HIMEDIA®
For Life is Precious

HiMedia Laboratories Pvt. Ltd.

Date: 07th March 2024.

TO WHOMSOEVER IT MAY CONCERN

We hereby certify that,

Sanmedico SRL
Str. Corobceanu 7A, Apt.9,
MD-2012, CITY CHISINAU
Republic of Moldova,
Tel:-00-373-231 31515 / 00-373-222 60595
Fax:-00-373-22 62 30 32
E-mail: sanmedico.office@gmail.com

have been appointed by us as our **Authorized Distributor** for selling our Products in **MOLDOVA**

This certificate is valid upto 06th March 2026.

This Authorization Letter shall stand effective from the date of signing and can be terminated by either party with two months advance notice.

For HIMEDIA LABORATORIES PVT. LTD.,

HiMedia Laboratories Pvt. Limited Thane 400604

V.M.WARKE.
DIRECTOR – SALES & MARKETING

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CERTIFICATE

Quality Austria Certification GmbH awards this **quality**austria certificate to the following organisation:

HIMEDIA

HiMedia Laboratories Pvt. Ltd.
Plot No. C40, Road - 21Y, WAGLE Industrial Estate,
Thane (West) - 400604 Maharashtra, India

This **quality**austria certificate confirms the application and further development of an effective

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes

Design,Development & Manufacturing of Biosciences Products for application in Microbiology,Cell Biology & Molecular Biology Products.

Registration No.: M-00391/0
Date of initial issue: 28 February 2022
Valid until: 27 February 2028

The validity of the **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Vienna, 10 March 2025

Quality Austria Certification GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

Mag. Christoph Mondl
CEO

Mag. Dr. Werner Paar
CEO

Ing. Christoph Baumgartner, MSc, MBA
Authorised representative,
management Customer Service Center

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MEMBER OF
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Quality Austria Certification GmbH is accredited according to the Austrian Accreditation Act by the BMWFW (Federal Ministry of Science, Research and Economy).

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Dok. Nr. FO_24_028

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HIMEDIA

HiMedia Laboratories Pvt. Ltd.
Plot No. C40, Road - 21Y, WAGLE Industrial Estate,
Thane (West) - 400604 Maharashtra, India

QUALITY MANAGEMENT SYSTEM
complying with the requirements of standard
ISO 9001:2015

Design,Development & Marnufacturing of Microbiology, Cell Biology,Plant Tissue Culture & Molecular Biology Products and Trading of Allied Plastic-wares,Lab Aid Instrument and Consumables (Sterile Disposable Petri Dishes,Sterile Swabs,Sterile Loops and Spreaders)

The validity of the **quality**austria certificate will be maintained by annual surveillance audits and one renewal audit after three years.

Registration No.: Q-27302/0

Date of initial issue: 28 February 2022

Valid until: 27 February 2028

Vienna, 10 March 2025

Quality Austria Certification GmbH,
AT-1010 Vienna, Zelinkagasse 10/3

Mag. Christoph Mondl
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HiMedia Laboratories Private Limited
C-40, Road No.21Y, MIDC, Wagle Industrial Area,
Thane(W) - 400604 , Website : www.himedialabs.com,
Email : info@himedialabs.com

Certificate of Analysis, Quality and Conformity

Material Code : M612I	**Material Name :** Slanetz and Bartley Medium	**Lot No :** 0000618737
Report No.: 40001417844	**Date of Release & Report :** 2023-11-27	**Expiry Date :** 2028-10

Appearance
Cream to yellow homogeneous free flowing powder. Observed : Light yellow

Gelling
Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium
Light yellow coloured clear to slightly opalescent gel forms in Petri plates

Reaction
Reaction of 4.65% w/v aqueous solution at 25°C.

