of IgG to TT virus	D-0802
4.	Vectohep E-IgG	ELISA kit for determination of IgG to hepatitis E virus	D-1056
5.	Vectohep E-IgM	ELISA kit for determination of IgM to hepatitis E virus	D-1058
6.	Vectohep G-IgG	ELISA kit for determination of IgG to hepatitis G virus	D-1252
7.	LymeBest-IgG	ELISA kit for determination of IgG to infectious borreliosis agents	D-1452
8.	LymeBest-IgM	ELISA kit for determination of IgM to infectious borreliosis agents	D-1454
9.	RecombiBest antipallidum-IgG	ELISA kit for determination of IgG to Treponema pallidum	D-1852
10.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1856
11.	RecombiBest antipallidum-IgM	ELISA kit for determination of IgM to Treponema pallidum	D-1858
12.	RecombiBest antipallidum-total antibodies	ELISA kit for determination of total antibodies to Treponema pallidum	D-1857
13.	VectoHSV-1,2 - IgG	ELISA kit for determination of IgG to herpes simplex virus types 1 and 2	D-2152
14.	VectoHSV - IgM	ELISA kit for determination of IgM to herpes simplex virus types 1 and 2	D-2154
15.	VectoHHV-8 - IgG	ELISA kit for determination of IgG to human herpes virus type 8	D-2160
16.	VectoHHV-6 - IgG	ELISA kit for determination of IgG to human herpes virus type 6	D-2166
17.	Ureaplasma urealyticum – IgG-EIA-BEST	ELISA kit for determination of IgG to Ureaplasma urealyticum antigens	D-2254
18.	Ureaplasma urealyticum – IgA-EIA-BEST	ELISA kit for determination of IgA to Ureaplasma urealyticum antigens	D-2258
19.	VectoParotitis-IgG	ELISA kit for determination of IgG to parotitis virus	D-2602
20.	VectoParotitis-IgM	ELISA kit for determination of IgM to parotitis virus	D-2604
21.	Toxocara-IgG-EIA-BEST	ELISA kit for determination of IgG to toxocara antigens	D-2752
22.	Opisthorchiasis – IgG-EIA-BEST	ELISA kit for determination of IgG to opisthorchiasis antigens	D-2952
23.	Echinococcus-IgG-EIA-BEST	ELISA kit for determination of IgG to Echinococcus	D-3356

		antigens	
24.	Ascarid-IgG-EIA-BEST	ELISA kit for determination of IgG to Ascaris lumbricoides	D-3452
25.	Lamblia-antibodies-EIA-BEST	ELISA kit for determination of IgG, IgM and IgA to Lamblia antibodies	D-3552
26.	Lamblia-IgM-EIA-BEST	ELISA kit for determination of IgM to Lamblia antibodies	D-3554
27.	Lamblia-antigen-EIA-BEST	ELISA kit for determination of Lamblia antigen	D-3556
28.	Helicobacter pylori-CagA-antigen-EIA-BEST	ELISA kit for determination of total antibodies to CagA Helicobacter pylori	D-3752
29.	TSH-EIA-BEST	ELISA kit for determination of concentration of thyroid-stimulating hormone	X-3952
30.	T3 total-EIA-BEST	ELISA kit for determination of concentration of total triiodothyronine	X-3954
31.	T4 total-EIA-BEST	ELISA kit for determination of concentration of total thyroxine	X-3956
32.	Anti-TPO-EIA-BEST	ELISA kit for determination of antibody concentration to thyroperoxidase	X-3968
33.	PAPP-A-EIA-BEST	ELISA kit for determination of concentration of pregnancy-associated plasma protein A	D-4160
34.	Mycoplasma hominis-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma hominis	D-4352
35.	Mycoplasma hominis-IgA-EIA-BEST	ELISA kit for determination of IgA to Mycoplasma hominis	D-4358
36.	Mycoplasma pneumoniae-IgG-EIA-BEST	ELISA kit for determination of IgG to Mycoplasma pneumoniae	D-4362
37.	Mycoplasma pneumoniae-IgM-EIA-BEST	ELISA kit for determination of IgM to Mycoplasma pneumoniae	D-4366
38.	Vectocrimean – CHF – IgG	ELISA kit for determination of IgG to Crimean-Congo hemorrhagic fever virus	D-5052
39.	Vectocrimean – CHF – IgM	ELISA kit for determination of IgM to Crimean-Congo hemorrhagic fever virus	D-5054
40.	CEA-EIA-BEST	ELISA kit for determination of concentration of carcinoembryonic antigen	T-8454
41.	AFP-EIA-BEST	ELISA kit for determination of concentration of Alpha-Fetal Protein	T-8456
42.	CA-125-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA-125	T-8466
43.	CA 19-9-EIA-BEST	ELISA kit for determination of concentration of CA 19-9	T-8470
44.	CA 15-3-EIA-BEST	ELISA kit for determination of concentration of oncomarker CA 15-3	T-8472
45.	NSE-EIA-BEST	ELISA kit for determination of concentration of neuron specific enolase	T-8476

