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.
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Instructions For Use
ENGLISH

Oxidase Test Disc

Rapid test for detection of cytochrome oxidase enzymatic activity.

DESCRIPTION

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

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

CONTENTS OF THE PACKAGES

Each package contains 1 cartridge of 30 discs.

METHOD PRINCIPLE

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

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

COMPOSITION

Each disc of Oxidase Test Disc is impregnated with a solution of N,N,N´,N´-tetramethyl-p-phenylenediamine dihydrochloride.

TEST PROCEDURE

1. Allow container to come to room temperature before opening, for minimizing condensation on the disc.
2. Pick up one or more than one well isolated colony and smear on the disc. Alternatively, deposit one disc into a suspension of test organism.
3. Observe for the development of a color within 60 seconds (NB. The usage of very dilute microbial suspensions may result in longer reactions time).

INTERPRETING RESULTS

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

LIMITATIONS

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

STORAGE

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

SHELF LIFE

1 year.

QUALITY CONTROL

Control strains are indicated in the QC table.

QC Table.

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

- ISO 9308-1:2014. Water quality – Enumeration of *Escherichia coli* and coliform bacteria – Part 1: Membrane filtration method for waters with low bacterial background flora.
- EN ISO 16266:2008. Water quality – Detection and Enumeration of *Pseudomonas aeruginosa* – Method by membrane filtration (ISO 16266:2006).
- Steel K. J. (1962) J. Appl. Bact. 25:445-447.

PRESENTATION	Contents	Ref.
Oxidase Test Disc	30 discs	88004

TABLE OF SYMBOLS

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

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CE IVD

Istruzioni per l'uso
ITALIANO

Oxidase Test Disc

Test rapido per la rilevazione dell'attività enzimatica della citocromo ossidasi.

DESCRIZIONE

Oxidase Test Disc è un test diagnostico utilizzato per la differenziazione e l'identificazione microbica, in particolare dei batteri Gram negativi, sulla base delle presenza dell'enzima citocromo ossidasi.

Il prodotto corrisponde alle indicazioni fornite da EN ISO 16266 ed ISO 9308-1 per la ricerca di *Pseudomonas aeruginosa* e la conferma di *Escherichia coli* e batteri coliformi, rispettivamente.

CONTENUTO DELLE CONFEZIONI

Ogni confezione contiene 1 cartuccia da 30 dischi.

PRINCIPIO DEL METODO

I batteri ossidasi positivi producono l'enzima citocromo ossidasi (indofenolo ossidasi) che catalizza il trasporto degli elettroni da un composto donatore (NADH) ad uno accettore (di solito l'ossigeno).

Il tetrametil-p-fenilenediammina dicloroidrato contenuto in Oxidase Test Stick agisce come un donatore artificiale di elettroni e viene ossidato dai batteri ossidasi positivi formando il composto colorato indofenolo blu.

COMPOSIZIONE

Ciascun disco di Oxidase Test Disc è impregnato con una soluzione di N,N,N´,N´-tetrametil-p-fenilenediammina dicloroidrato.

PROCEDURA DEL TEST

1. Prima di aprire il contenitore attendere che raggiunga la temperatura ambiente per minimizzare la formazione di condensa sul disco.
2. Prelevare una o più di una colonia ben isolata e strisciare sul disco. In alternativa, depositare il disco in una sospensione del microrganismo da testare.
3. Osservare lo sviluppo di colore entro 60 secondi (NB. l'uso di sospensioni microbiche molto diluite può causare un'aumento del tempo di reazione).

INTERPRETAZIONE DEI RISULTATI

Lo sviluppo di un colore blu-viola indica una reazione positiva. Nessun sviluppo di colore corrisponde ad un test negativo, ciò significa che il microrganismo esaminato non produce l'enzima citocromo ossidasi.

LIMITI

Le colture più adatte per il test dell'ossidasi sono quelle ottenute su terreni di coltura privi di coloranti, indicatori o inibitori. Le colonie batteriche prelevate da terreni con valori di pH inferiori a 5.5 (es. dopo il metabolismo dei carboidrati con conseguente acidificazione del terreno di coltura) possono originare dei risultati falsi negativi. Colonie prelevate da terreni contenenti nitrati possono originare risultati non attendibili. Non utilizzare anse di acciaio, nicromo o anse contenenti ferro per prelevare le colonie. Si consiglia l'utilizzo di anse di platino o plastica, o di bastoncini applicatori in legno.

CONSERVAZIONE

Conservare 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.

DURATA

1 anno.

CONTROLLO DI QUALITÀ

I ceppi microbici utilizzati per il controllo di qualità sono indicati nella tabella CQ.

Tabella CQ.

Microrganismo		Reazione ossidasi
Escherichia coli	WDCM 00013	Negativa,nessun sviluppo di colore
Pseudomonas aeruginosa	WDCM 00025	Positiva, colorazione blu intenso-viola

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

- ISO 9308-1:2014. Water quality – Enumeration of *Escherichia coli* and coliform bacteria – Part 1: Membrane filtration method for waters with low bacterial background flora.
- EN ISO 16266:2008. Water quality – Detection and Enumeration of *Pseudomonas aeruginosa* – Method by membrane filtration (ISO 16266:2006).
- Steel K. J. (1962) J. Appl. Bact. 25:445-447.

PRESENTAZIONE	Contenuto	Ref.
Oxidase Test Disc	30 dischi	88004

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

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CE IVD

ENGLISH

Urea/Indole Test

Rapid test for detection of urease and indole production.

DESCRIPTION

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

KIT CONTENTS

Each kit contains:

- 30 tubes with dessicated biochemical substrate
- 1 tube of Kovac's Reagent
- 1 instruction sheet

PRINCIPLE OF THE METHOD

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

COMPOSITION

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

PROCEDURE FOR USE

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

INTERPRETATION OF THE RESULTS

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

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

QUALITY CONTROL

Control strains		Urease	Indole
Escherichia coli	ATCC® 25922	Negative	Positive
Proteus mirabilis	ATCC® 25933	Positive	Negative
Salmonella Thyphimurium	ATCC® 14028	Negative	Negative

PRECAUTIONS

Urea/Indole Test is not classifiable as hazardous under current legislation; However it is recommended that the Safety Data Sheet be consulted on its use. The product is intended for *in vitro* diagnostic use only and must be used by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

STORAGE

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

REFERENCES

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

PRESENTATION

Product	Ref.	Contents
Urea/Indole Test	88024	30 tests

TABLE OF SYMBOLS

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

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CE IVD

Rev.1 / 26.06.2015

Instructions For Use
ENGLISH

Sabouraud Dextrose Agar

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

DESCRIPTION

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

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

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

The medium is also available as gamma-irradiated triple bagged plates, particularly suitable for use in restricted areas like isolators and clean rooms.

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

Final pH 5.6 ± 0.2 at 25°C

METHOD PRINCIPLE

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

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

PREPARATION

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

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

TEST PROCEDURE

For use in medical microbiology

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

For use in food, animal feed and water testing

Refer to EN ISO 11133 for specific instructions.

For use in industrial microbiology

Control of non-sterile products

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

Passive Air Monitoring

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

Surfaces and Personnel Hygiene Monitoring

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

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

INTERPRETING RESULTS

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

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

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

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

APPEARANCE

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

STORAGE

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

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles: 2 years.
Medium in tubes: 1 year.
Ready-to-use plates (90 and 60 mm): 6 months.
Contact plates (55 mm): 9 months

QUALITY CONTROL

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

QC Table.

Microorganism		Growth
Candida albicans	WDCM 00054	Good
Aspergillus brasiliensis	WDCM 00053	Good
Saccharomyces cerevisiae	WDCM 00058	Good

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

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

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

f: Not CE Marked

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

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CE IVD

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Istruzioni per l'uso
ITALIANO

Sabouraud Dextrose Agar

Terreno per la coltivazione ed il conteggio di lieviti e muffe da diversi materiali, secondo EN ISO 11133 ed USP/EP/JP.

DESCRIZIONE

Sabouraud Dextrose Agar (SDA) è un terreno non selettivo utilizzato per la crescita ed il mantenimento di funghi patogeni e non patogeni da campioni clinici e non clinici. È anche utilizzato per il recupero ed il conteggio totale di lieviti e muffe nel monitoraggio ambientale.

Questo terreno è conforme con EN ISO 11133 per l'esame microbiologico degli alimenti, mangimi ed acqua, dove viene descritto come principale terreno di riferimento per effettuare test quantitativi su terreni di coltura specifici per funghi.

Il terreno è formulato secondo le raccomandazioni del metodo armonizzato nelle Farmacopee Statunitense (USP), Europea (EP) e Giapponese (JP) per l'esame microbiologico dei prodotti non sterili. Disponibile anche come piastre confezionate in triplo involucro sottovuoto, sterilizzate a raggi gamma, idonee per l'impiego nelle aree microbiologicamente controllate, come isolatori e camere bianche.

