HIMEDIA®
For Life is Precious

HiMedia Laboratories Pvt. Ltd.

Date: 01st January 2021

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 **Exclusive Authorized Distributor** for selling our Products in **MOLDOVA**

This certificate is valid upto 31st December 2022.

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.,

V.M.WARKE.
DIRECTOR – SALES & MARKETING

HIMEDIA LABORATORIES PVT. LTD. Himedia

Digitally signed by Monastîrschii Viorica
Date: 2022.08.01 11:07:09 EEST
Reason: MoldSign Signature
Location: Moldova

REGISTERED OFFICE - 23, Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel: +91-22-6116 9797 / 2500 1607 | Fax: +91-22-2500 2286
CORPORATE OFFICE - A-516, Swastik Disha Business Park, Via Vadhani Indl Est, LBS Marg, Mumbai - 400 086, India.
Tel: +91-22-6147 1919 / 2500 3747 | Fax: +91-22-6147 1920 / 2500 5764 | Email: info@himedialabs.com
Web: www.himedialabs.com

Certificate of Compliance

CE

We hereby declare that the technical file of product complied with the requirement of directives (98/79/EC) In-Vitro Diagnostic Devices Directive.

Certificate No.: CE-12574

Manufacturer

Name : **M/S. HIMEDIA LABORATORIES PVT. LTD.**

Address : **23, VADHANI INDUSTRIAL ESTATE LBS MARG, MUMBAI- 400086, MAHARASHTRA, INDIA**

Products : **HI-GEL™ RUN0610, HI-GEL™ RUN1014, ELECTROPHORESIS POWER SUPPLY(4 TERMINAL), ELECTROPHORESIS POWER SUPPLY (2 TERMINAL), HI-GEL™ RUN0608, HI ECO MINI HORIZONTAL ELECTROPHORESIS SYSTEM, WEE VERT® PROTEIN ELECTROPHORESIS SYSTEM, WEE BLOT™ ELECTROPHORESIS SYSTEM, HI-GEL™ RUN 100 WELL, HI-GEL™ CASTER, CELLULOSE ACETATE ELECTROPHORESIS SYSTEM, PRIMA DUO, PRIMA 96, ECO 96, PRIMA TRIO, PRIMA 96PLUS, PRIMA 384, WEE 16®, WEE 32®, WEE 16 GO®, INSTA Q96®, INSTA Q48®M4, INSTA Q48®M2, INSTA Q96® PLUS, INSTA Q96®-6.0, INSTA NX®, INSTA NX® MAG32, INSTA NX® MAG96, HI-UV MAX, HI-WHITE SET, HI-UV INTENSE, HI-UV DUO, TABSPIN®006, TABSPIN®012, HI-REFRI™24, HIPER® TEMP SHAKER, HIPURA® SANITIZER, WEE DRY™**

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Directive (98/79/EC) In-Vitro Diagnostic Devices Directive.

This certificate is issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.
2. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
3. The certificate validity is conditioned by positive results or surveillance audits.

The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Validity of this certificate can be verified at www.ukcertifications.co.uk/verify

Date of Certification	16th March 2021
1st Surveillance Audit Due	15th March 2022
2nd Surveillance Audit Due	15th March 2023
Certificate Expiry (subject to the company maintaining its system to the required standard)	15th March 2024

Authorised Signatory

THE INTERNATIONAL CERTIFICATION NETWORK

CERTIFICATE

Quality Austria
has issued an IQNet recognized certificate that the organization:

HiMedia Laboratories Pvt. Ltd.
Plot NO. C40, ROAD - 21Y, WAGLE INDUSTRIAL ESTATE, THANE (WEST) - 400604 MAHARASHTRA, INDIA

for the following scope:

Design, Development & Testing of Biosciences Products for application in Microbiology, Animal Cell Culture & Molecular Biology products

EAC: 34

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

which fulfils the requirements of the following standard

ISO 13485:2016

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Issued on:	2022-02-28
Validity date:	2025-02-27
Quality Austria certified since:	2022-02-28

Registration Number: AT-00391/0

PARTNER OF IQNet

Alex Stoichitoiu
President of IQNet

Mag. Friedrich Khuen-Belasi
Authorised Representative of Quality Austria

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Succeed with Quality

IQNet Partners*:
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NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
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* The list of IQNet partners is valid at the time of issue of this certificate. Updated information is available under www.iqnet-certification.com