46.	Ferritin-EIA-BEST	ELISA kit for determination of concentration of ferritin	T-8552
47.	IgE total-EIA-BEST	ELISA kit for determination of concentration of total IgE	A-8660
48.	IgG total-EIA-BEST	ELISA kit for determination of concentration of total IgG	A-8662
49.	IgM total-EIA-BEST	ELISA kit for determination of concentration of total IgM	A-8664
50.	IgA total-EIA-BEST	ELISA kit for determination of concentration of total IgA	A-8666
51.	Gamma-Interferon-EIA-BEST	ELISA kit for determination of concentration of gamma-interferon	A-8752
52.	Interleukine-4-EIA-BEST	ELISA kit for determination of concentration of Interleukine-4	A-8754
53.	Alpha-TNF-EIA-BEST	ELISA kit for determination of concentration of alpha-tumor necrosis factor	A-8756
54.	Alpha-Interferon-EIA-BEST	ELISA kit for determination of concentration of alpha-interferon	A-8758
55.	Interleukine-6-EIA-BEST	ELISA kit for determination of concentration of Interleukine-6	A-8768
56.	Interleukine-2-EIA-BEST	ELISA kit for determination of concentration of Interleukine-2	A-8772
57.	Procalcitonin-EIA-BEST	ELISA kit for determination of concentration of procalcitonin	A-9004
58.	NTproBNP-EIA-BEST	ELISA kit for determination of concentration of N-terminal prohormone of brain natriuretic peptide	A-9102
59.	Troponin I-EIA-BEST	ELISA kit for determination of concentration of troponin I	A-9106

Monobind Inc.
The World Resource for Diagnostic Products

100 North Pointe Drive
Lake Forest, CA 92630
TEL 949.951.2665
FAX 949.951.3539

March 26, 2019

AUTHORIZATION LETTER

To whom it may concern:

Herewith, we Monobind Inc., 100 N. Pointe Dr., Lake Forest, CA 92630 USA, do confirm that "GBG-MLD"SRL with its address: Republic of Moldova, Chisinau, MD-2001, str. Tighina 65, office 607, is the exclusive distributor our AccuBind® ELISA and AccuLite® CLIA products and accessories in Moldova. IM Global Biomarketing Group is authorized to promote and supply our products, to contract for their delivery and take part in tenders with our products.

This authorization is valid until 31 March, 2020.

On behalf of the Monobind Inc.

MONOBIND, INC. INCORPORATED NOV. 20 1978 CALIFORNIA

Alicia Jerome Volkov
Marketing Director & Corporate Officer

SOCIETATEA CU RĂSPUNDERE LIMITATĂ S.R.L. "GBG-MLD" Nr.4 IDNO 1006600117582 REPUBLICA MOLDOVA, MUN.

DECLARATION OF CONFORMITY

1) Manufacturer *(Name, department)*: **Monobind Inc.**

Address: **100 North Pointe, LAKE FOREST, CA 92630. UNITED STATES**

and

2) European authorized representative: **CEpartner4U BV,**

Address: **ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS;**
(on product labels printed as:
CEpartner4U , ESDOORNLAAN 13, 3951DB MAARN, THE NETHERLANDS. www.cepartner4u.eu)

3) Product(s) *(name, type or model/batch number, etc.)*:

Immunoassay products;
ELISA,
CLIA,
Control,
Instruments (see appendix)

4) The product(s) described above is in conformity with:

Title	Document No.
In vitro Diagnostic Medical Devices Directive	98/79/EC

5) Additional information *(Conformity procedure, Notified Body, CE certificate, Registration nr., etc.)*:

Conformity assessment procedure for CE marking: *In vitro* Diagnostic Medical Device Directive, Annex iii

Registration nr. : **NL- CA002-22758 and NL- CA002-22762**

Lake Forest, USA; 2013-09-16 — AShatola

(Place & date of issue (yyyy-mm-dd))

Tony Shatola; QA Director, Monobind Inc.
(name, function and signature of manufacturer)

Maarn, NL; 2013-09-16

(Place & date of issue (yyyy-mm-dd))

Olga Teirlinck; Consultant, CEpartner4U BV
(name, function and signature of authorized representative)

Appendix

Date: 2013-09-16

List of devices.