FORMULA TIPICA	(g/l)
Digerito Pancreatico di Caseina	5.0
Digerito Peptico di Tessuti Animali	5.0
Destrosio	40.0
Agar	15.0

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'agar è l'agente solidificante. 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 65 g di polvere in 1 litro di acqua distillata o deionizzata sterile. Mescolare bene. Riscaldare agitando di frequente e bollire fino a completa dissoluzione. Sterilizzare in autoclave a 121°C per 15 minuti.

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

PROCEDURA DEL TEST

Per l'uso in microbiologia medica

Strisciare il campione clinico il prima possibile dopo il suo arrivo in laboratorio per ottenere colonie isolate.

Le provette pronte con terreno solidificato a becco di clarino sono principalmente destinate all'uso con colture pure per il mantenimento o per altri scopi.

Le condizioni di incubazione possono variare in funzione della tipologia del campione e del microrganismo testato.

Per l'uso nell'esame di alimenti, mangimi ed acque

Far riferimento ad EN ISO 11133 per istruzioni specifiche.

Per l'uso nella microbiologia industriale

Controllo di prodotti non sterili

Far riferimento alle procedure descritte nei capitoli armonizzati della Farmacopea.

Monitoraggio Passivo dell'Aria

Rimuovere il coperchio dalla piastra e lasciare il terreno esposto all'aria per un periodo di tempo non superiore alle 4 ore (le piastre per sedimentazione - settle plate - riempite con 30 ml di terreno possono compensare la disidratazione del terreno durante lunghi periodi di incubazione). Le piastre possono essere posizionate secondo lo schema 1/1/1 (per 1 ora, circa 1 m dal pavimento, almeno 1 m dalle pareti o da altri ostacoli).

Monitoraggio dell'Igiene delle Superfici e del Personale

Utilizzare un tampone per il campionamento di superfici irregolari o servirsi del sampling template 10x10 (ref. 96762) per campionare una area ben definita della superficie da esaminare. Inoculare una piastra da 90 mm strisciando il tampone sulla superficie dell'agar. Inoltre, il terreno è adatto per il monitoraggio dell'igiene del personale e la determinazione della contaminazione microbica di guanti o mani (5-finger-print).

Incubare le piastre a 20-25°C per 5-7 giorni o a 30-35°C per 24-48 ore.

INTERPRETAZIONE DEI RISULTATI

Può essere necessario trasferire la crescita dalle provette con terreno a becco di clarino a terreni in piastra per ottenere colture fungine pure.

Esaminare le colonie che mostrano morfologia tipica. L'identificazione finale può richiedere test biochimici.

La conta totale combinata lieviti/muffe (TYMC) viene considerata equivalente al numero di UFC trovate per ciascuna piastra. Quando è prescritto un criterio per stabilire la qualità microbiologica, i risultai sono interpretati come di seguito indicato:

- 10^1 CFU: conta massima accettabile = 20;
- 10^2 CFU: conta massima accettabile = 200;
- 10^3CFU: conta massima accettabile = 2000, e così via.

Nelle procedure destinate al monitoraggio dell'igiene ambientale e del personale, osservare giornalmente la formazione di colonie.

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

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CE IVD F00029 Rev.2 / 16.05.2011

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

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CE IVD F00020 Rev.2 / 16.05.2011

ITALIANO

EGG YOLK *Emulsion*

Supplemento per i batteri produttori di lecitinasi (*Bacillus* e *Clostridium*)

DESCRIZIONE

EGG YOLK *Emulsion* è un supplemento costituito da un'emulsione per uso microbiologico di tuorlo d'uovo, utilizzato nei terreni di coltura Bacillus cereus Agar Base (Mossel) cod. 610114 o 620114, Bacillus cereus Agar Base (Pemba) cod. 610136 o 620136, Clostridium perfrigens Agar Base cod. 610207 o 620207, per determinare l'attività lecitinasica delle specie *Bacillus* e *Clostridium*. E' stato dimostrato che l'aggiunta dell'EGG YOLK *Emulsion* al terreno di Palcam per l'isolamento di Listeria, migliora il recupero delle cellule stressate. L'EGG YOLK *Emulsion* può essere utilizzato anche per supplementare altri terreni di base in cui è prevista l'aggiunta di un'emulsione di tuorlo d'uovo.

CONTENUTO DELLE CONFEZIONI

Ciascuna confezione contiene:

Cod. 80019	**Cod. 80219**
• 2 flaconi da 50 ml di EGG YOLK *Emulsion* • 1 foglio istruzioni	• 4 flaconi da 50 ml di EGG YOLK *Emulsion* • 1 foglio istruzioni

PRINCIPIO DEL METODO

EGG YOLK *Emulsion* è un'emulsione, per uso microbiologico, stabilizzata di tuorlo d'uovo che viene aggiunta direttamente ai terreni nutritivi per l'identificazione delle specie *Bacillus* e *Clostridium* in base alla loro attività lecitinasica.

COMPOSIZIONE

	EGG YOLK Emulsion
	Contenuto / flacone
Tuorlo d'uovo	25.0 ml
Soluzione fisiologica sterile	25.0 ml

PROCEDURA DI UTILIZZO

1. Aggiungere asetticamente l'intero contenuto di un flacone di EGG YOLK *Emulsion* (50 ml) ad 1 l di terreno Bacillus cereus Agar Base (Mossel) cod. 610114 o 620114, o Bacillus cereus Agar Base (Pemba) cod. 610136 o 620136, oppure a 500 ml di Clostridium perfrigens Agar Base cod. 610207 o 620207, autoclavati e raffreddati a 45-50 °C. Nel caso in cui l' EGG YOLK *Emulsion* sia previsto nella composizione di altri terreni, fare riferimento alle istruzioni specifiche del terreno per quanto riguarda la quantità di EGG YOLK *Emulsion* da aggiungere al terreno stesso.
2. Mescolare con cura.
3. Distribuire in piastre Petri.

TECNICA ED INTERPRETAZIONE DEI RISULTATI

Fare riferimento alla scheda tecnica di Bacillus cereus Agar Base (Mossel) cod. 610114 o 620114, o di Bacillus cereus Agar Base (Pemba) cod. 610136 o 620136, oppure di Clostridium perfrigens Agar Base cod. 610207 o 620207, o del terreno specifico in preparazione.

CONTROLLO QUALITA'

1. Controllo aspetto: liquido opaco di colore giallo.
2. Controllo microbiologico.

Si procede alla preparazione delle piastre utilizzando come base il terreno Bacillus cereus Agar Base (Pemba) cod. 610136 o 620136 addizionato con EGG YOLK *Emulsion* (1 flacone in 1 litro di terreno). Le piastre vengono seminate con i ceppi indicati nella tabella del controllo microbiologico.
Condizioni di incubazione: 24 h a 30+/-1 °C.

Controllo microbiologico

Ceppi di controllo		**Crescita**	**Colonie**
Bacillus cereus	ATCC 11788	Buona	Blu
Bacillus cereus	ATCC 14579	Buona	Blu
Escherichia coli	ATCC 25922	Inibita	----

PRECAUZIONI

Il prodotto EGG YOLK *Emulsion* non è classificato come pericoloso ai sensi della legislazione vigente.
EGG YOLK *Emulsion* è un supplemento 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 EGG YOLK *Emulsion* a 2-8 °C nella sua confezione originale. In queste condizioni EGG YOLK *Emulsion* mantiene la sua validità fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento.

BIBLIOGRAFIA

- Mossel, D.A.A., Koopman, M.J. and Jongerius, E. (1967) J. Appl. Microbiol, **15(3)**: 650-653.
- Shaidi, S.A. and Ferguson A.R. (1971) Appl. Microbiol. **21**: 500-506.

PRESENTAZIONE

prodotto	REF	Σ
EGG YOLK *Emulsion*	80019	2 flaconi X 50 ml
EGG YOLK *Emulsion*	80219	4 flaconi X 50 ml

TABELLA DEI SIMBOLI

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

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CE IVD

F02711
Rev.0 / 29.04.2005

ITALIANO

UREA 40% *Supplement*

Supplemento per la determinazione dell'attività ureasica dei batteri.

DESCRIZIONE

UREA 40% *Supplement* è un supplemento per la determinazione dell'attività ureasica dei batteri ed è costituito da una soluzione acquosa di urea al 40% per uso microbiologico. UREA 40% *Supplement* viene utilizzato per l'arricchimento del terreno Urea Agar Base cod. 610107 o 620107.

CONTENUTO DELLE CONFEZIONI

Ciascuna confezione contiene:
- 10 flaconi di UREA 40% *Supplement* da 5 ml.
- 1 foglio istruzioni

PRINCIPIO DEL METODO

L'utilizzazione dell'urea da parte dei microrganismi dotati di ureasi determina l'alcalinizzazione del terreno ed il conseguente viraggio dell'indicatore rosso fenolo da color ambra a rosa.

