Instructions For Use
ENGLISH

Phenol Red Broth Base

Liquid medium for carbohydrate fermentation studies.

DESCRIPTION

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

TYPICAL FORMULA	(g/l)
Casein Peptone	10.0
Meat Extract	3.0
Sodium Chloride	5.0
Phenol Red	0.018

Final pH 7.4 ± 0.2 at 25°C

METHOD PRINCIPLE

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

PREPARATION

Dehydrated medium

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

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

Medium in tubes

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

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

TEST PROCEDURE

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

INTERPRETING RESULTS

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

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

APPEARANCE

Dehydrated medium: free-flowing, homogeneous, pinkish-beige.
Prepared medium: clear, bright red to red-orange.

STORAGE

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

SHELF LIFE

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

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: ≤100 CFU.
Incubation conditions: 18-48 h / 35 ± 2°C.

QC Table.

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

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

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

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

TABLE OF SYMBOLS

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

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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	Contenuto sufficiente per <n> saggi	Attenzione, Consultare le istruzioni per l'uso	Non riutilizzare

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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.

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

For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

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

REFERENCES

- 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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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	Consult instructions for use	Manufacturer	Use by
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Keep away from sunlight

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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.

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

La norma 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

Solo per uso professionale. Gli operatori devono essere formati e avere una certa esperienza nei metodi di laboratorio. Si prega di leggere il attentamente le istruzioni prima di utilizzare questo prodotto. L'affidabilità dei risultati del test non può essere garantita in caso di deviazioni dalle istruzioni riportate in questo documento.

Consultare la scheda di sicurezza (SDS) per informazioni sui pericoli e sulle modalità di manipolazione sicure.

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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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	Consultare le istruzioni per l'uso	Fabbricante	Data di scadenza
REF Numero di catalogo	Limiti di temperatura	Contenuto sufficiente per <n> test	Tenere al riparo dalla luce del sole

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ENDO AGAR

Medium for coliforms confirmatory test.

TYPICAL FORMULA	(g/l)
Peptone	10.0
Lactose	10.0
Dipotassium Phosphate	3.5
Agar	15.0
Sodium Sulphite	2.5
Basic Fuchsin	0.5

Final pH = 7.5 ± 0.2 at 25 °C.

DIRECTIONS

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

DESCRIPTION

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

TECHNIQUE

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

QUALITY CONTROL

Dehydrated medium
Appearance: free-flowing, homogeneous.
Color: medium purple.
Prepared medium
Appearance: opalescent with precipitates.
Color: pink.
Incubation conditions: 36 ± 1 °C for 24 ± 2 hours.

Microorganism	ATCC	Growth	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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PEPTONE WATER

Medium for cultivation of non-fastidious microorganisms and indole testing as recommended by ISO 7251.

TYPICAL FORMULA	(g/l)
Peptone	10.0
Sodium Chloride	5.0
Final pH 7.2 ± 0.2 at 25°C	

DESCRIPTION

PEPTONE WATER is a medium for cultivation of non-fastidious microorganisms and indole testing as recommended by ISO 7251.

PRINCIPLE

Peptone provides carbon, nitrogen, vitamins and minerals for growth of non-fastidious microorganisms. Sodium chloride maintains the osmotic balance of the medium.

PREPARATION

Suspend 15.0 g of powder in 1 liter of distilled or deionized water. Heat until completely dissolved. Dispense into tubes. Autoclave at 121°C for 15 minutes. .

TECHNIQUE

Inoculate the tube with the sample. Incubate at 36 ± 1°C for 24 ± 3 hours. Incubation at 44°C for 24 hours is advisable for detecting the indole production in the confirmation test for fecal coliform or *E.coli*. After incubation add 1 ml of KOVAC'S Reagent (ref. 80271).

INTERPRETATION OF RESULTS

After the addition of KOVAC'S Reagent, observe for the formation of a red-violet ring into the tube indicating a positive test for indole production.

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.

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. he 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. ISO 7251. Microbiology-General guidance for the eumeration of E.coli – MPN technique (1993).
2. MacFaddin, J. F. (1985) Media for isolation-cultivation-identification-maintenance of medical bacteria, vol. 1, p. 610-612. Williams & Wilkins, Baltimore, MD.
3. Balows, A., W. J. Hausler, K. L. Herrmann, H. D. Isenberg, and H. J. Shadomy (eds.) (1991) Manual of clinical microbiology, 5th ed. American Society for Microbiology, Washington, D.C.
4. Finegold, S. M., and W. Martin (1982) Bailey and Scott's diagnostic microbiology, 6th ed. St. Louis.

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CE IVD

PRODUCT SPECIFICATIONS

NAME
PEPTONE WATER

PRESENTATION
Dehydrated powdered

STORAGE
10-30°C

PACKAGE

Ref.	Content	Packaging
610038	500 g	500 g of powder in plastic bottle
620038	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
7.2 ± 0.2

USE
PEPTONE WATER is a medium for cultivation of non-fastidious microorganisms and indole testing as recommended by ISO 7251

APPEARANCE OF THE MEDIUM
Dehydrated medium
Appearance: free-flowing, homogeneous
Colour: beige
Prepared medium
Appearance: clear to very slightly opalescent
Colour: light amber

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: 18-24 h at 35 ± 2°C

Microorganism	ATCC®	Growth	Indole Production
Escherichia coli	25922	Good	+
Klebsiella pneumoniae	13883	Good	-

TABLE OF SYMBOLS

LOT Batch code	IVD *In vitro* Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF Catalogue number	Temperature limitation	Contains sufficient for <n> tests	Consult instructions for use	Keep away from heat sources

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CE IVD

Tryptic Soy Agar

General purpose medium for the cultivation of a wide variety of organisms from clinical and nonclinical specimens, according to EN ISO 11133.

DESCRIPTION

Tryptic Soy Agar (TSA) is a non selective isolation medium used for the growth of bacteria which do not have specific nutritional requirements and for the preparation of reference strains with the aim of growth promotion tests of culture media.

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 and qualitative testing of specific culture media.

Tryptic Soy Agar is also recommended in the harmonized chapters of the United States (USP), European (EP) and Japanese Pharmacopoeia (JP). For the usage in Pharmaceutical Industry, Liofilchem offers products having the same composition as TSA described in the ISO standard, but which are specifically controlled according to the Pharmacopoeial performance requirements. **See the IFU available for the product ref. number 10037S**.

TYPICAL FORMULA	(g/l)
Casein Peptone	15.0
Soy Peptone	5.0
Sodium Chloride	5.0
Agar	15.0

Final pH 7.3 ± 0.2 at 25°C

METHOD PRINCIPLE

Casein peptone and soy peptone provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Sodium chloride maintains osmotic balance in the medium. Agar is the solidifying agent.

The medium can be supplemented with blood for the growth of fastidious organisms and study of haemolytic reactions.

PREPARATION

Dehydrated medium	Suspend 40 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. If desired, add appropriate volume of sterile defibrinated blood for preparing 5 to 10% blood agar.
Medium in tubes/ bottles	Melt the content of the tube/bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the tube/bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

Perform serial dilutions of the test sample in order to achieve a colony count of between 15 and 300 colonies per plate. Use a suitable diluent such as Buffered Peptone Water (ref. 24099) or Maximum Recovery Broth (ref. 20071).

Inoculate the medium by pour plating, spread/streak method or membrane filtration.

Incubation conditions may vary depending on the organisms under study. For a general aerobic count, incubate aerobically at 30°C for 72 hours.

For use as standard medium, refer to EN ISO 11133 for specific instructions.

INTERPRETING RESULTS

Observe colony growth.

APPEARANCE

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

STORAGE

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

SHELF LIFE

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

QUALITY CONTROL

The medium is inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU.
Incubation conditions: set according to EN ISO 11133 and shown on the quality control certificate that is available for each lot on liofilchem's website.

QC Table.