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Thyroid							
Total Triiodothyronine (tT3) Test System	125-300	175-300			12.04.01.05.00	Low	2005-11-11
Free Triiodothyronine (fT3) Test System	1325-300	1375-300			12.04.01.01.00	Low	2005-11-11
Thyroxine (tT4) Test System	225-300	275-300			12.04.01.07.00	Low	2005-11-11
Free Thyroxine (fT4) Test System	1225-300	1275-300			12.04.01.02.00	Low	2005-11-11
Thyrotropin (TSH) Test System	325-300	375-300			12.04.01.11.00	Low	2005-11-11
Rapid TSH Test System	6025-300	6075-300			12.04.01.11.00	Low	2010-06-29
T3-Uptake (T3U) Test System	525-300	575-300			12.04.01.06.00	Low	2005-11-11
Thyroxine-Binding Globulin (TBG) Test System	3525-300	3575-300			12.04.01.09.00	Low	2005-11-11
Thyroglobulin (Tg) Test System	2225-300	2275-300			12.04.01.08.00	Low	2005-11-11
Total Thyroxine (tT4), Total Triiodothyronine (tT3) & Thyroid Stimulating Hormone (TSH) Thyroid Panel (VAST) Test System	8025-300	8075-300			12.04.01.01.00	Low	2005-11-11
Total Triiodothyronine (tT3 SBS) Test System	8125-300	8175-300			12.04.01.01.00	Low	2010-06-29
Total Thyroxine (tT4 SBS) Test System	8225-300	8275-300			12.04.01.01.00	Low	2010-06-29
Free Thyroxine (fT4), Free Triiodothyronine (fT3) & Thyroid Stimulating Hormone Free Thyroid Panel (VAST) Test System	7025-300	7075-300			12.04.01.01.00	Low	2010-06-29
Neonatal Thyroid & Genetics							
Neonatal TSH (N-TSH) Test System	3425-300	3475-300			12.04.01.90.00	Low	2005-11-11
Neonatal (N-T4) Thyroxine Test System	2625-300	2675-300			12.04.01.12.00	Low	2005-11-11
Neonatal 17OHP (N-17OHP) Test System	5525-300	5575-300			12.05.01.07	Low	2008-02-01
Neonatal TBG (N-TBG) Test System	8925-300	8975-300			12.04.01.09.00	Low	2013-09-16
Autoimmune Thyroid							
Anti-Thyroglobulin (Anti-Tg) Test System	1025-300	1075-300			12.10.03.04.00	Low	2005-11-11
Anti-Thyroperoxidase (Anti-TPO) Test System	1125-300	1175-300			12.10.03.01.00	Low	2005-11-11
Fertility & Prenatal							
Luteinizing Hormone (LH) Test System	625-300	675-300			12.05.01.05.00	Low	2005-11-11
Follicle Stimulating Hormone (FSH) Test System	425-300	475-300			12.05.01.04.00	Low	2005-11-11
Prolactin Hormone (PRL) Test System	725-300	775-300			12.05.01.08.00	Low	2005-11-11
Prolactin Hormone Sequential (PRLs) Test System	6025-300	6075-300			12.05.01.08.00	Low	2005-11-11
B-Human Chorionic Gonadotropin (hCG) Test System	825-300	875-300			12.05.02.05.00	Low	2005-11-11
B-Human Chorionic Gonadotropin Extended Range (Ext. Range hCG) Test System	8825-300	8875-300			12.05.02.05.00	Low	2013-09-16
Rapid B-Human Chorionic Gonadotropin (Rapid	3325-300				12.05.02.05.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
-hCG) Test System							
Human Chorionic Gonadotropin (hCG) , Human Prolactin (hPRL), Human Luteinizing Hormone (hLH), Follicle Stimulating Hormone (FSH) Fertility Panel (VAST) Test System	8325-300	8375-300			12.05.01.90.00	Low	2006-08-24
Alpha-Fetoprotein (AFP), Human Chorionic Gonadotropin (hCG), Unconjugated Estiol (u-E3) Triple Screen (VAST) Test System	8525-300	8575-300			12.05.01.90.00	Low	2010-06-29
Pregnancy Associated Plasma Protein - A (PAPP-A) Test System	7925-300	7975-300			12.05.02.10.00	Low	2013-09-16
Steroid							
Cortisol Test System	3625-300	3675-300			12.06.02.04.00	Low	2005-11-11
DHEA-S Test System	5125-300	5175-300			12.05.01.02.00	Low	2010-06-29
Dehydroepiandrosterone (DHEA) Test System	7425-300	7475-300			12.05.01.02.00	Low	2011-09-26
Estradiol (E2) Test System	4925-300	4975-300			12.05.01.03.00	Low	2010-06-29
Unconjugated Estiol (u-E3) Test System	5025-300	5075-300			12.05.02.02.00	Low	2010-06-29
Progesterone Test System	4825-300	4875-300			12.05.01.06.00	Low	2010-06-29
Sex Hormone Binding Globulin (SHBG) Test System	9125-300	9175-300			12.05.01.09.00	Low	2013-09-16
Testosterone Test System	3725-300	3775-300			12.05.01.10.00	Low	2007-11-01
Free Testosterone Test System	5325-300	5375-300			12.05.01.10.00	Low	2010-06-29
17α-OH Progesterone Test System	5225-300	5275-300			12.05.01.07.00	Low	2010-06-29
17α-OH Progesterone - SI Test System	9925-300	9975-300			12.05.01.07.00	Low	2010-10-18
Growth & Bone Metabolism							
Growth Hormone (hGH) Test System	1725-300	1775-300			12.06.04.02.00	Low	2005-11-11
Parathyroid Hormone (PTH) Test System	9225-300	9275-300			12.06.03.13.00	Low	2011-09-26
25-Hydroxyvitamin D3 (Vitamin D3) Test System	7725-300	7775-300			12.06.03.10.00	Low	2011-09-26
Diabetes							
Insulin Test System	2425-300	2475-300			12.06.01.03.00	Low	2005-11-11
Rapid Insulin Test System	5825-300				12.06.01.03.00	Low	2010-06-29
C-Peptide Test System	2725-300	2775-300			12.06.01.01.00	Low	2005-11-11
Insulin - C-Peptide (VAST)	7325-300	7375-300			12.06.01.03.00	Low	2005-11-11
Cardiac Markers							
CK-MB Test System	2925-300	2975-300			12.13.01.02.00	Low	2005-11-11
Troponin I (cTnI) Test System	3825-300	3875-300			12.13.01.07.00	Low	2005-11-11
Digoxin (DIG) Test System	925-300	975-300			12.08.01.01.00	Low	2005-11-11
High Sensitivity CRP (hs-CRP) Test System	3125-300	3175-300			12.13.01.90.00	Low	2005-11-11
Myoglobin Test System	3225-300	3275-300			12.13.01.05.00	Low	2005-11-11

