

# CERTIFICATO

N° Q5 071067 0006 Rev. 00

**Titolare del certificato:**

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

**Stabilimento(i):**

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

**Marchio di certificazione:**



**Campo di applicazione:**

**Progettazione e sviluppo, produzione e commercializzazione di dispositivi medico diagnostici in-vitro: terreni di coltura per batteriologia, sistemi di identificazione e antibiogramma, kit per la determinazione di plasmaproteine. Distribuzione di altri dispositivi medico diagnostici in-vitro**

**Norma(e) applicata(e):**

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

L'Organismo di Certificazione TÜV SÜD Product Service GmbH certifica che la società sopramenzionata ha istituito e mantiene un sistema di gestione qualità conforme ai requisiti della(e) norma(e) elencata(e). Vedere anche note sul retro.

**N° del rapporto:**

ITA1070742

**Valido da:**

2018-12-19

**Valido fino al:**

2021-12-18

**Data, 2018-12-19**

*S. Preis*

Stefan Preis

Pagina 1 di 1

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



# Certificate

No. Q5 071067 0006 Rev. 00

**Holder of Certificate:**

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

**Facility(ies):**

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

**Certification Mark:**



**Scope of Certificate:**

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

**Applied Standard(s):**

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

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

**Report No.:**

ITA1070742

**Valid from:**

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**Valid until:**

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**Date, 2018-12-19**

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80335 Munich • Germany



Product Service









Table listing CE products for 'Prodotti CE di Fibra Vendita / Free Sale CE Products'. Columns include product name, CE mark, and other technical specifications.

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Table listing various textile products with columns for product name, weight, and other specifications. Includes items like 'FIBRA VISCOSA', 'FIBRA VISCOSA', etc.

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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
<i>Staphylococcus aureus</i>	25923	markedly to completely inhibited	
<i>Escherichia coli</i>	25922	good	red colonies w / green metallic sheen
<i>Salmonella typhimurium</i>	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

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

### PRESENTATION

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

### TABLE OF SYMBOLS

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



**LIOFILCHEM s.r.l.**

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## E.M.B. LEVINE AGAR

Terrino selettivo per l'isolamento di enterobatteri gram-negativi (ammolizalo Farmacopoea SU)

### FORMULA TIPICA

	(g/l)
Phosphore	10,0
Lattosio	10,0
Fosfato dipotassico	2,0
Eosina Y	0,4
Blu di Metilene	0,065
Agar	15,0
pH finale 7,2 ± 0,2 a 25°C	

### DESCRIZIONE

E.M.B. LEVINE AGAR è un terreno selettivo per l'isolamento di enterobatteri gram negativi conforme con le specifiche della Farmacopoea degli Stati Uniti (USP). E.M.B. LEVINE AGAR è utilizzato per l'analisi sia di campioni clinici che alimentari come i prodotti caseari.

### PRINCIPIO

Il principio di azione di questo terreno è il lattosio e il carbonato fermentabile ed il fosfato dipotassico e il lattone. Eosina Y e blu di metilene sono gli indicatori. Questi coloranti permettono anche di differenziare i microrganismi che fermentano il lattosio dai non fermentanti sulla base del loro comportamento all'interno delle colonie batteriche. Il blu di metilene agisce anche come agente selettivo in grado di inibire parzialmente i batteri gram-positivi.

### PREPARAZIONE

Sospensione 32,5 g di polvere in 1 litro di acqua distillata. Scaldare fino a completo scioglimento. Autoclavare a 121°C per 15 minuti. Raffreddare a 45-50°C. Mescolare accuratamente. Distribuire in piastre petri.

### TECNICA

Utilizzare le procedure appropriate per ottenere colture isolate dai campioni in esame. Si dovrebbe seminare anche un terreno non selettivo per aumentare la probabilità di recupero quando la popolazione di batteri gram-negativi è bassa e per avere inoltre sulla base del loro comportamento all'interno delle colonie batteriche. Incubare le piastre, al riparo della luce, a 35±2 per 18-24 ore. Se dopo 24 ore non si verifica nessuna crescita rianalizzare per altre 24 ore.

### INTERPRETAZIONE DEI RISULTATI

I microrganismi che fermentano il lattosio (come: coliformi, mostardi colone blu-verde, mentre le colonie del lattosio non fermentanti come *Serratia* spp. e *Shigella* spp. appaiono incolore, trasparenti o color ambra. Alcuni batteri gram-positivi, come gli streptococchi fecali, stafilococchi e lieviti, crescono su questo terreno formando di solito colonie puriformi. Diversi batteri gram-negativi non patogeni e che non fermentano il lattosio sono in grado di crescere su questo terreno ma possono essere distinti dai ceppi patogeni tramite analisi biochimiche.

### CONSERVAZIONE

La polvere è molto igroscopica, conservare a 10-30°C in ambiente asciutto nel suo contenitore originale chiuso ermeticamente. Utilizzare prima della data di scadenza apposta sull'etichetta, e infine non sono da usare se presenti segni di deterioramento o contaminazione. Conservare le piastre pronte a 2-8°C al riparo dalla luce.

### AVVERTENZE E PRECAUZIONI

Il prodotto non contiene sostanze nocive in concentrazioni superiori ai limiti stabiliti dalla legislazione corrente e perciò non è classificato come pericoloso. Comunicare per un uso corretto del prodotto si raccomanda di consultare la scheda di sicurezza. Il prodotto è progettato esclusivamente per uso diagnostico in vitro e deve essere utilizzato da personale qualificato.

### SMALTIMENTO DEI RIFIUTI

Smaltimento dei rifiuti deve essere effettuato secondo le normative nazionali in vigore.

### BIBLIOGRAFIA

- Hoff-Harris and Tongan (1916). J. Infect. Dis., 8: 596.
- Levine (1918). J. Infect. Dis. 23:43.
- Murshall ed. (1993). Standard methods for the examination of dairy products, 16<sup>th</sup> ed. American Public Health Association, Washington, D.C.
- Dowens and Ho ed. (2001). Consensus of methods for the microbiological examination of foods, 4<sup>th</sup> ed. American Public Health Association, Washington, D.C.
- United States Pharmacopoeial Convention Inc. (2001). The United States Pharmacopoeia, The National Formulary 20 - 2002. The United States Pharmacopoeial Convention, Rockville, MD.



LIOFILCHEM® S.p.A.

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## SPECIFICHE DI PRODOTTO



### DENOMINAZIONE

E.M.B. LEVINE AGAR

### PRESENTAZIONE

Terrino desiccato in polvere

### CONSERVAZIONE

10-30°C

### CONFEZIONAMENTO

Confezionamento

610019 500 g

620019 100 g

500 g di polvere in contenitore di plastica

100 g di polvere in contenitore di plastica

7,2 ± 0,2

### PH DEL TERRENO

### IMPIEGO

E.M.B. LEVINE AGAR è un terreno selettivo per l'isolamento di enterobatteri gram-negativi conforme con le specifiche della Farmacopoea degli Stati Uniti (USP).

### TECNICA

Ferire riferimento alla scheda tecnica del prodotto

### ASPECTO DEL TERRENO

Aspetto omogeneo

Aspetto rosso cremoso-pingue

Aspetto bianco

Aspetto opaco

Aspetto rosso scuro blu-verde

### VALIDITÀ DALLA DATA DI PRODUZIONE

4 anni

### CONTROLLO DI QUALITÀ

1. Controllo analitico generale, etichettatura e stampa

2. Controllo microbiologico

Inoculo per produttività: 10-100 UFC/ml

Inoculo per selettività: 104-105 UFC/ml

Attività per sensibilità: 5104 UFC/ml

Condizioni di incubazione: 18-24 ore a 36 ± 1°C

### TABELLA DEI SIMBOLI

LOT: Numero di lotto

REF: Numero di riferimento

Limiti di temperatura

Contenuto all'interno per confezione

Attrezzatura consigliata per l'uso

Terreno

Contenitore di plastica

Contenitore di plastica

Contenitore di plastica

Contenitore di plastica

Contenitore di plastica

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Contenitore di plastica





### Brilliant Green Agar

### ENGLISH

Selective medium for isolation of *Salmonella* from clinical specimens and other materials of sanitary importance.

#### DESCRIPTION

Brilliant Green Agar is a selective medium used for the isolation *Salmonella* spp. other than *S. Typhi* and *S. Paratyphi* from pathogenic materials, stool, urine, environmental samples, and food.  
Brilliant Green Agar is recommended by APHA, FDA and USP.

#### TYPICAL FORMULA

	(g/l)
Meat Peptone	5.0
Casamino Peptone	5.0
Sodium Chloride	5.0
Yeast Extract	3.0
Lactose	10.0
Sucrose	10.0
Phenol Red	0.06
Brilliant Green	0.0125
Agar	20.0
Final pH 6.9 ± 0.2 at 25°C	

#### METHOD PRINCIPLE

Peptones provide amino acids, carbon, nitrogen, vitamins, and minerals for organisms; growth. Sodium chloride maintains the osmotic balance of the medium. Yeast extract is a source of vitamins, particularly of B-group. Lactose and sucrose are the fermentable carbohydrates. Lysine is the decarboxylase substrate. Phenol red is the pH indicator. Brilliant green is the selective agent inhibiting Gram-positive bacteria and most Gram-negative bacteria, other than *Salmonella* spp. Agar is the solidifying agent.

#### PREPARATION

**Dehydrated medium**  
Suspend 38.1 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to local shaking frequently until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes.

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

#### TEST PROCEDURE

Inoculate the plates by directly streaking the sample over the agar surface. Incubate aerobically at 35 ± 2 °C for 18-24 hours.

#### INTERPRETING RESULTS

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

#### ID Table

<i>Salmonella</i> spp. except <i>S. Typhi</i> and <i>S. Paratyphi</i>	<i>Escherichia coli</i> , <i>Enterobacteriaceae</i> , <i>Klebsiella</i> spp.	<i>Pseudomonas</i> spp.
White to pink with red zone	Yellow-green	Pink to red

#### APPEARANCE

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

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#### TYPICAL FORMULA

	(g/l)
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Sodium Chloride	5.0
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Brilliant Green	0.0125
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Final pH 6.9 ± 0.2 at 25°C	

#### METHOD PRINCIPLE

Peptones provide amino acids, carbon, nitrogen, vitamins, and minerals for organisms; growth. Sodium chloride maintains the osmotic balance of the medium. Yeast extract is a source of vitamins, particularly of B-group. Lactose and sucrose are the fermentable carbohydrates. Lysine is the decarboxylase substrate. Phenol red is the pH indicator. Brilliant green is the selective agent inhibiting Gram-positive bacteria and most Gram-negative bacteria, other than *Salmonella* spp. Agar is the solidifying agent.

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#### ID Table

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White to pink with red zone	Yellow-green	Pink to red

#### APPEARANCE

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

#### 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 10-15 °C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

#### SHELF LIFE

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

#### QUALITY CONTROL

Plates are now dated with the microbial strains indicated in the QC table.  
Inoculate for greater safety: 50 H10 CFU inoculum for selective media, 10<sup>5</sup>-10<sup>7</sup> CFU inoculum for selective media.

#### QC Table

Strain	ATCC	ATCC®	ATCC®	ATCC®	ATCC®	ATCC®
<i>Salmonella Typhimurium</i>	ATCC 6305	14076	Good	White to red colonies with red zone		
<i>Salmonella Enteritidis</i>	ATCC 13076	Good	White to red colonies with red zone			
<i>Shigella flexneri</i>	ATCC 25922	Inhibited				
<i>Staphylococcus aureus</i>	ATCC 25923	Inhibited				
<i>Escherichia coli</i>	ATCC 25922	Poor	Yellow-green colonies			

#### 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

- Kirsenson M.C., Lesser and A. Jorgensen (1975) On the use of resuspended casein, leucontherm blue, bromocresol purple, phenol red and brilliant green for the recognition of minimum media for TSP (part 1) (6/2/71).
- Kawler W.J. (1965) Isolation of *Shigella flexneri* strains, new media for isolation of enteric pathogens. Am J Clin Pathol. 44: 31-37.
- United States Pharmacopoeial Convention (1996) *Antibiotic Inoculum Test*. The United States Pharmacopoeia, 23<sup>rd</sup> ed. The United States Pharmacopoeial Convention, Rockville, MD, USA.
- US Food and Drug Administration (1998) *Biological Media*. *Manual of Clinical Microbiology*, 7<sup>th</sup> ed. ASM International, Carlisle, PA, USA.

#### PRESENTATION

Brilliant Green Agar	90 mm ready-to-use plates	Contents	Ref.
Brilliant Green Agar	90 mm ready-to-use plates	20 plates	10022
Brilliant Green Agar	Bottles	100 plates	10022
Brilliant Green Agar	Dehydrated medium	6 x 100 ml bottles	6021AD
Brilliant Green Agar	Dehydrated medium	500 g of powder	6130B9
Brilliant Green Agar	Dehydrated medium	100 g of powder	6130B9

#### TABLE OF SYMBOLS

LOT	ISO 9001	IVD	CE	LOT	ISO 9001	IVD	CE
Lot number	ISO 9001 certification	In vitro diagnostic use	CE mark	Lot number	ISO 9001 certification	In vitro diagnostic use	CE mark



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## S.S. AGAR (MODIFIED)

Selective medium for the isolation of *Salmonella* spp. and *Shigella* spp.