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Plot NO. C40, ROAD - 21Y, WAGLE INDUSTRIAL ESTATE, THANE (WEST) - 400604 MAHARASHTRA, INDIA

for the following scope:

Design, Development & Testing of Microbiology, Animal Cell Culture, Plant Tissue Culture & Molecular Biology products

EAC: 34

has implemented and maintains a

QUALITY MANAGEMENT SYSTEM

which fulfils the requirements of the following standard

ISO 9001:2015

This attestation is directly linked to the IQNet Partner's original certificate and shall not be used as a stand-alone document

Issued on:	2022-02-28
Validity date:	2025-02-27
Quality Austria certified since:	2022-02-28

Registration Number: AT-27302/0

PARTNER OF IQNet

Alex Stoichitoiu
President of IQNet

Mag. Friedrich Khuen-Belasi
Authorised Representative of Quality Austria

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FCAV *Brazil* FONDONORMA *Venezuela* ICONTEC *Colombia* Inspecta Sertifiointi Oy *Finland* INTECO *Costa Rica*
IRAM *Argentina* JQA *Japan* KFQ *Korea* MIRTEC *Greece* MSZT *Hungary* Nemko AS *Norway* NSAI *Ireland*
NYCE-SIGE *México* PCBC *Poland* Quality Austria *Austria* RR *Russia* SII *Israel* SIQ *Slovenia*
SIRIM QAS International *Malaysia* SQS *Switzerland* SRAC *Romania* TEST St Petersburg *Russia* TSE *Turkey* YUQS *Serbia*

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Bromothymol blue, Hi-Cert™/ACS GRM120

Product Identifier

CAS No.	:	76-59-5
EC No.	:	200-971-2
Molecular Formula	:	$C_{27}H_{28}Br_2O_5S$
Molecular Weight	:	624.38
Synonym	:	3',3''-Dibromothymolsulfonphthalein
HS Code	:	2934 99 00
Storage	:	Below 30°C
Shelf life	:	4 years

Technical Specification

Appearance	:	Light pink to brown or purple or buff crystals or powder
Solubility	:	20 ppm in ethanol yields clear solution
Visual pH Transition	:	pH 5.80 (yellow) to pH 7.60 (blue)
Absorption maxima 1	:	428 - 438 nm (20 ppm in pH 5.80 buffer solution)
Absorption maxima 2	:	611 - 621 nm (20 ppm in pH 7.60 buffer solution)
Specific Absorbance 1	:	260 - 300 (20 ppm in pH 5.80 buffer solution, at 433 nm)
Specific Absorbance 2	:	470 - 520 (20 ppm in pH 7.60 buffer solution, at 616 nm)
Loss on drying (at 110°C, 1 hr)	:	<= 3.00%

Safety Information

UN No.	:	Not dangerous goods
Class	:	-
Packing Group	:	-
WGK	:	3

Tween®80 GRM159

Product Identifier

CAS No.	:	9005-65-6
EC No.	:	500-019-9
Synonym	:	Polyoxyethylenesorbitan monooleate; Polysorbate-80
HS Code	:	3402 90 99
Storage	:	Below 30°C
Shelf life	:	4 years

Technical Specification

Appearance	:	Yellow to amber coloured viscous, oily liquid
Solubility	:	1 mL miscible in 1 mL of water
pH (5% in water at 25°C)	:	6.00 - 8.00
FTIR	:	Matches with the standard pattern
Hydroxyl value	:	65 - 80
Saponification value	:	45 - 55
Acid value	:	<= 2.0
Iodine value	:	18 - 24
Sulphated ash	:	<= 0.2%
Water (K.F.)	:	<= 3.0%

Safety Information

UN No.	:	Not Dangerous goods
Class	:	-
Packing Group	:	-
RTECS	:	WG2932500
WGK	:	1