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Infectious Diseases							
Anti-H. Pylori IgG Test System	1425-300	1475-300			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgM Test System	1525-300	1575-300			15.01.04.03.00	Low	2005-11-11
Anti-H. Pylori IgA Test System	1625-300	1675-300			15.01.04.03.00	Low	2005-11-11
Cancer Markers							
Alpha-Fetoprotein (AFP) Test System	1925-300	1975-300			12.03.90.01.00	Low	2005-11-11
CA-125 Test System	3025-300	3075-300			12.03.01.06.00	Low	2005-11-11
CA 15-3 Test System	5625-300	5675-300			12.03.01.02.00	Low	2010-06-29
CA -19-9 Test System	3925-300	3975-300			12.03.01.03.00	Low	2005-11-11
Carcinoembryonic Antigen (CEA) Test System	1825-300	1875-300			12.03.01.31.00	Low	2005-11-11
Next Generation Carcinoembryonic Antigen (CEA) Test System	4625-300	4675-300			12.03.01.31.00	Low	2010-06-29
Free β-Subunit Human Chorionic Gonadotropin (fβhCG) Test System	2025-300	2075-300			12.03.01.90.00	Low	2005-11-11
Allergy & Anemia							
Ferritin Test System	2825-300	2875-300			12.07.01.02.00	Low	2005-11-11
Folate Test System	7525-300	7575-300			12.07.01.03.00	Low	2010-06-29
Immunoglobulin E (IgE) Test System	2525-300	2575-300			12.02.01.02.00	Low	2005-11-11
Transferrin Soluble Receptor (sTfR) Test System	8625-300	8675-300			12.07.01.06.00	Low	2010-06-29
Vitamin B-12 (B12) Test System	7625-300	7675-300			12.07.02.04.00	Low	2011-09-26
Folate, Vitamin B-12 (VAST) Test System	7825-300	7875-300			12.07.01.00.00	Low	2013-09-16
Miscellaneous Controls							
Anti-Thyroglobulin (Anti-Tg), Anti-Thyroperoxidase (Anti-TPO) Control – Positive & Negative			AIT-101		12.50.01.16.00	Low	2010-06-29
High Level Fertility Control – Single Level – Progesterone, Estradiol, Human Chorionic Gonadotropin			FC-300		12.50.01.16.00	Low	2010-06-29
Maternal Control – Tri Level - Human Chorionic Gonadotropin, Free Beta Human Chorionic Gonadotropin Subunit, Alpha Feta Protein, Estriol			MC-300		12.50.01.16.00	Low	2010-06-29
Thyroglobulin (Tg) Control – Tri Level			TG-300		12.50.01.16.00	Low	2010-06-29
H. Pylori IgG Control – Positive & Negative			HPy-IgG-300		12.50.01.16.00	Low	2010-06-29
H. Pylori IgM Control – Positive & Negative			HPy-IgM-300		12.50.01.16.00	Low	2013-09-16
H. Pylori IgA Control – Positive & Negative			HPy-IgA-300		12.50.01.16.00	Low	2013-09-16
Thyroid Binding Globulin (TBG) Control – Tri-Level			TBG-300		12.50.01.16.00	Low	2013-09-16
Miscellaneous Instruments							
Autoplex ELISA & CLIA Analyzer				IN006	21.02.10.01	Low	2010-06-29
Autoplex Generation 2 ELISA & CLIA Analyzer				IN006-2	21.02.10.01	Low	2013-09-16
Lumax CLIA Analyzer				IN001	21.02.10.01	Low	2006-08-24
Neo-Lumax CLIA Analyzer				IN010	21.02.10.01	Low	2011-09-26

Device types	Item# AccuBind® ELISA Microwells	Item# AccuLite® CLIA Microwells	Item# QSure® Control	Item# Instrument	EDMS code	Risk Class	First date of CE-marking
Impulse 2 CLIA Analyzer				IN005	21.02.10.01	Low	2006-08-24
Impulse 3 CLIA Analyzer				IN007	21.02.10.01	Low	2010-06-29
Lumax96 CLIA Analyzer				IN004	21.02.10.01	Low	2007-03-01
LuMatic CLIA Analyzer				IN008	21.02.10.01	Low	2011-09-26
Eldex 3.8 ELISA Analyzer				IN003	21.02.10.01	Low	2007-09-10
Neo-Eldex ELISA Anatzyer				IN009	21.02.10.01	Low	2011-09-26
PrisMAtic ELISA Analyzer				IN013	21.02.10.01	Low	2013-09-16
Plate Washer Microplate Washer				IN002	21.02.10.01	Low	2010-06-29

Declaration of Conformity

HL-7-0664DC DOI 2015/08 (1)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro* Diagnostic Medical Devices & CE marking.

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5267L	Thromboplastin L	55983

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 06 Aug 2015

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Certificat
Certificate

N° 2007/28642.5

AFNOR Certification certifies that the management system implemented by:
AFNOR Certification удостоверяет, что система менеджмента организации:

EKOlab

ZAO "EKOlab"
ЗАО «ЭКОлаб»

ЭКОлаб

for the following activities:
для следующих областей деятельности:

DEVELOPMENT, PRODUCTION, STORAGE AND SALE OF MEDICAL DEVICES FOR IN-VITRO DIAGNOSTICS.