Microorganism		Growth
Listeria monocytogenes 4b	WDCM 00021	Good
Staphylococcus aureus	WDCM 00034	Good
Clostridium perfringens	WDCM 00007	Good
Bacillus cereus	WDCM 00001	Good
Escherichia coli	WDCM 00012	Good
Bacillus subtilis	WDCM 00003	Good
Pseudomonas aeruginosa	WDCM 00024	Good
Enterococcus faecalis	WDCM 00087	Good

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is intended for professional use 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. United States Pharmacopoeia 41 NF 33 (2018) <61> Microbiological examination of non-sterile products: Microbial enumeration tests; <1116> Microbiological control and monitoring of aseptic processing environments.
3. European Pharmacopoeia 9.0 (2016) 2.6.12. Microbiological examination of non-sterile products: Microbial enumeration tests.
4. Japanese Pharmacopoeia 16th ed. (2011): 4.05 Microbial limit test.
5. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.
6. Vanderzant C. and D.F. Splittstoesser (1992) Compendium of methods for the microbiological examination of foods, 3rd ed. American Public Health Association, Washington D.C.
7. Greenberg A.E, L.S. Clesceri and A.D. Eaton (1995) Standards methods for the examination of water and wastewater, 19th ed. American Public Health Association, Washington D.C.

PRESENTATION	Format	Packaging	Ref.
Tryptic Soy Agar	90 mm Plate	20 plates	10037
Tryptic Soy Agar	90 mm Plate	100 plates	10037*
Tryptic Soy Agar	60 mm Plate (membrane placement)	20 plates	163682 ◆
Tryptic Soy Agar	Slant tubes	10 x 9 ml tubes	30082
Tryptic Soy Agar	Slant tubes	20 x 9 ml tubes	31082
Tryptic Soy Agar	Tubes	100 x 20 ml tubes	26475
Tryptic Soy Agar	Bottles	6 x 500 ml bottles	470010
Tryptic Soy Agar	Bottles	6 x 225 ml bottles	414110 ◆
Tryptic Soy Agar	Bottles	6 x 200 ml bottles	432290
Tryptic Soy Agar	Bottles	25 x 200 ml bottles	452290
Tryptic Soy Agar	Bottles	6 x 100 ml bottles	442290
Tryptic Soy Agar	Dehydrated media	500 g of powder	610052
Tryptic Soy Agar	Dehydrated media	100 g of powder	620052
Tryptic Soy Agar	Dehydrated media	5 kg of powder	6100525

◆, 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	Contains sufficient for <n> tests	Caution, consult Instruction For Use	Do not reuse

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CE IVD

Istruzioni per l'uso
ITALIANO

Tryptic Soy Agar

Terreno multiuso per la coltivazione di un'ampia varietà di microrganismi da campioni clinici e non clinici, secondo ISO 11133.

DESCRIZIONE

Tryptic Soy Agar (TSA) è un terreno non selettivo utilizzato per la crescita di batteri che non presentano requisiti nutrizionali specifici e per la preparazione di ceppi microbici di riferimento per i test di controllo qualità (growth promotion) dei terreni di coltura.

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 a qualitativi su terreni di coltura specifici.

Tryptic Soy Agar è anche raccomandato nei capitoli armonizzati delle Farmacopee Statunitense (USP), Europea (EP) e Giapponese (JP). Per l'utilizzo nell'Industria Farmaceutica, Liofilchem offre prodotti formulati esattamente come il TSA descritto nella norma ISO, ma che vengono controllati secondo i requisiti di performance specifici stabiliti dalla Farmacopea. **Consultare la Scheda Tecnica disponibile per il prodotto con numero di catalogo 10037S**.

FORMULA TIPICA	(g/l)
Peptone di Caseina	15.0
Peptone di Soia	5.0
Sodio Cloruro	5.0
Agar	15.0

pH Finale 7.3 ± 0.2 a 25°C

PRINCIPIO DEL METODO

Peptone di caseina e peptone di soia forniscono aminoacidi, azoto, carbonio, minerali, vitamine ed altri nutrienti che supportano la crescita dei microrganismi. Il sodio cloruro mantiene il bilancio osmotico del terreno. L'agar è l'agente solidificante.

Si può aggiungere il sangue nella preparazione del terreno per favorire la crescita dei microrganismi esigenti ed osservare le reazioni emolitiche.

PREPARAZIONE

Terreno disidratato	Sospendere 40 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. Se lo si di desidera, aggiungere il volume appropriato di sangue sterile defibrinato per la preparazione di piastre contenenti dal 5 al 10% di sangue.
Terreno in provette/ flaconi	Sciogliere il contenuto di una provetta/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 la provetta/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

Preparare diluizioni seriali del campione da testare in modo da ottenere un numero di colonie per piastra compreso tra 15 e 300. Utilizzare un diluente adatto come ad esempio Buffered Peptone Water (ref. 24099) o Maximum Recovery Broth (ref. 20071).

Inoculare il terreno per inclusione, spatolamento/striscio o mediante filtrazione su membrana.

Le condizioni di incubazione possono variare in base agli organismi investigati. Per una conta aerobica generale, incubare a 30°C per 72 ore in atmosfera aerobica.

Per l'utilizzo come terreno standard, far riferimento ad EN ISO 11133 per istruzioni specifiche.

INTERPRETAZIONE DEI RISULTATI

Osservare la crescita delle colonie.

ASPETTO

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

CONSERVAZIONE

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

VALIDITÀ

Terreno disidratato: 4 anni.
Terreno in provette/flaconi: 2 anni.
Terreno in provette a becco di clarino: 1 anno.
Piastre pronte all'uso: 6 mesi.

CONTROLLO DI QUALITÀ

Il terreno viene inoculato con i ceppi microbici indicati nella tabella CQ.
Inoculo per produttività: 50-100 UFC.
Condizioni di incubazione: stabilite secondo EN ISO 11133 e riportate nel certificato di controllo qualità di ciascun lotto.

Tabella CQ.

Microrganismo		Crescita
Listeria monocytogenes 4b	WDCM 00021	Buona
Staphylococcus aureus	WDCM 00034	Buona
Clostridium perfringens	WDCM 00007	Buona
Bacillus cereus	WDCM 00001	Buona
Escherichia coli	WDCM 00012	Buona
Bacillus subtilis	WDCM 00003	Buona
Pseudomonas aeruginosa	WDCM 00024	Buona
Enterococcus faecalis	WDCM 00087	Buona

AVVERTENZE E PRECAUZIONI

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

SMALTIMENTO DEI RIFIUTI

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

BIBLIOGRAFIA

1. EN ISO 11133:2014+Amd1:2018. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. United States Pharmacopoeia 41 NF 33 (2018) <61> Microbiological examination of non-sterile products: Microbial enumeration tests; <1116> Microbiological control and monitoring of aseptic processing environments.
3. European Pharmacopoeia 9.0 (2016) 2.6.12. Microbiological examination of non-sterile products: Microbial enumeration tests.
4. Japanese Pharmacopoeia 16th ed. (2011): 4.05 Microbial limit test.
5. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.
6. Vanderzant C. and D.F. Splittstoesser (1992) Compendium of methods for the microbiological examination of foods, 3rd ed. American Public Health Association, Washington D.C.
7. Greenberg A.E, L.S. Clesceri and A.D. Eaton (1995) Standards methods for the examination of water and wastewater, 19th ed. American Public Health Association, Washington D.C.

