

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.**

V.M. WARKE.

DIRECTOR – SALES & MARKETING



REGISTERED OFFICE -

Plot No. C40, Road No. 21Y, MIDC, Wagle Industrial Estate, Thane (West) - 400604, Maharashtra, India.
Tel : +91-22-6147 1919 / 6116 9797 / 6903 4800 | Fax : +91-22-6147 1920
Email : info@himedialabs.com | Web : www.himedialabs.com



... expect only quality from us™
CIN : U85195MH1982PTC028194

HiMedia Laboratories Private Limited

C-40, Road No.21Y, MIDC, Wagle Ind. Area,Thane(W) - 400604

Website : www.himedialabs.com, Email : info@himedialabs.com

Certificate of Analysis , Quality and Conformity

Material Code : GRM026	Material Name : Agar powder, Bacteriological grade	Lot No : 0000580529
AR No.: 10000541779	Date of Report : 2023-03-24	Exp. Date : 2027-03
TEST	SPECIFICATIONS	RESULTS
<u>Appearance</u> 1 Appearance 2 Nature 3 Consistency	Cream coloured powder. homogenous free flowing powder	Complies Complies Complies
<u>Solubility</u> 1 Solubility	Freely soluble in hot water at temperatures above 85°C. Insoluble in cold water.	Complies
<u>Clarity</u> 1 Clarity	A firm solid, clear to slightly opalescent gel is formed at a concentration of 1.5% at 38-40°C.	Complies
<u>Dye Diffusion</u> 1 Dye Diffusion	Agar dye diffusion :- 18-20mm	Complies
<u>pH</u> 1 pH of 1.5% w/v aqueous solution at 25°C	6.50 - 7.50	7.45
<u>Identification test</u> Identification test 1 Test A 2 Test B 3 Test C	As per method specified in USP 2022 Infrared absorption Iodine TS colours some of the fragments of the Agar bluish black, with some areas reddish to violet. Agar forms a clear liquid that congeals at 30-39 ° C to form a firm resilient gel, which does not liquefy below 80°C.	Complies Complies Complies
<u>Microbial Load</u> 1 Total aerobic microbial count (cfu/gm) 2 total aerobic microbial count (cfu/gm) 3 Total yeast and mold count (cfu/gm) 4 total yeast and mold count (cfu/gm)	By plate method, when incubated at 30-35°C for not less than 3 days. ≤ 1000 By plate method, when incubated at 20-25°C for not less than 5 days. ≤ 100	- 30 - 7

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AR No.: 10000541779	Date of Report : 2023-03-24	Exp. Date : 2027-03

TEST	SPECIFICATIONS	RESULTS
<u>Test for pathogens</u> 1 Test for pathogens	1. Escherichia coli- Absent/gram of sample 2. Salmonella species- Absent/10 gram of sample 3. Pseudomonas aeruginosa- Absent/gram of sample 4. Staphylococcus aureus- Absent/gram of sample 5. Candida albicans- Absent/gram of sample 6. Clostridia- Absent/gram of sample	Absent
<u>Test for Water absorption</u> 1 Test for Water absorption 2 Water absorption capacity	As per method specified in USP 2022 NMT 75 ml of water is absorbed by 5.0 g of agar	Complies
<u>Limit of Gelatin</u> 1 Limit of Gelatin 2 Gelatin	As per method specified in USP 2022 No yellow precipitate is formed.	Complies
<u>Limit of Foreign Starch</u> 1 Limit of Foreign Starch 2 Starch	As per method specified in USP 2022 The sample solution does not ,upon cooling ,produce a blue colour upon the addition of iodine TS.	Complies
<u>Growth Promotion Test</u> 1 Growth Promotion Test	As per method specified in USP 2022	Complies
<u>Cultural response</u> 1 Cultural response	Cultural response observed after an incubation at 35-37°C for 18-24 hours by preparing Nutrient Agar (M001) using Agar Powder, Bacteriological as an ingredient.	
<u>Escherichia coli ATCC 25922 (WDCM00013)</u> 1 Growth	Luxuriant	Complies
<u>Pseudomonas aeruginosa ATCC 27853 (WDCM 00025)</u> 1 Growth	Luxuriant	Complies

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Material Code : GRM026	Material Name : Agar powder, Bacteriological grade	Lot No : 0000580529
AR No.: 10000541779	Date of Report : 2023-03-24	Exp. Date : 2027-03