РАЗРАБОТКА, ПРОИЗВОДСТВО, ХРАНЕНИЕ И РЕАЛИЗАЦИЯ МЕДИЦИНСКИХ ИЗДЕЛИЙ ДЛЯ IN-VITRO ДИАГНОСТИКИ.

has been assessed and found to meet the requirements of:
проверена и признана соответствующей требованиям стандарта:

ISO 13485:2016

and is developed on the following locations:
и действует на следующих площадках:

142530, RUSSIA, MOSCOW REGION, ELEKTROGORSK CITY, Budennogo str., 1-1A
142530, РОССИЯ, МОСКОВСКАЯ ОБЛАСТЬ, г. ЭЛЕКТРОГОРСК, ул. Буденного, 1-1A

This certificate is valid from (year/month/day) **2019-06-28** until **2022-06-27**
Данный сертификат действителен с (год/ месяц/ день) *до*

Ce document est signé électroniquement. Il constitue un original électronique à valeur probatoire
This document is electronically signed. It stands for an electronic original with probationary value

Franck LEBEUGLE
Managing Director of AFNOR Certification
Генеральный директор AFNOR Certification

Scan this QR code to check the validity of the certificate
Чтобы проверить действительность данного сертификата, отсканируйте этот QR код

СИСТЕМА СЕРТИФИКАЦИИ
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
ПРИЛОЖЕНИЕ №1
к сертификату соответствия **№ ST.RU.0001.M0013380**
Область сертификации системы менеджмента качества:

Разработка, производство и продажа медицинских изделий для in vitro диагностики: реагентов и наборов реагентов для клинической биохимии, а также калибраторов и контрольных материалов.

Руководитель органа _____ Концев В. В.

Эксперт _____ Гундарева О. В.

СИСТЕМА СЕРТИФИКАЦИИ
ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ

СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ
«СМК СТАНДАРТ»
Рег. № РОСС RU.31060.04ЖЖЮ0

Орган по сертификации:
РЕГ № SMK STANDART.RU.0005
Общество с ограниченной ответственностью
«МЕЖДУНАРОДНЫЙ ЦЕНТР СЕРТИФИКАЦИИ»
Адрес: 190020, г. Санкт-Петербург, наб. Обводного канала, д. 138, корпус 1, офис 421
тел +7 (812) 438-76-71 standart@iso-smk.ru
подлинность сертификата проверяйте в реестре на сайте http://www.iso-smk.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ

№ ST.RU.0001.M0013380

выдан

Обществу с ограниченной ответственностью «Агат-Мед»
Адрес: 105173, г. Москва, ул. Главная, д.6, кв.12
ИНН 7719187311 ОГРН 1037739078970

Дата выдачи: 26.01.2018 г. Срок действия до: 26.01.2021 г.

Настоящий сертификат удостоверяет:
Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования применительно к работам согласно приложению №1к настоящему сертификату
(приложение является неотъемлемой частью сертификата)

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ ГОСТ ISO 13485-2011 (EN ISO 13485:2003)

Руководитель органа _____ **Коппев В. В.**

Эксперт _____ **Гундарева О. В.**

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМ СТАНДАРТОМ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ «СМК СТАНДАРТ» И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-А во флаконах по 10 мл с красными крышками

Серия: 096111 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 40

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: А096111 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.1 Гематглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009

(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-В во флаконах по 10 мл с синими крышками

Серия: 095810 **Единица:** 100 мл

Изготовлен: 21.10.2019 **Количество единиц** 40

~~**Годен до:** 21.10.2021~~ ~~**Объем серии:** 10000 мл.~~

Паспорт: В095810 от 21.10.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид 1.1 Цоликлон анти-А 1.2 Цоликлон анти-В 1.3 Цоликлон анти-АВ	 Прозрачная жидкость красного цвета. Прозрачная жидкость синего цвета. Прозрачная бесцветная жидкость.	Соответствует
2. Серологические свойства 2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I) Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и О(I) Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует Соответствует Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64 Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64 Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:32 - 1: 64 Соответствует 1:64 Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН

ООО "Медиклон"

127276 Москва, Ботаническая ул., 35 , т\ф +7495 231-2272 +7499 502-1214

ПАСПОРТ – СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОНЫ Анти-А, Анти-В и Анти-АВ)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-АВ

Серия: 098611 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 10

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: АВ098611 от 05.11.2019

Наименование показателя	Норма по ТУ	Результаты испытаний
1. Внешний вид		
1.1 Цоликлон анти-А	Прозрачная жидкость красного цвета.	Соответствует
1.2 Цоликлон анти-В	Прозрачная жидкость синего цвета.	
1.3 Цоликлон анти-АВ	Прозрачная бесцветная жидкость.	
2. Серологические свойства		
2.1 Специфичность	Цоликлон анти-А не должен давать агглютинации с эритроцитами групп В(III) и О(I)	Соответствует
	Цоликлон анти-В не должен давать агглютинации с эритроцитами групп А(III) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.1 Гемагглютинирующая способность	Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:64
	Титр Цоликлона анти-АВ в реакции агглютина-ции на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	Соответствует 1:32 - 1: 64

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С. Орлова

МЕДИКЛОН
127276 Москва, Ботаническая ул., 35, т\ф (495) 231-2272 (499) 502-1214

ООО "Медиклон"

ПАСПОРТ–СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ
на «Набор реагентов для определения групп крови человека систем АВО, Резус и Kell» по ТУ-9398-101-51203590-2009
(ЦОЛИКЛОН Анти-D Супер)

Регистрационное удостоверение № ФСР 2009/06043 от 05 ноября 2009 г

Наименование: Цоликлон Анти-D Супер во флаконах по 10 мл с зелеными крышками

Серия: 292711 **Единица:** 100 мл

Изготовлен: 05.11.2019 **Количество единиц** 40

Годен до: 05.11.2021 **Объем серии:** 10000 мл.