pH
pH Range :7.00-7.40 Observed : 7.27

Cultural Response
Cultural characteristics observed after an incubation at 44-45°C for 44- 48 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Colour of colony
Cultural Response				
Enterococcus faecalis ATCC 29212 (WDCM 00087)	50-100	good-luxuriant	>=50%	red or maroon
Enterococcus faecalis ATCC 19433 (WDCM 00009)	50-100	good-luxuriant	>=50%	red or maroon
Enterococcus faecalis DSM 24916 (WDCM 00176)	50-100	good-luxuriant	>=50%	red or maroon
Enterococcus faecium ATCC 6057 (WDCM 00177)	50-100	good-luxuriant	>=50%	red or maroon
Enterococcus faecium NCTC 13169 (WDCM 00178)	50-100	good-luxuriant	>=50%	red or maroon
Escherichia coli ATCC 25922 (WDCM 00013)	>=10^4	inhibited	0%	-
Escherichia coli ATCC 8739 (WDCM 00012)	>=10^4	inhibited	0%	-
Staphylococcus aureus subsp. aureus ATCC 6538	>=10^4	inhibited	0%	-
Staphylococcus aureus subsp. aureus ATCC 25923	>=10^4	inhibited	0%	-

. ATCC is a registered trade mark of the American Type Culture Collection
. NCTC and National Collection of Type Culture are registered trade mark of the Health Protection Agency

Control Media :

HiMedia Laboratories Private Limited
C-40, Road No.21Y, MIDC, Wagle Industrial Area,
Thane(W) - 400604 , Website : www.himedialabs.com,
Email : info@himedialabs.com

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. For Bacteria : Soyabean Casein Digest Agar / Columbia Blood Agar base enriched with 5% v/v Sheep/Horse blood.
. For Yeast & Mold : Sabouraud Dextrose Agar.

. All ISO 11133 : 2014/Amd.1:2018(E) control strains are included in the Quality parameter
. HiMedia Laboratories Pvt Ltd is Certified for ISO 9001:2015, ISO 13485:2016 , WHO GMP

. Information for BSE/TSE Risk: The material was subjected to pH <= 7.0 and/or a temperature in excess of 75ºC for no less than 2 hours during the manufacturing process. The bovine raw material for this product was collected entirely from Indian Origin animals in a licensed based establishment. The animals are inspected under a Govt. approved veterinarian's supervision and were apparently free from infectious and contagious diseases. BSE (Bovine Spongiform Encephalopathy)/ TSE (Transmissible Spongiform Encephalopathy) and dioxine are not known to exist in India. This material does not contain, nor is derived from the specific risks material as defined in The Maharashtra Animal Preservation Act Govt. of Maharashtra, India.

STATUS OF THE MATERIAL : APPROVED

This is to certify that this lot passes and it confirms to the above mentioned tests and specifications . The information given here is believed to be correct and accurate, however, both the information and products are offered without warranty for any particulars use, other than that specified in the current HiMedia manual or product sheets. The results reported were obtained at the time of release.

This document has been produced electronically and is valid

Sheetal Shewale	Ujwala M. Kokate	Dr. Santosh Kaul
Microbiologist/Sr.Executive Microbiologist	Asst./Dy/QC Manager	Dy/QA Manager

2023-11-27

Slanetz and Bartley Medium

M612I

Intended use

Recommended for detection and enumeration of faecal Streptococci from water samples by membrane filtration technique. The composition and performance criteria of this medium are as per the specifications laid down in ISO/ DIS 7899 -2: 2000 (E) and APHA.

Composition**

ISO 7899-2:2000 (E), APHA		**Slanetz and Bartley Medium**	**M612I**
Ingredients	**g / L**	**Ingredients**	**g / L**
Tryptose	20.000	Tryptose	20.000
Yeast extract	5.000	Yeast extract	5.000
Glucose	2.000	Dextrose (Glucose)	2.000
Dipotassium hydrogen phosphate	4.000	Dipotassium hydrogen phosphate	4.000
Sodium azide	0.400	Sodium azide	0.400
2,3,5-triphenyl tetrazolium chloride	10.00ml	2,3,5-Triphenyl tetrazolium chloride	0.100
Agar	8-18	Agar	15.000
Final pH (at 25°C)	7.2±0.1	Final pH (at 25°C)	7.2±0.1

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 46.5 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. DO NOT AUTOCLAVE OR OVERHEAT. Excessive heating is detrimental. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Slanetz and Bartley Medium was originally devised by Slanetz and Bartley (1) for the detection and enumeration of Enterococci by membrane filtration technique. It can be also used as a direct plating medium (2,3). M612I differs from M612 in the type of buffering system used. This medium composition is as per specifications laid in ISO (4), APHA (5).