Product Information

GRM408 Silver nitrate, Hi-LR™

Product Number		Packing
GRM408	:	100G
GRM408	:	10G
GRM408	:	25G

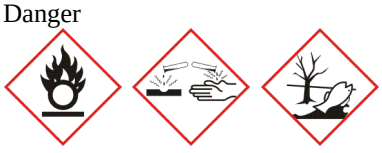
Product Information

Product Code	:	GRM408
Product Name	:	Silver nitrate, Hi-LR™
Synonym	:	Nitric acid silver(I) salt
Molecular Formula	:	$AgNO_3$
Molecular Weight	:	169.87
CAS No.	:	7761-88-8
EC No.	:	231-853-9
HS Code	:	2843 21 00
EC Index No.	:	047-001-00-2
Shelf Life	:	4 years

Technical Specification

Appearance	:	White crystals or powder, darkening on exposure to light.
Solubility	:	1000 mg soluble in 1 mL of water
Chloride (Cl)	:	<= 0.001%
Iron (Fe)	:	<= 0.01%
Sulfate (SO_4)	:	<= 0.02%
Assay (NH_4SCN Titration)	:	99.00 - 100.50%

GHS Safety Information

Hazard Statement(s)	:	H272-H314-H410
Precautionary Statement(s)	:	P220-P273-P280-P305+P351+P338-P310-P501
Signal Word	:	Danger
Hazard Pictogram(s)		

Risk and Safety Information

R-Phrase(s)	:	8-34-50/53
S-Phrase(s)	:	26-36/37/39-45-60-61
WGK	:	3
RTECS	:	VW4725000
Storage Temperature(°C)	:	Store below 30°C
Hazard Symbol(s)		

A-516, Swastik Disha Business Park, Via Vadhani Indl. Est., LBS Marg, Mumbai-400 086, India. Phone:+91-022-6147 1919
Fax:+91-022-6147 1920 Gram : STERILITY . email : info@himedialabs.com. Visit us at our website: www.himedialabs.com

Transport Information

UN No.	:	1493
Class	:	5.1
Packaging Group	:	2
Marine Pollutant	:	Yes
ADR/RID	:	1493 5.1/PG 2
IMDG	:	1493 5.1/PG 2
IATA	:	1493 5.1/PG 2

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Fax:+91-022-6147 1920 Gram : STERILITY . email : info@himedialabs.com. Visit us at our website: www.himedialabs.com

Product Information

GRM912 Bromocresol purple, Practical grade

Product Number		Packing
GRM912	:	25G
GRM912	:	5G

Product Information

Product Code	:	GRM912
Product Name	:	Bromocresol purple, Practical grade
Synonym	:	5-5'-Dibromo-o-cresolsulphonphthalein, Practical grade; Bromcresol purple sultone
Molecular Formula	:	$C_{21}H_{16}Br_2O_5S$
Molecular Weight	:	540.22
CAS No.	:	115-40-2
EC No.	:	204-087-8
HS Code	:	2934 99 90
Shelf Life	:	4 years

Technical Specification

Appearance	:	Grey to light purple or pink to yellow-tan crystals or powder
Solubility	:	20 ppm in 50% ethanol yields clear solution
Visual pH Transition	:	pH 5.20 (yellow) - pH 6.80 (purple)
FTIR (KBr disc)	:	Matches with the standard pattern
Absorption maxima (pH 5.2)	:	426 - 436 nm (20 ppm in 50% ethanol)
Absorption maxima (pH 6.8)	:	584 - 594 nm (20 ppm in 50% ethanol)
Loss on drying (at 110°C, 2hr)	:	<= 5.0%

GHS Safety Information

Hazard Statement(s)	:	H315-H319-H335
Precautionary Statement(s)	:	P261-P305+P351+P338
Signal Word	:	Warning
Hazard Pictogram(s)		

Risk and Safety Information

R-Phrase(s)	:	36/37/38
S-Phrase(s)	:	26-36
WGK	:	3
Storage Temperature(°C)	:	Store below 30°C
Hazard Symbol(s)		

Transport Information

Marine Pollutant	:	No

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Fax:+91-022-6147 1920 Gram : STERILITY . email : info@himedialabs.com. Visit us at our website: www.himedialabs.com

ADR/RID	:	Not Dangerous Goods
IMDG	:	Not Dangerous Goods
IATA	:	Not Dangerous Goods

A-516, Swastik Disha Business Park, Via Vadhani Indl. Est., LBS Marg, Mumbai-400 086, India. Phone:+91-022-6147 1919
Fax:+91-022-6147 1920 Gram : STERILITY . email : info@himedialabs.com. Visit us at our website: www.himedialabs.com