### TYPICAL FORMULA

Ingredient	(g/l)
Peptone	6.5
Meat Extract	4.0
Lactose	1.0
Sodium Trosulfate	1.0
Yeast Extract	0.5
Sodium Citrate	1.0
Bile Salts N.3	1.5
Ferric Ammonium Citrate	1.5
Brilliant Green	0.33 mg
Neutral Red	0.025
Agar	14.0
Final pH 7.0 ± 0.2	

### DESCRIPTION

S.S. AGAR (MODIFIED) is a highly selective medium for the isolation of *Salmonella* spp. and some species of *Shigella* from clinical specimens and food.

### PRINCIPLE

Gram-positive microorganisms and coliforms are inhibited by selective components, brilliant green, bile salts n.3, sodium tetrathionate and citrate. The differentiations of microorganisms is obtained through the introduction of lactose in the medium. Lactase form either hydrolysis cause acidification, thus formation of red colonies for the presence of neutral red. Non-fermented microorganisms form instead colourless colonies. Sodium tetrathionate in combination with iron acts as indicator for sulphur production causing the blackening of the colony center.

### PREPARATION

Suspend 52.0 g of the powder in 1 litre of distilled or deionized water. Mix well. Heat to boil shaking frequently until dissolved completely. DO NOT AUTOCLAVE. Cool to 45-50°C. In aseptic conditions dispense in their dishes and let solidify the medium with the lids of the plates partially removed.

### TECHNIQUE

Inoculate the plate streaking the sample onto the agar surface to isolate pure cultures from samples containing a mixed flora. Incubate at 36±1°C for 18-24 hours.

### INTERPRETATION OF RESULTS

*Salmonella* spp. and other lactose non-fermented microorganisms can produce opaque, translucent or transparent colonies, with or without black center. *Shigella* colonies are colourless. The few lactose fermented microorganisms, that are able to growth on the medium, show reddish mucoid colonies.

### STORAGE

10-30°C away from light, until the expiry date on the label. Eliminate if signs 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. The product is designed for *in vitro* diagnostic use only and must be used by properly trained operators.

### DISPOSAL OF WASTE

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

### REFERENCES

1. Gray J.D. (1994). *Identifying Salmonella Shigella and Yersinia*, p. 152-156. In: Manual of clinical microbiology, 8th ed. American Society of Microbiology.
2. Lofson E. (1933). *J. Pathol. Bacteriol.* 40: 561.
3. Rose H. W. and R.H. Kobayashi (1962). *J. Lab. Clin. Med.* 27: 1081-1083.



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## PRODUCT SPECIFICATIONS

**NAME**  
 S.S. AGAR (MODIFIED)

**PRESENTATION**  
 Dehydrated medium

**STORAGE**  
 10-30°C

Ref.	Content	Packaging
610042	500 g	500 g of powder in plastic bottle
620042	100 g	100 g of powder in plastic bottle
610042S	5 kg	5 kg of powder in plastic container

**pH OF THE MEDIUM**  
 7.0 ± 0.2

### USE

S.S. AGAR (MODIFIED) is a highly selective medium for the isolation of *Salmonella* spp. and some species of *Shigella* from clinical specimens and foods.

### TECHNIQUE

Refer to technical sheet of the product

### APPEARANCE OF THE MEDIUM

Dehydrated medium  
 Appearance: free-flowing homogeneous,  
 Colour: light pink  
 Rehydrated medium  
 Appearance: opalescent  
 Colour: purple

### SHELF LIFE

4 years

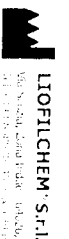
### QUALITY CONTROL

1. Control of general characteristics, label and print
2. Microbiological control  
 Inoculum for productivity: 10<sup>7</sup>-10<sup>8</sup> UFC/ml  
 Inoculum for sensitivity: 10<sup>4</sup>-10<sup>7</sup> UFC/ml  
 Inoculum for specificity: 5-10<sup>7</sup> UFC/ml  
 Incubation Conditions: 18-24 h at 36 ± 2°C, in aerobiosis

Microorganisms	ATCC#	Growth	Features
<i>Shigella flexneri</i>	ATCC# 12022	Growth	Colourless colonies
<i>Salmonella typhimurium</i>	ATCC# 14028	Growth	Colourless colonies with or without black center
<i>Enterococcus faecalis</i>	ATCC# 29212	Inhibited	---
<i>Staphylococcus aureus</i>	ATCC# 25923	Inhibited	---
<i>Escherichia coli</i>	ATCC# 25922	Partially inhibited	Pink or red colonies

### TABLE OF SYMBOLS

LOT	REF	IVD	MANUFACTURER	USE BY
Batch code	Catégorie réactifs	In vitro Diagnostic Medical Device	Manufacturer	Caution: consult product data sheet
		Temperature limitation	Contains sufficient for analysis	



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## LAURYL TRYPTOSE BROTH (LAURYL SULPHATE BROTH)

Selective medium for coliforms detection in water and wastewater.

### TYPICAL FORMULA

	(g/l)
Tryptose	20.0
Lactose	5.0
Sodium Chloride	5.0
Sodium Lauryl Sulphate	0.1
Dipotassium Phosphate	2.75
Monopotassium Phosphate	2.75
Final pH 6.8 ± 0.2 at 25°C	

### DESCRIPTION

LAURYL TRYPTOSE BROTH provides a selective medium which is used for the detection of coliform organisms in water and wastewater, according to the formula of the American Public Health Association.

### PRINCIPLE

Tryptose provides the nitrogen and vitamins required for organism growth. Lactose is the fermentable carbohydrate. Sodium chloride maintains the osmotic balance of the medium. Sodium lauryl sulphate is the selective agent used to inhibit organism other than coliforms. Potassium phosphates are the buffering agents.

### PREPARATION

Suspend 35.9 g of powder in 1 liter of distilled or deionized water. Heat until completely dissolved. Dispense into final containers provided with Durham tubes. Autoclave at 121°C for 15 minutes.

### TECHNIQUE

Inoculate 1 ml of the sample (or its serial tenfold dilutions) into a tube of LAURYL TRYPTOSE BROTH. Invert once the tube to permit the coming out of air from the Durham tube. Incubate for 24-48 hours at 36±1°C.

### INTERPRETATION OF RESULTS

Turbidity of the medium and formation of gas is a positive presumptive test for the presence of coliforms. Perform indole test directly in the tubes for confirmation.

### STORAGE

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

### WARNING AND PRECAUTIONS

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

### DISPOSAL OF WASTE

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

### REFERENCES

1. Clesceri, G.L., P.N. Davidson, J.S. N. Atkicker, and L.A. Roth (1997). Coliforms and other indicator bacteria, p. 247-267.
2. Eaton, A.D., L.S. Clesceri, and A.E. Greenberg (ed.) Standard methods for the examination of water and wastewater, 19th ed. Association of Official Analytical Chemist (1995). Bacteriological analytical manual 8th ed.
3. American Public Health Association (1980). Standard methods for the examination of water and wastewater, 15<sup>th</sup> ed. APHA.
4. ISO Standard 11890-2 Milk and milk products-Enumeration of presumptive *Escherichia coli*.



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## PRODUCT SPECIFICATIONS

**NAME**  
 LAURYL TRYPTOSE BROTH (LAURYL SULPHATE BROTH)

**PRESENTATION**  
 Dehydrated medium

**STORAGE**  
 10-30°C

**PACKAGE**

Ref.	Content	Packaging
610085	500 g	500 g of powder in plastic bottle
620085	100 g	100 g of powder in plastic bottle
610085S	5000 g	5 kg of powder in plastic container

**pH OF THE MEDIUM**  
 6.8 ± 0.2

**USE**

LAURYL TRYPTOSE BROTH provides a selective medium which is used for the detection of coliform organisms in water and wastewater, according to the formula of the American Public Health Association.

**TECHNIQUE**

Refer to technical sheet of the product.

**APPEARANCE OF THE MEDIUM**

Appearance: free-flowing, homogeneous  
 Dispersed medium  
 Colour: beige  
 Prepared medium  
 Appearance: clear to very slightly opalescent  
 Colour: light amber

**SHELF LIFE**  
 4 years

**QUALITY CONTROL**

1. Control of general characteristics, label and print
2. Microbiological control  
 medium for productivity 10<sup>7</sup>-10<sup>8</sup> CFU/ml  
 medium for selectivity 10<sup>7</sup>-10<sup>8</sup> UFC/ml  
 medium for specificity ≤ 10<sup>3</sup> UFC/ml  
 incubation conditions: 48 h at 36 ± 1°C

Microorganism	ATCC#	Growth	Gas
<i>Escherichia coli</i>	28922	Good	+
<i>Salmonella typhimurium</i>	14028	Good	-
Organic nitrogen nitrogen	26993	Inhibited	-
<i>Mycobacteria paratuberculosis</i>	13883	Good	+

### TABLE OF SYMBOLS

LOT	Batch code	Keep away from heat sources	Manufacturer	Use by	Example of anti-arrhythmia
REF. number	Catalogue number	Temperature limitation	Company's reference for sales texts	Consult instructions for use	



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Asking for the clarification and preparation of goods and materials from different materials, according to EN ISO 11133 and USP/EPF.

**DESCRIPTION**

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

This medium complies with EN ISO 11133 for the microbiological examination of food, animal feed and water, where it is also used as the main reference medium to carry out quantitative testing on culture media intended for fungi. Its formula conforms to the recommendations of the harmonized method in the United States Pharmacopoeia (USP), European Pharmacopoeia (EP) and Japanese Pharmacopoeia (JP) for the microbiological examination of non-sterile products. The medium is also available as gamma-irradiated single-logged plates, particularly suitable for use in standard areas like isolations and clean rooms.

**TYPICAL FORMULA**

	(g/l)
Fungal Yeast Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	10.0
Agar	15.0
Final pH 5.6 ± 0.2 at 25°C	

**METHOD PRINCIPLE**

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

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

**PREPARATION**

**Dissolved medium**

Suspend 65.8 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil.

**Medium in bottles**

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

**TEST PROCEDURE**

**For use in medical microbiology**

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

**For use in food, animal feed and water testing**

Refer to EN ISO 11133 for specific instructions.

**For use in industrial microbiology**

Control of most sterile products is

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

**Essence: All Media**

Take the lid of the sterile plate, and leave the medium exposed to the air for a period of time no longer than 4 hours, so that the plate is filled with 20 ml of medium. The composition or volume has changed according to the above procedure. Plates can be stored according to the IATA scheme for 1 h. about 1 above the floor at least 1 m from the walls or any obstruction.

**Media use and Storage**

Take a swab sample for irregular surfaces or use the sampling template (08/10 ref. 96) (0/1) to sample a swab removed area or the top surface. Inoculate a 90 mm plate by streaking the swab over the agar surface. Furthermore, the medium is suitable for personnel hygiene monitoring to detect microbial contamination of gloves or hands e.g. in a finger print.

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

**INTERPRETING RESULTS**

Indicators of growth from slants or spread media may be required in order to obtain more evidence of fungal infection. For fungal colonies exhibiting typical yeast-like and colonial morphology. For removal of both may be required for final identification.

The total count of yeasts moulds count (CYM) is considered to be equal to the number of CFU found per each plate.

When an acceptable count of a microorganism is suspected, it is important to identify:

- 10<sup>6</sup> CFU: maximum acceptable count = 20;
- 10<sup>5</sup> CFU: maximum acceptable count = 200;
- 10<sup>4</sup> CFU: maximum acceptable count = 2000; and so forth.

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

**APPEARANCE**

Dissolved medium: free flowing, homogeneous, light beige.

Prepared medium: slightly granular, light beige.

**STORAGE**

The product is very hygroscopic. Store the powder at 10-10°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 if the seal has expired due to the label or if a product shows any evidence of contamination or any sign of deterioration.

**SHELF LIFE**

Dissolved medium: 4 years  
 Medium in bottles: 2 years  
 Medium in tubes: 1 year  
 Ready to use plates (90 and 60 mm): 6 months.  
 Casted plates: 53 months (9 months).

**QUALITY CONTROL**

The medium is inoculated with microbial strains indicated in the QC table.  
 How often for product type: 50/100/117  
 Incubation conditions: 42.5 ± 2.5°C for 24-48 h at 48-60% RH and at 22.5 ± 2.5°C for up to 7 days (all listed organisms, under aerobic atmosphere).