PRESENTAZIONE	Formato	Confezionamento	Ref.
Tryptic Soy Agar	Piastre 90 mm	20 piastre	10037
Tryptic Soy Agar	Piastre 90 mm	100 piastre	10037*
Tryptic Soy Agar	Piastre 60 mm (posizionamento membrana)	20 piastre	163682 ◆
Tryptic Soy Agar	Provette a becco di clarino	Provette 10 x 9 ml	30082
Tryptic Soy Agar	Provette a becco di clarino	Provette 20 x 9 ml	31082
Tryptic Soy Agar	Provette	Provette 100 x 20 ml	26475
Tryptic Soy Agar	Flaconi	Flaconi 6 x 500 ml	470010
Tryptic Soy Agar	Flaconi	Flaconi 6 x 225 ml	414110 ◆
Tryptic Soy Agar	Flaconi	Flaconi 6 x 200 ml	432290
Tryptic Soy Agar	Flaconi	Flaconi 25 x 200 ml	452290
Tryptic Soy Agar	Flaconi	Flaconi 6 x 100 ml	442290
Tryptic Soy Agar	Terreni disidratati	500 g di polvere	610052
Tryptic Soy Agar	Terreni disidratati	100 g di polvere	620052
Tryptic Soy Agar	Terreni disidratati	5 kg di polvere	6100525

◆, non marcato CE

TABELLA DEI SIMBOLI

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

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CE IVD

Instrucciones de Uso
ESPAÑOL

Tryptic Soy Agar

Medio genérico para el cultivo de una amplia variedad de organismos a partir de muestras clínicas o no clínicas según EN ISO 11133.

DESCRIPCIÓN

Tryptic Soy Agar (TSA) es un medio no selectivo utilizado para el crecimiento de bacterias que no tienen requisitos nutritivos específicos y para la preparación de cepas de referencia con el objetivo de realizar pruebas de crecimiento en medios de cultivo.

Este medio sigue la EN ISO 11133 para el análisis microbiológico de alimentos para humanos o animales y agua, donde se describe como el principal medio para realizar pruebas cuantitativas y cualitativas de medios de cultivo específicos.

Tryptic Soy Agar también es recomendado en los capítulos armonizados de la Farmacopea de los Estados Unidos (USP), Farmacopea Europea (EP) y Farmacopea Japonesa (JP). Para el uso en la Industria Farmacéutica, Liofilchem ofrece productos que tienen la misma composición que la TSA descrita en el estándar ISO, pero que se han controlado específicamente según los requisitos de rendimiento de la Farmacopea. **Consultar la Ficha Técnica disponible para el producto con número de catálogo 10037S**.

FÓRMULA	(g/l)
Peptona de Caseína	15.0
Peptona de Soja	5.0
Cloruro Sódico	5.0
Agar	15.0

pH final 7.3 ± 0.2 a 25°C

PRINCIPIO DEL MÉTODO

La peptona de caseína y la peptona de soja suministran los aminoácidos, nitrógeno, carbono, vitaminas y minerales necesarios para el crecimiento de los microorganismos. El cloruro sódico mantiene el equilibrio osmótico del medio. El agar es el agente solidificante.

A este medio se le pueden añadir suplementos con sangre para el crecimiento de organismos exigentes y el estudio de reacciones hemolíticas.

PREPARACIÓN

Medio deshidratado	Suspender 40g del polvo deshidratado en 1 litro de agua destilada o desionizada. Mezclar bien. Calentar hasta la ebullición removiendo frecuentemente hasta la completa disolución. Esterilizar en autoclave a 121°C durante 15 minutos. Si lo desea, añada la cantidad necesaria de sangre defibrinada estéril para preparar agar sangre al 5 o 10%
Medio en tubos/ botellas	Disolver el contenido de la botella en un baño con agua a 100°C (con el tapón ligeramente desenrroscado) hasta su completa disolución. Comprobar la homogeneidad del medio disuelto, girar la botella si es necesario para ayudar a la homogeneización. Enfriar a 45-50°C, mezclar bien evitando la formación de burbujas y distribuir en placas Petri de forma aséptica.

PROCEDIMIENTO DEL TEST

Realizar diluciones en serie de la muestra a analizar hasta conseguir un contaje microbiano de entre 15 y 300 colonias por placa. Utilizar un diluyente adecuado como Buffered Peptone Water (ref. 24099) o Maximum Recovery Broth (ref. 20071).

Inocular el medio vertiendo la muestra, por estriación/extensión o con el método de filtración por membrana.

Las condiciones de incubación pueden variar dependiendo de los organismos a analizar. Para un contaje total genérico aeróbico, incubar en aerobiosis a 30°C durante 72 horas.

Para utilizar como medio estándar, siga la EN ISO 11133 para instrucciones detalladas.

INTERPRETACIÓN DE LOS RESULTADOS

Observe el crecimiento de las colonias.

ASPECTO

Medio deshidratado: suelto, homogéneo, beige claro.
Medio preparado: ligeramente opalescente, ámbar claro

ALMACENAMIENTO

El polvo deshidratado es muy higroscópico, almacenar a 10-30°C, en un entorno seco, en su frasco original correctamente cerrado. Almacenar las botellas y las placas preparadas a 10-25°C fuera del contacto de la luz. No utilizar el producto fuera de la fecha de caducidad descrita en la etiqueta o si el producto presenta alguna muestra de deterioro o contaminación.

VIDA ÚTIL

Medio deshidratado: 4 años.
Medio en tubos/botellas: 2 años.
Medio en tubos semitendidos: 1 año
Placas preparadas: 6 meses.

CONTROL DE CALIDAD

Las placas se inoculan con las cepas indicadas en la siguiente tabla.
Inóculo para productividad: 50-100 CFU.
Condiciones de incubación: fijadas de acuerdo a EN ISO 11133; se muestran en el certificado de CC de cada lote.

Tabla CC.

Microorganismo		Crecimiento
Listeria monocytogenes 4b	WDCM 00021	Bueno
Staphylococcus aureus	WDCM 00034	Bueno
Clostridium perfringens	WDCM 00007	Bueno
Bacillus cereus	WDCM 00001	Bueno
Escherichia coli	WDCM 00012	Bueno
Bacillus subtilis	WDCM 00003	Bueno
Pseudomonas aeruginosa	WDCM 00024	Bueno
Enterococcus faecalis	WDCM 00087	Bueno

ADVERTENCIAS Y PRECAUCIONES

Este producto no contiene sustancias peligrosas en concentraciones que excedan los límites fijados por la legislación actual y no está clasificado como peligroso. Se recomienda de todas formas las lectura de la hoja de seguridad para el uso apropiado. El producto está pensado para un uso exclusivo de diagnóstico in vitro y debe ser utilizado sólo por operadores debidamente adiestrados.

DESECHO DE RESÍDUOS

El desecho de los resíduos debe realizarse según la regulación nacional y local vigente.

BIBLIOGRAFÍA

1. EN ISO 11133:2014+Amd1:2018. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. United States Pharmacopoeia 41 NF 33 (2018) <61> Microbiological examination of non-sterile products: Microbial enumeration tests; <1116> Microbiological control and monitoring of aseptic processing environments.
3. European Pharmacopoeia 9.0 (2016) 2.6.12. Microbiological examination of non-sterile products: Microbial enumeration tests.
4. Japanese Pharmacopoeia 16th ed. (2011): 4.05 Microbial limit test.
5. Swanson, K.J., F.F. Busta, E.H. Peterson, and M.G. Johnson (1992). Colony Count Methods, p. 75-95.
6. Vanderzant C. and D.F. Splittstoesser (1992) Compendium of methods for the microbiological examination of foods, 3rd ed. American Public Health Association, Washington D.C.
7. Greenberg A.E, L.S. Clesceri and A.D. Eaton (1995) Standards methods for the examination of water and wastewater, 19th ed. American Public Health Association, Washington D.C.