Паспорт: Дс292711 от 05.11.2019

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная жидкость светло-бежевого цвета	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-D Супер не должен агглютинировать D(–) эритроциты.	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации должна наступать в течение 30 сек. после смешивания реагента с D(+) эритроцитами	Соответствует 30 сек.
2.3 Титр	Титр Цоликлона Анти-D Супер в реакции агглютинации на плоскости с D(+) эритроцитами 1:32 Титр Цоликлона Анти-D Супер в реакции прямой агглютинации с D(+) эритроцитами в микроплате не ниже 1:256	Соответствует 1:32 1:256

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009

Заведующая ОТК ООО «Медиклон» М.С.Орлова

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, г. Москва, ул. Госпитальный вал, д.5, стр.7А, пом.VIII
Для писем: 105094, г. Москва, а/я 26
тел/факс: (495) 988-76-67, 360-61-46, 360-72-19
http:\\www.vinar.ru e-mail: main@vinar.ru

Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

ПАСПОРТ КАЧЕСТВА

Индикаторы контроля параметров паровой стерилизации химические одноразовые ТУ 9398-042-11764404-2003

Регистрационное удостоверение
№ РЗН 2013/40
от 08.02.2013 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н17796
от 21.06.2016 г.

Наименование продукта **«Стеритест-П-132/20-02»**

Партия *8177108* ***Дата изготовления*** *Октябрь 2018 г.*

Гарантийный срок *3 года*
Условия эксплуатации и хранения *в соответствии с инструкцией производителя*
Код ОКП 93 9854

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

Ответственный
за контроль качества О.С.Громаковская

М.П.

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, г. Москва, ул. Госпитальный вал, д.5, стр.7А, пом.VIII
Для писем: 105094, г. Москва, а/я 26
тел/факс: (495) 988-76-67, 360-61-46, 360-72-19
http:\\www.vinar.ru e-mail: main@vinar.ru

Общество с ограниченной ответственностью «Научно-производственная фирма «ВИНАР»

ПАСПОРТ КАЧЕСТВА

Индикаторы контроля параметров паровой стерилизации химические одноразовые ТУ 9398-086-11764404-2010

Регистрационное удостоверение
№ ФСР 2010/09575
от 19.03.2013 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н17836
от 05.09.2016 г.

Наименование продукта **«ВИНАР-121/20»**

Партия ***6343108*** ***Дата изготовления*** ***Октябрь 2018 г.***

Гарантийный срок ***3 года***
Условия эксплуатации и хранения ***в соответствии с инструкцией производителя***
Код ОКП 93 9854

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-086-11764404-2010	Соответствует
Соответствие ГОСТ	класс 6 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный
за контроль качества О.С.Громаковская

М.П.

Общество с ограниченной ответственностью
«Научно-производственная фирма «ВИНАР»
Юр.адрес: 105094, г. Москва, ул. Госпитальный вал, д.5, стр.7А, пом.VIII
Для писем: 105094, г. Москва, а/я 26
тел./факс: (495) 988-76-67, 360-61-46, 360-72-19
http:\\www.vinar.ru e-mail: main@vinar.ru

ПАСПОРТ КАЧЕСТВА

Индикаторы бумажные воздушной стерилизации химические многопараметрические одноразовые ТУ 9398-032-11764404-2004

Регистрационное удостоверение
№ ФСР 2009/05017
от 06.03.2013 г.

Сертификат соответствия
№ РОСС RU. ИМ02.Н17797
от 21.06.2016 г.

Наименование продукта **«МедИС-В-180/60-1»**

Партия 7046077 *Дата изготовления* Июль 2017 г.

Гарантийный срок 3 года
Условия эксплуатации и хранения в соответствии с инструкцией производителя
Код ОКП 93 9854

Наименование показателя	Норма	Значение
Технические характеристики	ТУ 9398-032-11764404-2004	Соответствует
Соответствие ГОСТ	класс 4 по ГОСТ ISO 11140-1-2011	Соответствует

Ответственный за контроль качества О.С. Громаковская

М.П. ОТДЕЛ КОНТРОЛЯ КАЧЕСТВА

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
ASO Latex kit	031100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

File No A12241;
ISO 13485:2003; ISO 9001:2008

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
RF Latex kit	830100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

File No A12241:
ISO 13485:2003; ISO 9001:2008

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

LORNE LABORATORIES

EC DECLARATION OF CONFORMITY

Lorne Laboratories Ltd declares that the following in vitro diagnostic reagent:

Product name	Catalogue number
CRP Latex kit	850100A

has been classified as non List A, non List B (Directive 98/79/EC, Annex II) and complies with the essential requirements and provisions of Directive 98/79/EC of the European Parliament and of the Council (also SI 2002 No.618 which transposes the requirements of Directive 98/79/EC).

and is in conformity with the national standards transposing harmonised standards:

- BS EN 980:2008
- BS EN ISO 13485:2012
- BS EN 13612:2002
- BS EN 13640:2002
- BS EN 13641:2002
- BS EN ISO 14971:2012
- BS EN ISO 18113, parts 1&2

The conformity assessment procedure performed was in accordance with Annex III of Directive 98/79/EC.

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 13 April 2016.