Product Information

GRM914 Bromophenol blue, Practical grade

Product Number		Packing
GRM914	:	25G
GRM914	:	5G

Product Information

Product Code	:	GRM914
Product Name	:	Bromophenol blue, Practical grade
Molecular Formula	:	$C_{19}H_{10}Br_4O_5S$
Molecular Weight	:	669.96
CAS No.	:	115-39-9
EC No.	:	204-086-2
HS Code	:	2934 99 90
Shelf Life	:	4 years

Technical Specification

Appearance	:	Beige to brown or purple crystals or powder
Solubility	:	20 ppm in ethanol yields clear solution
Visual pH Transition	:	pH 3.00 (yellow) - pH 4.60 (blue)
Absorption maxima 1	:	432 - 442 nm (20ppm in pH 3.10 buffer solution)
Absorption maxima 2	:	586 - 596 nm (20ppm in pH 4.60 buffer solution)
Loss on drying (at 105°C, 2hr)	:	<= 5.00%

Risk and Safety Information

WGK	:	3
RTECS	:	SJ7453000
Storage Temperature(°C)	:	Store below 30°C

Transport Information

Marine Pollutant	:	No
ADR/RID	:	Not Dangerous Goods
IMDG	:	Not Dangerous Goods
IATA	:	Not Dangerous Goods

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Fax:+91-022-6147 1920 Gram : STERILITY . email : info@himedialabs.com. Visit us at our website: www.himedialabs.com

Methylene blue trihydrate, Practical grade GRM956

Product Identifier

CAS No.	:	7220-79-3
EC No.	:	200-515-2
C.I. No.	:	52015
Molecular Formula	:	$C_{16}H_{18}ClN_3S.3H_2O$
Molecular Weight	:	373.90
HS Code	:	3212 90 90
Storage	:	Below 30°C
Shelf life	:	4 years

Technical Specification

Appearance	:	Green to dark green crystals or powder with metallic luster
Solubility	:	20 ppm in water yields clear blue solution
Absorption maxima	:	658 - 668 nm (20 ppm in water)
Loss on drying (at 105°C, 2 hr)	:	8.00 - 18.00%

Safety Information

Hazard Pictogram(s) :

Signal Word	:	Warning
Hazard Statement(s)	:	H302- H315- H319- H335
Precautionary Statement(s)	:	P261- P305+P351+P338
UN No.	:	Not dangerous goods
Class	:	-
Packing Group	:	-
RTECS	:	SP5740000
WGK	:	3

Crystal violet, Practical grade GRM961

Product Identifier

CAS No.	:	548-62-9
EC No.	:	208-953-6
EC Index No	:	612-204-00-2
C.I. No.	:	42555
Molecular Formula	:	$C_{25}H_{30}ClN_3$
Molecular Weight	:	407.98
Synonym	:	Methyl violet 10, Practical grade; Gentian violet, Practical grade
HS Code	:	3212 90 90
Storage	:	Below 30°C
Shelf life	:	4 years

Technical Specification

Appearance	:	Green to green-brown crystals or powder or glistening pieces withmetallic luster
Solubility	:	20 ppm in water yields clear dark purple solution
FTIR	:	Matches with the standard pattern
Absorption maxima	:	580 - 595 nm (20 ppm in water)
Loss on drying (at 110°C, 2 hr)	:	<= 10.0%
Dye content	:	~ 75.0%

Safety Information

Hazard Pictogram(s)	:	
Signal Word	:	Danger
Hazard Statement(s)	:	H302- H318- H351- H410
Precautionary Statement(s)	:	P273- P280- P305+P351+P338- P501
UN No.	:	3077
Class	:	9
Packing Group	:	III
RTECS	:	Not available
WGK	:	3

Starch soluble, Hi-AR™/ACS GRM3029

Product Identifier

CAS No.	:	9005-84-9
EC No.	:	232-679-6
Molecular Formula	:	$(C_6H_{10}O_5)n$
Molecular Weight	:	(162.14)n
HS Code	:	3505 10 90
Storage	:	Below 30°C
Shelf life	:	4 years

Technical Specification

Appearance	:	White powder or solid
Solubility	:	33.3 mg soluble in 1 mL of hot water
pH (2% in water at 25°C)	:	5.00 - 7.00
Clarity	:	1% in boiling water gives clear solution
Residue after ignition	:	<= 0.40%
Sensitivity	:	Passes test

Safety Information

UN No.	:	Not dangerous goods
Class	:	-
Packing Group	:	-
RTECS	:	GM5090000
WGK	:	1

Grams Stain-Kit

K001

Intended Use

Grams Stain Kit is used for differentiation of bacteria on the basis of their gram nature.