TEST	SPECIFICATIONS	RESULTS
<u>Staphylococcus aureus</u> <u>subsp.aureus ATCC</u> <u>25923(WDCM 00034)</u> 1 Growth	Luxuriant	Complies
<u>Salmonella enterica subsp.</u> <u>enterica Typhi ATCC 6539</u> 1 Growth	Luxuriant	Complies
<u>Streptococcus pyogenes ATCC</u> <u>19615</u> 1 Growth	Luxuriant	Complies
<u>Salmonella enterica</u> <u>subsp.enterica Enteritidis ATCC</u> <u>13076 (WDCM 00030)</u> 1 Growth	Luxuriant	Complies
<u>Salmonella enterica</u> <u>subsp.enterica Typhimurium</u> <u>ATCC 14028 (WDCM 00031)</u> 1 Growth	Luxuriant	Complies
<u>Yersinia enterocolitica subsp.</u> <u>enterocolitica ATCC 9610</u> <u>(WDCM 00038)</u> 1 Growth	Luxuriant	Complies
<u>Yersinia enterocolitica subsp.</u> <u>enterocolitica ATCC 23715</u> <u>(WDCM 00160)</u> 1 Growth	Luxuriant	Complies
<u>Chemical Analysis</u> 1 Gelling temperature 2 Melting Range 3 Water (KF) 4 Calcium (Ca) 5 Arsenic (As) 6 Lead(Pb)	38-40°C ≥ 85°C ≤ 20% ≤ 0.1% ≤ 3ppm ≤ 10ppm	Complies Complies Complies Complies Complies Complies

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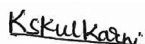
Material Code : GRM026	Material Name : Agar powder, Bacteriological grade	Lot No : 0000580529
AR No.: 10000541779	Date of Report : 2023-03-24	Exp. Date : 2027-03

TEST	SPECIFICATIONS	RESULTS
7 Acid- Insoluble Ash (On dry-Weight basis)	≤ 0.5%	Complies
8 Total Ash (On dry-weight basis)	≤ 6.5%	Complies
9 Foreign organic matter	≤ 1.0%	Complies
10 Limit of Foreign insoluble matter	≤ 15 mg in 7.5 gm of Agar	Complies
11 Gelling Strength	≥ 800g/cm ²	Complies

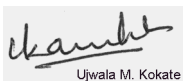
STATUS OF THE MATERIAL : APPROVED

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 particular use, other than that specified in the current HiMedia manual or product sheets.

This document has been produced electronically and is valid



Kashmira Kulkarni

Microbiologist/Sr.Executive Microbiologist

Ujwala M. Kokate

Asst./Dy/QC Manager

Dr. Santosh Kaul

Dy/QA Manager

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Certificate of Analysis, Quality and Conformity

Material Code : M146	Material Name : Corn Meal Agar	Lot No : 0000613630
Report No.: 40001409193	Date of Release & Report : 2023-10-28	Expiry Date : 2028-09

Appearance

Cream to yellow coarse free flowing powder. Observed : Cream

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured, opalescent gel forms in Petri plates

Reaction

Reaction of 1.7% w/v aqueous solution at 25°C.

pH

pH Range :5.80-6.20 Observed : 6.19

Cultural Response

Cultural characteristics observed after an incubation at 23-27°C for up to 4 days.

Organism	Inoculum (CFU)	Growth	Chlamydospores	Recovery
Cultural Response				
<i>Aspergillus brasiliensis</i> ATCC 16404 (WDCM 00053)	50-100	luxuriant	negative	-
<i>Candida albicans</i> ATCC 10231 (WDCM 00054)	50-100	luxuriant	positive	>=70%
<i>Saccharomyces cerevisiae</i> ATCC 9763 (WDCM 00058)	50-100	luxuriant	negative	>=70%
<i>Saccharomyces uvarum</i> ATCC 28098	50-100	luxuriant	negative	>=70%

- . 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 :

- . 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

. For observing Chlamydospore formation :Using a straight wire, make a deep cut in the Corn Meal Agar plate with inoculum. Place a flamed sterile coverslip over the line of inoculum. After incubation, the streaks are examined microscopically,through the coverslip,using low and high power objectives, for chlamydospore formation.