PRESENTACIÓN	Formato	Embalaje	Ref.
Tryptic Soy Agar	Placa 90 mm	20 placas	10037
Tryptic Soy Agar	Placa 90 mm	100 placas	10037*
Tryptic Soy Agar	Placa 60 mm (colocación de membrana)	20 placas	163682 ◆
Tryptic Soy Agar	Tubos semitendidos	10 x 9 ml tubos	30082
Tryptic Soy Agar	Tubos semitendidos	20 x 9 ml tubos	31082
Tryptic Soy Agar	Tubos	100 x 20 ml tubos	26475
Tryptic Soy Agar	Botellas	6 x 500 ml botellas	470010
Tryptic Soy Agar	Botellas	6 x 225 ml botellas	414110 ◆
Tryptic Soy Agar	Botellas	6 x 200 ml botellas	432290
Tryptic Soy Agar	Botellas	25 x 200 ml botellas	452290
Tryptic Soy Agar	Botellas	6 x 100 ml botellas	442290
Tryptic Soy Agar	Medios deshidratados	500 g de polvo	610052
Tryptic Soy Agar	Medios deshidratados	100 g de polvo	620052
Tryptic Soy Agar	Medios deshidratados	5 kg de polvo	6100525

◆, no marcado CE

TABLA DE SÍMBOLOS

LOT Código de lote	**IVD** Diagnóstico In vitro Sistema médico	Fabricante	Utilizar antes de	Frágil, manipular con cuidado
REF Número de catálogo	Límites de temperatura	Contenido suficiente para <n> análisis	Atención, consultar el documento adjunto	No reutilizar

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CE IVD

Slanetz Bartley Agar Base

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

TYPICAL FORMULA	(g/l)
Tryptose	20.0
Yeast Extract	5.0
Glucose	2.0
Dipotassium Hydrogen Phosphate	4.0
Sodium Azide	0.4
Agar	13.0
Final pH 7.2 ± 0.2 at 25°C	

DESCRIPTION

Slanetz Bartley Agar Base is a selective medium used with supplement for isolating and enumerating enterococci from environmental samples of sanitary importance and clinical specimens.

This medium complies with ISO 7899-2 for the detection of intestinal enterococci in water by the membrane filtration technique.

PRINCIPLE

Tryptose provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Glucose is the fermentable carbohydrate. Sodium phosphate acts as buffer. Sodium azide is the selective agent suppressing the growth of Gram-negative bacteria. Agar is the solidifying agent.

Supplementation with TTC 1% Supplement serves to add triphenyl tetrazolium chloride (TTC) as indicator of bacterial growth.

PREPARATION

Suspend 44.4 g of powder in 1 liter of deionized or distilled water. Bring to boil and shake until completely dissolved. Sterilize at 121°C for 15 minutes. Cool up to 45-50°C. Aseptically, add 10 ml of TTC 1% Supplement (ref. 80300). Mix well. 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 and incubate aerobically at 36 ± 2°C for 40-48 hours.

Alternatively, sample can be inoculated by spread plating, pour plating or by direct streaking on the medium surface.

INTERPRETATION OF RESULTS

Count all raised colonies which show a red, maroon or pink color as enterococci.

Confirm by subculturing to Bile Aesculin Azide Agar (ref. 163572).

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.
- 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
Slanetz Bartley Agar Base

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

Ref.	Content	Packaging
610134	500 g	500 g of powder in plastic bottle
620134	100 g	100 g of powder in plastic bottle

pH OF THE MEDIUM
7.2 ± 0.2

USE
Slanetz Bartley Agar Base is a selective medium used with supplement for isolating and enumerating 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: light beige
Ready-to-use medium
Appearance: slightly opalescent
Colour: light amber

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: 44-48 h at 36 ± 2°C, in aerobiosis

Microorganism		Growth	Colony color
Enterococcus faecalis	WDCM 00009	Good	Red-maroon-pink
Enterococcus faecium	WDCM 00177	Good	Red-maroon-pink
Escherichia coli	WDCM 00013	Inhibited	---
Staphylococcus aureus	WDCM 00034	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

Slanetz Bartley Agar Base

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

FORMULA TIPICA	(g/l)
Triptose	20.0
Estratto di Lievito	5.0
Glucosio	2.0
Sodio Fosfato Bibasico	4.0
Sodio Azide	0.4
Agar	13.0
pH Finale 7.2 ± 0.2 a 25°C	

DESCRIZIONE

Slanetz Bartley Agar Base è un terreno selettivo utilizzato con supplementi 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 ricerca degli enterococchi intestinali nelle acque con la tecnica delle membrane filtranti.

PRINCIPIO

Triptose fornisce aminoacidi, azoto, carbonio, vitamine e minerali per la crescita dei microrganismi. L'estratto di lievito è una fonte di vitamine, sopratutto del gruppo-B. Il glucosio è il carboidrato fermentabile. Il sodio fosfato agisce da tampone. Il sodio azide è l'agente selettivo che sopprime la crescita dei batteri Gram negativi. L'agar è l'agente solidificante.

TTC 1% Supplement contenente trifeniltetrazolio cloruro (TTC) viene aggiunto al terreno come indicatore di crescita batterica.

PREPARAZIONE

Sospendere 44.4 g di polvere in 1 litro di acqua deionizzata o distillata. Portare ad ebollizione ed agitare fino a completa dissoluzione. Sterilizzare a 121°C per 15 minuti. Raffreddare a 45-50°C. In condizioni asettiche, aggiungere 10 ml di TTC 1% Supplement (ref. 80300). Miscelare bene. 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 ed incubare a 36 ± 2°C per 40-48 ore in atmosfera aerobica.

In alternativa, il campione può essere inoculato per spatolamento, inclusione o per striscio diretto sulla superficie del terreno.

INTERPRETAZIONE DEI RISULTATI

Contare e considerare enterococchi tutte le colonie rialzate che appaiono rosse, marroni o rosa.

Confermare con sub-coltura su Bile Aesculin Azide Agar (ref. 163572).

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 contiene sostanze nocive ed è classificato come pericoloso. Si consiglia di consultare la scheda di sicurezza per il suo corretto impiego. 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. 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
Slanetz Bartley Agar Base

PRESENTAZIONE
Terreno disidratato

CONSERVAZIONE
10-30°C

CONFEZIONAMENTO

Ref.	Contenuto	Confezionamento
610134	500 g	500 g in flacone di plastica
620134	100 g	100 g in flacone di plastica

pH DEL TERRENO
7.2 ± 0.2

IMPIEGO
Slanetz Bartley Agar Base è un terreno selettivo utilizzato con supplementi per l'isolamento 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 chiaro
Terreno pronto all'uso
Aspetto: leggermente opalescente
Colore: ambra chiaro

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: 44-48 h a 36 ± 2°C, in aerobiosi

Microrganismo		Crescita	Colore colonie
Enterococcus faecalis	WDCM 00009	Buona	Rosso-marrone-rosa
Enterococcus faecium	WDCM 00177	Buona	Rosso-marrone-rosa
Escherichia coli	WDCM 00013	Inibita	---
Staphylococcus aureus	WDCM 00034	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	Contenuto sufficiente per <n> test	Attenzione, consultare le istruzioni per l'uso	Non riutilizzare

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CE IVD

Instructions For Use
ENGLISH

Yeast Extract Agar

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

DESCRIPTION

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

TYPICAL FORMULA	(g/l)
Enzymatic Digest of Casein	6.0
Yeast Extract	3.0
Agar	15.0
Final pH 7.2 ± 0.2 at 25°C	

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Agar is the solidifying agent.

PREPARATION

Dehydrated medium	Suspend 24 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.
Medium in tubes/bottles	Melt the content of the tube/bottle in a water bath at 100°C (loosing the cap partially removed) until completely dissolved. Then screw the cap and check the homogeneity of the dissolved medium, if it is the case turning the tube/bottle upside down. Cool at 45-50°C, mix well avoiding foam formation and aseptically distribute into Petri dishes.

TEST PROCEDURE

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

INTERPRETING RESULTS

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

APPEARANCE

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

STORAGE

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

SHELF LIFE

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

QUALITY CONTROL

Plates are inoculated with the microbial strains indicated in the QC table.
Inoculum for productivity: 50-100 CFU
Incubation conditions: aerobically at 36 ± 2°C for 40-48 hours.