Composition**

Ingredients

Gram's Crystal Violet (S012)(Solution A)	-
Crystal Violet	2.000 gm
Ethyl alcohol,95%	20.000 ml
Gram's Crystal Violet (S012)(Solution B)	-
Ammonium oxalate	0.800 gm
Distilled Water	80.000 ml

Solution A and B are mixed and stored for 24 hours before use.The resulting stain is stable.

Gram's Decolourizer(S032)	-
Ethyl alcohol, 95%	50.0 ml
Acetone	50.0 ml
Gram's Iodine(S013)	-
Iodine	1.000 gm
Potassium iodide	2.000 gm
Distilled water	300.000 ml
Safranin,0.5% w/v(S027)	-
Safranin O	0.500 gm
Ethyl alcohol, 95%	100.000 ml

**Formula adjusted, standardized to suit performance parameters

Directions

1)Prepare a thin smear on clear, dry glass slide.

2)Allow it to air dry and fix by gentle heat.

3)Flood with Gram's Crystal Violet (S012) for 1 minute. (If over staining results in improper decolourization of known gram-negative organisms,use less crystal violet).

4)Drain the stain.

5)Flood the smear with Gram’s Iodine (S013). Allow it to remain for 1 minute.

6)Decolourize with Gram's Decolourizer (S032) until the blue dye no longer flows from the smear.

7)Wash with tap water.

8)Counter stain with 0.5% w/v Safranin (S027). Allow it to remain for 1 minute.

9)Wash with water.

10)Allow the slide to air dry or blot dry between sheets of clean bibulous paper and examine under oil immersion objective.

Principle And Interpretation

The Gram stain is a differential staining technique most widely applied in all microbiology disciplines laboratories. It is one of the most important criteria in any identification scheme for all types of bacterial isolates. Different mechanisms have been proposed to explain the gram reaction. There are many physiological differences between gram-positive and gram-negative cell walls (1). Ever since Christian Gram has discovered Gram staining, this process has been extensively investigated and redefined. In practice,a thin smear of bacterial cells is stained with crystal violet, then treated with an iodine containing mordant to increase the binding of primary stain (2). A decolourizing solution of alcohol or acetone is used to remove the crystal violet from cells which bind it weakly and then the counterstain (like safranin) is used to provide a colour contrast in those cells that are decolourized.

Gram-positive bacteria have a thick mesh-like cell wall made of peptidoglycan (50–90% of cell envelope), and as a result are stained purple by crystal violet, whereas gram-negative bacteria have a thinner layer (10% of cell envelope), so do not retain the purple stain and are counter-stained pink by safranin.In a properly stained smear by gram staining procedure, the gram-positive bacteria appear blue to purple and gram negative cells appear pink to red.

Type of specimen

Clinical samples - Blood, urine, CSF, pus, wounds, lesions, body tissues, sputum etc. ; food & dairy samples ; Water samples

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (3, 4).
For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (5, 6).
For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards(7).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use only. 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 guidleines should be followed while handling clincal specimens. Saftey guidelines may be referred in individual safety data sheets

Limitations :

1. Use results of Gram stains in conjunction with other clinical and laboratory findings. Use additional procedures (e.g., special stains, inclusion of selective media, etc.)to confirm findings suggested by gram-stained smears (8).
2. False Gram stain results may be related to inadequately collected specimens or delay in transit.
3. Careful adherence to procedure and interpretive criteria is required for accurate results. Accuracy is highly dependent on the training and skill of microscopists (9).
4. The sensitivity of Gram stain is 10^5 cells/ml or 10^4 if the specimen has been prepared with the cytocentrifuge (10). This is particularly applicable to the smear of a drop of urine, where an average of the one bacterial cell per field from an examination of 20 fields correspond to a count of >= 10^5 cfu/ml.

Performance and Evaluation

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

Quality Control

Microscopic examination

Gram staining is carried out and observed under oil immersion lens.