COMPOSIZIONE

UREA 40% *Supplement*

	Contenuto / flacone	*Contenuto / l di terreno*
Urea	2.0 g	20.0 g

PROCEDURA DI UTILIZZO

1. Prelevare asetticamente il contenuto di un flacone di UREA 40% *Supplement* ed aggiungerlo a 95 ml di Urea Agar Base cod. 610107 o 620107 autoclavato e raffreddato a 45-50 °C.
2. Mescolare con cura evitando la formazione di schiuma.
3. Distribuire nei contenitori finali.

TECNICA ED INTERPRETAZIONE DEI RISULTATI

Fare riferimento alla scheda tecnica del terreno Urea Agar Base cod. 610107 o 620107.

CONTROLLO QUALITA

1. Controllo aspetto: soluzione limpida ed incolore.
2. Controllo microbiologico.

Si procede alla preparazione delle piastre utilizzando come base il terreno Urea Agar Base cod. 610107 o 620107 addizionato con UREA 40% *Supplement* .
Le piastre vengono seminate con i ceppi indicati nella tabella del controllo microbiologico.
Condizioni di incubazione: 6-24 h a 36 ± 1 °C.
Controllo microbiologico:

Ceppi di controllo		**Attività ureasica**
Proteus vulgaris	ATCC 13315	Positiva / terreno rosa
Escherichia coli	ATCC 25922	Negativa / nessun cambiamento di colore

PRECAUZIONI

Il prodotto UREA 40% *Supplement* è classificabile come prodotto irritante ai sensi della legislazione vigente; per il suo impiego si consiglia di consultare la scheda di sicurezza.
UREA 40% *Supplement* è un supplemento selettivo 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 UREA 40% *Supplement* a 2-8 °C nella sua confezione originale. In queste condizioni UREA 40% *Supplement* mantiene la sua validità fino alla data di scadenza indicata in etichetta. Non utilizzare oltre questa data. Eliminare se vi sono segni di deterioramento.

BIBLIOGRAFIA

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

PRESENTAZIONE

prodotto	REF	Σ
UREA 40% *Supplement*	**80292**	**10 flaconi**

Un flacone serve per preparare 100 ml di terreno

TABELLA DEI SIMBOLI

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

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CE IVD *Rev.0 / 06.04.2005*

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.

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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. 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.

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

TABLE OF SYMBOLS

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

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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.

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CE IVD

Dehydrated culture medium
Rev. 0 - 3rd Ed. 2004

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	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

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CE IVD

Instructions For Use
ENGLISH

Chromatic™ Candida

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

DESCRIPTION

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

Although *Candida albicans* remains the most common cause of human Candidiasis, the frequency of infection attributed to other members of the genus is also increasing. Effective treatment requires both early diagnosis and prompt initiation of therapy against fungal infection.

TYPICAL FORMULA	(g/l)
Peptone	10.0
Chloramphenicol	0.5
Chromogenic Mix	25.2
Agar	15.0

Final pH 6.1 ± 0.2 at 25°C

METHOD PRINCIPLE

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

PREPARATION

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

TEST PROCEDURE

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

INTERPRETING RESULTS

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

ID Table.

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

See pictures in Appendix I.

APPEARANCE

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

© Liofilchem® - Chromatic™ Candida- Rev.0.1 / 08.07.2015

STORAGE

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

SHELF LIFE

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

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU
Inoculum for selectivity: 10^4-10^6 CFU.
Incubation conditions: aerobically at 35 ± 2°C for 24-48 hours.

QC Table.

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

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

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

TABLE OF SYMBOLS

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

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CE IVD

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.

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CE IVD

Dehydrated culture medium
Rev. 0 - 3rd Ed. 2004

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

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CE IVD

PHENYLALANINE AGAR

Medium for eneterobacteria differentiation.

TYPICAL FORMULA (g/l)

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

Final pH = 7.3 ± 0.2 at 25 °C.

DIRECTIONS

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

DESCRIPTION

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

TECHNIQUE

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

QUALITY CONTROL

Dehydrated medium
Appearance: free-flowing, homogeneous.
Color: light tan.
Prepared medium
Appearance: slightly opalescent without precipitate.
Color: light amber.
Incubation conditions: 36 ± 1 °C for 18-24 hours.

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

STORAGE

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

REFERENCES

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

PRESENTATION

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

TABLE OF SYMBOLS

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

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UREA AGAR BASE

Medium for urease test, recommended by ISO 6785 and IDF 93.

TYPICAL FORMULA	(g/l)
Peptone	1.0
Glucose	1.0
Sodium Chloride	5.0
Monopotassium Phosphate	2.0
Phenol Red	0.012
Agar	15.0

Final pH 6.8 ± 0.2 at 25°C

DESCRIPTION

UREA AGAR BASE is a medium used for urease test, recommended by ISO 6785 and IDF 93.

PRINCIPLE

Peptone provides nitrogen, carbon, and amino acids required for organism growth. Glucose is an energy source. Sodium chloride maintains the osmotic balance of the medium. Monopotassium phosphate is the buffer. Phenol red is the pH indicator. Agar is the solidifying agent. Urea is added to the medium as substrate for urease enzyme. The splitting of urea by urease causes the release of ammonia, increasing pH of the medium to the alkaline side. This is indicated by a color change of the pH indicator.

PREPARATION

Suspend 24.0 g of powder in 950 ml of distilled or deionized water. Heat until completely dissolved. Autoclave at 121°C for 15 minutes. Cool to 45-50°C. Aseptically add 50 ml of Urea 40% Supplement (ref. 80292). Dispense into sterile tubes and allow to solidify in a slanting position.

TECHNIQUE

Use a heavy inoculum of the growth from a pure 18-24 hours culture. Inoculate by streaking back and forth over the entire slant surface. Do not stab the butt because it serves as color control. Incubate the tubes with the caps loosened at 36 ± 1°C for 6-24 hours. Longer period of incubation may not be necessary.

INTERPRETATION OF RESULTS

The production of urease is a positive reaction, indicated by an intense red or pink color on the slant.

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

DISPOSAL OF WASTE

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

REFERENCES

1. Christensen, W.B. (1946) J. Bact. 52:461-466.
2. Maslen, L.G.C. (1952) Brit. Med. J. 2:545-546.
3. ISO 6785:2001. IDF 93:2001.

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CE IVD

PRODUCT SPECIFICATIONS

NAME

UREA AGAR BASE

PRESENTATION

Dehydrated medium

STORAGE

10-30°C

PACKAGE

Ref.	Content	Packaging
610107	500 g	500 g of powder in plastic bottle
620107	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM

6.8 ± 0.2

USE

UREA AGAR BASE is a medium used for urease test, recommended by ISO 6785 and IDF 93

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM

Dehydrated medium
Appearance: free-flowing, homogeneous
Colour: orange
Prepared medium
Appearance: slightly opalescent
Colour: reddish-orange

SHELFLIFE

4 years

QUALITY CONTROL

1. Control of general characteristics, label and print
2. Microbiological control
   Inoculum for productivity: 10-100 CFU/ml
   Incubation conditions: 6-24 h at 36 ± 1°C

Microorganism	ATCC®	Urease Production
Proteus vulgaris	13315	+
Escherichia coli	25922	-

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	Consult instructions for use	Keep away from heat sources

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CE IVD

BLOOD AGAR BASE

Basal medium for fastidious microorganisms isolation.

TYPICAL FORMULA (g/l)

Beef Extract	10.0
Tryptose	10.0
Sodium Chloride	5.0
Agar	15.0

Final pH = 7.3 ± 0.2 at 25 °C.

DIRECTIONS

Suspend 40.0 g of powder in 1 liter of distilled or deionized water. Heat until completely dissolved. Sterilize in autoclave at 121 °C for 15 minutes. Cool to 45-50 °C and aseptically add 5-7% sterile defibrinated sheep or horse blood. Mix well. Dispense in petri dishes.

DESCRIPTION

BLOOD AGAR BASE is a general purpose medium that can be utilized as it is or with addition of substances as blood or serum, for cultivating fastidious microorganisms such as streptococci, pneumococci, meningococci.

TECHNIQUE

Inoculate the medium with the specimen to examine spreading with a sterile loop and incubate at 36 ± 1 °C for 18-24 hours under aerobic or anaerobic conditions, depending on the case.

QUALITY CONTROL

Dehydrated medium
Appearance: free-flowing, homogeneous.
Color: tan.
Prepared medium
Appearance: clear.
Color: cherry red.
Incubation conditions: 36 ± 1 °C for 24 hours at 5-10% CO_2.

Microorganism	ATCC	Growth	Hemolysis
Streptococcus pneumoniae	6305	good	alpha
Escherichia coli	25922	good	
Streptococcus pyogenes	19615	good	beta
Staphylococcus aureus	25923	good	beta

PERFORMANCE AND LIMITATIONS

Enriched with 5-7% sterile sheep blood, BLOOD AGAR BASE is particularly suitable for the determination of hemolytic activity of streptococci, staphylococci and other microorganisms. Blood Agar Base is intended for use with blood supplementation. Although certain diagnostic tests may be performed directly on this medium, biochemical and, if indicated, immunological testing using pure cultures are recommended for complete identification.