STATUS OF THE MATERIAL : APPROVED

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Certificate of Analysis, Quality and Conformity

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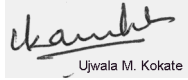
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Prachi Ratnakar

**Microbiologist/Sr.Executive
Microbiologist**



Ujwala M. Kokate

Asst./Dy/QC Manager



Dr. Santosh Kaul

Dy/QA Manager

2023-10-28

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Certificate of Analysis, Quality and Conformity

Material Code : M253	Material Name : Malt Agar	Lot No : 000570585
Report No.: 40001315815	Date of Release & Report : 2023-01-07	Expiry Date : 2027-12

Appearance

Cream to brownish yellow homogeneous free flowing powder. Observed : Yellow

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured clear to slightly opalescent gel forms in tubes or Petri plates

Reaction

Reaction of 4.5% w/v aqueous solution at 25°C.

pH

pH Range :5.30-5.70 Observed : 5.69

Cultural Response

Cultural characteristics was observed after an incubation at 25 - 30°C for 40 - 48 hours.(Incubate for 7 days for Trichophyton species)

Organism	Inoculum (CFU)	Growth	Recovery
Cultural Response			
<i>Aspergillus brasiliensis</i> ATCC 16404 (WDCM 00053)	50-100	luxuriant	-
<i>Candida albicans</i> ATCC 10231 (WDCM 00054)	50-100	luxuriant	>=70%
<i>Saccharomyces cerevisiae</i> ATCC 9763 (WDCM 00058)	50-100	luxuriant	>=70%
<i>Penicillium chrysogenum</i> ATCC 9179	50-100	luxuriant	-
<i>Trichophyton interdigitale</i> ATCC 9533	50-100	luxuriant	-

- . 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 :

- . 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

STATUS OF THE MATERIAL : APPROVED

HiMedia Laboratories Private Limited

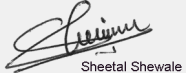
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Thane(W) - 400604 , Website : www.himedialabs.com,
Email : info@himedialabs.com

Certificate of Analysis, Quality and Conformity

Material Code : M253	Material Name : Malt Agar	Lot No : 0000570585
Report No.: 40001315815	Date of Release & Report : 2023-01-07	Expiry Date : 2027-12


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This document has been produced electronically and is valid



Sheetal Shewale

**Microbiologist/Sr.Executive
Microbiologist**



Ujwala M. Kokate

Asst./Dy/QC Manager



Dr. Santosh Kaul

Dy/QA Manager

2023-01-07



Agar powder, Bacteriological Grade

GRM026

Intended use

Agar powder, Bacteriological Grade is manufactured from species of red seaweeds by observing good manufacturing practice. It is a Bacteriological grade powder with high mineral/metal content and is advantageous to use in certain media. It is recommended for use in bacteriological culture media and plant tissue culture media, where clarity and compatibility are not of prime importance.

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. Safety guidelines may be referred in individual safety data sheets.

Limitations

1. It is biological origin product since variation in colour of powder and clarity may observed.
2. Each lot of the product has been tested for the organisms specified on the COA. It is recommended to users to validate the medium for any specific microorganism other than mentioned in the COA based on the user's requirement.
3. Individual organisms differ in their growth requirement and may show variable growth patterns on the medium prepared by the product.

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 coloured powder homogeneous free flowing powder
- **Solubility** : Freely soluble in hot water at temperatures above 85°C. Insoluble in cold water.
- **Clarity** : A firm solid, clear to slightly opalescent gel is formed at a concentration of 1.5% at 38-40°C.
- **Dye Diffusion** : Agar dye diffusion :- 18-20mm
- **pH** : pH of 1.5% w/v aqueous solution at 25 °C 6.5 - 7.5
- **Identification test** : As per method specified in USP 2022
 - A: Infrared absorption
 - B: Iodine TS colours some of the fragments of the Agar bluish black, with some areas reddish to violet.
 - C: Agar forms a clear liquid that congeals at 30-39 ° C to form a firm resilient gel, which does not liquefy below 80°C.
- **Microbial Load** :
 - Bacterial Count : <= 1000 CFU/gram by plate method, when incubated at 30-35°C for not less than 3 days
 - Yeast & mould Count : <= 100 CFU/gram by plate method, when incubated at 20-25°C for not less than 5 days.
- **Test for pathogens** : 1. *Escherichia coli*- Absent/gram of sample 2. *Salmonella* species- Absent/10 gram of sample 3. *Pseudomonas aeruginosa*- Absent/gram of sample 4. *Staphylococcus aureus*- Absent/gram of sample 5. *Candida albicans*- Absent/gram of sample 6. *Clostridia*- Absent/gram of sample