Results

Gram-positive organisms : Violet coloured
Gram-negative organisms : Pinkish red coloured

Storage and Shelf Life

Store between 10- 30°C in tightly closed container and away from bright light. Use before expiry date on label. On opening, product should be properly stored in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use.

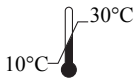
Disposal

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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (3,4).

Reference

1. Lamanna and Mallette, 1965, Basic Bacteriology, 3rd ed., Williams and Wilkins Co.,Baltimore.
2. Salton, 1964, The Bacterial Cell Wall, Elsevier, Amsterdam.
3. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
4. Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.
5. Downes F. P. and Ito K. (Ed.), 2001, Compendium of Methods for the Microbiological Examination of Foods, 4th ed., APHA, Washington, D.C.
6.Wehr H. M. and Frank J. H., 2004, Standard Methods for the Microbiological Examination of Dairy Products, 17th Ed., APHA Inc., Washington, D.C.
7. Rice E.W., Baird, R.B., Eaton A. D., Clesceri L. S. (Eds.), 2012, Standard Methods for the Examination of Water and Wastewater, 22nd ed., APHA, Washington, D.C.
8. Brown,M.S.,and T.C. Wu. 1986. The Gram stain morphology of fungi, mycobacteria, and Pneumocytis carinii. J.Med .Technol3:495-499.
9. Washington, J.A.1986.Rapid diagnosis by microscopy. Clin.Microbiol. Newsl.8:135-137.
10. Shanhooltzer,C.J.,P. Schaper ,and L.R. Peterson.1982.Concentrated Gram stain smear prepared with a cytospin centrifuge. J.clin. Microbiol.16:1052-1056

Revision : 02 / 2018

IVD	In vitro diagnostic medical device
CE	CE Marking
	Storage temperature
	Do not use if package is damaged
	HiMedia Laboratories Pvt. Limited, 23 Vadhani Industrial Estate, LBS Marg,Mumbai-86,MS,India
EC REP	CE Partner 4U ,Esdoornlaan 13, 3951 DB Maarn The Netherlands, www.cepartner 4u.eu

2,3,5-Triphenyltetrazolium chloride MB188

For Molecular Biology

Product Identifier

CAS No.	:	298-96-4
EC No.	:	206-071-6
Molecular Formula	:	$C_{19}H_{15}N_4Cl$
Molecular Weight	:	334.80
HS Code	:	2933 99 90
Storage	:	Below 30°C
Shelf life	:	4 years

Technical Specification

Appearance	:	White to yellow crystals or powder
Solubility	:	33.3 mg soluble in 1 mL of water
DNases	:	None detected
RNases	:	None detected
FTIR	:	Matches with the standard pattern
Melting range	:	235 - 245°C
Assay (AT/NT)	:	min. 99.00%

Safety Information

Hazard Pictogram(s) :

Signal Word	:	Warning
Hazard Statement(s)	:	H315- H319- H335
Precautionary Statement(s)	:	P261- P305+P351+P338
UN No.	:	Not dangerous goods
Class	:	-
Packing Group	:	-
RTECS	:	XF8100000
WGK	:	3

Kovac's Indole Reagent

R008

Intended use

For detection of presence of indole produced by microorganisms due to tryptophan deamination.

Composition**

Ingredients	-
p-dimethylamino benzaldehyde	5.000
Amyl alcohol	75.000
Hydrochloric acid, concentrated	25.000

**Formula adjusted, standardized to suit performance parameters

Directions

Add 0.2 - 0.3 ml of Kovac's reagent to 5 ml of a 24 - 48 hours old culture of the organism under investigation. Formation of a red coloured ring indicates positive indole test.

Principle And Interpretation

Peptone Water is particularly suitable as a substrate in the study of indole production. Peptone used in Peptone Water, is rich in tryptophan content (1). Other peptones which contain tryptophan can be used to study indole production. Tryptone Water is also recommended by APHA (2) for detection of indole production by coliforms, which is a key feature in differentiation of bacteria. It is used as part of the IMViC procedures. Most strains of *E. coli*, *P. vulgaris*, *P. rettgeri*, *M. morgani* and *Providencia* species break down the amino acid tryptophan with the release of indole. The presence of indole can be detected by the addition of Ehrlich's or Kovac's reagent (p-dimethylaminobenzaldehyde).