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. Brown, J.H.. 1919. The use of blood agar for the study of streptococci, NY Monograph No. 9. In Rockefeller Istitute for Medical Research.
2. Ruoff, K.L. 1995. Streptococcus, p. 299-305. Manual of clinical microbiology, 6th ed.
3. NCCLS document M22-A2, 1996. Approved Standard.

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CE IVD

PRESENTATION

Product	REF	Σ
BLOOD AGAR BASE (12.5 l)	610005	500 g
BLOOD AGAR BASE (2,5 l)	620005	100 g
SHEEP BLOOD DEFIBRINATED	83296	50 ml

TABLE OF SYMBOLS

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

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CE IVD

Instructions For Use
ENGLISH

Fluid Thioglycollate Medium

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

DESCRIPTION

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

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

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

Final pH 7.1 ± 0.2 at 25°C

METHOD PRINCIPLE

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

PREPARATION

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

TEST PROCEDURE

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

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

INTERPRETING RESULTS

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

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, light beige.
Prepared medium: slightly opalescent, light amber (20% or less of upper layer may be pink).

STORAGE

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

SHELF LIFE

Dehydrated medium: 4 years.
Medium in bottles: 2 years.
Medium in tubes: 1 year.

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QUALITY CONTROL

Fluid Thioglycollate Medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: ≤ 100 CFU.
Incubation conditions: 24 h at 30-35°C for bacteria, 48 h at 20-25°C for yeasts, 72 h at 20-25°C for moulds (Pharmacopoeia growth promotion);
18-24 at 37 ± 1°C for *Clostridium perfringens* (ISO 11133).

QC Table.

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

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

PRESENTATION		Contents	Ref.
Fluid Thioglycollate Medium	Tubes	20 x 10 ml tubes	24124
Fluid Thioglycollate Medium	Tubes	100 x 10 ml tubes	26124
Fluid Thioglycollate Medium	Tubes	10 x 20 ml tubes	21241
Fluid Thioglycollate Medium	Tubes	20 x 20 ml tubes	24241
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (flip-off cap)	400020
Fluid Thioglycollate Medium	Bottles	6 x 300 ml bottles (flip-off cap)	400120
Fluid Thioglycollate Medium	Bottles	6 x 1000 ml bottles (flip-off cap)	400220
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (screw cap)	452060
Fluid Thioglycollate Medium	Bottles	25 x 100 ml bottles (screw cap)	453060
Fluid Thioglycollate Medium	Bottles	6 x 900 ml bottles (screw cap)	463100
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (crimp cap)	495020
Fluid Thioglycollate Medium	Bottles	6 x 100 ml bottles (perforable cap)	493000
Fluid Thioglycollate Medium	Bottles	6 x 500 ml bottles (wide neck)	470300
Fluid Thioglycollate Medium	Dehydrated medium	500 g of powder	610050
Fluid Thioglycollate Medium	Dehydrated medium	100 g of powder	620050
Fluid Thioglycollate Medium	Dehydrated medium	5 kg of powder	6100505

TABLE OF SYMBOLS

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

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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.

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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

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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, sopratutto 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.

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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

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CE IVD

KIMA

articoli per laboratorio analisi
disposable labware

www.kima.it

Messrs

"GBG-MLD" SRL
STR. TIGHINA 65
2001 CHISINAU
MOLDOVA

Piove di Sacco, 25/02/2019

DISTRIBUTOR AGREEMENT

To whom it may concern, we hereby declare that:

KIMA sas – Via Leonardo Da Vinci 22 – 35028 piove di Sacco - (PD) - ITALY

appoints "GBG-MLD" SRL – STR. TIGHINA 65. - 2001 CHISINAU –MOLDOVA

as authorized distributor of KIMA plastic labware products in the territory of MOLDOVA

GBG MLD has the right to import and distribute KIMA plastic labware products.

This Agreement is valid one (2) years from the present date.

The Distributor does not have any possibility to oblige the company KIMA sas with quantities or delivery time as well as prices without prior written authorization from KIMA sas.

KIMA sas keeps the right to modify the prices according to the market of the raw materials.

Renzo Chiarin
Managing Director

KIMA S.R.L.
Via Leonardo Da Vinci, 22
35028 PIOVE DI SACCO (PD)
Partita IVA 01466290283

meus
Progettazione e produzione stampi per articoli in plastica. Produzione kit diagnostici per analisi e terreni di coltura per microbiologia.

ICIM CISQ

DICHIARAZIONE DI CONFORMITÁ CE
EC DECLARATION OF CONFORMITY

conforme all'Allegato III della Direttiva 98/79/CE *Dispositivi Medico-Diagnostici In Vitro* e s.m.i.
according to Annex III of the Directive 98/79/EC In Vitro Diagnostic Medical Devices as amended

fabbricante *manufacturer*	***MEUS S.r.l. - Produzione kit diagnostici per analisi e terreni di coltura per microbiologia***
indirizzo *address*	***Via Leonardo da Vinci, 24 Z.I. 35028 Piove di Sacco (PD) - Italia***
telefono *phone*	***++39-049-9719544***
fax *fax*	***++39-049-9719542***
posta elettronica *e-mail*	***meus@tecnomeus.it***
identificazione dei prodotti *product identification*	**Provette con tappo a vite, provette sterili, provette con separatore di siero, provette con anticoagulanti, contenitori e provette per liquidi biologici.** **Test tubes with screw cap, sterile test tubes, test tubes with serum separators, test tubes with anticoagulants, containers and test tubes for biological liquids.**
classificazione dei prodotti *product identification*	**dispositivi diversi da quelli elencati nell'Allegato II della Direttiva 98/79/CE e s.m.i.** ***devices other then those mentioned in Annex II of the Directive 98/79/EC as amended***

Si dichiara

sotto la propria responsabilità che i dispositivi sopraelencati rispettano le disposizioni applicabili della Direttiva 98/79/CE e s.m.i. Dispositivi Medico–Diagnostici In Vitro.

Tutta la documentazione tecnica richiesta dall'Allegato III della succitata Direttiva, e comprovante il rispetto dei Requisiti Essenziali di cui all'Allegato I della Direttiva, sono conservati a cura del Fabbricante

Hereby we declare

under our sole responsibility that the above mentioned devices meet the applicable provisions of the Directive 98/79/EC as amended on In Vitro Diagnostic Medical Devices.

All the supporting documents, as required by Annex III of the 98/79/EC Directive, in order to prove conformity to the Essential Requirements as listed in Annex I, are retained under the premises of the Manufacturer

luogo e data
place and date

Piove di Sacco, 02/01/2013

firma
signature

Assicurazione Qualità / Quality Manager
Giovanni Chiarin

Giovanni Chiarin

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WE HEREBY CERTIFY THAT THE QUALITY MANAGEMENT SYSTEM OPERATED BY

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

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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.

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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.

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0449CM_03_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