- **Test for Water absorption :** As per method specified in USP 2022
NMT 75 ml of water is absorbed by 5.0 g of agar
- **Limit of Gelatin :** As per method specified in USP 2022 No yellow precipitate is formed.
- **Limit of Foreign Starch :** As per method specified in USP 2022
The sample solution does not, upon cooling ,produce a blue colour upon the addition of iodine TS.
- **Growth Promotion Test :** As per method specified in USP 2022
- **Cultural response :** Cultural response observed after an incubation at 35-37°C for 18-24 hours by preparing Nutrient Agar (M001) using Agar Powder, Bacteriological as an ingredient.

Cultural Response

Organism	Growth
<i>Escherichia coli</i> ATCC 25922 (WDCM00013)	Luxuriant
<i>Pseudomonas aeruginosa</i> ATCC 27853 (WDCM 00025)	Luxuriant
<i>Staphylococcus aureus</i> subsp. <i>aureus</i> ATCC 25923(WDCM 00034)	Luxuriant
<i>Salmonella enterica</i> subsp. <i>enterica</i> Typhi ATCC 6539	Luxuriant
<i>Streptococcus pyogenes</i> ATCC 19615	Luxuriant
<i>Salmonella enterica</i> subsp. <i>enterica</i> Enteritidis ATCC 13076 (WDCM 00030)	Luxuriant
<i>Salmonella enterica</i> subsp. <i>enterica</i> Typhimurium ATCC 14028 (WDCM 00031)	Luxuriant
<i>Yersinia enterocolitica</i> subsp. <i>enterocolitica</i> ATCC 9610 (WDCM 00038)	Luxuriant
<i>Yersinia enterocolitica</i> subsp. <i>enterocolitica</i> ATCC 23715 (WDCM 00160)	Luxuriant

Chemical Analysis :

Gelling temperature : 38-40°C

Melting Range : ≥85°C

Water (KF) : ≤20%

Calcium (Ca) : ≤ 0.1%

Arsenic (As) : ≤3 ppm

Lead(Pb) : ≤ 10 ppm

Acid- Insoluble Ash (On dry-Weight basis) : ≤0.5%

Total Ash (On dry-weight basis) : ≤6.5%

Foreign organic matter : ≤1.0%

Limit of Foreign insoluble matter : ≤15 mg in 7.5 gm of Agar

Gelling Strength : ≥ 800g/cm²

Storage and Shelf Life

Store below 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.

Below
30°C

Storage temperature



Do not use if package is damaged



HiMedia Laboratories Pvt Limited
C-40,21/Y, MIDC, Wagle Ind Area
Thane(W)-400604,Maharashtra,India

Revision : 03/2022

Disclaimer :

User must ensure suitability of the product(s) in their application prior to use. Products conform solely to the information contained in this and other related HiMedia™ publications. The information contained in this publication is based on our research and development work and is to the best of our knowledge true and accurate. HiMedia™ Laboratories Pvt Ltd reserves the right to make changes to specifications and information related to the products at any time. Products are not intended for human or animal or therapeutic use but for laboratory, diagnostic, research or further manufacturing use only, unless otherwise specified. Statements contained herein should not be considered as a warranty of any kind, expressed or implied, and no liability is accepted for infringement of any patents.



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 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

Alex Stoichitoiu
President of IQNet

Mag. Friedrich Khuen-Belasi
Authorised Representative
of Quality Austria



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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

CERTIFICATE

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH awards this **qualityaustria** certificate to the following organisation:

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

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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

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH is accredited according to the Austrian Accreditation Act by the BMWFV (Federal Ministry of Science, Research and Economy).

Quality Austria is accredited as an organisation for environmental verification by the BMLFUW (Federal Ministry of Agriculture, Forestry, Environment and Water Management).

Quality Austria is authorized by the VDA (Association of the Automotive Industry).

For accreditation registration details please refer to the applicable decisions or recognition documents.