Kovacs reagent is a biochemical reagent consisting of isoamyl alcohol, para-dimethylaminobenzaldehyde (DMAB), and concentrated hydrochloric acid. It is used for the diagnostic test, to determine the ability of the organism to split tryptophan into indole and alpha-aminopropionic acid by hydrolytic activity of bacteria that express tryptophanase enzyme (3). The indole produced is indicated by formation of a red coloured ring, soluble in ether, chloroform and alcohol. This was invented by the Hungarian-Swiss Chemist, Ervin Kovats. Indole production is used as, a tests designed to distinguish among members of the family Enterobacteria.

Type of specimen

Clinical samples ; Water samples

Specimen Collection and Handling

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (4,5).
For water samples, follow appropriate techniques for sample collection, processing as per guidelines and local standards(2).
After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use only. 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 guidleines should be followed while handling clincal specimens. Saftey guidelines may be referred in individual safety data sheets

Limitations :

1. Growth media must contain an adequate amount of tryptophan. Do not use Mueller- Hinton Agar for test, because tryptophan is destroyed during the acid hydrolysis of casein.
2. Do not used media that contain dyes (e.g., EMB, MAC).
3. Do not use medium with a nitrate disc/strip to perform the indole test, as nitrate can interfere with indole test by including false positive results.

Performance and Evaluation

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

Quality Control

Appearance
Greenish yellow coloured solution

Solubility
Immiscible with water

Clarity
Clear with no insoluble particles.

Cultural Response
Characteristic reactions observed when Kovac's Indole Reagent is added to growth in Tryptone Broth (M463)

Organism	Indole production
Enterobacter aerogenes ATCC 13048	negative reaction ,no red ring
Escherichia coli ATCC 25922	positive reaction, red ring at the interface of the medium

Storage and Shelf Life

Store between 10-30°C in tightly closed container and away from bright light. Use before expiry date on label. On opening, product should be properly stored in dry ventilated area protected from extremes of temperature and sources of ignition. Seal the container tightly after use.

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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (4,5).

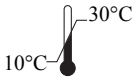
Reference

1.MacFaddin J., 1980, Biochemical Tests for Identification of Medical Bacteria, 2nd ed., Williams and Wilkins, Baltimore.
2.Greenberg A. E., Clesceri L. S. and Eaton A. D., (Eds.), 2005, Standard Methods for the Examination of Water and Wastewater, 21st ed., APHA, Washington, D.C.
3.MacFaddin J. F., 2000, Biochemical Tests for Identification of Medical Bacteria, 3rd Ed., Williams and Wilkins, Baltimore.
4.Isenberg, H.D. Clinical Microbiology Procedures Handb0ook. 2nd Edition.
5. Jorgensen,J.H., Pfaller , M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

Revision :01 / 2018

IVD — In vitro diagnostic medical device

CE Marking



Storage temperature

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Product Information

RM224 Carmine, Hi-Cert™

Product Number		Packing
RM224	:	25G
RM224	:	5G

Product Information

Product Code	:	RM224
Product Name	:	Carmine, Hi-Cert™
Synonym	:	Alum lake of carminic acid; Natural Red 4
CAS No.	:	1390-65-4
EC No.	:	215-724-4
HS Code	:	3212 90 00
Colour Index No.	:	75470
Shelf Life	:	4 years

Technical Specification

Appearance	:	Red to dark red to red-purple crumbly solid or powder
Solubility	:	20 ppm in alkali gives clear solution
Sulphated ash	:	<= 12.00%
Loss on drying (at 135°C, 3hr)	:	<= 20.0%
Carminic acid (UV, on dry basis)	:	>= 42.00%

Risk and Safety Information

WGK	:	1
RTECS	:	FH8891000
Storage Temperature(°C)	:	Store below 30°C

Transport Information

Marine Pollutant	:	No
ADR/RID	:	Not Dangerous Goods
IMDG	:	Not Dangerous Goods
IATA	:	Not Dangerous Goods

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Product Information

RM1073 N-(1-Naphthyl)ethylenediamine dihydrochloride, A.R.