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SGQ N° 023A PRD N° 122B
SGA N° 030D ISP N° 079E
PRS N° 094C
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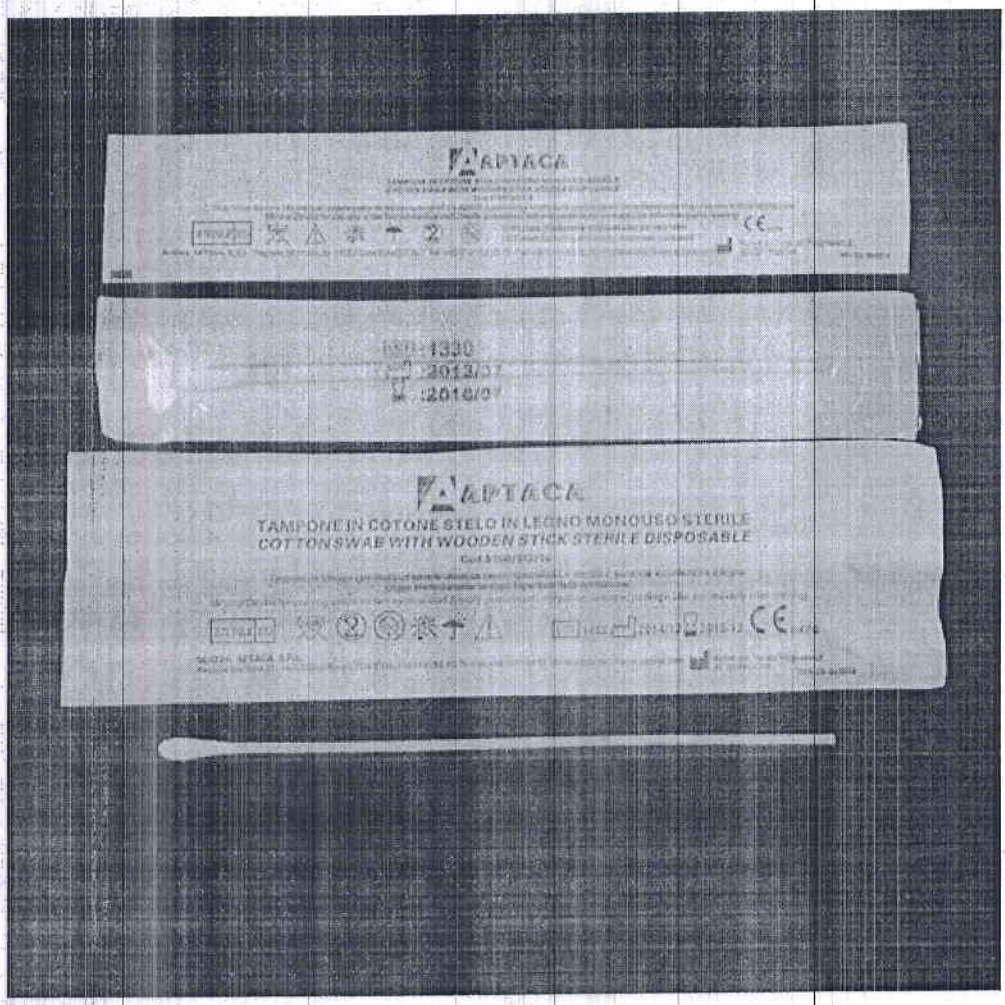
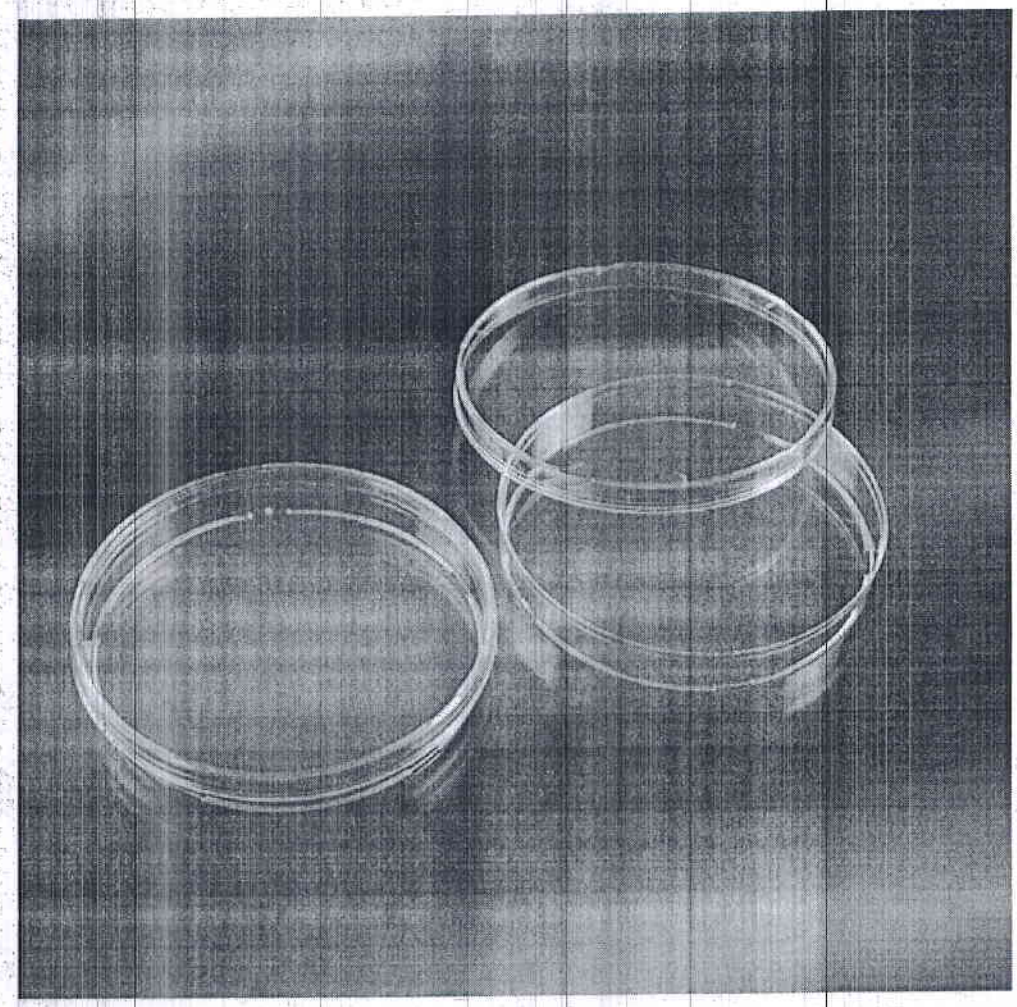


SWABS WOODEN STICK

Cotton swabs with wooden stick. Length 150 mm.

Cod.	Description	TDS
5100	Non sterile	
5100/SG/CS	Sterile - Ind. wrapped	
5100/SG/2	Sterile - Pack of 2 pcs	
5100/SG/10	Sterile - Pack of 10 pcs	



PETRI DISHES Ø90 MM

In polystyrene with high optical clarity. Available, upon request, with inner bag for use in Cleanroom.

Technical Data Sheet

Cod.	Description
91	With triple vents - Aseptic
91/SG	With triple vents - Sterile R
101	Without vents - Aseptic
101/SG	Without vents - Sterile R

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

CERTIFIED COMPANY UNI EN ISO 9001:2008 & UNI EN ISO 13485:2012

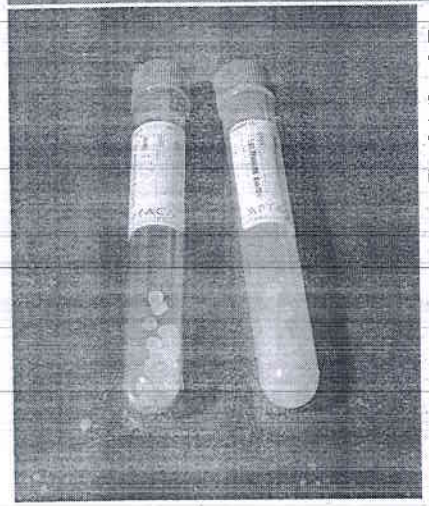
SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
23.10.2015

MADE IN ITALY

CODICE ARTICOLO: / *ITEM CODE:* **5995/E**

DESCRIZIONE / *DESCRIPTION*



Provetta cilindrica Ø16x100 mm prodotta in Polimetilmetacrilato (PMMA) perfettamente trasparente ed inerte, materiale ideale e particolarmente idoneo per sierare. Le provette contengono granuli separatori in polistirolo (inerti, tondeggianti e privi di asperità al fine di evitare la rottura delle cellule durante la centrifugazione) per 10,0 ml di sangue i quali formano una sufficiente barriera (non totalmente ermetica) tra plasma e siero in seguito alla centrifugazione (raccomandiamo di non superare RCF 1.500 x g). Corredate di tappo in polietilene (PE) di colore verde a perfetta tenuta. Con etichetta. R.P.M. max 3.000

Cylindrical test tube Ø16x100 mm in Polymethylmethacrylate (PMMA), perfectly transparent and inert; raw material ideal and particularly suitable for serum process. Test tubes contain PS separating granules (inert and smoothly rounded to avoid cells breakage during centrifugation) for 10.0 ml of blood, forming a sufficient barrier (not totally hermetic) between plasma and serum following to centrifugation (it is recommended not to centrifuge at more than RCF 1,500 x g). Supplied with Polyethylene (PE) cap, green colour, perfectly tight and label. R.P.M. max 3,000

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

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

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	**NON STERILE / *NOT STERILE***	*Microbilogical status*
Materiale impiegato provetta	POLIMETILMETACRILATO / *POLYMETHYLMETHACRYLATE*	*Raw material – test tube*
Materiale impiegato tappo	POLIETILENE / *POLYETHYLENE*	*Raw material – cap*
Temperature tollerate provetta	MIN -40°C MAX +85°C	*Temperature range - test tube*
Temperature tollerate tappo	MIN -50°C MAX +75°C	*Temperature range - cap*
Volume nominale (ml)	10 ML	*Nominal volume (ml)*
Dimensioni provetta (mm)	Ø 16 X 100	*Dimensions – test tube (mm)*
Taratura provetta (ml)	2,5 – 5,0 - 10,0	*Calibration – test tube (ml)*
Validità del prodotto	2 ANNI / *YEARS*	*Shelf life*

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

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione d'uso è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" atto a contenere un campione biologico umano (sangue) al fine di effettuare analisi diagnostiche di laboratorio.
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.
Classificazione Nazionale dei Dispositivi Medici (CND) >W050301020101 (Provette con additivi in materiale plastico per analisi)
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1246117/R
Classificazione EDMA: 51011001 - Tubes for serum (without anticoagulant)

The intended purpose is "IN VITRO DIAGNOSTIC MEDICAL DEVICE" able to contain a human biological sample (blood) and in order to carry out analysis of laboratory diagnosis. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > W050301020101 (Samples analyses, plastic tubes with additives)
EDMA: 51011001 - Tubes for serum (without anticoagulant)

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, lontano da fonti di calore e non esporre alla luce diretta del sole.
Store in dry place, far away from heat sources and not to expose to the direct light of the sun.