QC Table.

Microorganism		Growth
Escherichia coli	WDCM 00012	Good
Bacillus subtilis	WDCM 00003	Good

WARNING AND PRECAUTIONS

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

DISPOSAL OF WASTE

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

BIBLIOGRAPHY

1. EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. ISO 6222:2009. Water quality –Enumeration of culturable microorganisms – Colony count technique by inoculation in a nutrient agar culture medium.

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

TABLE OF SYMBOLS

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

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Istruzioni per l'uso
ITALIANO

Yeast Extract Agar

Terreno nutriente per il conteggio dei microrganismi nell'acqua e materiali di importanza sanitaria, secondo ISO 6222.

DESCRIZIONE

Yeast Extract Agar è un terreno nutriente utilizzato per la determinazione della conta microbica totale in tutti i tipi di acqua secondo le raccomandazioni in ISO 6222.

FORMULA TIPICA	(g/l)
Digerito Enzimatico di Caseina	6.0
Estratto di Lievito	3.0
Agar	15.0
pH Finale 7.2 ± 0.2 a 25°C	

PRINCIPIO DEL METODO

Il digerito enzimatico di caseina fornisce aminoacidi, azoto, carbonio, vitamine e minerali per la crescita degli organismi. L'estratto di lievito è una fonte di vitamine, sopratutto del gruppo-B. L'agar è l'agente solidificante.

PREPARAZIONE

Terreno disidratato	Sospendere 24 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 provette/flaconi	Sciogliere il contenuto di una provetta/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 la provetta/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

1. Preparare diluizioni del campione tenendo in considerazione il grado di inquinamento atteso.
2. Inoculare il terreno (due serie di piastre per ciascun campione) per inclusione o con il metodo delle membrane filtranti.
3. Incubare una serie di piastre at 36 ± 2°C per 40-48 ore e l'altra serie a 22 ± 2°C per 64-72 ore.

INTERPRETAZIONE DEI RISULTATI

Contare le colonie su ciascuna piastra (eliminare le piastre che presentano una crescita a confluenza) ed esprimere i risultati come UFC/ml di campione tenendo conto del fattore di diluizione.

ASPETTO

Terreno disidratato: omogeneo, fine granulometria, beige.
Terreno preparato: ambra, leggermente opalescente.

CONSERVAZIONE

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

VALIDITÀ

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

CONTROLLO DI QUALITÀ

Le piastre vengono inoculate con i ceppi microbici indicati nella tabella CQ.
Inoculo per produttività: 50-100 UFC.
Condizioni di incubazione: ambiente aerobico a 36 ± 2°C per 40-48 ore.

Tabella CQ.

Microrganismo		Crescita
Escherichia coli	WDCM 00012	Buona
Bacillus subtilis	WDCM 00003	Buona

AVVERTENZE E PRECAUZIONI

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

SMALTIMENTO DEI RIFIUTI

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

BIBLIOGRAFIA

1. EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. ISO 6222:2009. Water quality –Enumeration of culturable microorganisms – Colony count technique by inoculation in a nutrient agar culture medium.

PRESENTAZIONE		Contenuto	Ref.
Yeast Extract Agar	Piastre da 60 mm pronte all'uso	20 piastre	163582
Yeast Extract Agar	Provette	Provette 20 x 22 ml	34074
Yeast Extract Agar	Provette	Provette 100 x 22 ml	26074
Yeast Extract Agar	Provette a becco di clarino	Provette 10 x 9 ml	31102
Yeast Extract Agar	Flaconi	Flaconi 6 x 200 ml	412120
Yeast Extract Agar	Flaconi	Flaconi 6 x 100 ml	403120
Yeast Extract Agar	Terreno disidratato	500 g di polvere	611016
Yeast Extract Agar	Terreno disidratato	100 g di polvere	621016

TABELLA DEI SIMBOLI

LOT Codice del lotto	Tenere al riparo dalla luce	Fabbricante	Utilizzare entro	Fragile, maneggiare con cura
REF Numero di catalogo	Limiti di temperatura	Contenuto sufficiente per <n> saggi	Attenzione, Consultare le istruzioni per l'uso	Non riutilizzare

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Instrucciones de Uso
ESPAÑOL

Yeast Extract Agar

Medio nutritivo para el contaje de microorganismos en agua y materiales de importancia sanitaria según la ISO 6222.

DESCRIPCIÓN

Yeast Extract Agar es un medio nutritivo utilizado para el contaje de la carga micróbica total en aguas de todo tipo según la ISO 6222.

FÓRMULA	(g/l)
Digerido enzimático de Caseína	6.0
Extracto de Levadura	3.0
Agar	15.0
pH final 7.2 ± 0.2 a 25°C	

PRINCIPIO DEL MÉTODO

El Digerido enzimático de Caseína proporciona los aminoácidos, nitrógeno, carbono, vitaminas y minerales necesarios para el crecimiento de los microorganismos. El extracto de levadura es una fuente de vitaminas, especialmente para las del grupo B. El Agar es el agente solidificante.

PREPARACIÓN

Medio deshidratado	Suspender 24 g del polvo deshidratado en 1 litro de agua destilada o desionizada*. Mezclar bien. Calentar hasta la ebullición removiendo frecuentemente hasta la completa disolución. Esterilizar en autoclave a 121°C durante 15 minutos.
Medio en tubos/botellas	Disolver el contenido de la botella en un baño con agua a 100°C (con el tapón ligeramente desenrroscado) hasta su completa disolución. Comprobar la homogeneidad del medio disuelto, girar la botella si es necesario para ayudar a la homogeneización. Enfriar a 45-50°C, mezclar bien evitando la formación de burbujas y distribuir en placas Petri de forma aséptica.

PROCEDIMIENTO DEL TEST

1. Realizar diluciones en serie de la muestra a analizar teniendo en cuenta el nivel de contaminación esperado.
2. Inocular el medio (dos grupos de placas por muestra) por versamiento o por el método de las membranas filtrantes.
3. Incubar un grupo a 36 ± 2°C durante 40-48 h y el otro a 22 ± 2°C durante 64-72 h.

INTERPRETACIÓN DE LOS RESULTADOS

Contar las colonias en cada placa (rechazar las placas donde no se observe un crecimiento independiente de las colonias) e informar de los resultados como CFU/ml por muestra, permitiendo factores de dilución.

ASPECTO

Medio deshidratado: suelto, homogéneo, beige claro.
Medio preparado: ligeramente opalescente, ámbar claro.

ALMACENAMIENTO

El polvo deshidratado es muy higroscópico, almacenar a 10-30°C, en un entorno seco, en su frasco original correctamente cerrado. Almacenar las botellas y las placas preparadas a 10-25°C fuera del contacto de la luz. No utilizar el producto fuera de la fecha de caducidad descrita en la etiqueta o si el producto presenta alguna muestra de deterioro o contaminación.

VIDA ÚTIL

Medio deshidratado: 4 años.
Medio en botellas/tubos: 2 años.
Placas preparadas: 6 meses.

CONTROL DE CALIDAD

Las placas se inoculan con las cepas indicadas en la siguiente tabla.
Inóculo para productividad: 50-100 CFU
Condiciones de incubación: aeróbicas a 36 ± 2°C durante 40-48 horas.

Tabla CC.

Microorganismo		Crecimiento
Escherichia coli	WDCM 00012	Bueno
Bacillus subtilis	WDCM 00003	Bueno

ADVERTENCIAS Y PRECAUCIONES

Este producto no contiene sustancias peligrosas en concentraciones que excedan los límites fijados por la legislación actual y no está clasificado como peligroso. Se recomienda de todas formas las lectura de la hoja de seguridad para el uso apropiado. El producto debe ser utilizado sólo por operadores debidamente adiestrados.