**QC Table:**

Microorganism	ATCC	Code
<i>Candida albicans</i>	MYA SA 00074	Good
<i>Aspergillus fumigatus</i>	MYC SA 00073	Good
<i>Saccharomyces cerevisiae</i>	MYC SA 00078	Good

**WARNING AND PRECAUTIONS**

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

**DISPOSAL OF WASTE**

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

**BIBLIOGRAPHY**

1. EN ISO 11133:2014 April 2018. Microbiology of food – animal feed and water – Preparation, production, storage and performance testing of culture media.
2. European Pharmacopoeia 6.5 (2009) 2.6.13. Microbiology of examination of non-sterile products: Test for specified microorganisms
3. United States Pharmacopoeia 12 NF 27 (2009) <62> Microbiological examination of non-sterile products: Test for specified microorganisms
4. Japanese Pharmacopoeia 1405-2480A Microbiology of examination of non-sterile products: Test for specified microorganisms
5. Substratum R 1892: Ann. Dermatol. Syphilid. 3:1061

**PRESENTATION**

Substratum Dextrose Agar	Category	Packaging	Ref.
Substratum Dextrose Agar	90 mm plates	20 plates	250175
Substratum Dextrose Agar	90 mm plates	100 plates	100357
Substratum Dextrose Agar	90 mm plates, triple wrapped and gamma irradiated	20 plates	140175
Substratum Dextrose Agar	90 mm plates, triple wrapped and gamma irradiated	20 plates	101148
Substratum Dextrose Agar	60 mm plates	20 plates	341402
Substratum Dextrose Agar	60 mm plates	130 plates	123102
Substratum Dextrose Agar	Tubes, Bottles	10 x 9 and 10ml tubes	80993
Substratum Dextrose Agar	55 mm circular plates irradiated	20 plates	17437
Substratum Dextrose Agar	Tubes, Bottles	20 x 9 and 10ml tubes	34074
Substratum Dextrose Agar	Tubes, Bottles	6 x 9 and 10ml tubes	32944
Substratum Dextrose Agar	Tubes, Bottles	6 x 200 ml bottles	412280
Substratum Dextrose Agar	Tubes, Bottles	25 x 200 ml bottles	432293
Substratum Dextrose Agar	Tubes, Bottles	0 x 1000 ml bottles	402284
Substratum Dextrose Agar	Dedicated culture medium	500 g or powder	610103
Substratum Dextrose Agar	Dedicated culture medium	100 g or powder	620104
Substratum Dextrose Agar	Dedicated culture medium	5 kg of powder	610105



### Sabouraud Dextrose Broth

Liquid medium for the cultivation of yeasts and moulds from different materials, according to USP1 P3P.

#### DESCRIPTION

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

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

#### TYPICAL FORMULA

	(g/l)
Pancreatic Digest of Casein	5.0
Peptic Digest of Animal Tissue	5.0
Dextrose	20.0
Final pH 5.6 ± 0.2 at 25°C	

#### METHOD PRINCIPLE

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

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

#### PREPARATION

Suspend 80 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into appropriate containers. Sterilize in autoclave at 121°C for 15 minutes.

#### TEST PROCEDURE

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

#### For use in industrial microbiology

To prepare the fungal test strains grow *C. albicans* or *A. brasiliensis* at 30-35°C for 48-72 hours or 5-7 days, respectively.

To test for *C. albicans*, inoculate the preparation of the product to be examined 1:100 in SDB and incubate at 30-35°C for 3-5 days. Subculture on a plate of Sabouraud Dextrose Agar (ref. 10015).

#### INTERPRETING RESULTS

Turbidity indicates microbial growth.

#### APPEARANCE

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

#### STORAGE

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

#### SHELF LIFE

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

#### QUALITY CONTROL

The medium is now related with the micro-organism strains listed in the QC table. Incubation conditions: 32.5 ± 2.5°C for 48-72 h for *C. albicans* and at 22.5 ± 2.5°C for up to 5 days listed organisms, under aerobic atmosphere.

#### QC Table:

Organism	ATCC	Code
<i>Candida albicans</i>	ATCC® 10231	Good
<i>Aspergillus brasiliensis</i>	ATCC® 16404	Good
<i>Saccharomyces cerevisiae</i>	ATCC® 9763	Good

#### WARNING AND PRECAUTIONS

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

#### DISPOSAL OF WASTE

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

#### BIBLIOGRAPHY

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

#### PRESENTATION

Product	Units	Contents	Ref.
Sabouraud Dextrose Broth	Tubus	20 x 10 ml tubes	24109
Sabouraud Dextrose Broth	Bottles	6 x 100 ml bottles	402040
Sabouraud Dextrose Broth	Bottles	25 x 100 ml bottles	452040
Sabouraud Dextrose Broth	Bottles	6 x 500 ml bottles	471070
Sabouraud Dextrose Broth		500 g of powder	610104
Sabouraud Dextrose Broth		1000 g of powder	620104

#### TABLE OF SYMBOLS

LOT	Label code	IVD	In vitro Diagnostic Medical Device	Minimum use	For use only according to the	Single handle work area
REF	Reference	Temperature	Minimum use	For use only according to the	Single handle work area	Single handle work area



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## MOTILITY INDOLE UREA AGAR (M.I.U.)

Medium used for differentiating Enterobacteriaceae based on motility, indole production and urease activity

### TYPICAL FORMULA (g/L)

Tryptone	30.0
Sodium Chloride	5.0
Potassium Dihydrogen Phosphate	5.0
Phenol Red	0.004
Agar	3.0
Final pH @ 25 ± 0.2	

### DESCRIPTION

MOTILITY INDOLE UREA AGAR (M.I.U.) is a semisolid medium designed for detection in Enterobacteriaceae of urease activity, motility and indole production. It was also used in combination with Kligler Iron Agar (Code 300987) for the recognition and differentiation of *Salmonella* and *Shigella* species from colonies picked from plating media in fecal cultures (1).

### PRINCIPLE

Tryptone is a pancreatic digest of casein. Casein is the main protein of milk and is a rich source of amino acid nitrogen. This nitrogen has high tryptophan content and is therefore used in media for testing the indole reaction. Sodium chloride maintains the osmotic balance. Potassium dihydrogen phosphate buffer the medium. Phenol Red is a pH indicator. The small amount of agar makes the medium semisolid. Bacterial motility can be observed directly from examination of the tubes following incubation. Growth spreads out of the line of inoculation if the organism is motile. Highly motile organisms provide growth throughout the tube. Growth of non motile organisms only occurs along the stab line. Urease activity was observed by a change of color to red. When organisms utilize urea, ammonia is formed during incubation which makes the reaction of these media alkaline producing a red-pink color. Consequently, urease production may be detected by the change in the phenol red indicator. Organisms that possess the enzyme "tyrosinase" degrade the amino acid tyrosophan to indolepyruvic acid from which indole can be formed through decarboxylation.

### PREPARATION

Suspend 43.0 g in 1 liter of distilled water. Heat until completely dissolved. Autoclave at 121 °C for 15 minutes. Cool to 50 °C. Aseptically add 50 ml of Urea 40% supplement (Code 80292).

### TECHNIQUE

Inoculate tubes with a pure culture by stabbing the center of the column of medium to greater than half the depth. Incubate tubes for 18-48 hours at 35 ± 2 °C in aerobic, atmospheric air.

### INTERPRETATION OF RESULTS

- Motility was observed by growth extending from the line of inoculation or diffuse turbidity of the medium. Nonmotile organisms grow only along the line of inoculation.
  - Urease activity was observed by a change of color to red.
  - Indole production is indicated by the formation of a pink to red color after the addition of three or four drops of Kovac's reagent (Code 20073) to the surface of the medium. A negative reaction is indicated by the development of a yellow color.
- The red color of phenol red in alkaline pH did not interfere because of the acidity of Kovac's reagent. The efficacy of MOTILITY INDOLE UREA AGAR (M.I.U.) and Kligler Iron Agar (Code 300987) for presumptive recognition of *Salmonella* and *Shigella* is shown in the work of Rosa Fraille et al (1).

### STORAGE

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

### WARNING and PRECAUTIONS

The product is not classified as hazardous by current legislation and does not contain harmful substances in concentrations of > 1%.

The product is designed for *in vitro* diagnostic use and must be used only by properly trained operators.

### DISPOSAL OF WASTE

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

### REFERENCES

- Sosa Fraille, Vega and Gutierrez, (1980). Evaluation of Urea-Motility-Indole Medium for Recognition and Differentiation of *Salmonella* and *Shigella* Species in Stool Cultures.
- Eller and Clark, (1970). *Applied Microbiology*, 29:83.
- Kaplan, (1970). *Journal of Clinical Microbiology*, 81:1970.
- Ward, (1970). *Journal of Clinical Microbiology*, 81:1970.
- Journal of Clinical Microbiology, Sept. (1980), p. 310-313



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## PRODUCT SPECIFICATIONS

NAME  
MOTILITY INDOLE UREA AGAR (M.I.U.)

PRESENTATION  
Dehydrated culture medium

STORAGE  
10-30 °C

### PACKAGING

Code	Content	Final kg/ing
610236	500 gr	500 gr of powder in plastic bottle
610236	100 gr	100 gr of powder in plastic bottle

pH OF THE MEDIUM  
6.9 ± 0.2

### USE

MOTILITY INDOLE UREA AGAR (M.I.U.) is a semisolid medium designed for detection in Enterobacteriaceae of urease activity, motility and indole production.

### TECHNIQUE

Refer to technical sheet of the product

### APPEARANCE OF THE MEDIUM

Dehydrated medium  
Appearance: free-flowing, homogeneous  
Colour: light beige  
Prepared medium  
Appearance: clear, semisolid  
Colour: light amber

### SHELF LIFE

4 years

### QUALITY CONTROL

- Control of general characteristics, label and print
- Sterility control  
7 days at 25 ± 1 °C, in aerobic conditions  
7 days at 36 ± 1 °C, in aerobic conditions
- Microbiological control  
Inoculum for productivity: 10<sup>8</sup> UFC/ml  
Inoculum for specificity: 2 10<sup>8</sup> UFC/ml  
Incubation conditions: 18-48 hours at 35 ± 2 °C, aerobically

Microorganisms	Motility	Indole production	Urease reaction
<i>Escherichia coli</i>	ATCC 25922	+	+
<i>Shigella flexneri</i>	ATCC 49619	+	+
<i>Salmonella typhi</i>	ATCC 14028	+	+
<i>Providencia stuartii</i>	ATCC 29633	+	+
<i>Enterobacter aerogenes</i>	ATCC 13048	+	+

### TABLE OF SYMBOLS

LOT	Batch code	Temperature limitation	Manufacturer	Use by	Caution symbol	IVD
REF	Code/lot number	Keep away from heat	Use by		Caution symbol	Medical Device



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# UREA 40% Supplement

Supplement for the detection of urease activity of bacteria

## DESCRIPTION

UREA 40% Supplement is a supplement for the detection of urease activity of bacteria and it is made of a 40% urea aqueous solution for microbiological use. UREA 40% Supplement is used for the enrichment of medium Urea Agar Base cod. 610107 or 620107.

## KIT CONTENTS

Each kit contains:

- 6 bottles each containing 100 ml of UREA 40% Supplement.
- 1 Instruction sheet

## PRINCIPLE OF THE METHOD

The utilization of urea by microorganisms provided of urease causes the alkalization of medium and consequently the colour turning of indicator red phenol from amber to pink colour.

## COMPOSITION

### UREA 40% Supplement

	Contents / bottle	Contents / l of medium
Urea	40.0 g	20.0 g

## PROCEDURE FOR USE

1. Aseptically take 50 ml of solution from one bottle of UREA 40% Supplement and add to 950 ml of Urea Agar Base cod. 610107 or 620107 autoclaved and cooled to 45-50 °C.
2. Mix with care avoiding the formation of foam.
3. Distribute into the final containers.

## TECHNIQUE AND INTERPRETATION OF THE RESULTS

Refer to the technical documentation for medium Urea Agar Base cod. 610107 or 620107.

## QUALITY CONTROL

1. Control of the appearance: clear, colourless solution.
2. Microbiological control:  
prepare the plates using as base the medium Urea Agar Base cod. 610107 or 620107 added with UREA 40% Supplement.  
The plates are inoculated with the strains indicated in the table of microbiological control.  
Conditions of incubation: 6-24 h at 36 ± 1 °C.  
Microbiological control:

### Control strains

<i>Proteus vulgaris</i>	ATCC 13315
<i>Escherichia coli</i>	ATCC 25922

### Ureasic activity

Positive / pink medium  
Negative / no change in colour

## PRECAUTIONS

The product UREA 40% Supplement is not classified as hazardous under current legislation. UREA 40% Supplement is a supplement to be used only for *in vitro* diagnostic use. It is intended for use in a professional environment and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

## STORAGE

Store UREA 40% Supplement at 2-8°C in its original packaging. In such conditions UREA 40% Supplement maintains its validity until the expiry date indicated on the label. Non utilizzare oltre questa data. Eliminate without using if there are signs of deterioration.

## REFERENCES

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

## PRESENTATION

product	REF	
UREA 40% Supplement	80110	6 bottles

One bottle is sufficient to prepare 2 L of medium

## TABLE OF SYMBOLS

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

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## MSRV Medium Base

Medium for detection of molle *Salmonella* spp. in animal faeces and environmental samples, according to ISO 6579.

### TYPICAL FORMULA

	(g/l)
Lyticatic Digest of Animal and Plant Tissue	4,6
Acid Hydrolyzate of Casein	4,6
Sodium Chloride	7,3
Potassium Dihydrogenphosphate	1,5
Magnesium Chloride anhydrous	10,9
Malachite Green Oxalate	0,04
Agar	2,7
Final pH 5,2 ± 0,1 at 25 °C	

### DESCRIPTION

Modified semi-solid Rappaport-Vassiliadis (MSRV) Medium Base is used with Novobacter for the selective enrichment of molle *Salmonella* in animal faeces and environmental samples. The medium meets the specifications for formulation and performance recommended by ISO 6579 Amendment 1.

### PRINCIPLE

Enzymatic digest of animal and plant tissue and acid hydrolyzate of casein provide amino acids, nitrogen, carbon, vitamins and minerals. Sodium chloride maintains the osmotic balance of the medium. Potassium dihydrogenphosphate is the buffer. Magnesium chloride raises the osmotic pressure. Malachite green oxalate inhibits organisms other than *Salmonella* spp. Novobacter is added as a selective agent active mostly against Gram-positive bacteria. Agar is the solidifying agent.