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substance check the resistance / compatibility chart on our catalogue

IMBALLO / *PACKING*

Quantità (pz): / *Quantity (pcs):* 1.000
Confezione interna (pz): / *Internal packing (pcs):* 50 (rack)
QUANTITÀ MINIMA VENDIBILE / *MINIMUM SALEABLE QUANTITY*

Misura esterna scatola (cm): / *External box dimensions (cm):* 56 X 23,5 X 43
Peso (Kg): / *Weight (Kg):* 9,1
Volume (m^3): / *Volume (m^3):* 0,056

SIMBOLI UTILIZZATI SULL'IMBALLO / PACKING SYMBOLS

Data di fabbricazione / *Manufacturing date*
Data di scadenza / *Expiry date*
Consultare i documenti accompagnatori / *Please consult accompanying documents*
LOT Numero di lotto / *Lot number*
Monouso / *Disposable*

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

CERTIFIED COMPANY UNI EN ISO 9001 & UNI CEI EN ISO 13485

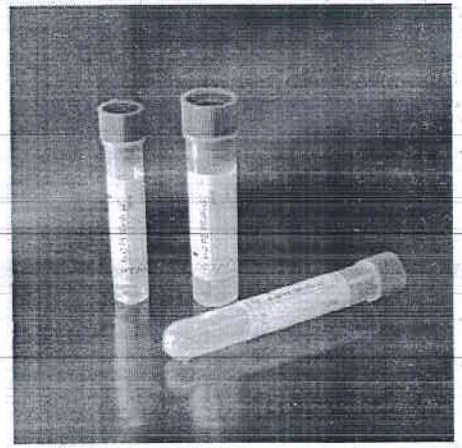
SCHEDA TECNICA PRODOTTO
TECHNICAL DATA SHEET

DATA EMISSIONE / DATE OF ISSUE
22.02.2017

MADE IN ITALY

CODICE ARTICOLO: / *ITEM CODE:* **2100**

DESCRIZIONE / *DESCRIPTION*



Provette con anticoagulante K_3 EDTA
Provette fondo piatto Ø12 x 56 mm con anticoagulante liquido K_3 EDTA per 2,5 ml di sangue idonee per analisi in ematologia e in immunoematologia.
Con etichetta con indicazione di livello di riempimento a 2,5 ml. Provetta in polipropilene medicale (PP) particolarmente trasparente e con tappo a pressione di colore verde scuro perfettamente a tenuta. Dispositivo Latex free

Blood collecting tubes with K_3 EDTA
Blood collecting flat bottom test tubes Ø12 x 56 mm with liquid anti-coagulants K_3 EDTA, for 2.5 ml of blood, suitable for analysis in hematology and immunohematology. With label with filling line at 2.5 ml. Test tubes manufactured in medical polypropylene (PP) particularly transparent. With dark green pressure cap which guarantees the perfect leak-proof. Latex free device

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

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

CARATTERISTICHE PRINCIPALI		*TECHNICAL FEATURES*
Stato microbiologico	NON STERILE / *NOT STERILE*	*Microbilogical status*
Materiale impiegato provetta	Polipropilene / *Polypropylene*	*Raw material – Test tube*
Materiale impiegato tappo	Polietilene / *Polyethylene*	*Raw material - cap*
Colore tappo:	Verde scuro / *Dark green*	*Color - cap:*
Temperature tollerate:	min 0°C max +40°C	*Temperature range*
Dimensioni provetta (mm)	Ø12 x 56	*Dimensions - test tube (mm)*
Volume provetta:	3 ml	*Test tube volume*
Freccia livello riempimento:	2,5 ml	*Filling arrow:*
Anticoagulante:	K_3 EDTA	*Anticoagulant*
Validità del prodotto	2 Anni / *Years*	*Shelf life*

APTACA
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E-Mail: info@aptaca.com – Website: www.aptaca.com

DESTINAZIONE D'USO / *INTENDED PURPOSE*

La destinazione d'uso è quella di "DISPOSITIVO MEDICO DIAGNOSTICO IN VITRO" atto a contenere un campione biologico umano (sangue) al fine di effettuare analisi diagnostiche di laboratorio.
Il dispositivo in oggetto è destinato esclusivamente ad uso professionale.
Classificazione Nazionale dei Dispositivi Medici (CND) > W050101010201 (Provette con additivi o separatori di siero per raccolta di sangue)
Repertorio Nazionale dei Dispositivi Medici (RDM) > 1246130/R
Classificazione EDMA: 51011002 - Tubes with EDTA

The intended purpose is "IN VITRO DIAGNOSTIC MEDICAL DEVICE" able to contain a human biological sample (blood) and in order to carry out analysis of laboratory diagnosis. ***For professional use only.***
National classification of medical devices (CND - For Italian law) > *W050101010201 (Blood collection, tubes with additives or serum separator)*
EDMA: *51011002 - Tubes with EDTA*

AVVERTENZE PER L'USO / *OPERATING INSTRUCTIONS*

Non avvicinare il dispositivo alla fiamma o a fonti di calore che lo potrebbero danneggiare.
Keep out of flame or heat sources which might damage the product

Non utilizzare il prodotto scaduto o con la confezione aperta
Do not use after expiry date or if packing is opened

Non riutilizzare: Dispositivo monouso
Do not re-use: Disposable device

Non variare la destinazione d'uso
Do not vary the intended purpose of the product

Prodotto non adatto ai bambini
Keep out of reach of children

Conservare in luogo asciutto, lontano da fonti di calore e non esporre alla luce diretta del sole.
Store in dry place, far away from heat sources and not to expose to the direct light of the sun.

Smaltimento: utilizzare gli appositi D.P.I e smaltire secondo le normative vigenti
Disposal: use appropriate personal protective equipment and act according to applicable regulations

Prima dell'utilizzo con sostanze particolari consultare sul catalogo le tabelle di resistenza/compatibilità dei materiali.
Before use with particular substance check the resistance / compatibility chart on our catalogue

IMBALLO / *PACKING*

Quantità (pz): / *Quantity (pcs):* 1.500
Confezione interna (pz): / *Internal packing (pcs):* 50 pezzi in rack polistirolo espanso / *50 pièces in styrofoam racks*
QUANTITÀ MINIMA VENDIBILE / *MINIMUM SALEABLE QUANTITY*

Misura esterna scatola (cm): / *External box dimensions (cm):* 47 x 23 x 37
Peso (Kg): / *Weight (Kg):* 4,8
Volume (m^3): / *Volume (m^3):* 0,039

SIMBOLI UTILIZZATI SULL'IMBALLO / *PACKING SYMBOLS*

Data di fabbricazione / *Manufacturing date*
Data di scadenza / *Expiry date*
Consultare i documenti accompagnatori / *Please consult accompanying documents*
LOT Numero di lotto / *Lot number*
Monouso / *Disposable*

ФЕДЕРАЛЬНОЕ АГЕНТСТВО
ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
СИСТЕМА ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ ГОСТ Р
«EAC AUDIT»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028.04EAC1
ОРГАН ПО СЕРТИФИКАЦИИ ООО «ГОРТЕСТ»
РЕГИСТРАЦИОННЫЙ НОМЕР РОСС RU.32028
ИНН 7717616798 ОГРН 1087746489060
Юридический адрес: 109028, Россия, г. Москва, Серебряническая набережная, д. 27,
этаж 4, пом. 1, ком. 17
Телефон: 8 (800) 1000-730, e-mail: info@eacaudit.ru

№003749

СЕРТИФИКАТ СООТВЕТСТВИЯ

Регистрационный номер № 04EAC1.CM.00813

Общество с ограниченной ответственностью «МиниМед»

(наименование лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

(юридический адрес лица)

241520, Россия, Брянская область, Брянский район, с. Супонево, ул. Шоссейная, д.17А

(фактический адрес лица)

ИНН: 3234007127 **ОГРН: 1023202138332**

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ СООТВЕТСТВИЕ

системы менеджмента качества изделий медицинских Общества с ограниченной ответственностью «МиниМед» требованиям ГОСТ ISO 13485-2017 (ISO 13485:2016) «Изделия медицинские. Системы менеджмента качества. Системные требования для целей регулирования» применительно к Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики

Дата регистрации: 19-03-2019

Срок действия до: 18-03-2022

Руководитель органа по сертификации: (подпись) **В. И. Погодин**

Председатель экспертной комиссии: (подпись) **Е. Д. Курбатова**

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ВЫПОЛНЯЕМЫХ РАБОТ В СООТВЕТСТВИИ С ВЫШЕУКАЗАННЫМИ СТАНДАРТАМИ, ЧТО БУДЕТ НАХОДИТЬСЯ ПОД КОНТРОЛЕМ ОРГАНА ПО СЕРТИФИКАЦИИ СИСТЕМЫ ДОБРОВОЛЬНОЙ СЕРТИФИКАЦИИ "EAC AUDIT" И ПОДТВЕРЖДАТЬСЯ ПРИ ПРОХОЖДЕНИИ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ

Федеральное агентство по техническому регулированию и метрологии

НОПСС

Система добровольной сертификации "НОПСС". РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

www.nopss.ru

СЕРТИФИКАТ СООТВЕТСТВИЯ

выдан

Общество с ограниченной ответственностью

«МиниМед»

ИНН 3234007127 / ОГРН 1023202138332

241520, Брянская область, Брянский район, с. Супоиево, ул. Шоссейная, д. 17А

Подтверждает что система менеджмента качества
соответствует требованиям ГОСТ ISO 9001-2015 (ISO 9001:2015)

При осуществлении работ согласно приложению №1 к настоящему сертификату

Сертификат выдан на основании решения экспертной комиссии

от 24.09.2018

Срок действия до 24 сентября 2021

Номер в едином реестре системы С1256

Руководитель органа по сертификации: Подпись Платонов Б.А.