DESECHO DE RESÍDUOS

El desecho de los resíduos debe realizarse según la regulación nacional y local vigente.

BIBLIOGRAFÍA

1. EN ISO 11133:2014. Microbiology of food, animal feed and water – Preparation, production, storage and performance testing of culture media.
2. ISO 6222:2009. Water quality –Enumeration of culturable microorganisms – Colony count technique by inoculation in a nutrient agar culture medium.

PRESENTACIÓN		Contenido	Ref.
Yeast Extract Agar	Placas de 60 mm listas para su uso	20 placas	163582
Yeast Extract Agar	Tubos	20 x 22 ml tubos	34074
Yeast Extract Agar	Tubos	100 x 22 ml tubos	26074
Yeast Extract Agar	Tubos agar semitendido	20 x 9 ml tubos	31102
Yeast Extract Agar	Botellas	6 x 200 ml botellas	412120
Yeast Extract Agar	Botellas	6 x 100 ml botellas	403120
Yeast Extract Agar	Medio deshidratado	500 g de polvo deshidratado	611016
Yeast Extract Agar	Medio deshidratado	100 g de polvo deshidratado	621016

TABLA DE SÍMBOLOS

LOT	Código de lote		Mantener fuera del alcance de la luz		Fabricante		Utilizar antes de		Frágil, manipular con cuidado
REF	Número de catálogo		Límites de temperatura	Σ	Contenido suficiente para <n> análisis		Atención, consultar el documento adjunto		No reutilizar

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

Iron Sulphite Agar

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

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

DESCRIPTION

Iron Sulphite Agar is a medium used for the detection and enumeration of sulphite-reducing bacteria in food and other samples.

PRINCIPLE

Enzymatic digest of casein provides nitrogen, vitamins, minerals and amino acids essential for growth. Sodium sulphite and ferric citrate are H_2S indicators: Sulphite-reducing bacteria reduce sulphite to sulphide which react with iron of ferric citrate to form a black precipitate of iron sulphide turning the colonies black. Agar is the solidifying agent.

PREPARATION

Suspend 26 g of powder in 1 liter of distilled water. Heat until completely dissolved. Autoclave at 121°C for 15 minutes. Dispense aseptically into final containers.

TECHNIQUE

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

INTERPRETATION OF RESULTS

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

STORAGE

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

WARNING AND PRECAUTIONS

For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

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

REFERENCES

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

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PRODUCT SPECIFICATIONS

NAME
Iron Sulphite Agar

PRESENTATION
Dehydrated medium

STORAGE
10-30°C

PACKAGING

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

pH OF THE MEDIUM
7.1 ± 0.2

USE
Iron Sulphite Agar is a medium used for the detection and enumeration of sulphite-reducing bacteria in food and other samples

TECHNIQUE
Refer to technical sheet of the product

APPEARANCE OF THE MEDIUM
Dehydrated medium
Appearance: free-flowing, homogeneous
Colour: beige

Prepared medium
Appearance: slightly opalescent
Colour: light amber

SHELFLIFE
4 years

QUALITY CONTROL
1. Control of general characteristics, label and print
2. Microbiological control
   Inoculum for productivity: 10-100 CFU/ml
   Inoculum for specificity: ≤10^4 CFU/ml
   Incubation Conditions: 24-48 hours at 55°C, in anaerobic atmosphere

Microorganism		Growth	Colour
Clostridium sporogenes	ATCC® 19404	Good	Black colonies
Clostridium perfringens	ATCC® 11437	Good	Black colonies
Escherichia coli	ATCC® 25922	Good	No blackening

TABLE OF SYMBOLS

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

LIOFILCHEM® S.r.l.
Via Scozia, 64026 Roseto degli Abruzzi (TE) ITALY
Tel +39 0858930745 Fax +39 0858930330 www.liofilchem.com liofilchem@liofilchem.com

Italia

CERTIFICATO

Nr. 50 100 11497 Rev.006

SI ATTESTA CHE / *THIS IS TO CERTIFY THAT*

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

LIOFILCHEM S.r.l.

SEDE LEGALE:
REGISTERED OFFICE:

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

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

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

UNI EN ISO 9001:2015

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

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in vitro: terreni di coltura per batteriologia, micologia e parassitologia, controlli/standard/calibratori– microbiologia, test di identificazione e di suscettibilità, e test di microbiologia. Distribuzione di reagenti diagnostici in vitro per chimica clinica e immunochimica
(IAF 12, 29)

Design and development, production and sales of in vitro diagnostic culture media for bacteriology, mycology and parasitology, in vitro diagnostic controls/standards/calibrators – microbiology, in vitro diagnostic identification and susceptibility testing, and microbiology tests. Distribution of in vitro diagnostic reagents for chemical chemistry and immunochemistry (IAF 12, 29)

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

Validità /*Validity*
Dal / From: **2025-02-11**
Al / To: **2028-02-10**

ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO
SGQ N° 049A

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

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Data emissione /
Issuing Date
2024-09-10

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE 2025-02-10
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2025-02-10*

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

Italia

ALLEGATO 1 AL CERTIFICATO NR **50 100 11497 Rev.006**
ANNEX 1 *TO CERTIFICATE NO* ***50 100 11497 Rev.006***
pagina 1 di 1 / *page 1 of 1*

IL CERTIFICATO NR 50 100 11497 Rev.006 COPRE ANCHE LE SEGUENTI SEDI OPERATIVE:
THE CERTIFICATE N *50 100 11497 Rev.006 COVERS ALSO THE FOLLOWING OFFICES:*

LIOFILCHEM S.r.l.

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

Produzione di dispositivi medico diagnostici in vitro: terreni di coltura per batteriologia, micologia e parassitologia

Production of in vitro diagnostic culture media for bacteriology, mycology and parasitology

VIA URUGUAY IT - 64026 ROSETO DEGLI ABRUZZI (TE)

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in vitro: terreni di coltura per batteriologia, micologia e parassitologia, controlli/standard/calibratori– microbiologia, test di identificazione e di suscettibilità, e test di microbiologia. Distribuzione di reagenti diagnostici in vitro per chimica clinica e immunochimica

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ACCREDIA
L'ENTE ITALIANO DI ACCREDITAMENTO

SGQ N° 049A

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

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

Francesco Scarlata
Direttore Divisione Business Assurance
Business Assurance Division Manager

Validità /*Validity*

Dal / From: **2025-02-11**

Al / To: **2028-02-10**

Data emissione /
Issuing Date

2024-09-10

PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION:* 2012-09-25

DATA DI SCADENZA DELL'ULTIMO CICLO DI CERTIFICAZIONE: 2025-02-10
EXPIRATION DATE OF THE LAST CERTIFICATION CYCLE: *2025-02-10*

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

ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 071067 0006 Rev. 03

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

Certification Mark:

TÜV SÜD EN ISO 13485 tuvsud.com/ps-cert

Scope of Certificate: **Design and development, production and sales of in vitro diagnostic culture media for bacteriology, mycology and parasitology, in vitro diagnostic controls/standards/calibrators for microbiology, in vitro diagnostic identification and susceptibility testing, and microbiology tests. Distribution of in vitro diagnostic reagents for clinical chemistry and immunochemistry.**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with. For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:Q5 071067 0006 Rev. 03

Report No.: ITA200220002478

Valid from: 2024-12-19
Valid until: 2027-12-18

Date, 2024-09-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

Certificate

No. Q5 071067 0006 Rev. 03

Applied Standard(s):

ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Medical devices - Quality management systems - Requirements for regulatory purposes

Facility(ies):

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

Production of in vitro diagnostic culture media for bacteriology, mycology and parasitology.

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

Design and development, production and sales of in vitro diagnostic culture media for bacteriology, mycology and parasitology, in vitro diagnostic controls/standards/calibrators for microbiology, in vitro diagnostic identification and susceptibility testing, and microbiology tests. Distribution of in vitro diagnostic reagents for clinical chemistry and immunochemistry.