### PREPARATION

Suspend 31,6 g of powder in 1 liter of deionized or distilled water. Heat with frequent agitation and boil for 1 minute to completely dissolve the powder. DO NOT AUTOCLAVE. Cool up to 45-50°C. Aseptically add 10 ml of Novobacter suspension (ref. 81021) each reconstituted with 1 ml sterile distilled water. Mix well. Pour in Petri dishes.

### TECHNIQUE

For pre-enrichment, add the sample to Buffered Peptone Water (ref. 414022) at a ratio of 1 (g): 25 g per 225 ml; homogenize well and incubate at 37 ± 1°C for 18-20 h.  
Inoculate the MSRV Medium plates with 0,1 ml of the pre-enrichment culture (inoculate 3 drops in three different spots, equally spaced on the medium surface). Incubate at 41,5 ± 1°C for 18-22 h.

### INTERPRETATION OF RESULTS

A grey will be turbid zone extending out from the inoculated drop indicates a positive result for molle *Salmonella* spp. Negative plates, where the medium remains blue-green around inoculation drops, should be re-inoculated for a further 18-22 h. Subculture should be carried out from the positive plates, with the inoculum being taken from the furthest edge of the migration zone. Presumptive identification is achieved by subculture onto XLD Agar (ref. 10056) and a second *Salmonella* agar of choice such as Chromatic *v.* Salmonella (ref. 11614). Characteristic presumptive *Salmonella* colonies should be confirmed with biochemical and serological tests.

### STORAGE

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

### WARNING AND PRECAUTIONS

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

### DISPOSAL OF WASTE

Dispose of waste in accordance with the current and/or forthcoming national or local regulations in force.

### REFERENCES

- ISO 6579:2002/Amend 1:2007. Microbiology of food and animal feeding stuffs—horizontal method for the detection of *Salmonella* spp. AMENDMENT 1. Annex D. Detection of *Salmonella* spp. in animal faeces and in environmental samples from the manure production stage.
- Deonisti J.M., R. Ballesteros, H. Rapado and D. Lourenço-Chaper (1986). Rapid *Salmonella* detection in food by means of a modified semi-solid Rappaport-Vassiliadis (MSRV) Medium. J. Food Prot. 49: 570-574.
- Vassiliadis P. O., Papanicolaou A., Kalantzi and J. Kiferos (1978). Isolation of *Salmonella* from seawater with a new semisolid of use change. J. Appl. Bacteriol. 44: 233-236.
- Rappaport V. N., Konforti and B. Nixson (1956). A new enrichment medium for certain *Salmonella*. J. Clin. Microbiol. 9: 241-250.



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## PRODUCT SPECIFICATIONS

<b>NAME</b>	MSRV Medium Base
<b>PRESENTATION</b>	Lyophilized medium
<b>STORAGE</b>	10-30 °C
<b>PACKAGING</b>	
Ref. 610018	Content 500 g of powder in plastic bottle
620018	100 g of powder in plastic bottle

### pH OF THE MEDIUM

5,2 ± 0,1

### USE

Modified semi-solid Rappaport-Vassiliadis (MSRV) Medium Base is used with Novobacter for the selective enrichment of molle *Salmonella* in animal faeces and environmental samples. The medium meets the specifications for formulation and performance recommended by ISO 6579 Amendment 1.

### TECHNIQUE

Refer to technical sheet of the product.

### APPEARANCE OF THE MEDIUM

Powder medium  
Appearance: free-flowing homogeneous  
Colour: blue  
Reconstituted medium  
Appearance: slightly opalescent, semi-solid gel  
Colour: blue

### SHELF LIFE

4 years

### QUALITY CONTROL

- Control of general characteristics: label and print
- Microbiological control  
Inoculum for productivity: 10<sup>7</sup> CFU  
Inoculum for selectivity: 10<sup>7</sup>·10<sup>8</sup> CFU  
Incubation Conditions: 2 x 18-24 hours at 41,5 ± 1°C

### Microorganism

<i>Salmonella</i> Enteritidis	WDCM 00070
<i>Salmonella</i> Typhimurium	WDCM 00031
<i>Escherichia coli</i>	WDCM 00073
<i>Enterobacteriaceae</i>	WDCM 00009

### TABLE OF SYMBOLS

LOT	Batch	Do not reuse	Manufacturer	Use by	Fragile handle with care
REF	Catalogue number	Temperature limitation	Contains sufficient for 100 tests	Caution: consult instructions for use	



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**MUELLER HINTON AGAR**  
Medium for susceptibility test (Kirby-Bauer method).

**TYPICAL FORMULA (g/L)**

Meat Extract	2.0
Casamino Acids, Technical	17.5
Sodium	1.5
Agar	15.0
Final pH 7.3 ± 0.1	

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

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

**PREPARATION**  
Suspend 30.0 g of powder in 1 liter of distilled or deionized water. Heat to boiling and shake until completely dissolved. Sterilize in autoclave at 121°C for 15 minutes. Dispense in final containers.

**TECHNIQUE**  
Transfer disk colonies in an appropriate broth. Inoculate in a 3-7°C incubator until an opacity is obtained equivalent to the standard opacity of 0.5 on the McFarland scale. Produce a sterile suspension into the inoculum and inoculate the agar passing 2 or 3 times onto the entire surface. Press the disk firmly on the antimicrobial on the agar surface. Incubate at 36±1°C for 18 hours, measure the inhibition zone with a compass and compare to the NCCLS recommended zone ranges.

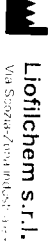
**INTERPRETATION OF RESULTS**  
Compare obtained values of inhibition halo diameter with the values reported on NCCLS M100(M2) document.

**STORAGE**  
15-30°C away from light, until the expiry date on the label or until signs of deterioration or contamination are evident.

**WARNING AND PRECAUTIONS**  
The product is not classified as hazardous by current legislation and does not contain harmful substances in concentrations of 31%. The product is designed for *In vitro* diagnostic use and must be used only by properly trained operators.

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

- REFERENCES**
- Bauer et al. (1996). J. Clin. Microb. 35: 403-404.
  - Muller, J.H., and Hinton 1947. Proc. Soc. Exp. Biol. Med. 48: 330-333.
  - NCCLS Performance standards for susceptibility testing. Twelve Informational Supplement. NCCLS Document M100-S-12, January 2002.



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**PRODUCT SPECIFICATIONS**

**NAME**  
MUELLER HINTON AGAR

**PRESENTATION**  
Dehydrated culture medium

**STORAGE**  
15-30°C

**PACKAGING**

Code	Content	Packaging
610033	500 g	500 g of powder in plastic bottle
620033	100 g	100 g of powder in plastic bottle
610033b	5 kg	5 kg of powder in plastic container

**pH OF THE MEDIUM**  
7.3 ± 0.1

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

**TECHNIQUE**  
Refer to technical sheet of the product.

**APPEARANCE OF THE MEDIUM**  
Aster medium, slightly opalescent.

**SHELF LIFE**  
4 years

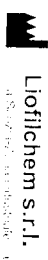
**QUALITY CONTROL**

- Control of general characteristics, label and print
- Sterility control  
7 days at 25 ± 1°C, in aerobiosis  
7 days at 36 ± 1°C, in aerobiosis
- Microbiological control  
Incubation conditions: 18, 21 h at 36 ± 1°C

**TABLE OF SYMBOLS**

Macroorganism	ATCC 29212	Growth	Characteristics
<i>Enterobacteriaceae</i> Enterob. <i>subsp. coli</i>	ATCC 25922	Good	White colonies
<i>Proteus mirabilis</i>	ATCC 25933	Good	Colony colonies
<i>Staphylococcus aureus</i>	ATCC 25923	Good	Yellow colonies

YVD	Batch	Diagnosis	Medical	LOT	Batch code	Manufacturer	Use by	Instructions
REF	Catalogue number	Temperature	Inhibitor	Manufacturer	Use by	Instructions	Caution	consult accompanying documents



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**Fluid Thioglycollate Medium**

ENGLISH

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

**TYPICAL FORMULA**

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

**METHOD PRINCIPLE**

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

**PREPARATION**

**Delayed inoculation:**  
Suspend 29.9 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boiling and shake frequently until completely dissolved. Dispense into appropriate containers. Sterilize in autoclave at 121 °C for 15 minutes.  
**Medium in glass bottles:**  
If the medium exhibits more than 3% pink color after 24 hours of incubation, the medium may be reduced in oxygen 5 minutes with cap slightly loosened in steam or hot water in order to expel the oxygen.

**TEST PROCEDURE**

The medium can be directly inoculated with the test sample. The amount of the inoculated sample material should not exceed 10% volume of the medium. The incubation should be up to 14 days. Growth of strictly aerobic bacteria can be improved by slightly loosening the cap.  
According to ISO 7937 for concentration of *Clostridium perfringens* in or on food, heat 100 ml of the medium and inoculate at 40 ± 1 °C for 18-24 hours. Subsequently transfer a drop of the culture into a tube of Fluid Thioglycollate Medium and incubate at 40 ± 1 °C for 18-24 hours.

**INTERPRETING RESULTS**

Indicates if the medium indicates micro-organisms. Obligate anaerobes and microorganisms such as *Clostridium sporangium* are growing in the lower, yellowish part of the medium. The growth of facultative anaerobic microorganisms such as *Staphylococcus aureus* is distributed throughout all the medium. Aerobic microorganisms such as *Pseudomonas aeruginosa* are able to grow in the upper, slightly pink part of the medium.

**APPEARANCE**

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

**STORAGE**

The powder is stable by gross open, sterile container at 10-30 °C in a dry environment in its original container. Lightly closed, sterile bottles and tubes of Fluid Thioglycollate Medium can be stored for up to 2 years. Do not use the product beyond its expiration date or the label on it providing it is only a source of contamination.

**SHELF LIFE**

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

**QUALITY CONTROL**

Fluid Thioglycollate Medium is now related with the micro-organisms indicated in the QC table.  
How often to perform tests: 1000 (11)  
Incubation conditions: 24 h at 30-35 °C for both media, 48 h at 20-25 °C for yeast, 7-14 h at 20-25 °C for bacteria.  
(Pharmaceuticals: 24 h at 37 ± 1 °C for *Clostridium perfringens* (ISO 11111)).

**QC table:**

Bacterial strains	ATCC no./DSMZ	Visible turbidity
<i>Clostridium sporangium</i>	ATCC 9645	Visible turbidity
<i>Clostridium coli</i>	ATCC 3619/04	Visible turbidity
<i>Pseudomonas aeruginosa</i>	ATCC 27852/9	Visible turbidity
<i>Staphylococcus aureus</i>	ATCC 29212	Visible turbidity
<i>Candida albicans</i>	ATCC 90034	Visible turbidity
<i>Aspergillus brasiliensis</i>	ATCC 16404	Visible turbidity
<i>Clostridium perfringens</i>	ATCC 49619	Slight to good turbidity

**WARNING AND PRECAUTIONS**

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

**DISPOSAL OF WASTE**

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

**BIBLIOGRAPHY**

- ISO 11111:2014. Microbiology of food and animal feed and water - Population production, storage and performance testing of culture media.
- ISO 7937:2004. Microbiology of food and animal feed and water - Horizontal method for the enumeration of *Clostridium perfringens* in food.
- United States Pharmacopoeial Convention, 20th ed., The United States Pharmacopoeia, 31st National Formulary, 26, Supp. 1, 2814m.
- European Pharmacopoeia for the Quality of Medicines and Biologics, 2006. The European Pharmacopoeia, 9th ed., Supp. 1, 4.2.108.
- European Agency of Biotechnology and Virology, 2006. The European Pharmacopoeia, 9th ed., Supp. 1, 4.2.108.
- Revised HIC criteria for liquid media for the aerobic cultivation of anaerobes - European Association of Microbiologists (EAM).

**PRESENTATION**

Fluid Thioglycollate Medium	Contents	Ref.
Fluid Thioglycollate Medium	20 x 10 ml tubes	24174
Fluid Thioglycollate Medium	100 x 10 ml tubes	36174
Fluid Thioglycollate Medium	10 x 20 ml tubes	17174
Fluid Thioglycollate Medium	20 x 30 ml tubes	11174
Fluid Thioglycollate Medium	6 x 100 ml bottles (flip-off cap)	43674
Fluid Thioglycollate Medium	6 x 100 ml bottles (flip-off cap)	29074
Fluid Thioglycollate Medium	6 x 100 ml bottles (flip-off cap)	43774
Fluid Thioglycollate Medium	6 x 100 ml bottles (screw cap)	12364
Fluid Thioglycollate Medium	25 x 100 ml bottles (screw cap)	47364
Fluid Thioglycollate Medium	6 x 90 ml bottles (screw cap)	26174
Fluid Thioglycollate Medium	6 x 100 ml bottles (screw cap)	39329
Fluid Thioglycollate Medium	6 x 100 ml bottles (screw cap)	40194
Fluid Thioglycollate Medium	6 x 500 ml bottles (wide neck)	473304
Fluid Thioglycollate Medium	400 g/20 bottles	6509531
Fluid Thioglycollate Medium	100 g/4 bottles	6509531
Fluid Thioglycollate Medium	100 g/4 bottles	6509531

**PART OF SYMBOLS**

LIOFILCHEM s.r.l.  
 Via...  
 Tel: ...  
 Fax: ...  
 Email: ...



**KLIGLER IRON AGAR**  
Differential medium for enterobacteria identification.

TYPICAL FORMULA	(g/l)
Protease Peptone	20,0
Sodium Chloride	5,0
Yeast Extract	3,0
Meat Extract	3,0
Ferrous Sulfate	0,2
Sodium Thiosulfate	0,3
Lactose	10,0
Glucose	1,0
Phenol Red	0,024
Agar	11,0

Final pH = 7,4 ± 0,2 at 25 °C.