Настоящий сертификат обязывает организацию поддерживать состояние выполняемых работ в соответствии с вышеуказанным стандартом, что будет находиться под контролем органа по сертификации СДС "НОПСС" и подтверждаться при прохождении ежегодного инспекционного контроля.

Федеральное агентство по техническому регулированию и метрологии

НОПСС

Система добровольной сертификации "НОПСС". РОСС RU.31827.04ЖСН1

Орган по сертификации ООО "Невский Альянс". ОГРН 1147847286960 ИНН 7842525530

www.nopss.ru

ПРИЛОЖЕНИЕ №1

К сертификату соответствия № С1256

Применительно к видам деятельности :

Производство лабораторной посуды, медицинских изделий, приборов и принадлежностей, красителей, реагентов и наборов реагентов для in-vitro диагностики.

Руководитель органа по сертификации: Подпись Платонов Б.А.

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

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

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.

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Technical Director

Lorne Laboratories Limited
Unit 1 Cutbush Park Industrial Estate
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Berkshire RG6 4UT United Kingdom

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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.

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Technical Director

Lorne Laboratories Limited
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Danehill, Lower Earley
Berkshire RG6 4UT United Kingdom

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www.lornelabs.com

МЕДИКЛОН®

ООО "Медиклон"

127276 Москва, Ботаническая ул. 35 , т\ф (495) 231-2272, (499) 502-12-14
e-mail : Mediclone@mediclone.ru

ИНН 7719191607 Р/с 40702810038040106975 в ПАО Сбербанк г.Москва, К/С 30101810400000000225 КПП 771501001 БИК 044525225 ОКПО 51203590 ОГРН 1С27700153766

Исх 74-17
10.01.2017

СВИДЕТЕЛЬСТВО
НА ЭКСКЛЮЗИВНОЕ ПРАВО ПРОДАЖИ

Общество с ограниченной ответственностью «МЕДИКЛОН» 127276 Россия Москва ул.Ботаническая, 35, ОГРН 1027700153766 - производитель реагентов для трансфузиологии (Цоликлонов) в лице генерального директора Викторова Н.А. официально удостоверяет, что фирма IM «GBG-MLD» SRL , расположенная по адресу : MD-2001 г Кишинёв, ул.Тигина , 65 , оф. 607 , Республика Молдова , является официальным дистрибьютором (авторизованным дилером) всей продукции производства ООО «МЕДИКЛОН» на всей территории Республики Молдова.

IM «GBG-MLD» SRL имеет право на распространение (реализацию), продвижение (рекламу) а также поддержку продукции, выпускаемой фирмой ООО «МЕДИКЛОН» в Республике Молдова

IM «GBG-MLD» SRL имеет право участвовать от имени фирмы ООО «Медиклон» в частных и Государственных тендерах и тем самым действовать как официальный представитель фирмы ООО «Медиклон» на всей территории Республики Молдова

ООО «Медиклон» распространяет свои полные гарантии на продукцию, проданную фирмой IM «GBG-MLD» SRL .

Генеральный
директор ООО «Медиклон» Н.А.Викторов

ООО "Медиклон"

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

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

Серия: 282211 **ОКП:** 93 9816

Годен: 1 ноября 2020 г. **Объем серии:** 10000 мл.

Единица: 100 мл **Паспорт:** Т-18-11-92 от 27.11.2018

Количество единиц 50

Наименование показателя	Характеристика нормы	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(II) и О(I)	Соответствует
	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I)	Соответствует
2.2 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 1:64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009
Заведующая
лабораторией ООО «Медиклон»
М.С.Орлова

ООО "Медиклон"

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

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

Серия: 282111 **ОКП:** 93 9816

Годен: 1 ноября 2020 г. **Объем серии:** 10000 мл.

Единица: 100 мл **Паспорт:** Т-18-11-91 от 22.11.2018

Количество единиц 50

Наименование показателя	Характеристика нормы	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(II) и О(I)	Соответствует
		Соответствует
2.2 Гемагглютинирующая способность	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I) Агглютинация на плоскости эритроцитов А1 и В с соответствующими Цоликлонами должна появиться не позднее 10 сек. после смешивания	Соответствует 10 секунд
2.3 Титр		Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-А в реакции агглютинации на плоскости с эритроцитами группы А(II) 1:32 - 1:64	Соответствует 1:64
	Титр Цоликлона анти-В в реакции агглютинации на плоскости с эритроцитами группы В(III) 1 : 64	Соответствует 1:32 - 1: 64
	Титр Цоликлона анти-АВ в реакции агглютинации на плоскости с эритроцитами групп А(II) 1:32 - 1: 64 и В(III) 1 : 64	

Цоликлон соответствует требованиям ТУ – 9398-101-51203590-2009
Заведующая
лабораторией ООО «Медиклон»
М.С.Орлова

ООО "Медиклон"

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

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)

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

Серия: 281411 **ОКП:** 93 9816

Годен: 11 декабря 2020 г. **Объем серии:** 10000 мл

Единица: 100 мл **Паспорт:** Т-18-11-90 от 19.11.2018

Количество единиц 50

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1. Внешний вид	Прозрачная слегка окрашенная жидкость	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 микропланшете не ниже 1:256	Соответствует 1:32 1:256

Соответствует требованиям ТУ - 9398-101-51203590-2009

Зав. лабораторией М.С. Орлова

ООО "Медиклон"

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

Наименование: Цоликлон Анти-АВ

Серия: 081211 **ОКП:** 93 9816

Годен: 1 ноября 2020 г. **Объем серии:** 10000 мл.

Единица: 100 мл **Паспорт:** Т-18-11-92 от 27.11.2018

Количество единиц 6

Наименование показателя	Характеристика нормы	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(II) и О(I)	Соответствует
2.2 Гемагглютинирующая способность	Цоликлон анти-АВ не должен давать агглютинации с эритроцитами группы О(I) 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 агглютинации 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 лабораторией ООО «Медиклон» М.С.Орлова

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

ПАСПОРТ-СЕРТИФИКАТ ПРОИЗВОДИТЕЛЯ

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

(ЦОЛИКЛОН Анти-Kell Супер)

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

Наименование: Цоликлон Анти-Kell Супер

Серия: 181711 **ОКП:** 93 9816

Годен: 1 ноября 2020 г. **Объем серии:** 10000 мл.

Единица: 100 мл **Паспорт:** Т-18-11-91 от 22.11.2018

Количество единиц 10

Наименование показателя	Характеристика нормы по ТУ	Результаты испытаний
1.Внешний вид	Прозрачная желтоватая или розоватая жидкость	Соответствует
2. Серологические свойства		
2.1 Специфичность	Цоликлон Анти-Kell супер не должен агглютинировать эритроциты К(-)	Соответствует
2.2 Гемагглютинирующая способность	Четкая реакция агглютинации на плоскости должна наступать в течение 30 сек. после смешивания	Соответствует
2.2 Активность	Титр Цоликлона Анти-Kell Супер в реакции прямой агглютинации в микроплате не ниже 1:16	Соответствует 1:16

Цоликлон соответствует требованиям ТУ 9398-101-51203590-2009

Заведующая лабораторией ООО «Медиклон»

М.С.Орлова

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

Helena Laboratories (UK) Ltd
trading as Helena Biosciences Europe
Queensway South
Team Valley Trading Estate
Gateshead
Tyne and Wear
NE11 0SD
United Kingdom

Holds Certificate Number: **MD 69326**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

For and on behalf of BSI:

Stewart Brain, Head of Compliance & Risk - Medical Devices

Original Registration Date: 2002-10-25
Latest Revision Date: 2018-11-28

Effective Date: 2018-04-14
Expiry Date: 2021-04-13

...making excellence a habit.

Certificate No: **MD 69326**

Location	Registered Activities
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Sunderland Enterprise Park Colima Avenue Sunderland SR5 3XB United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.
Helena Laboratories (UK) Ltd trading as Helena Biosciences Europe Queensway South Team Valley Trading Estate Gateshead Tyne and Wear NE11 0SD United Kingdom	The design, manufacture, supply, servicing and repair of in-vitro diagnostic devices, molecular biology products, immunochemistry products and medical laboratory equipment and consumables.