/

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ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

Product Service

C E R T I F I C A T O

N°Q5 071067 0006 Rev. 03

Titolare del certificato: **Liofilchem S.r.l.**
Via Scozia
64026 Roseto degli Abruzzi (TE)
ITALIA

Marchio di certificazione:

Campo di applicazione:

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in vitro: terreni di coltura per batteriologia, micologia e parassitologia, controlli/standard/calibratori per microbiologia, test di identificazione e di suscettibilità, e test di microbiologia. Distribuzione di reagenti diagnostici in vitro per chimica clinica e immunochimica.

L'Organismo di Certificazione TÜV SÜD Product Service GmbH certifica che la società sopramenzionata ha istituito e mantiene un sistema di gestione qualità conforme ai requisiti della(e) norma(e) elencata(e). Tutti i requisiti applicabili del Regolamento "Testing, Certification, Validation and Verification" del gruppo TÜV SÜD devono essere rispettati. Per dettagli e validità del certificato vedi: www.tuvsud.com/ps-cert?q=cert:Q5 071067 0006 Rev.

N° del rapporto: ITA200220002478

Valido da: 2024-12-19
Valido fino al: 2027-12-18

Data, 2024-09-16

Christoph Dicks
Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-11321-01-00

TÜV SÜD Product Service

C E R T I F I C A T O

N°Q5 071067 0006 Rev. 03

Norma(e) applicata(e): ISO 13485:2016
(EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021)
Dispositivi medicali - Sistemi di gestione qualità - Requisiti per scopi regolamentari

Stabilimento(i):

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

Produzione di dispositivi medico diagnostici in vitro: terreni di coltura per batteriologia, micologia e parassitologia.

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

Progettazione e sviluppo, produzione e vendita di dispositivi medico diagnostici in vitro: terreni di coltura per batteriologia, micologia e parassitologia, controlli/standard/calibratori per microbiologia, test di identificazione e di suscettibilità, e test di microbiologia. Distribuzione di reagenti diagnostici in vitro per chimica clinica e immunochimica.

/

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ISO CONSULTING
ИСОКОНСАЛТИНГ

Goodwill Certification System
IST
«InterSertTest»

RA.RU.13HA90

ISO 17021
MANAGEMANT SYSTEMS CERTIFICATION

object of conformity confirmation
ISO 13485:2016

Certification System

Works and Services, Management Systems

InterSertTest

MANAGEMENT SYSTEM CERTIFICATION BODY
OF LIMITED LIABILITY COMPANY
"ISO CONSULTING"

PREMISES 126, 127, 128, AND 129, BLOCK 2, FLOOR 2, 3, DAVYDKOVSKAYA STR., MOSCOW, 121352
UNIQUE NUMBER OF THE ACCREDITATION RECORD IN THE REGISTER OF ACCREDITED PERSONS: RA.RU.13HA90

CERTIFICATE OF CONFORMITY

Issue 2. QMS is certified since January 2021

№ РОСС RU.С.04ША.СК.2015

Is given to: "Research and Production Company "VINAR"
Limited Liability Company
("RPC "VINAR", LLC)

TIN 5023001024

Office VIII, Building 7A, 5, Gospitalniy Val, Moscow, 105094

THIS CERTIFICATE CERTIFIES THAT

QUALITY MANAGEMENT SYSTEM AS APPLIED TO DESIGN, DEVELOPMENT, PRODUCTION AND SALES OF THE FOLLOWING MEDICAL DEVICES: CHEMICAL AND BIOLOGICAL STERILIZATION, DISINFECTION AND DECONTAMINATION INDICATORS; PROCESS CHALLENGE DEVICES; CHEMICAL INDICATORS FOR DISINFECTING AND STERILIZING SOLUTIONS CONCENTRATION CONTROL; WASH MONITORING AND PRE-CLEANING TESTS; PACKAGING MATERIALS FOR STERILIZATION AND WASHING; "COLD CHAIN" CONTROL INDICATORS; DISPOSABLES FOR STERILIZATION AREAS, OPERATING ROOMS AND CLEAN AREAS; ANTISEPTICS AND DISINFECTANTS

COMPLIES WITH THE REQUIREMENTS OF ISO 13485:2016

The Appendix forms are integral part of the Certificate of Conformity

By virtue of: *Decision of the Certification Body № 0096 dated 24 January 2024*

THIS CERTIFICATE SHALL BIND THE ORGANIZATION TO MAINTAIN THE STATE OF THE QUALITY MANAGEMENT SYSTEM IN THE WORKABLE CONDITION IN COMPLIANCE WITH THE REQUIREMENTS OF THE ABOVE STANDARD, TO CONFIRM THIS COMPLIANCE BY RESULTS OF THE ANNUAL INSPECTION CHECK-UP IN "ISO CONSULTING" LLC MANAGEMENT SYSTEM CERTIFICATION BODY WITHIN THE ENTIRE PERIOD OF THE CERTIFICATE DURATION.

Issued 24 January 2024

Expiry date: 24 January 2027
(If the inspection control is passed)

ISO 13485

Terms for the start of the first inspection: Not later than 18 January 2025
Terms for the start of the second inspection: Not later than 18 January 2026

S.A. KORKIN
Head of the Certification Body _____

T.V. GRICHANAYA
Head of the Audit Team _____

№ 006416

FEDERAL AGENCY OF TECHNICAL REGULATION AND METROLOGY
Goodwill Certification System "InterSertTest", Registration №РОСС RU.3570.04ША00
Certification parent body "EuroStandard - certifica" OGRN 1097746081498
Address: 121170, Moscow, Kutuzovskiy prospect 36, build. 3, tel: (495) 744-2923

Certification System

Works and Services, Management Systems

InterSertTest

Appendix
Is an integral part of
Certificate № РОСС RU.C.04ША.СК.2015

Scope of Certification of the Quality Management System

Design, development, production and sales of the following medical devices: chemical and biological sterilization, disinfection and decontamination indicators; process challenge devices; chemical indicators for disinfecting and sterilizing solutions concentration control; wash monitoring and pre-cleaning tests; packaging materials for sterilization and washing; "cold chain" control indicators; disposables for sterilization areas, operating rooms and clean areas; antiseptics and disinfectants except p. 7.5.3, p. 7.5.4, p. 7.5.6 in terms of the validation of the application of computer software used in production and service provision, p. 7.5.9.2, p. 7.5.10, 8.2.6 in terms of records, for implantable products, for the identification of personnel conducting any type of control or testing ISO 13485:2016

"Research and Production Company "VINAR"
Limited Liability Company,

Including:

Production site "RPC "VINAR", LLC
17/2 Kolontsova str., Mytishchi, Moscow region, 141009
Production medical devices: chemical and biological sterilization, disinfection and decontamination indicators; process challenge devices; chemical indicators for disinfecting and sterilizing solutions concentration control; wash monitoring and pre-cleaning tests; "cold chain" control indicators; disposables for sterilization areas, operating rooms and clean areas

Production site "RPC "VINAR", LLC
51b, Bolshaya Protechnaya str., Pereslavl-Zalessky, Yaroslavl region, 152020,
Production medical devices: packaging materials for sterilization and washing; antiseptics and disinfectants

S.A. KORKIN
Head of the Certification Body _____

T.V. GRICHANAYA
Head of the Audit Team _____

FEDERAL AGENCY OF TECHNICAL REGULATION AND METROLOGY
Goodwill Certification System "InterSertTest", Registration №РОСС RU.3570.04ША00
Certification parent body "EuroStandard - certifica" OGRN 1097746081498
Address: 121170, Moscow, Kutuzovskiy prospect 36, build. 3, tel: (495) 744-2923