**DIRECTIONS**

Suspend 63,5 g of powder in 1 liter of distilled or deionized water. Heat to boiling until completely dissolved. Dispense into 10ml tubes. Sterilize in autoclave at 121°C for 15 minutes. Cool in a slanting position.

**DESCRIPTION**

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

**TECHNIQUE**

Inoculate by stabbing the butt and abundantly streaking the slope. Incubate at 36 ± 1°C for 18-24 hours and check the color of the medium both in the butt and at the slope. Also check for the presence of gas in the butt and the presence of the black precipitate (H<sub>2</sub>S).

**QUALITY CONTROL**

Dehydrated medium  
Appearance: free-flowing, homogeneous.  
Color: pinkish beige.  
Prepared medium  
Appearance: slightly opalescent, slight precipitate.  
Color: slightly orange-red.  
Incubation conditions: 36 ± 1°C for 18-24 hours.

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

**PERFORMANCE AND LIMITATIONS**

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

**STORAGE**

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

**REFERENCES**

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



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

**TABLE OF SYMBOLS**

<b>LOT</b>	Batch code		Carbon dioxide accompanying documents		Manufacturer		Contains substance for use tests		in Vitro Diagnostic Medical Device
<b>REF</b>	Catalogue number		Frangible number with date		Use by		Temperature limit (min)		Know your IVD in all stages



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## Nutrient Broth

Liquid medium for the cultivation of nonfastidious microorganisms.

### DESCRIPTION

Nutrient Broth is a liquid medium used for the cultivation of a wide variety of organisms from clinical specimens and other materials.

This medium can be enriched with other ingredients such as blood, serum, sugars, etc., for special purposes.

### TYPICAL FORMULA

	(g/l)
Beef Extract	1.0
Peptone	5.0
Yeast Extract	2.0
Sodium Chloride	5.0
Final pH (6.8 ± 0.2 at 25°C)	

### METHOD PRINCIPLE

Beef extract and peptone provide amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, parts of alkali of B-group. Sodium chloride maintains the osmotic balance of the medium.

### PREPARATION

**Dry powder medium** Suspend 13.6 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.

### TEST PROCEDURE

Inoculate broth with test sample. Incubate at 35 ± 2°C for 18-24 hours or longer if necessary.

### INTERPRETING RESULTS

Turbidity indicates microbial growth.

### APPEARANCE

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

### STORAGE

The powder is very hygroscopic. Store the powder at 18-30°C in a dry environment, in its original container tightly closed. Store bottles and tubes at 18-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

### SHELF LIFE

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

### QUALITY CONTROL

The medium is pre-sterilized with the microbicide slants indicated in the QC Table for broth and products (MVE - 1100 C11) in the absence of contaminants, aerobically at 35 ± 2°C for 18-24 hours.

#### QC Table:

Test	ATCC	ATCC	Result
<i>Listeria monocytogenes</i>	ATCC 8259	22	Good
<i>Staphylococcus aureus</i>	ATCC 25923		Good

### WARNING AND PRECAUTIONS

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

### DISPOSAL OF WASTE

Disposed as waste must be carried out according to national and local regulations. In France:

### BIBLIOGRAPHY

1. Association of Official Analytical Chemists (1995). Official methods of analysis of AOAC International, 16<sup>th</sup> ed.
2. Asheshall, R. L. (ed.) (1993). Standard methods for the microbiological examination of dairy products, 16<sup>th</sup> ed.
3. American Public Health Association (1993). Standard methods of water analysis, 19<sup>th</sup> ed.

### PRESENTATION

Nutrient Broth	Tubes	Contents	Ref.
Nutrient Broth	Tubes	20 x 10 ml tubes	24103
Nutrient Broth	Bottles	50 x 5 ml tubes	27503
Nutrient Broth	Bottles	6 x 100 ml bottles	402090
Nutrient Broth	Bottles	6 x 500 ml bottles	470050
Nutrient Broth	Dehydrated medium	500 g of powder	610037
Nutrient Broth	Dehydrated medium	100 g of powder	629037
Nutrient Broth	Dehydrated medium	5 kg of powder	6100375

### TABLE OF SYMBOLS

IOI	IVD	CE	IVD
Intended for use in vitro	Medical device	Manufacturer	Responsible laboratory
Intended for use in vitro	Intended for use in vitro	Intended for use in vitro	Intended for use in vitro
Intended for use in vitro	Intended for use in vitro	Intended for use in vitro	Intended for use in vitro



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**CE IVD**







# COAGULASE TEST

*Lyophilic citrate rabbit plasma for coagulase test*

## DESCRIPTION

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

## CONTENT OF THE PACKAGES

Each package contains :

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

## ITEMS NECESSARY NOT INCLUDED IN THE PACKAGES

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

## PRINCIPLE OF THE METHOD

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

## COMPOSITION

	(mL/vial)
Lyophilic rabbit plasma	4.0

## USE

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

## INTERPRETATION OF RESULTS

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

## QUALITY CONTROL

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

Microorganism	ATCC	Coagulation
<i>Escherichia coli</i>	ATCC 25922	-
<i>Staphylococcus aureus</i>	ATCC 25923	+

## PRECAUTIONS

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

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

## STORAGE

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

## DISPOSAL OF USED MATERIAL

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

## BIBLIOGRAPHY

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

## PRESENTATION

Product	REF	
COAGULASE TEST	88030	5

## TABLE OF SYMBOLS

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



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IVD 100026  
Rev. 2 16.05.2011





# X FACTOR TEST V FACTOR TEST V+X FACTOR TEST

ENGLISH

## DESCRIPTION

X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST are constituted by paper discs with special features, containing the respective coagulation factors, used for differentiating *Haemophilus* spp.

## CONTENT OF THE PACKAGES

Each package contains:

- 2 cartridges with 50 discs each, packaged in a heat-sealed container
- 1 dryer
- 1 instruction sheet

## PRINCIPLE OF THE METHOD

Different strains of *Haemophilus* grow on a culture medium only in presence of the coagulation factor or factors (X, V, or both) which they need. These different requirements allow the differentiation and the identification of *Haemophilus* spp.

## COMPOSITION

- Each disc of X FACTOR TEST contains Hemin.
- Each disc of V FACTOR TEST contains NAD (Nicotinamide-Adenine-Dinucleotide).
- Each disc of V+X FACTOR TEST contains Hemin and NAD (Nicotinamide-Adenine-Dinucleotide).

## TEST PROCEDURE

1. Take the cartridges container from the refrigerator and leave it on the test bench until it reaches room temperature (about 30 minutes). This will prevent humidity being deposited on the discs when the package is opened, which could prejudice their long-term stability.
2. Using a sterile swab, evenly inoculate the surface of a plate of Tryptic Soy Agar (ref. 10037) or Mueller Hinton Agar (ref. 10031) with a pure suspension of the microorganism to test.
3. Using sterile tools, press one disc of X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST on the inoculated surface, at a distance of 120° from one to another and at 1-2 cm from the edge of the plate. Incubate at 36±1°C for 24-48 h in 5-10% carbon dioxide atmosphere.

## INTERPRETATION OF THE RESULTS

If the organism requires X Factor alone, it will grow only at the edge of the X and the X+V FACTOR TEST discs; if it requires V Factor alone, it will grow only at the edge of the V and the X+V FACTOR TEST discs; if both X and V Factors are required, it will grow only at the vicinity of the X+V FACTOR TEST discs.

Some examples are indicated in the following table:

	Without Factors	Factor X	Factor V	Factors V+X
<i>Haemophilus influenzae</i>	-	-	-	+
<i>Haemophilus aegyptius</i>	-	-	-	+
<i>Haemophilus parainfluenzae</i>	-	-	+	+
<i>Haemophilus ducreyi</i>	-	+	-	+
<i>Bordetella pertussis</i>	+	+	+	+

## QUALITY CONTROL

Each batch of X FACTOR TEST, V FACTOR TEST and V+X FACTOR TEST is subjected to microbial control, inoculating pure suspensions of *Haemophilus influenzae* ATCC 19418 and *Haemophilus parainfluenzae* ATCC 7901 on plates of Tryptic Soy Agar.

## PRECAUTIONS

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

## STORAGE

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

## DISPOSAL OF USED MATERIAL

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

## BIBLIOGRAPHY

- Kilian M. (1980) *Haemophilus*. in Manual of Clinical Microbiology. Eds. Lennette et al. Amer. Soc. for Microbiol. 3<sup>rd</sup> edn. Washington.

## PRESENTATION

Product	REF	µg	⚠
X FACTOR TEST	9503	5	100
V FACTOR TEST	9504	4	100
V+X FACTOR TEST	9505	4+5	100

## TABLE OF SYMBOLS

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



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F00005

Rev. 1/28.03.2013



## COLUMBIA AGAR BASE

Medium for fastidious microorganisms isolation from clinical samples.

TYPICAL FORMULA	(g/l)
Peptospical	23.0
Starch	1.0
Sodium Chloride	5.0
Agar	14.0
Final pH =	7.3 ± 0.2 at 25 °C.

### DIRECTIONS

Suspend 43.0 g of powder in 1 liter of distilled or deionized water. Heat to boiling until completely dissolved. Sterilize in autoclave at 121 °C for 15 minutes. Cool to 45-50 °C and aseptically add 5% defibrinated sterile sheep blood. Mix well. Dispense in petri dishes.

Columbia Agar Base can be also enriched in various way:

- with 2 vials of CNA (Staf. Strep) supplement (colistin sulphate 5 mg/vial, nalidixic acid 8 mg/vial, code 81048) each one reconstituted with 5 ml of sterile distilled water. Final medium will contain colistin sulphate 10 mg/l and nalidixic acid 16 mg/l.
- with 2 vials of *Gardnerella vaginalis* supplement (gentamicin 3 mg/vial, amphotericin B 1 mg/vial, nalidixic acid 15 mg/vial, code 81049), each one reconstituted with 5 ml of a 1:1 solution of ethyl alcohol and sterile distilled water; final medium will contain gentamicin 6 mg/l, amphotericin B 2 mg/l and nalidixic acid 30 mg/l.

### DESCRIPTION

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

### TECHNIQUE

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

### QUALITY CONTROL

Dehydrated medium  
Appearance: free-flowing homogeneous.  
Color: beige.  
Prepared medium  
Appearance: opaque.  
Color: cherry red.  
Incubation conditions:  $36 \pm 1$  °C for 18-48 hours at 5-10% CO<sub>2</sub>.

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



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### PERFORMANCE AND LIMITATIONS

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

### STORAGE

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

### REFERENCES

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

### PRESENTATION

Product	REF	Net weight
COLUMBIA AGAR BASE (11.6 l)	610013	500 g
COLUMBIA AGAR BASE (2.3 l)	620013	100 g
COLUMBIA AGAR BASE (116.2 l)	6100135	5 Kg
SHEEP BLOOD DEFIBRINATED	83296	50 ml
CNA (Staf. Strep) supplement	81048	10 vials
Gardnerella vaginalis supplement	81049	10 vials

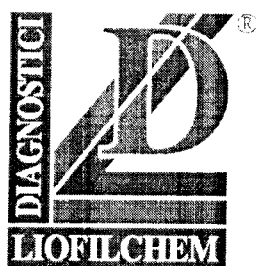
### TABLE OF SYMBOLS

LOT	Batch code	Certificate number	Caution: handle with care	Packaging	Manufacture	Contains substance for culture	IVD
REF	Reference	Reference	Reference	Reference	Reference	Reference	Reference



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# Enterosystem 24R

System for the identification of Gram-negative, oxidase negative enterobacteria.

Ref. 71619 - 79619

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# Enterosystem 24R

ENGLISH

System for the identification of Gram-negative, oxidase negative enterobacteria.

## DESCRIPTION

Enterosystem 24R is a 24-well system containing desiccated biochemical substrates for the identification of Gram-negative bacteria that belong to the family of Enterobacteriaceae. The system is inoculated with the suspension of the organism to be examined and incubated in thermostat. The wells are examined for color changes and the resulting pattern of positive and negative reactions determines the numerical profile used for identification. The complete list of those organisms that is possible to identify with this system is provided in the Identification Table at the end of this document.

## CONTENT OF THE PACKAGE

Ref. 71619	Ref. 79619
<ul style="list-style-type: none"> <li>• 20 Enterosystem 24R</li> <li>• 20 Vials of Physiological Solution (7.0 mL)</li> <li>• 1 Cartridge of Xylose Disc (20 discs)</li> <li>• 1 Cartridge of Arabinose Disc (20 discs)</li> <li>• Instructions sheet and Data chart</li> </ul>	<ul style="list-style-type: none"> <li>• 4 Enterosystem 24R</li> <li>• 4 Vials of Physiological Solution (7.0 mL)</li> <li>• 1 Cartridge of Xylose Disc (20 discs)</li> <li>• 1 Cartridge of Arabinose Disc (20 discs)</li> <li>• Instructions sheet and Data chart</li> </ul>

## ITEMS NECESSARY BUT NOT INCLUDED IN THE PACKAGE

- Enterosystem 18R Reagent (ref. 80252): Vaseline Oil, Indole Test Reagent, VP Test Reagents
- Gram Color Kit (ref. 80293)
- Oxidase Test Stick (ref. 88029)
- McFarland 0.5 Barium Sulphate Standard (ref. 80400)
- Identification Software online (free-access)

## PRINCIPLE OF THE METHOD

Enterosystem 24R allows the identification of Gram-negative, oxidase negative enterobacteria of clinical significance. 24 different tests are carried out, each in every single well of the system. These wells are inoculated with a bacterial suspension that reconstitutes the dehydrated media contained in. The reactions occurring in the wells during incubation produce color changes which are read according to the Interpretive Table. The organism numerical profile is determined and the identification is obtained by using the Identification Software on Liofilchem website.