Original Registration Date: 2002-10-25
Latest Revision Date: 2018-11-28
Effective Date: 2018-04-14
Expiry Date: 2021-04-13

This certificate was issued electronically and remains the property of BSI and is bound by the conditions of contract.
An electronic certificate can be authenticated online.
Printed copies can be validated at www.bsigroup.com/ClientDirectory

Information and Contact: BSI, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes MK5 8PP. Tel: + 44 345 080 9000
BSI Assurance UK Limited, registered in England under number 7805321 at 389 Chiswick High Road, London W4 4AL, UK.
A Member of the BSI Group of Companies.

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

Declaration of Conformity

HL-7- 0512 DC DOI 2013/08 (4)

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
5556	Clauss Fibrinogen 50	55997
5556H	Clauss Fibrinogen 50	55997

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: 05 Aug 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- 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

Avantor Performance Materials Poland Spółka Akcyjna
Sowińskiego 11
44-101 Gliwice
Tel. 48 32 2392 000

Declaration of conformity

Avantor Performance Materials Poland S.A. who is an established manufacturer of reagents and products for diagnostic in vitro located at:

Sowińskiego 11 Street
44-101, Gliwice
Poland

Herewith declares the following:
Reagents mentioned in attached list are labeled with J.T.Baker label, comply with the In Vitro Diagnostic Medical Devices Directive 98/79/EC and the requirements of ISO 13485 Standard.
This declaration is the basic for CE marking of the In Vitro Diagnostic Medical Devices.
The products are not part of List A and List B of Annex II of the IVD Directive 98/79/EC but are subject to self registration.
This declaration is valid for all the IVD medical devices described above and which are placed on the market by ourselves on or after the date hereof and which bear the CE marking

Gliwice, Poland

January 25, 2019

Anna Szuba
Quality Director

NIP 631-010-13-07
Numer w KRS: 0000010108
Sąd rejestrowy: Sąd Rejonowy w Gliwicach
X Wydział Gospodarczy KRS
Kapitał zakładowy 2 360 793,00 zł
Regon: 271563380

J.T.Baker product list for CE marked products

Product	Product number		Pack size
Diluents			
Diluid™ 100 Plus	3961		20 L
Diluid™ 22	2990.9010PC		10 L
Diluid™ 610	3969		20 L
	3969-00		20 L
Diluid™ Abacus	3430.9020		20 L
	3430.9010		10 L
	3430-00		20 L
Diluid™ AC 900	3996		20 L
Diluid™ APR	3476.9020PC		20 L
Diluid™ Azide free	3957		20 L
Diluid™ III Diff	3963		20 L
	3963.9010		10 L
	3963-00		20 L
Diluid™ Erma	3459.9020		20 L
	3459-00		20 L
Diluid™ Mindray	3439.9020PC		20 L
	3439-00		20 L
Diluid™ NR	3483.9020PC		20 L
	3483-00		20 L
Diluid™ Ruby	2987.9020PC		20 L
Diluid™/Sheath 3200-4000	3832.9020		20 L
Diluid™ ST1600/2000	3976		20 L
Sheath D	3495.9010PC		10 L
Sheath Fluid 3000/3500	3471.9020PC		20 L
Lysers			
CN-free Lyse Diff AC 900	3998		5 L
CyMet™ 22 CN Free	2986.0500PE		500 ml
CyMet™ 3000	3469.9010PC		10 L
CyMet™ 3200 CN free	3823.1000		1 L
CyMet™ 3500	3839.5000PC		5 L
CyMet™ 3500 CN free	3825		5 L
CyMet™ 610 CN free	3970		10 L
	3970-00		10 L
	3977		5 L
CyMet™ Abacus CN free	3431.1000		1 L
	3431-00		1 L
CyMet™ APR Baso II	3479.1000PE		1 L
CyMet™ APR CN free	3417.0500PE		500 ml
CyMet™ APR EO	3478.1000PE		1 L
CyMet™ ASA	2950.2500PE		2.5 L
CyMet™ ASB	2951.0500PE		500 ml
CyMet™ AS CN free	2952.9010PC		10 L
CyMet™ BS3 CN free	2982.0500PE		500 ml
CyMet™ III Diff	3968		1 L
	3968-00		500 ml
CyMet™ III Diff CN free	3511.1000		1 L
	3511-00		5 L
CyMet™ Erma	3416-00		500 ml
	3416.0500		500 ml
CyMet™ H20	3853.1000		1 L
CyMet™ KX CN Free	3425-00		500 ml
	3425.0500		500 ml
CyMet™ Micro	3852.1000		1 L
CyMet™ Micro CN free	3863.1000		1 L micros
	3863-00		1 L micros
CyMet™ Mindray	3441-00		500 ml
CyMet™ Mindray CN Free	3440.0500PE		500 ml

J.T.Baker product list for CE marked products

Product	Product number		Pack size
CyMet™ NR III	3484.1000PE		1 L
CyMet™ NR III CN Free	3486-00		1 L
	3486.1000PE		1 L
CyMet™ NR V	3485.1000PE		1 L
CyMet™ Ruby CN Free	2988.5000PC		5 L
CyMet™ ST 1600/2000 CN free	3759.5000		5 L
LeucoLyse	3475.5000PC		5 L
LeucoLyse Ruby	2989.5000PC		5 L
Cleaners			
Blanking Solution 1600/2000	3947		20 L
DetectoTerge™	3763		5 L
	3766		1 L
DetectoTerge™ BS	2970.0900PE		900 ml
ProClean™	3900		5 L
	3900-00		5 L
	3768.1000		1 L micros
ProClean™ Abacus	3432.5000		5 L
	3432.1000PE		1 L
ProClean™ CD	3902.0100PE		100 ml
ProClean™ Extra	3862.5000		5 L
	3862.9020PC		20 L
	3862-00		5 L
	3867-00		1 L micros
	3867.1000PE		1 L micros
ProClean™ Plus	3901		100 ml
Rinse Mindray	3442.5000PE		5 L
Hematology Controls			
8-Parameter Control L/N/H	3427/3428/3429		2.5 ml
	3463/3464/3465		2.5 ml
8-Parameter Control 4xN	3747		4 x 2.5 ml
8-Parameter Control 1xL+4xN+1xH	3751		6 x 2.5 ml
8-Parameter Control extended L/N/H	3633/3634/3635		2.5 ml
3-Diff Control L/N/H	3433/3434/3435		2.5 ml
	3502/3503/3504		4.5 ml
3-Diff Control extented L/N/H	3421/3422/3423		2.5 ml
CD-Diff Control L/N/H	3452/3453/3454		3.0 ml
CD-Diff Control 2xL+2xN+2xH	3838		6 x 3.0 ml
K-Diff Control L/N/H	3455/3456/3457		2.5 ml
Platelet Control- Extended value	3424		5 x 3.0 ml
WBC Reduced RBC L/H	3698/3699		3.0 ml
XE-Diff Control L/N/H	3731/3732/3733		4.5 ml
Fixatives			
Cervix Spray Fixative	3869.1200		12 x 125 ml
10% v/v Buffered Formaldehyde (4% w/v)	3933.1000		1 L
	3933.5000PC		5 L
	3933.9010		10 L
	3933.9020		20 L
	3933.1000MB		1000 L
	3933.9020PE		20 L
	3933.9010JL		10 L
	3933.9020JL		20 L
Cleaning agents			
UltraClear™	3905.2500PE		2.5 L
	3905.5000PE		5 L
	3905.9010PE		10 L

J.T.Baker product list for CE marked products

Product	Product number	Pack size
Stains and Dyes		
Eosin-Y Alcoholic	3800.1000PE	1 L
	3800.2500PE	2.5 L
Giemsa	3856,1000	1 L
	3856,2500	2.5 L
	3856.9180ST	180 L
Hematoxylin er (Mayer)	3870,1000	1 L
	3870,2500	2.5 L
Hematoxylin Modified (Harris, Gill II)	3873,1000	1 L
	3873,2500	2.5 L
May-Grünwald	3855,1000	1 L
	3855,2500	2.5 L
Papanicolaou 2A	3554.1000PE	1 L
	3554.2500PE	2.5 L
Papanicolaou 2B	3555.1000PE	1 L
	3555,2500PE	2,5 L
Papanicolaou 3B	3556,1000PE	1 L
	3556.2500PE	2.5 L
Mounting media		
UltraKitt™	3921,0500	500 ml
	3921,0600	6 x 100 ml
	3921,9025ST	25 L
Mounting medium High	3882,0500	500 ml
Mounting medium Low	3883,0500	500 ml
PBS		
PBS	3059	20 L
	3059.9010PC	10 L

BeneSphera™
3 PART
DIFFERENTIAL
Hematology Analyzer

BeneSphera TRAINING

Mr /-Ms **Sergiu Sorocovici**

Global Biomarketing Group

str. Tighina 65, of. 607

2001 Chisinau, Moldau

has attended a 2-days training on goods manufactured or distributed by us.

April 12th – April 13th, 2012

Deventer, The Netherlands

Place, Date 13.04.2012

BeneSphera | AVANTOR

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