Tryptose and yeast extract serves as a source of essential nutrients along with B-complex vitamins and nitrogenous nutrients. The medium is highly selective for Enterococci. Sodium azide has inhibitory effect on gram-negative organisms. Triphenyl Tetrazolium Chloride is reduced to the insoluble formazan inside the bacterial cell forming dark red-coloured colonies. When the medium is incubated at higher temperature (44-45°C), all red or maroon colonies can be considered as presumptive Enterococci (6,7).

The Department of Health (8) has recommended this medium to be used for enumeration of Enterococci in water supplies. Water is filtered through a membrane filter which is then placed on the surface of the Slanetz and Bartley Medium plates and incubated at 35°C for 4 hours and then at 44-45°C for 44-48 hours. Red or maroon colonies are counted as Enterococci. If typical colonies are observed, a confirmation step is necessary, by transfer of the membrane, with all the colonies, onto bile-aesculin-azide agar, preheated at 44 °C. Intestinal enterococci hydrolyse aesculin on this medium in 2 h. The end-product, 6,7-dihydroxycoumarin, combines with iron(III) ions to give a tan-coloured to black compound which diffuses into the medium.The preliminary incubation at 35°C helps for the recovery of stressed organisms. Not all the species reduce TTC, hence pale colonies also should be considered. Food samples are homogenized and so diluted with physiological saline to give 15-150 colonies on each petri plate. Homogenates or dilutions are spread on agar surface and incubated at 35° C for 48 hours. Pink or dark red colonies with a narrow whitish border are counted (9).

Type of specimen

Water samples

Specimen Collection and Handling:

ISO 7899-2:2000:

Preparation of test sample: Prepare tenfold dilutions of water samples

Choice of technique:

a) Pour plate method
b) Spread plate method
c) Membrane filtration method

Warning and Precautions :

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. Further biochemical testing is required for identification of species.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light yellow coloured clear to slightly opalescent gel forms in Petri plates

Reaction

Reaction of 4.65% w/v aqueous solution at 25°C. pH : 7.2±0.1

pH

7.10 -7.30

Cultural Response

Productivity : Cultural response was observed after an incubation at 36±2°C for 44 ± 4 hours. Recovery rate is considered as 100% for bacteria growth on Reference medium - Soyabean Casein Digest Agar (Tryptone Soya Agar).

Selectivity : Cultural response was observed after an incubation at 36±2°C for 44 ± 4 hours.

Organism	Inoculum (CFU)	Growth	Recovery #	Colour of colony
Productivity				
Enterococcus faecalis ATCC 29212 (00087*)	50-100	good-luxuriant	>=50%	red or maroon or pink
Enterococcus faecalis ATCC 19433 (00009*)	50-100	good-luxuriant	>=50%	red or maroon or pink
Enterococcus faecalis WDCM 00176	50-100	good-luxuriant	>=50%	red or maroon or pink
Enterococcus faecium ATCC 6057 (00177*)	50-100	good-luxuriant	>=50%	red or maroon or pink
Enterococcus faecium WDCM 00178	50-100	good-luxuriant	>=50%	red or maroon or pink
Selectivity				
Escherichiacoli ATCC 25922 (00013*)	>=10^4	inhibited	0%	
Escherichia coli ATCC 8739 (00012*)	>=10^4	inhibited	0%	

Staphylococcus aureus subsp. *aureus* ATCC 6538 (00032*)	>=10^4	inhibited	0%
Staphylococcus aureus subsp. aureus ATCC 25923 (00034)*	>=10^4	inhibited	0%

Key : (*) - Corresponding WDCM numbers, # - Recovery obtained for productivity is >=70% when compared to a previously validated batch of Slanetz and Bartley Medium is used.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 2-8°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (10,11).

Reference

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Revision : 07/2024

Bile Esculin Agar

M972

Intended use

Recommended for isolation and presumptive identification of group D Streptococci from food and pharmaceutical products.