## CONFIGURATION

Well	Test	Well	Test
1-ONPG	Hydrolysis of ONPG (Ortho-nitrophenyl- $\beta$ -galactoside)	13-MAN	Utilization of mannitol
2-LDC <input type="checkbox"/>	Decarboxylation of lysine	14-INO	Utilization of inositol
3-ODC <input type="checkbox"/>	Decarboxylation of ornithine	15-SOR	Utilization of sorbitol
4-ADC <input type="checkbox"/>	Decarboxylation of arginine	16-SAC	Utilization of saccharose
5-PD	Deamination of phenylalanine	17-ARA	Utilization of arabinose
6-CIT	Utilization of citrate	18-RAF	Utilization of raffinose
7-UR <input type="checkbox"/>	Hydrolysis of urea	19-RAM	Utilization of rhamnose
8-H <sub>2</sub> S <input type="checkbox"/>	Production of hydrogen sulphide	20-MEL	Utilization of melibiose
9-MLN	Utilization of malonate	21-LAC	Utilization of lactose
10-VP *	Production of acetoin (Voges-Proskauer test)	22-TRE	Utilization of trehalose
11-IND *	Production of indole (Kovac's test)	23-XYL	Utilization of xylose
12-GLU	Utilization of glucose	24-DUL	Utilization of dulcitol

: overlay the well with vaseline oil

\* : after incubation, add the indicated reagent to perform the test

## COLLECTION OF THE SAMPLE

Enterosystem 24R is not for use directly with clinical or other specimens. The microorganism to be identified must first be isolated on a culture medium suitable for growth of enterobacteria such as MacConkey Agar (ref. 10029), Eosin Methylene Blue Agar (ref. 10048), Salmonella and Shigella Agar (ref. 10036), Hektoen Enteric Agar (ref. 10043) as well as a non selective blood agar (e.g. Tryptic Soy Agar with 5% Sheep Blood, ref. 11037).

## TEST PROCEDURE

### PREPARATION OF BACTERIAL SUSPENSION

- The microorganism to be identified must be recently isolated (18-24 h); bacterial cultures older than 48 hours can provide not reliable results.
- Before inoculating the microorganism to be examined, Gram staining and oxidase testing are required. Use Enterosystem 24R with Gram-negative, oxidase negative bacteria only.
- Take one or more morphologically similar well isolated colonies from the agar culture medium and suspend in physiological solution. The final turbidity should be equal to 0.5 McFarland. This suspension must be used immediately after preparation.

**Note:** A drop from the inoculum tube, either before or after inoculating the system, can be spread onto an agar slant or plate (any appropriate media) for purity check.

### INOCULATION OF THE SYSTEM

1. Take a system from its wrapper and bring it to room temperature.
2. Write down the name of the patient and the date of the start of the examination.
3. Transfer a disc of Arabinose Disc into the well **17-ARA** and a disc of Xylose Disc into the well **23-XYL**.
4. Dispense 0.2 mL of bacterial suspension into each well of the system and overlay with 1 drop of vaseline oil the wells **2-LDC**, **3-ODC**, **4-ADC**, **7-UR** and **8-H<sub>2</sub>S**.
5. Cover the system with the lid provided and incubate at  $36\pm 1^{\circ}\text{C}$  for 18-24 hours.

## INTERPRETATION OF THE RESULTS

At the end of the incubation period:

1. Add 2 drops of Alpha-naphthol and 1 drop of NaOH 40% to the well **10-VP** (wait 15-20 min for reading after adding the reagents).
2. Add 2 drops of Kovac's reagent to the well **11-IND** (wait 1-2 min for reading after adding the reagent).
3. Watch for the color change in the wells and interpret the results by referring to the Interpretive Table.
4. Note the results on the test results form and determine the 8-digit code following instructions provided as outlined under NUMERICAL CODE FORMATION.
5. Identify the organism by using the Identification Software.

**Interpretive table.**

Well	Test	Well color	
		Positive reaction	Negative reaction
1-ONPG	ONPG hydrolysis	yellow	colorless
2-LDC	Lysine decarboxylation	red	yellow-orange
3-ODC	Ornithine decarboxylation	red	yellow-orange
4-ADC	Arginine decarboxylation	red	yellow-orange
5-PD	Phenylalanine deamination	black-brown	yellow
6-CIT	Citrate utilization	blue-dark green	light green
7-UR	Urea hydrolysis	red-fuchsia	yellow-orange
8-H <sub>2</sub> S	Hydrogen sulphide production	black	yellow
9-MLN	Malonate utilization	blue-green	yellow
10-VP	Voges-Proskauer (add reagents)	pink-red	yellow
11-IND	Indole (add Kovac's Reagent)	red ring	yellow
12-GLU	Glucose	yellow	blue-green
13-MAN	Mannitol	yellow	blue-green
14-INO	Inositol	yellow	blue-green
15-SOR	Sorbitol	yellow	blue-green
16-SAC	Saccharose	yellow	blue-green
17-ARA	Arabinose	yellow	blue-green
18-RAF	Raffinose	yellow	blue-green
19-RAM	Rhamnose	yellow	blue-green
20-MEL	Melibiose	yellow	blue-green
21-LAC	Lactose	yellow	blue-green
22-TRE	Trehalose	yellow	blue-green
23-XYL	Xylose	yellow	blue-green
24-DUL	Dulcitol	yellow	blue-green

**NUMERICAL CODE FORMATION**

The biochemical tests are separated into 8 groups of 3 and a value of 1, 2 or 4 is indicated for each:

- Value 1 : first test positive in each group (**ONPG, ADC, UR, VP, MAN, SAC, RAM, TRE**);
- Value 2 : second test positive in each group (**LDC, PD, H<sub>2</sub>S, IND, INO, ARA, MEL, XYL**);
- Value 4 : third test positive in each group (**ODC, CIT, MLN, GLU, SOR, RAF, LAC, DUL**);
- Value 0 : every negative test.

A 8-digit code is obtained by adding together the values corresponding to positive reactions within each group.

The example below shows how a numerical code is formed.

Test	Group 1			Group 2			Group 3			Group 4			Group 5			Group 6			Group 7			Group 8		
	ONPG	LDC	ODC	ADC	PD	CIT	UR	H <sub>2</sub> S	MLN	VP	IND	GLU	MAN	INO	SOR	SAC	ARA	RAF	RAM	MEL	LAC	TRE	XYL	DUL
Value	1	2	4	1	2	4	1	2	4	1	2	4	1	2	4	1	2	4	1	2	4	1	2	4
Result	+	-	+	+	-	+	-	-	+	+	-	+	+	+	+	+	+	+	+	+	+	+	-	-
Sum of values	5			5			4			5			7			7			7			1		

NUMERICAL CODE: 55457771 IDENTIFICATION: *Enterobacter cloacae*

**QUALITY CONTROL**

Each batch of Enterosystem 24R is subjected to the quality control using the following reference strains: *Escherichia coli* ATCC® 25922, *Salmonella Typhimurium* ATCC® 14028, *Proteus mirabilis* ATCC® 25933, *Klebsiella pneumoniae* ATCC® 13883, *Enterobacter cloacae* ATCC® 13047.

**PERFORMANCE**

The results obtained with the Enterosystem 24R agree with those obtained using other microbiological and biochemical tests for microbial identification.

**FACTORS THAT MAY INVALIDATE THE RESULTS**

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

**PRECAUTIONS**

The product Enterosystem 24R does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. Enterosystem 24R is a disposable device to be used only for diagnostic use *in vitro*. The product must be used in the laboratory by properly trained personnel, using approved aseptic and safety methods for handling pathogenic agents.

**STORAGE**

Store Enterosystem 24R at 2-8°C in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions the product will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.








**DISPOSAL OF USED MATERIAL**

After use, Enterosystem 24R and material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

**PRESENTATION**

Product	Ref.	Package
Enterosystem 24R	71619	20 tests
Enterosystem 24R	79619	4 tests

**TABLE OF SYMBOLS**

<b>IVD</b> for <i>in vitro</i> diagnostic use	 Do not reuse	 Manufacturer	 Contains sufficient for <n> test	 Temperature limits
<b>REF</b> Catalogue number	 Fragile, handle with care	 Use by	 Caution, consult accompanying documents	<b>LOT</b> Batch number





# Enterosystem 18R Reagent

Reagents for indole and Voges-Proskauer tests for use with Enterosystem 18R.

## DESCRIPTION

Enterosystem 18R Reagent is a kit containing the reagents Alpha Naphthol, NaOH 40%, Kovac's Reagent and Vaseline Oil necessary for the proper use of Enterosystem 18R (ref. 71618), a system for the identification of Gram-negative, oxidase negative, enterobacteria.

## KIT CONTENTS

- 1 x 10 ml vial of Alpha Naphthol.
- 1 x 10 ml vial of NaOH 40%.
- 1 x 10 ml vial of Kovac's Reagent.
- 2 x 40 ml bottles of Vaseline Oil.
- 1 instruction sheet.

## METHOD PRINCIPLE

Alpha Naphthol and NaOH 40% are used to carry out the Voges-Proskauer test into the well 10-VP. Kovac's Reagent is used to carry out the indole test into the well 11-IND.

Vaseline Oil is used for the maintenance of a sufficiently anaerobic environment into the wells 2-LDC, 3-ODC, 4-ADC, 7-UR and 8-11 S.

## REAGENTS

- Alpha Naphthol: 6% (w/v) alpha naphthol dissolved in ethyl alcohol.
- NaOH 40%: 40% (w/v) sodium hydroxide in aqueous solution.
- Kovac's Reagent: 5% (w/v) *p*-dimethylaminobenzaldehyde dissolved in a solution of 25% hydrochloric acid and 75% isobutyl alcohol.
- Vaseline Oil.

## TEST PROCEDURE AND RESULTS INTERPRETATION

Refer to the package insert provided with Enterosystem 18R.

## QUALITY CONTROL FOR THE USER

For each reagent, check positive and negative results by using suitable organisms, according to bibliographic references.

## PRECAUTIONS

Enterosystem 18R Reagent is classifiable as hazardous under current legislation; it is recommended that the Safety Data Sheet be consulted on its use. The product is intended for *in vitro* diagnostic use only and must be used in the laboratory by properly trained personnel, using approved asepsis and safety methods for handling pathogenic agents.

## STORAGE AND TRANSPORT CONDITIONS

Store at 2-8°C away from light in its original package, until the expiry date shown on the label. However, our stability studies have shown that the storage or transport at 18-25°C for 4 days, or at 35-39°C for 48 hours, do not alter in any way the performance of the product. Eliminate if signs of deterioration or contamination are evident.

## ELIMINATING USED MATERIAL

After use, used Enterosystem 18R Reagent and the material that has come into contact with the sample must be decontaminated and disposed of in accordance with the laboratory procedures for the decontamination and disposal of potentially infected material.

## BIBLIOGRAPHY

1. Murray, Baron, Pfaller, Tenev and Tenover: Manual of Clinical Microbiology (1995).
2. Bailey and Scott's: Diagnostic Microbiology (1986).
3. Edwin H. Tenette: Manual of Clinical Microbiology (1995).

## PRESENTATION

Product	Ref.	Content
Enterosystem 18R Reagent	80252	100-200 tests

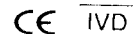
## TABLE OF SYMBOLS

LOT	batch code	IVD	<i>In vitro</i> Diagnostic Medical Device	Manufacturer	Use by	Fragile, handle with care
REF	Catalogue number	Temperature limitation	Contains Sufficient for tests	Caution, consult accompanying documents	Do not reuse	



LIOFILCHEM\* S.r.l.

Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY  
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Ref. 4.1.1.001.1.1





# Optochine Test

ENGLISH

## Diagnostic discs for pneumococci identification.

### DESCRIPTION

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

### CONTENT OF THE PACKAGES

Each package contains:

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

### PRINCIPLE OF THE METHOD

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

### COMPOSITION

Each disc contains 5 µg of Optochin.

### PREPARATION OF THE SPECIMEN

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

### TEST PROCEDURE

1. Take the cartridges container from the refrigerator and leave it on the test bench until it reaches room temperature (about 30 minutes). This will prevent humidity being deposited on the discs when the package is opened, which could prejudice their long-term stability.
2. Using a sterile swab, evenly inoculate the surface of a plate of blood agar such as Tryptic Soy Blood Agar (ref. 11037), Columbia Blood Agar (ref. 11025) or other blood medium, with the suspension of the streptococcus under examination.
3. Using sterile tools, gently press one disc of Optochin on the inoculated surface.
4. Turn the plate upside down and incubate at  $36 \pm 1^\circ\text{C}$  for 18-24 hours in atmosphere containing 5% of  $\text{CO}_2$ .
5. Check for presence or absence of an inhibition halo around the disc of Optochin.

### INTERPRETATION OF THE RESULTS

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

### QUALITY CONTROL

Each batch of Optochine Test is tested for susceptibility to Optochin by using *Streptococcus pneumoniae* ATCC 49619 for positive control, and *Streptococcus pyogenes* ATCC 19615 for negative control, inoculated on Columbia Blood Agar with 5% of defibrinated sheep blood.