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Dok. Nr. FO_24_028

1702280c-6c19-4683-8f36-3ea2e4167c18

The current validity of the certificate is documented exclusively on the Internet under <http://www.qualityaustria.com/en/cert> EAC: 34

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

Registration No.: 27302/0

Date of initial issue: 28 February 2022

Valid until: 27 February 2025

Vienna, 28 February 2022

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3



 **qualityaustria**

PARTNER OF




Mag. Christoph Mondl
General Manager



Mag. Dr. Werner Paar
General Manager



Mag. Dr. Anni Koubek
Specialist representative



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

Alex Stoichitoiu
President of IQNet

Mag. Friedrich Khuen-Belasi
Authorised Representative
of Quality Austria



IQNet Partners*:

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CQC China CQM China CQS Czech Republic Cro Cert Croatia DQS Holding GmbH Germany EAGLE Certification Group USA
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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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QUALITY MANAGEMENT SYSTEM

complying with the requirements of standard

ISO 13485:2016

Medical devices - Quality management systems -
Requirements for regulatory purposes

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Design, Development & Testing of Biosciences Products
for application in Microbiology, Animal Cell Culture &
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Registration No.: 00391/0

Date of initial issue: 28 February 2022

Valid until: 27 February 2025

Vienna, 28 February 2022

Quality Austria - Trainings, Zertifizierungs und Begutachtungs GmbH,
AT-1010 Vienna, Zelinkagasse 10/3



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Mag. Christoph Mondl
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Mag. Dr. Werner Paar
General Manager



Mag. Dr. Anni Koubek
Specialist representative



Corn Meal Agar

M146

Intended use

Recommended for chlamyospore production by *Candida albicans* and the maintenance of fungal stock cultures.

Composition**

Ingredients	Gms / Litre
Corn meal, infusion from	50.000
Agar	15.000
Final pH (at 25°C)	6.0±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 17 grams in 1000 ml purified/ distilled water. Heat to boiling to dissolve the medium completely. If desired add 1% polysorbate 80. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Chlamyospore production is an accepted criterion for the identification of *Candida* species. Corn Meal Agar is a well-established mycological medium used for the cultivation of fungi and to study chlamyospores production of *Candida* species (6). Corn Meal Agar is a general purpose medium used for the cultivation of fungi and for the study of *Candida* species for chlamyospore production. Pollack and Benham (6) have described the usefulness of this medium for studying the morphology of *Candida*. Walker and Huppert (8) modified this medium by adding polysorbate 80, which then stimulated faster and plenty of chlamyospore formation of *Candida* species.

This is a very simple formulation containing only cornmeal infusion and agar. However this infusion has enough nutrients to enhance the growth of fungi. Polysorbate 80 is a mixture of oleic esters, which activates the production of chlamyospore by *Candida albicans*, *Candida stellatoidea* and *Candida tropicalis* (3). Some *Candida* species lose their ability of chlamyospore formation by repeated sub culturing.

Pick a suspected colony from Sabouraud Dextrose Agar (M063) using a straight wire, and make a deep cut in the Corn Meal Agar plate. Repeat for each colony. Place a flamed sterile coverslip over the line of inoculum. After incubation for 24-48 hours at 25-30°C, the streaks are examined microscopically, through the coverslip, using low and high power objectives.

C.albicans produces mycelium bearing ball-like clusters of budding cells and characteristics thick walled round chlamyospores (2).

Type of specimen

Food and dairy samples.

Specimen Collection and Handling:

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (7,8).

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. Further biochemical tests must be carried out for confirmation.

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 coarse free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured, opalescent gel forms in Petri plates

Reaction

Reaction of 1.7% w/v aqueous solution at 25°C. pH : 6.0±0.2

pH

5.80-6.20

Cultural Response

Cultural characteristics observed after an incubation at 23-27°C for upto 4 days.

Organism	Inoculum (CFU)	Growth	Chlamydo spores	Recovery
<i>Aspergillus brasiliensis</i> ATCC 16404 (00057*)	50-100	luxuriant	negative	
<i>Candida albicans</i> ATCC 10231 (00054*)	50-100	luxuriant	positive	≥70%
<i>Saccharomyces cerevisiae</i> ATCC 9763 (00058*)	50-100	luxuriant	negative	≥70%
<i>Saccharomyces uvarum</i> ATCC 28098	50-100	luxuriant	negative	≥70%

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. Use before expiry date on the label.

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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,4).