ISO CONSULTING
ИСОКОНСАЛТИНГ

Добровольная система сертификации «ИнтерСертТест» ИСТ

RA.RU.13HA90

ISO 17021 СЕРТИФИКАЦИЯ СИСТЕМ МЕНЕДЖМЕНТА

объект подтверждения соответствия ГОСТ ISO 13485-2017

Система Сертификации

Продукции, Работ и Услуг, Систем Менеджмента

ИнтерСертТест

ОРГАН ПО СЕРТИФИКАЦИИ СИСТЕМ МЕНЕДЖМЕНТА ОБЩЕСТВА С ОГРАНИЧЕННОЙ ОТВЕТСТВЕННОСТЬЮ «ИСО КОНСАЛТИНГ»

121352, г. Москва, ул. Давыдковская, дом 3, этаж 2, блок 2, пом. 126, 127, 128, 129

Уникальный номер записи об аккредитации в реестре аккредитованных лиц: RA.RU.13HA90

СЕРТИФИКАТ СООТВЕТСТВИЯ

Выпуск 2. СМК сертифицирована с января 2021 года

№ РОСС RU.С.04ША.СК.2015

Выдан: Обществу с ограниченной ответственностью «Научно-производственная фирма «ВИНАР» (ООО «НПФ «ВИНАР»)

ИНН 5023001024

105094, г. Москва, ул. Госпитальный вал, д.5, стр.7А, пом. VIII

НАСТОЯЩИЙ СЕРТИФИКАТ УДОСТОВЕРЯЕТ:

СИСТЕМА МЕНЕДЖМЕНТА КАЧЕСТВА ПРИМЕНИТЕЛЬНО К ПРОЕКТИРОВАНИЮ, РАЗРАБОТКЕ, ПРОИЗВОДСТВУ И РЕАЛИЗАЦИИ МЕДИЦИНСКИХ ИЗДЕЛИЙ: ХИМИЧЕСКИХ И БИОЛОГИЧЕСКИХ ИНДИКАТОРОВ КОНТРОЛЯ СТЕРИЛИЗАЦИИ, ДЕЗИНФЕКЦИИ И ОБЕЗЗАРАЖИВАНИЯ; УСТРОЙСТВ КОНТРОЛЯ ПРОЦЕССА СТЕРИЛИЗАЦИИ; ИНДИКАТОРОВ ЭКСПРЕСС-КОНТРОЛЯ КОНЦЕНТРАЦИЙ РАБОЧИХ РАСТВОРОВ ДЕЗИНФИЦИРУЮЩИХ И СТЕРИЛИЗУЮЩИХ СРЕДСТВ; ИНДИКАТОРОВ КОНТРОЛЯ ЭФФЕКТИВНОСТИ ПРЕДСТЕРИЛИЗАЦИОННОЙ ОЧИСТКИ МЕДИЦИНСКИХ ИНСТРУМЕНТОВ; УПАКОВОЧНЫХ МАТЕРИАЛОВ ДЛЯ ФИНИШНОЙ СТЕРИЛИЗАЦИИ И СТИРКИ; ИНДИКАТОРОВ КОНТРОЛЯ ХОЛОДОВОЙ ЦЕПИ; РАСХОДНЫХ МАТЕРИАЛОВ ДЛЯ СТЕРИЛИЗАЦИОННЫХ, ОПЕРАЦИОННЫХ, ЧИСТЫХ ПОМЕЩЕНИЙ; АНТИСЕПТИЧЕСКИХ И ДЕЗИНФИЦИРУЮЩИХ СРЕДСТВ

СООТВЕТСТВУЕТ ТРЕБОВАНИЯМ ГОСТ ISO 13485-2017 (ISO 13485:2016)

Приложение является неотъемлемой частью сертификата соответствия

Основание: *Решение Органа по сертификации № 0096 от 24 января 2024 года*

НАСТОЯЩИЙ СЕРТИФИКАТ ОБЯЗЫВАЕТ ОРГАНИЗАЦИЮ ПОДДЕРЖИВАТЬ СОСТОЯНИЕ ПРОЦЕССОВ СИСТЕМЫ МЕНЕДЖМЕНТА КАЧЕСТВА В РАБОТОСПОСОБНОМ СОСТОЯНИИ В СООТВЕТСТВИИ С ТРЕБОВАНИЯМИ ВЫШЕУКАЗАННОГО СТАНДАРТА, ПОДТВЕРЖДАТЬ ЭТО СООТВЕТСТВИЕ РЕЗУЛЬТАТАМИ ПРОХОЖДЕНИЯ ЕЖЕГОДНОГО ИНСПЕКЦИОННОГО КОНТРОЛЯ В ОС СМ ООО «ИСО КОНСАЛТИНГ» ВО ВРЕМЯ ВСЕГО СРОКА ДЕЙСТВИЯ СЕРТИФИКАТА.

Дата выдачи: 24.01.2024 ***Срок действия до: 24.01.2027***

(при прохождении инспекционного контроля)

ISO 9001 86459

Срок начала прохождения первого инспекционного контроля: не позднее 18.01.2025

Срок начала прохождения второго инспекционного контроля: не позднее 18.01.2026

С.А. КОРКИН
Руководитель Органа по сертификации _____

Т.В. ГРИЧАНАЯ
Руководитель аудиторской группы _____

№ 006416

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
Система добровольной сертификации «ИнтерСертТест», Регистрационный №РОСС RU.3570.04ША00
Головной орган по сертификации «ЕвроСтандарт-сертифика» ОГРН 1097746081498
Адрес: 121352, г. Москва, ул. Давыдковская, д. 3, тел. 8 (800) 100-0037

Система Сертификации

Продукции, Работ и Услуг, Систем Менеджмента

ИнтерСертТест

Приложение
является неотъемлемой частью
сертификата № РОСС RU.С.04ША.СК.2015

Область сертификации системы менеджмента качества

Проектирование, разработка, производство и реализация медицинских изделий: химических и биологических индикаторов контроля стерилизации, дезинфекции и обеззараживания; устройств контроля процесса стерилизации; индикаторов экспресс-контроля концентраций рабочих растворов дезинфицирующих и стерилизующих средств; индикаторов контроля эффективности предстерилизационной очистки медицинских инструментов; упаковочных материалов для финишной стерилизации и стирки; индикаторов контроля холодовой цепи; расходных материалов для стерилизационных, операционных, чистых помещений; антисептических и дезинфицирующих средств за исключением п.7.5.3, п. 7.5.4, п. 7.5.6 в части валидации применения компьютерного программного обеспечения, используемого в производстве и обслуживании, п. 7.5.9.2, п. 7.5.10, п. 8.2.6 в части записей, для имплантируемых изделий, по идентификации персонала, проводящего любые виды контроля или испытаний ГОСТ ISO 13485-2017 (ISO 13485:2016)

Обществу с ограниченной ответственностью
Научно-производственная фирма «ВИНАР»,

включая:

Производственная площадка ООО «НПФ «ВИНАР»:
141009, Московская область, г. Мытищи, ул. Колонцова, д.17/2
Производство медицинских изделий: химических и биологических индикаторов контроля стерилизации, дезинфекции и обеззараживания; устройства контроля процесса стерилизации; индикаторов экспресс-контроля концентраций рабочих растворов дезинфицирующих и стерилизующих средств; индикаторы контроля эффективности предстерилизационной очистки медицинских инструментов; индикаторов контроля холодовой цепи; расходных материалов для стерилизационных, операционных, чистых помещений

Производственная площадка ООО «НПФ «ВИНАР»:
152020, Ярославская область, г. Переславль-Залесский, ул. Большая Протечная, д.51б
Производство медицинских изделий: упаковочных материалов для финишной стерилизации и стирки; антисептических и дезинфицирующих средств

С.А. КОРКИН
Руководитель
Органа по сертификации _____

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аудиторской группы _____

ФЕДЕРАЛЬНОЕ АГЕНТСТВО ПО ТЕХНИЧЕСКОМУ РЕГУЛИРОВАНИЮ И МЕТРОЛОГИИ
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