Product Number		Packing
RM1073	:	25G
RM1073	:	5G

Product Information

Product Code	:	RM1073
Product Name	:	N-(1-Naphthyl)ethylenediamine dihydrochloride, A.R.
Synonym	:	2-(1-Naphthylamino)ethylamine dihydrochloride
Molecular Formula	:	$C_{12}H_{14}N_2.2HCl$
Molecular Weight	:	259.18
CAS No.	:	1465-25-4
EC No.	:	215-981-2
HS Code	:	2921 59 90
Shelf Life	:	4 years

Technical Specification

Appearance	:	White to pink to grey crystals or powder or chunks
Solubility	:	33.3 mg soluble in 1 mL of dilute hydrochloric acid
Sensitivity to diazotised sulphanilamide	:	Passes test
Water (K.F)	:	<= 5.00%
Assay (AT, on anhydrous basis)	:	min. 90.00%

GHS Safety Information

Hazard Statement(s)	:	H315-H319-H335
Precautionary Statement(s)	:	P261-P305+P351+P338
Signal Word	:	Warning
Hazard Pictogram(s)		

Risk and Safety Information

R-Phrase(s)	:	36/37/38
S-Phrase(s)	:	26-36
WGK	:	3
RTECS	:	KV5330000
Storage Temperature(°C)	:	Store below 30°C
Hazard Symbol(s)		

Transport Information

Marine Pollutant	:	No

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ADR/RID	:	Not Dangerous Goods
IMDG	:	Not Dangerous Goods
IATA	:	Not Dangerous Goods

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Product Information

RM3649 N-Phenylanthranilic acid, A.R.

Product Number		Packing
RM3649	:	100G
RM3649	:	25G

Product Information

Product Code	:	RM3649
Product Name	:	N-Phenylanthranilic acid, A.R.
Synonym	:	2-(Phenylamino)benzoic acid; Diphenylamine-2-carboxylic acid; DpC
Molecular Formula	:	$C_{13}H_{11}NO_2$
Molecular Weight	:	213.23
CAS No.	:	91-40-7
EC No.	:	202-066-8
HS Code	:	2922 49 85
Other Information	:	For Synthesis
Shelf Life	:	4 years

Technical Specification

Appearance	:	White to yellow to brown powder
Solubility	:	33.3 mg soluble in 1 mL of methanol
FTIR (KBr disc)	:	Matches with the standard pattern
Melting range	:	182 - 187°C
Assay (NaOH Titration/HPLC)	:	99.00 - 103.00%

GHS Safety Information

Hazard Statement(s)	:	H315-H319-H335
Precautionary Statement(s)	:	P261-P305+P351+P338
Signal Word	:	Warning
Hazard Pictogram(s)		

Risk and Safety Information

R-Phrase(s)	:	36/37/38
S-Phrase(s)	:	26-36
WGK	:	3
RTECS	:	CB3730000
Storage Temperature(°C)	:	Store below 30°C
Hazard Symbol(s)		

Transport Information

Marine Pollutant	:	No
ADR/RID	:	Not Dangerous Goods

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IMDG	:	Not Dangerous Goods
IATA	:	Not Dangerous Goods

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Technical Data

Methylene Blue (Loeffler's)

S022

Methylene Blue (Loeffler's) is used as staining solution in metachromatic staining.

Composition**

Ingredients

Methylene blue	0.30 gm
Ethyl alcohol, 95%	30.0 ml
Distilled water	100.0 ml

**Formula adjusted, standardized to suit performance parameters

Directions

1) Prepare a thin smear of *Corynebacterium diphtheriae.*

2) Allow it to air dry and fix with gentle heat.

3) Flood the smear with Methylene Blue (S022) for 1 minute.

4) Wash in the tap water.

5) Blot dry, then examine under oil immersion objective.

Principle And Interpretation

Loefflers Methylene Blue stain is used for the identification of diphtheria bacilli, since it differentiates the deeply staining metachromatic granules from the pale blue-staining cytoplasm .

Quality Control

Appearance
Dark blue coloured solution.

Clarity
Clear solution without any particles

Microscopic Examination
Metachromatic staining is carried out where Methylene Blue is used as one of the stains and staining characteristic of organisms is observed under microscope by using oil immersion lens.

Results

Metachromatic granules	:	Deep blue
Cytoplasm	:	Pale blue

Storage and Shelf Life

Store below 30°C in tightly closed container and away from bright light. Use before expiry date on label.

Revision : 1 / 2015

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