Composition**

Ingredients	Gms / Litre
Peptone	5.000
HM peptone B #	3.000
Bile □	40.000
Esculin	1.000
Ferric citrate	0.500
Agar	15.000
Final pH (at 25°C)	6.6±0.2

**Formula adjusted, standardized to suit performance parameters
Equivalent to Beef extract
□ Equivalent to Oxgall

Directions

Suspend 64.5 grams in 1000 ml purified / distilled water. Heat to boiling to dissolve the medium completely. Mix and dispense into tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Allow the tubed medium to solidify in slanted position.

Principle And Interpretation

Group D Streptococci possess the group D lipoteichoic acid antigen in their cell walls. Former Group D species, which are predominant normal inhabitants of the human gastrointestinal tract, are termed as faecal Streptococci or Enterococci (8). The unique ability of Enterococci to split esculin was reported by Meyer and Schonfeld (10). Enterococci and Group D Streptococci hydrolyse esculin to esculetin and dextrose, which reacts with ferric citrate producing brownish black precipitate (9). The use of esculin hydrolysis in identification of Enterococci was first cited by Rochaix (12). Bile Esculin Agar was originally formulated by Swan (4) for the isolation and identification of Group D Streptococci from food. Facklam and Moody (2,5) further reported that using Bile Esculin Agar, Group D Streptococci could be differentiated from non-Group D Streptococci.

Bile Esculin Agar was also shown to aid differentiation of *Enterobacteriaceae, Klebsiella, Enterobacter, Serratia* from other *Enterobacteriaceae* genera (11) on the basis of esculin hydrolysis. However, other tests such as salt tolerance should be performed for identifying Enterococci (3).

The medium is highly nutritious. Peptone and HM peptone B serves as sources of carbon, nitrogen, amino acids, vitamins and essential growth nutrients. Bile inhibits most of the other accompanying bacteria. Esculin in the medium is hydrolyzed to esculetin and dextrose. Esculetin reacts with ferric citrate to form a dark brown or black complex, visualized as a zone of black precipitate around the colonies. If the media is dispensed in tubes in the form of slants, a positive reaction is indicated by blackening of more than half of the slant within 24-48 hours. If blackening is totally absent or if less than half of the slant is blackened within 24-48 hours, the test is negative. Viridians Streptococci sometimes exhibit a weak positive reaction. Also, *Leuconostoc, Pediococcus, Lactococcus* species causing human infections give a positive bile esculin test (6). To enhance the growth of Enterococci, Bile Esculin Agar can be supplemented with 50ml/L horse serum (9). Inoculate and incubate the test sample in Todd Hewitt Broth (M313). After 24 hours incubation add two drops of the culture onto the surface of slant or plate media (3, 9).

Type of specimen

Food samples

Specimen Collection and Handling

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (1,13,14). After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations :

1. This medium is general purpose medium and may not support the growth of fastidious organisms.

Performance and Evaluation

Performance of the medium is expected when used as per the direction on the label within the expiry period when stored at recommended temperature.

Quality Control

Appearance

Light yellow to brownish yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Amber coloured, clear to slightly opalescent gel with a bluish tinge forms in Petri plates or in tubes as slants.

Reaction

Reaction of 6.5% w/v aqueous solution at 25°C. pH : 6.6±0.2

pH

6.40-6.80

Cultural Response

Cultural characteristics observed in an increased atmosphere of Carbon dioxide after an incubation at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery	Esculin Hydrolysis
Enterococcus faecalis ATCC 29212 (00087*)	50-100	luxuriant	>=50%	positive reaction,blackening of medium around the colony
Proteus mirabilis ATCC 25933	50-100	luxuriant	>=50%	negative reaction
Streptococcus pyogenes ATCC 19615	50-100	none-poor	<=10%	negative reaction

Key : *Corresponding WDCM numbers.

Storage and Shelf Life

Store between 10-30°C in a tightly closed container and the prepared medium at 20-30°C. Use before expiry date on the label. On opening, product should be properly stored dry, after tightly capping the bottle in order to prevent lump formation due to the hygroscopic nature of the product. Improper storage of the product may lead to lump formation. Store in dry ventilated area protected from extremes of temperature and sources of ignition Seal the container tightly after use.

Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that comes into contact with sample must be decontaminated and disposed of in accordance with current laboratory techniques (6,7).

Reference

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