Eddy Velthuis
Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

Tel: +44 (0) 118 921 2264
Fax: +44 (0) 118 986 4518
Email: info@lornelabs.com
www.lornelabs.com

File No A12241:
ISO 13485:2003; ISO 9001:2008

Registered office as above. Registered in England No. 04540797. VAT No. 800 3655 66

Declaration of Conformity

HL-7- 0137 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5186	Routine Control N	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0138 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5187	Routine Control A	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

Declaration of Conformity

HL-7- 0135 DC DOI 2013/10 (6)

In Application of the Council Directive 98/79/EC on the approximation of the laws of the Member States relating to *In Vitro Diagnostic Medical Devices & CE marking.*

Declaration of conformance to applicable sections of Annex I - Essential Requirements and Annex III (EC Declaration of Conformity) imposed by sections 2 to 5. The below listed products are not classified under Annex II Lists A or B. Access to the appropriate technical files will be made available to the appropriate body in the event this is required.

Product Code	Description	GMDN Classification Code
5183	Routine Control SA	30590

I, the undersigned declare that the devices registered against the above GMDN Classification Code conforms to the said Directives.

Full Name: M.J. Stephenson

Title: Managing Director

Signed:

Date: 31st October 2013

Tel +44 (0)191 482 8440
Fax +44 (0)191 482 8442
info@helena-biosciences.com
www.helena-biosciences.com

Helena Biosciences Europe
Queensway South, Team Valley Trading Estate,
Gateshead, Tyne and Wear, NE11 0SD,
United Kingdom

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

DECLARATION DE CONFORMITE CE

Nous, ELITech Clinical Systems SAS, zone industrielle 61500 SEES France, déclarons sous notre seule responsabilité que les réactifs appartenant au groupe 5 «CONTRÔLES/ CALIBRANTS/ STANDARDS », référencés dans la liste ci-jointe, sont conformes aux exigences essentielles des annexes I et III de la Directive Européenne 98/79/CE relative aux dispositifs médicaux de diagnostic *in vitro* et au code de la santé publique.

Cette déclaration est basée sur le contenu de chaque dossier technique DOS-CE-XXXX et s'appuie sur la certification de notre système qualité selon la norme NF EN ISO 13485 : 2016 (Certification valable jusqu'au 27 juillet 2020).

(Voir liste ci-jointe).

DECLARATION OF EC CONFORMITY

We, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, hereby certify, under our own responsibility, that the reagents belonging to Group 5, "CONTROLS/ CALIBRATORS/ STANDARDS", such as listed hereto, conform to the essential requirements of appendices I and III of European Directive 98/79/EC, relating to in vitro diagnostic medical devices and to the public health code.

This declaration is based on the contents of each DOS-CE-XXXX technical file and is supported by the certification of our quality system according to the standard NF EN ISO 13485 : 2016 (Certification valid until July 27th , 2020).

(See attached list).

DECLARACIÓN CE DE CONFORMIDAD

Nosotros, ELITech Clinical Systems SAS, Zone Industrielle 61500 SEES France, declaramos bajo nuestra única responsabilidad que los reactivos pertenecientes al grupo 5 "CONTROLES/ CALIBRADORES/ ESTÁNDARES", referenciados en la lista adjunta, son conformes con los requisitos esenciales de los anexos I y III de la Directiva Europea 98/79/CE sobre dispositivos médicos para diagnóstico in vitro y el código de salud pública.

Esta declaración se basa en el contenido de cada DOS-CE-XXXX técnica y está respaldado por la certificación de nuestro sistema de calidad según la norma NF EN ISO 13485 : 2016 (Certificación válida hasta el 27 de Julio 2020).

(Ver lista adjunta)

Sées, le 28 Juillet 2017

Valérie GOURDON,
Responsable des Affaires Réglementaires
Regulatory Affairs Manager
Responsable de los Asuntos Reglementarios

Cécile GOUBAULT,
Directeur Général Délégué
Managing Director
Directora General

ELITech Clinical Systems SAS
Zone industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51
www.elitechgroup.com

GROUPE 5 – CONTROLES/CALIBRANTS/STANDARDS
GROUP 5 – CONTROLS/CALIBRATORS/STANDARDS
GRUPO 5 – CONTROLES/CALIBRADORES/ESTÁNDARES

DESIGNATION DU REACTIF/ REAGENT DESIGNATION/ DESIGNACIÓN DE REACTIVO	REFERENCES/ REFERENCIAS	NOM DU DOSSIER CE/ EC FILE NAME/ NOMBRE DEL ARCHIVO CE	Code GMDN/ GMDN Code/ Codigo GMDN
CHOLESTEROL HDL 2G CALIBRATOR	HDLL-0011/0041	DOS-CE-HDLL-CAL	44696
CHOLESTEROL LDL 2G CALIBRATOR	LDLL-0011/0041	DOS-CE-LDLL-CAL	41728
CHOLESTEROL Standard 200 mg/dL	CHOL-0055	DOS-CE-CHOL200	44698
CK-MB CONTROL	CKMB-0900	DOS-CE-CKMB-CT	44693
CREATININE Standard 2 mg/dL	CREN-0055	DOS-CE-CREN2	44700
ELICAL 2	CALI-0550	DOS-CE-CALI2	47868
ELITROL I	CONT-0060	DOS-CE-ELIT I	47869
ELITROL II	CONT-0160	DOS-CE-ELIT II	
GLUCOSE Standard 100 mg/dL	GLUP-0055	DOS-CE-GLUP100	41818
ISE CONTROL I	ISCT-0046	DOS-CE-ISCT	47869
ISE CONTROL II	ISCT-0047		
MICROPROTEIN PLUS Standard 100 mg/dL	PRTU-0022	DOS-CE-PRTU100	53482
TRIGLYCERIDES Standard 200 mg/dL	TRIG-0055	DOS-CE-TRIG200	44702
UREA Standard 50 mg/dL	URUV-0055	DOS-CE-URUV50	53588
URIC ACID Standard 6 mg/dL	ACUR-0055	DOS-CE-ACUR6	44704