Reference

1. American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., Washington D.C.
2. Conant N. F., Smith D. T., Baker R. D., Callaway J. L. and Martin D. S., 1971, Manual of Clinical Mycology, 3rd Ed., USA
3. Cooper and Silvo-Hunter, 1985, Manual of Clinical Microbiology, Lennette, Balows, Hausler and Shadomy (Eds.), 4th ed., ASM, Washington, D.C.
4. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 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.
6. Pollack and Benham, 1960, J. Lab. Clin. Med., 50:313.
7. Salfinger Y., and Tortorello M.L. Fifth (Ed.), 2015, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
8. Walker and Huppert, 1960, Tech. Bull. Reg. Med. Technol., 30:10.

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Malt Agar

M253

Intended Use

Recommended for the detection and isolation of yeasts and moulds from dairy products, foods and other materials. Also used for carrying stock cultures of yeasts and moulds.

Composition**

Ingredients	Gms / Litre
Malt extract	30.000
Agar	15.000
Final pH (at 25°C)	5.5±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 45 grams in 1000 ml distilled water. Heat to boiling to dissolve the medium completely. Sterilize by autoclaving at 118°C for 15 minutes. Avoid overheating, as it will result in a softer and darker agar. Cool to 45-50°C. Mix well and pour into sterile Petri plates.

Principle And Interpretation

Media based on malt extract may be considered as general growth substrates due to their richness and nutrient balance. They are very suitable for the cultivation of fastidious microorganisms. With acidic pH, they are used for the isolation, cultivation and maintenance of yeast and moulds.

Malt media for yeasts and moulds have been widely used for many years. In 1919, Reddish (1) prepared a satisfactory substitute for beer wort from malt extract. Malt Agar is included in Official Methods of Analysis of AOAC International (2). It is recommended by APHA (3) for use in both antibiotic and acidified standard methods for yeast and mould counts in food. This medium is also used for maintaining stock cultures of fungi.

Malt Agar contains malt extract, which provides carbon, protein and nutrient sources required for the growth of microorganisms. The acidified medium inhibits the growth of bacteria and allows good recovery of yeasts and moulds (4). Heating process during rehydration and sterilization should be for shorter period as excessive heat causes partial hydrolysis of the agar, which results in inability to gel properly when cooled. If desired additional 5 grams of agar may be added.

Type of specimen

Food and dairy samples

Specimen Collection and Handling

For food and dairy samples, follow appropriate techniques for sample collection and processing as per guidelines (3,5,6). 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 guidelines should be followed while handling clinical specimens. Safety guidelines may be referred in individual safety data sheets

Limitations :

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

Cream to brownish yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.5% Agar gel

Colour and Clarity of prepared medium

Light amber coloured clear to slightly opalescent gel forms in tubes or Petri plates

Reaction

Reaction of 4.5% w/v aqueous solution at 25°C. pH : 5.5±0.2

pH

5.30-5.70

Cultural Response

Cultural characteristics was observed after an incubation at 25 - 30°C for 40 - 48 hours.

Organism	Inoculum (CFU)	Growth	Recovery
<i>#Aspergillus brasiliensis</i> ATCC 16404 (00053*)	50-100	luxuriant	
<i>Candida albicans</i> ATCC 10231 (00054*)	50-100	luxuriant	≥70%
<i>Saccharomyces cerevisiae</i> ATCC 9763 (00058*)	50-100	luxuriant	≥70%
<i>Penicillium chrysogenum</i> ATCC 9179	50-100	luxuriant	
<i>Trichophyton mentagrophytes</i> ATCC 9533	50-100	luxuriant	

Key: (#) Formerly known as *Aspergillus niger*, (*) Corresponding WDCM numbers

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. Use before expiry date on the label.

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 clinical sample must be decontaminated and disposed of in accordance with current laboratory techniques (7,8).

Reference

1. Reddish, 1919, Abstr. Bacteriol., 3:6.
2. Williams, (Ed.), 2005, Official Methods of Analysis of the Association of Official Analytical Chemists, 19th Ed., AOAC, Washington, D.C.
3. Salfinger Y., and Tortorello M.L. Fifth (Ed.), 2001, Compendium of Methods for the Microbiological Examination of Foods, 5th Ed., American Public Health Association, Washington, D.C.
4. Can. Dept. Agr. Pamphlet, 92-N.S.
5. American Public Health Association, Standard Methods for the Examination of Dairy Products, 1978, 14th Ed., 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. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2nd Edition.
8. 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.

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