### PRECAUTIONS

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

### STORAGE

Store Optochine Test at  $-20^\circ\text{C}/-8^\circ\text{C}$  in the original packaging. Keep away from sources of heat and avoid excessive changes in temperature. In such conditions, the product will remain valid until the expiry date indicated on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration.

### DISPOSAL OF USED MATERIAL

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

### BIBLIOGRAPHY

- [https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/394193/TP\\_2513.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/394193/TP_2513.pdf)
- J. Lab. Clin. Med., 49: 641, 1957.
- J. Clin. Path., 8: 58, 1955.
- Serological Studies on Pneumococci, Munksgaard, Copenhagen, Oxford University Press, London, 1943.
- J. Exp. Med., 22: 269, 1915.

### PRESENTATION

Product	Ref.	Test
Optochine Test	9501	100

### TABLE OF SYMBOLS

IVD	In Vitro Diagnostic Medical Device		Do not reuse
REF	Catalogue number		Fragile, handle with care
	Manufacturer		Contains sufficient for 1 test
	Use by		Caution, consult accompanying documents
	Temperature limitation		Batch code



**LIOFILCHEM® S.r.l.**

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130010



# GRAM COLOR KIT

## DESCRIPTION

GRAM COLOR KIT is a kit for staining micro-organisms that allows them to be differentiated into two categories: Gram-positives (Gram+), which are coloured blue, and Gram-negatives (Gram-), which are coloured red. Combined with direct observation of the cell morphology, this staining constitutes the first level in the taxonomic classification of prokaryotes.

## CONTENT OF THE PACKAGES

The reagents are contained in plastic bottles, sealed by thermo-induction and provided with a dropper lid. Each pack contains:

- 1 bottle containing 250 ml of Crystal Violet Solution
- 1 bottle containing 250 ml of Lugol-PVP Solution
- 1 bottle containing 250 ml of Decolourant Solution
- 1 bottle containing 250 ml of Safranin Solution

## PRINCIPLE OF THE METHOD

Gram staining is based on the property of Crystal Violet of combining with iodine to form compounds that cannot be decoloured with alcohol or with an alcohol-acetone mixture. Some bacteria have a special affinity for this reaction and, once stained with crystal violet, do not lose the colour if treated with alcohol or alcohol-acetone mixture, thus retaining the blue colouring (Gram-positive bacteria). Others lose the blue colour and are stained by Safranin, taking a red colour (Gram-negative bacteria).

## COLLECTION OF SAMPLES

Samples to be subjected to Gram staining are usually clinical material and microbial cultures. The colonies to be subjected to Gram staining must be taken from young cultures (18-24 hours) preferably on an agar medium.

## TEST PROCEDURE

### Preparation and fixing

On clean slides, make a smear of the culture or pathological material. Leave to dry in the air and fix by heat, passing rapidly over the flame. Do not overheat the sample when fixing. Other fixing methods may be used.

### Staining

1. Cover the slide with the Crystal Violet Solution. Wait 1 minute, then rinse gently with water.
2. Cover the slide with the Lugol-PVP Solution. Wait 1 minute, then rinse delicately with water.
3. Decolour with the Decolourant Solution for as long as the preparation releases colour (about 30-60 seconds), then rinse delicately with water.
4. Cover the slide with the Safranin Solution. Wait 30-60 seconds, then rinse delicately with water.
5. Dry.
6. Examine the preparation under the microscope with the objective for immersion.

## INTERPRETATION OF THE RESULTS

The Gram-negative micro-organisms appear as red in colour.

The Gram-positive micro-organisms appear as blue in colour.

The Gram staining makes it possible to distinguish between:

- Gram-negative bacilli from Gram-positive ones;
- Gram-negative cocci from Gram-positive ones;
- Gram-negative coccobacilli from Gram-positive ones;
- Gram-negative diplococci from Gram-positive ones.

## QUALITY CONTROL

Each lot of GRAM COLOR KIT is subjected to quality control using a culture of *Escherichia coli* ATCC 25922 for the test for Gram-negative bacteria (red colour) and a culture of *Staphylococcus aureus* ATCC 25923 for the test for Gram-positive bacteria (blue colour).

## LIMITS

- Gram staining provides a preliminary identification but does not replace normal cultural studies of the sample.
- Antibiotic therapy may make Gram-positive bacteria more sensitive to decolouration, so that they appear pinkish-red instead of blue.
- Cells taken from young, 18-24 hour cultures have a greater affinity for the stains than cells taken from older cultures.
- Gram staining is altered by the physical destruction of the cell wall or protoplasm. In fact the cell wall of Gram-positive bacteria constitutes a barrier which impedes release of the Crystal Violet-iodine complex from the cytoplasm, and the cell wall of Gram-negative bacteria contains lipids soluble in organic solvents that

permit decolouration of the cytoplasm. Hence, micro-organisms physically destroyed by an excess of heat do not react as expected to the Gram stain test.

## PRECAUTIONS

The GRAM COLOR KIT package contains substances classified as hazardous by current legislation. It is recommended that the Safety Data Sheets be consulted on their use. GRAM COLOR KIT is a kit for bacteria staining, only for diagnostic use *in vitro*. It is intended for use in a professional environment and must be used in a laboratory by adequately trained personnel using approved asepsis and safety methods for dealing with pathogenic agents.

## CONSERVATION

Store GRAM COLOR KIT at 10-25°C in the original packaging. Keep away from sources of heat and avoid excessive changes of temperature. In such conditions the product GRAM COLOR KIT will be valid until the expiry date shown on the label. Do not use beyond that date. Eliminate without using if there are signs of deterioration (changes in the colour of the solutions or presence of substantial precipitates).

## DISPOSAL OF USED MATERIAL

After use, the slides stained with the GRAM COLOR KIT and any material that has come into contact with the sample must be decontaminated and disposed of in accordance with the techniques used in the laboratory for decontamination and disposal of potentially infected material.

## BIBLIOGRAPHY

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

## PRESENTATION

Product	Ref	Content
GRAM COLOR KIT	80293	4 x 250 ml

## TABLE OF SYMBOLS

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



# CERTIFICATE

The certification body confirms to

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

for the development, manufacturing and sale of products for human and veterinary medical in-vitro-diagnostics as well as for the microbiological examination of water and food and other diagnostic applications the conformity of the introduced quality management system with the standard

## DIN EN ISO 9001:2015

Start of validity:	07.07.2017
End of validity:	06.07.2020
Report and certificate number:	IC00016 038 17
The certificate consists of	1 page

*This certificate includes an annual examination of the QMS by IFTA AG, according to the specified standard.*

Berlin, 06.07.2017

Prof. Dr. Jörn Karge  
CEO

**DAKKS**  
Deutsche  
Akkreditierungsstelle  
D-ZM-16072-01-00

# Certificate

**mdc medical device certification GmbH**  
certifies that

## sifin

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

for the scope

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

has introduced and applies a

## Quality Management System

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

### EN ISO 13485

Medical devices – Quality management systems +  
Requirements for regulatory purposes

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

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

  
Head of Certification Body

medical device certification  
**mdc**  
certification

**DAkKS**

Deutsche  
Akkreditierungsstelle  
D ZM-16002 06-CC

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

# sifin

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

CE  
Nr./No. 103

Wir / Nous / We

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

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

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

**Anti-Salmonella A-67 + Vi, omnivalent**  
**Anti-Salmonella I (A-E + Vi)**  
**Anti-Salmonella II (F-67)**

### Sonstiges Produkt

Other device/Autre dispositif

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

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

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


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

**Anhang III**  
Annexe III  
Annex III

Gültig bis:  
Valable jusqu'au:  
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz 

Sicherheitsbeauftragter für Medizinprodukte  
Agent de sécurité / Safety Officer

# sifin

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

CE  
Nr./No. 110

Wir / Nous / We

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Berliner Allee 317-321, 13088 Berlin, Germany

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

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

**Anti-Shigella I**  
**Anti-Shigella II**  
**Anti-Shigella III**  
**Anti-Shigella flexneri**

### Sonstiges Produkt

Other device/Autre dispositif

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

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

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

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

**Anhang III**  
Annexe III  
Annex III

Gültig bis:  
Valable jusqu'au:  
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz

Sicherheitsbeauftragter für Medizinprodukte  
Agent de sécurité / Safety Officer



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

**CE  
Nr./No. 111**

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

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

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

**Sonstiges Produkt**

Other device/Autre dispositif

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

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

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


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

**Anhang III**  
Annexe III  
Annex III

Gültig bis:  
Valable jusqu'au:  
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz   
Sicherheitsbeauftragter für Medizinprodukte  
Agent de sécurité /Safety Officer



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

**CE**  
Nr./No. 104

Wir / Nous / We

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Berliner Allee 317-321, 13088 Berlin, Germany

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

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

**Anti-Salmonella Group B**  
**Anti-Salmonella Group C**  
**Anti-Salmonella Group D**  
**Anti-Salmonella Group E**

**Sonstiges Produkt**

Other device/Autre dispositif

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

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

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


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

**Anhang III**  
Annexe III  
Annex III

Gültig bis:  
Valable jusqu'au:  
Valid until:

2021-10-22

Berlin, 31.10.2018

Dr. T. Schwarz 

Sicherheitsbeauftragter für Medizinprodukte  
Agent de sécurité /Safety Officer









**Назначение:**  
 Анализ фекалий на наличие возбудителей дизентерии, вызываемой бактериями рода *Shigella*.

**Применение/показания:**  
 Для выявления возбудителей дизентерии, вызываемой бактериями рода *Shigella*.

**Состав:**  
 1 флакон с 10 порциями реагента для проведения 10 тестов. Состав реагента: 10 порций реагента.

**Предлагаемые варианты специфических реагентов для бытовых реагентов**

Наименование	Состав реагента
Анти-SHIGELLA	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei, Shigella boydii, Shigella sonnei)
Анти-SHIGELLA	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)
Анти-SHIGELLA	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)

**Предлагаемые варианты специфических реагентов для лабораторных реагентов**

Наименование	Состав реагента	Вид реагента
Анти-SHIGELLA	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)
Анти-SHIGELLA	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)
Анти-SHIGELLA	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)
Анти-SHIGELLA	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)	Анти-SHIGELLA (Shigella flexneri, Shigella sonnei)

**Формулы для расчета стоимости**

Формулы для расчета стоимости реагента для бытовых реагентов:

Стоимость реагента = (Стоимость реагента / Количество порций) \* Количество порций

Формулы для расчета стоимости реагента для лабораторных реагентов:

Стоимость реагента = (Стоимость реагента / Количество порций) \* Количество порций

**Предупреждения и меры предосторожности:**

Внимание! Реагент содержит химические вещества, которые могут вызвать раздражение кожи и слизистых оболочек. При попадании на кожу или слизистые оболочки немедленно промыть большим количеством воды. При попадании в глаза немедленно промыть большим количеством воды и обратиться к врачу.

**Материалы и оборудование, входящие в комплект поставки:**

1 флакон с 10 порциями реагента для проведения 10 тестов.

**Исходный материал и методика:**

Исходный материал: фекалии человека. Методика: анализ фекалий на наличие возбудителей дизентерии, вызываемой бактериями рода *Shigella*.

**Интерпретация результатов анализа:**

Положительный результат: наличие возбудителей дизентерии, вызываемой бактериями рода *Shigella*.



**Зеркальные зеркала и другие материалы:**

Зеркальные зеркала и другие материалы, необходимые для проведения теста.

**Составляющие реагента:**

Составляющие реагента, необходимые для проведения теста.

**Как правильно использовать реагент:**

LOT	1234567890	1	1234567890
REF	1234567890	1	1234567890
QVD	1234567890	1	1234567890
FR	1234567890	1	1234567890
INT	1234567890	1	1234567890
LYC	1234567890	1	1234567890

## EC DECLARATION OF CONFORMITY

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

Product name	Catalogue number
Strep Test kit	860050

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

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

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

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

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 24 March 2016.



\_\_\_\_\_  
 Eddy Velthuis  
 Technical Director



## EC DECLARATION OF CONFORMITY

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

Product name	Catalogue numbers
Staph Test kit	870050 870100

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

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

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

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

This declaration of conformity is issued under the sole responsibility of Lorne Laboratories Ltd and is valid from 24 March 2016.



\_\_\_\_\_  
 Eddy Velthuis  
 Technical Director





LORNE LABORATORIES LTD.  
GREAT BRITAIN



## BACTERIAL IDENTIFICATION DIRECTIONS FOR USE

### Staph-Check Kit: For Identification Of Species Possessing Clumping Factor And/OR Protein A.

#### SUMMARY:

Over 95% of pathogenic strains of *Staphylococcus aureus* produce protein A, either with or without clumping factor. Protein A has a high affinity for the Fc moiety of IgG.

#### PRINCIPLE:

When used by the recommended techniques, latex particles in the reagent will agglutinate (clump) in the presence of either clumping factor and/or protein A. No agglutination generally indicates the absence of either clumping factor and/or protein A (see Limitations)

#### KIT DESCRIPTION:

Lorne Staph-Check kit is for identification of *Staphylococcus* species possessing clumping factor and/or protein A. The *Aureus* reagent consists of latex particles coated with human fibrinogen and IgG, and the control reagent consists of latex particles that are not coated with fibrinogen and IgG. All the reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. Lot reference number and expiry dates are printed on the kit box and individual vial labels.