ELITech Clinical Systems SAS
Zone Industrielle
61500 Sées - France
Tél : +33 (0)2 33 81 21 00 Fax : +33 (0)2 22 28 77 51

Société par actions simplifiée au capital de 1 219 592,14€ – SIREN : 318 365 228 – RCS ALENCON

DCCE-G5 – V23 – Juillet /July /Julio 2017

ITALIANO

COAGULASE TEST

Plasma di coniglio liofilo per il test della coagulasi

DESCRIZIONE

COAGULASE TEST è costituito da plasma di coniglio liofilo con EDTA (Acido Etilen-diammino-tetra-acetico), utilizzato per la determinazione dell'enzima coagulasi prodotto da *Staphylococcus aureus*.

CONTENUTO DELLE CONFEZIONI

Ciascuna confezione contiene :

- 5 flaconi contenenti 4 mL di plasma di coniglio
- 1 foglio di istruzioni

PRODOTTI NECESSARI NON CONTENUTI

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

PRINCIPIO DEL METODO

La coagulasi prodotta da *Staphylococcus aureus* agisce sul fibrinogeno trasformandolo in fibrina. La reazione avviene in assenza di calcio che viene chelato dall' EDTA.

COMPOSIZIONE	(mL/flacone)
Plasma di coniglio liofilo	4.0

PROCEDURA DEL TEST

- Prelevare un flacone di **COAGULASE TEST** dalla confezione e ricostituire asetticamente con 4 mL di Physiological Solution (cod. 20095).
- Allestire una coltura in Brain Heart Infusion Broth (cod. 20104) prelevando una o più colonie da terreni selettivi per l' isolamento di *Staphylococcus aureus* ed incubare a 36 ± 1°C per 4-6 ore.
- In una provetta sterile mescolare 0.5 mL di **COAGULASE TEST** con 0.5 mL di brodocoltura ed incubare a 36 ± 1°C per 1-2-4-8-24 ore.

INTERPRETAZIONE DEI RISULTATI

- Verificare la formazione di un coagulo, eventualmente utilizzando un' ansa sterile. Non incubare oltre le 24 ore perché possono verificarsi fenomeni di fibrinolisi.

CONTROLLO QUALITA'

Ogni lotto di **COAGULASE TEST** è sottoposto al controllo qualità utilizzando i seguenti microrganismi di riferimento:

Microrganismo		Coagulazione
Escherichia coli	ATCC 25922	-
Staphylococcus aureus	ATCC 25923	+

PRECAUZIONI

Il prodotto, **COAGULASE TEST**, non è classificato come pericoloso ai sensi della legislazione vigente, né contiene sostanze nocive in concentrazioni ≥1%; non richiede pertanto la disponibilità della Scheda di Sicurezza.
COAGULASE 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 **COAGULASE TEST** a 2-8 °C nella sua confezione originale. Non conservare vicino a fonti di calore ed evitare eccessive variazioni di temperatura. In queste condizioni **COAGULASE TEST** è valido fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento.

ELIMINAZIONE DEL MATERIALE USATO

Dopo l'utilizzazione **COAGULASE 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

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

PRESENTAZIONE

Prodotto	REF	Σ
COAGULASE TEST	88030	5

TABELLA DEI SIMBOLI

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

LIOFILCHEM® s.r.l.
64026 Roseto degli Abruzzi (Te) Italy
Tel. +39.0858930745 - Fax +39.0858930330 www.liofilchem.net liofilchem@liofilchem.net

CE IVD

ENGLISH

COAGULASE TEST

Lyophilic citrate rabbit plasma for coagulase test

DESCRIPTION

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

CONTENT OF THE PACKAGES

Each package contains :

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

ITEMS NECESSARY NOT INCLUDED IN THE PACKAGES

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

PRINCIPLE OF THE METHOD

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

COMPOSITION	(mL/vial)
Lyophilic rabbit plasma	4.0

USE

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

INTERPRETATION OF RESULTS

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

QUALITY CONTROL

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

Microorganism		Coagulation
Escherichia coli	ATCC 25922	-
Staphylococcus aureus	ATCC 25923	+

PRECAUTIONS

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

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

STORAGE

Store **COAGULASE TEST** at 2-8°C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions, **COAGULASE TEST** will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

DISPOSAL OF USED MATERIAL

After use, **COAGULASE TEST** and material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

BIBLIOGRAPHY

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

PRESENTATION

Product	REF	Σ
COAGULASE TEST	88030	5

TABLE OF SYMBOLS

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

LIOFILCHEM® s.r.l.

64026 Roseto degli Abruzzi (Te) Italy

Tel. +39.0858930745 - Fax +39.0858930330 www.liofilchem.net liofilchem@liofilchem.net

CE IVD F00020 Rev.2 / 05.05.2011