#### STORAGE CONDITIONS, TRANSPORT & HANDLING:

Keep all vials clean, well sealed and store upright at 2-8°C during storage and transportation. Do not freeze or expose to elevated temperatures. Prolonged storage outside the recommended temperature range may result in accelerated loss of reagent reactivity. Protective clothing should be worn when handling the kit components, such as disposable gloves and a laboratory coat.

#### SPECIMEN COLLECTION:

Cultures should be fresh 24-hour growths, and may be tested directly from the plate. If there is insufficient growth, sub-culture to blood or nutrient agar and incubate overnight at 37°C. Organisms grown on high salt media such as mannitol salt agar may show stringiness when mixed with reagents. Testing control latex reagent in parallel can eliminate any discrepancies. Alternatively, sub-culturing to blood agar base of nutrient agar should be sufficient.

#### PRECAUTIONS:

- The kit for *in vitro* diagnostic use only.
- Do not use kit past expiration date (see Vial and Box Labels).
- The reagent contains less than 0.1% sodium azide. Sodium azide may be toxic if ingested and may react with lead and copper plumbing to form explosive metal azides. On disposal flush away with large volumes of water.
- Materials used to produce the kit were tested at source and found to be free of HIV-1, 2 and HBV, using appropriate serological tests. However, no known tests can guarantee that products, prepared from human or animal sources, are free from infectious agents. Care must be taken in the use and disposal of kits with animal contents.

#### DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLS:

For disposal and re-use of kit reagent and decontamination of a spillage, see the Material Safety Data Sheets, available on request.

#### CONTROLS AND ADVICE:

- F. S. reagent must be positive control specimen for tested in parallel with each batch of tests. Tests must be considered invalid if control is not positive.
- All kit reagents must be allowed to warm to room temperature.
- Shake the reagent vial before use to ensure homogeneity.
- Do not touch latex particles with fingers to ensure homogeneity.
- Use of kit using inter-substituted reagents must be carried out by specially trained and qualified personnel.
- The user must determine the stability of the kit for use in other laboratories.

#### SPECIFIC PERFORMANCE CHARACTERISTICS:

- The kit has been characterized by all the procedures mentioned in the Recommended Techniques.
- A blind trial was undertaken at the Lorne PHLS. Two hundred and fourteen reference strains were tested. These represented a number of species commonly isolated and some rare species. The reagents used in the trial were 12 months old and at the end of the recommended shelf life. All strains of *S. aureus* examined gave the expected positive results. Lorne Staph-Check Kit was considered to be easy to use and the provision of a control was a beneficial feature. The Lorne kit was judged to provide a rapid accurate, easy to read method for detecting *S. aureus* in a routine clinical laboratory and was comparable with other rapid slide latex methods commercially available.

#### DISCLAIMER:

- The user is responsible for the performance of the kit by any method other than those mentioned in the Recommended Techniques.
- Any deviations should be validated prior to use using established laboratory procedures.

#### BIBLIOGRAPHY:

- Phillips W, Kinos W. (1981). *J. Clin. Microbiol.* **14**: 671.
- Freney J, Brun Y, Bes M. (1988). *Int. J. Syst. Bacteriol.* **38**: 108.
- Stevens M, Geary C. (1989). *Eur. J. Clin. Mic. Inf. Dis.* **8**: 153-156.
- Berke A, Tilton R.C. (1987). *J. Clin. Mic.* **23**: 916-919.
- Gregson D.B., Low D.E., Skulnick M., Simor A.E. (1988). *J. Clin. Mic.* **26**: 1398-1399.

#### AVAILABLE KIT SIZES:

Kit Size	Catalogue Number
50 Test Kit	870050
100 Test Kit	870100

For the availability of other sizes, please contact:

Lorne Laboratories Limited  
Unit 1 Danhall  
Cotswold Park Industrial Estate  
Lower Earley, Reading,  
Berkshire, RG6 4UT  
Tel: +44 (0) 118 921 2264  
Fax: +44 (0) 118 986 4514  
E-mail: info@lornelabs.com

#### TABLE OF SYMBOLS

	Batch Number		<i>In-vitro</i> Diagnostic
	Catalogue Reference		Store At
	Expiry Date		Manufacturer
	Read Pack Insert		



**BACTERIAL IDENTIFICATION DIRECTIONS FOR USE**

**Strep-Check Kit: For Identification Of Streptococci, Lancefield's Groups A, B, C, D, F And G.**

**SUMMARY**

Streptococci carry group specific carbohydrate antigens in their cell walls, and after extraction using a specially developed enzyme preparation these antigens will agglutinate latex particles coated with the corresponding antibody.

**PRINCIPLE**

When used by the recommended techniques, latex particles in the reagent will agglutinate (clump) in the presence of the corresponding streptococcal antigen. No agglutination, generally indicates absence of the corresponding streptococcal antigen (see Limitations).

**KIT DESCRIPTION**

Lorne Strep-Check is for identification of streptococci, Lancefield's groups A, B, C, D, F and G. The different reagents are coated with the specific antibody and will agglutinate in the presence of enzymatically-extracted antigen. All the reagents are supplied at optimal dilution for use with all recommended techniques without the need for further dilution or addition. For lot reference number and expiry date see **Vial Labels**.

**STORAGE**

Keep all vials clean, well sealed and store upright at 2-8°C during storage and transportation. Do not freeze. The latex reagents, streptococci and disposable gloves may result in accelerated loss of reagent reactivity. The reagents, latex reagent enzyme will maintain activity for 3 months or until the date shown on the original bottle when stored at 2-8°C. Alternatively, reagents may be stored in aliquots and frozen at -20°C, where it will remain active for 6 months or until date shown on the bottle, whichever is shorter. Do not freeze and thaw extraction enzyme more than once.

**SPECIMEN COLLECTION**

Note the cultural characteristics, haemolysis and cell morphology before starting the test. Ensure that the organisms to be tested are Gram-positive and catalase-positive. Blood agar plate cultures yielding 2-6 well-separated colonies may be used. They should have been inoculated from a pure culture of the organism.

**PRECAUTIONS**

1. The kit is for *in vitro* diagnostic use only.
2. Do not use kit past expiration date.
3. Protective clothing should be worn when handling the reagents, such as disposable gloves and a laboratory coat.
4. The reagents contain less than 0.1% sodium azide. Sodium azide, used as a preservative, may react with copper reagent plumbing to form explosive azide salts. Or, repeated flush away with large volumes of water.
5. No known toxic or quantitative hazards derived from use of animal antigens are known from animal sources. Care should be taken in the use and disposal of such material as wastes.

**DISPOSAL OF KIT REAGENT AND DEALING WITH SPILLAGES**

For information on disposal of kit reagent and decontamination of spillages see our **Material Safety Data Sheets**, available on request.

**CONTROLS AND ADVICE**

1. It is not recommended the Positive Control be used in conjunction with other batches of tests. Tests must be considered invalid if control does not show correct test result.
2. All the reagents must be above 18°C (64°F) before use.
3. Shake the reagents well before use to ensure homogeneous suspension.
4. Do not refrigerate reagents. Reagents should be stored at room temperature.
5. Use of kit and interpretation of results must conform with the preparation of the country with which you are operating.
6. User must be advised that the kit is for use in the laboratory only.

**KIT COMPONENTS SUPPLIED**

- Streptococcal A Test Reagent (Yellow label)
- Streptococcal B Test Reagent (Yellow label)
- Streptococcal C Test Reagent (Yellow label)
- Streptococcal F Test Reagent (Yellow label)
- Streptococcal G Test Reagent (Yellow label)
- Polyvalent Positive Control (Red label)
- Extraction Enzyme (2 bottles) (Green label)
- Disposable Agglutination Slides.
- Stirrers.

**MATERIALS AND EQUIPMENT REQUIRED**

- Glass Test Tubes (10 x 75 mm or 12 x 75 mm).
- 37°C Water Bath.
- Sterile Bacteriological Loops.
- Pasteur and Graduated Pipettes.

**RECONSTITUTION OF EXTRACTION ENZYME**

To one bottle of Extraction Enzyme add 10 ml of de-ionised water. Shake the bottle's contents thoroughly and then allow the contents to stand for 5 minutes. The Extraction Enzyme is now reconstituted and ready for use.

**RECOMMENDED TECHNIQUE**

1. Using a sterile loop pick 2-6 colonies of streptococci making sure to avoid other types of colony on the plate.
2. Finally the colonies in 0.4 ml of the Extraction Enzyme. If a broth culture is to be grouped, pipette 0.1 ml of an overnight culture into 0.4 ml of the Extraction Enzyme.
3. Incubate the mixture in a water bath at 37°C for 10 minutes, shaking tubes vigorously after 5 minutes incubation.
4. Add one drop of each latex reagent into the appropriate labelled circle on the test slide.
5. Add one drop of the extract to each drop of latex reagent, and mix the contents of each circle with a separate mixing stick.
6. Rock the slide for not longer than 1 minute and then observe for agglutination.
7. Record the results.

**INTERPRETATION OF RESULTS**

1. **Positive:** Strong agglutination of specimen with ONE latex reagent, normally within a few seconds, of mixing constitutes a positive result and when the accepted technique is used **immediately indicates the presence of that specific streptococcal group either A, B, C, D, F or G.**
2. **Negative:** No visible agglutination of latex particles in a milky liquid constitutes a negative result when using the accepted techniques of the test. Incomplete agglutination, the absence of agglutination or groups A, B, C, D, F and G.
3. **Equivalent:** If agglutination occurs in all groups then either the enzyme has been over-inactivated or a mixed culture is present or there is some check for purity and re-try.

**LIMITATIONS**

1. Latex particle reactions have been known to occur with antigens from unrelated groups, e.g. Escherichia, Klebsiella and other organisms. These are likely to be gradually inhibited over time.
2. Certain Bacteria is known to agglutinate groups A, B, C, D, F and G. These results can occur if an inadequate amount of latex reagent is used.
3. For correct use of the kit, the user must be advised that:
  - A certain reduction of test results may occur due to the presence of other bacteria in the culture.
  - Inoculation with Bacteria is not recommended.
  - Inoculation with Bacteria is not recommended.

**SPECIFIC PERFORMANCE CHARACTERISTICS**

1. The kit has been characterised by all the procedures mentioned in the **Recommended Techniques**.
2. Prior to release, each lot of Lorne Strep-Check Kit is tested by the **Recommended Techniques** to ensure suitable reactivity.

**DISCLAIMER**

1. The user is responsible for the performance of the kit by any method other than those mentioned in the **Recommended Techniques**.
2. Any deviations should be validated prior to use using established laboratory procedures.

**BIBLIOGRAPHY**

1. Lancefield RC. (1938) Proc. Soc. Exp. Bio. Med. 38: 473.
2. Harvey CL, McMurray MB. (1984) Eur. J. Clin. Microbiol. 3: 6526.
3. Facklam RR. (1980). "Manual of Clinical Microbiology" 3<sup>rd</sup> Ed. American Society for Microbiology, Washington, DC. Pp 88-110.

**AVAILABLE KIT SIZES**

Kit Size	Catalogue Number
6 X 50 Tests Per Kit	660050

For the availability of other sizes, please contact:

**Lorne Laboratories Limited**  
Unit 1, Daneshill  
Cubush Park Industrial Estate  
Lower Earley, Reading,  
Berkshire, RG5 4UT  
England  
Tel: +44 (0) 118 921 2264  
Fax: +44 (0) 118 986 4518  
E-mail: [info@lorneabs.com](mailto:info@lorneabs.com)

**TABLE OF SYMBOLS**

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	Expiry Date		Manufacturer
	Read Pack Insert		



# ICIM

CERTIFICATO n. **4264/4**  
CERTIFICATE No.

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Sistema di Gestione per la Qualità / Quality Management System

PER LE SEGUENTI ATTIVITÀ / FOR THE FOLLOWING ACTIVITIES

EA: 14 - 29

Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine.  
Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto.  
Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico.  
Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.  
*Design and production of test tubes with predetermined vacuum for collection of haematological samples, biological liquids and urine samples. Production of test tubes for micro-collection of haematological samples. Design and production of Holders for vacuum sampling. Design and production of diagnostic kits for blood and biological liquids analysis. Design and production of culture media for microbiology. Design and production of sterile needles and devices for collection of haematological samples. Trading of the products of the Group: diagnostic kits, culture media for microbiology, plastic disposable labware, test tubes with predetermined vacuum and sterile needles. Design and production of moulds for plastic labware. Injection moulding of thermoplastic materials for medical devices.*

Riferirsi alla documentazione del Sistema di Gestione per la Qualità aziendale per l'applicabilità dei requisiti della norma di riferimento  
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Progettazione e produzione di provette con vuoto predeterminato ad uso prelievo ematico, liquidi biologici e urine. Produzione di provette per microprelievi di sangue. Progettazione e produzione di Holders (camicie) per prelievo sottovuoto. Progettazione e produzione di kit diagnostici per l'analisi del sangue e dei liquidi biologici. Progettazione e produzione di terreni di coltura per microbiologia. Progettazione e produzione di aghi e dispositivi sterili per il prelievo ematico. Commercializzazione di prodotti del Gruppo: kit diagnostici, terreni di coltura per microbiologia, articoli in plastica per laboratorio analisi, provette con vuoto predeterminato e aghi sterili. Progettazione e produzione di stampi per articoli in plastica per laboratorio analisi. Stampaggio di materie termoplastiche ad iniezione per articoli medicali.

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