Soyabean Casein Digest Agar w/ Yeast Extract and Hemin (Tryptone Soya Agar w/ Yeast Extract and Hemin)

M109

Intended Use:

For cultivation of fastidious microorganisms like *Bordetella pertussis* and *Neisseria meningitidis.*

Composition**

Ingredients	g / L
Tomato juice (400 ml)	17.000
Soya peptone	3.000
Sodium chloride	5.000
Yeast extract	5.000
Dipotassium hydrogen phosphate	2.500
Hemin	0.020
Agar	13.000
Final pH (at 25°C)	7.3±0.2

**Formula adjusted, standardized to suit performance parameters

Directions

Suspend 45.52 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. 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

Soyabean Casein Digest Agar is recommended by various pharmacopoeias as sterility testing medium (1,2). Trytone Soya Agar w/ Yeast Extract and Hemin is a modification of Soyabean Casein Agar with the additional ingredients tomato juice, yeast extract and hemin.

Tomato juice serves as a source of carbon, protein and nutrients. Yeast extract and soya peptone provides essential nutrients like nitrogen and carbon compounds, long chain amino acids and vitamins. Dipotassium phosphate provides buffering action to the medium. Hemin provides essential growth for fastidious microorganisms like *Bordetella pertussis* (3) and *Neisseria meningitidis.*

Type of specimen

Clinical samples - sputum samples, Cerebrospinal fluid

Specimen Collection and Handling:

For clinical samples follow appropriate techniques for handling specimens as per established guidelines (4,5).

After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions :

In Vitro diagnostic Use only. For professional 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 :

1.Individual organisms differ in their growth requirement and may show variable growth patterns on the medium.

2.Each lot of the medium 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 unique requirement.

3.Further biochemical and serological tests must be carried out for further identification.

4.*B. pertussis* colonies may not be visible without the aid of a microscope for 2-4 days.

Performance and Evaluation

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

Quality Control

Appearance

Cream to yellow homogeneous free flowing powder

Gelling

Firm, comparable with 1.3% Agar gel.

Colour and Clarity of prepared medium

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

Reaction

Reaction of 4.55% w/v aqueous solution at 25°C. pH : 7.3±0.2

pH

7.10-7.50

Cultural Response

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours.

Organism	Inoculum (CFU)	Growth	Recovery
Neisseria meningitidis ATCC 13090	50-100	good-luxuriant	>=70%
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50-100	good-luxuriant	>=70%
Enterococcus faecalis ATCC 29212 (00087*)	50-100	good-luxuriant	>=70%
Streptococcus pneumoniae ATCC 6303	50-100	good-luxuriant	>=70%

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

Reference

1.Indian Pharmacopoeia, 2022, Indian Pharmacopoeia Commission, Ministry of Health and Family Welfare Government of India.

2.The United States Pharmacopoeia-National Formulatory (USP-NF), 2022.

3.Quinto G. and Sebald M., (1964), Am. J. Med. Technol. 30:381-384.

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.

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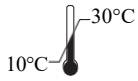
IVD ***In vitro* diagnostic medical device**



Storage temperature

EC REP

CEpartner4U, Esdoornlaan 13,
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CE Marking

Do not use if package is damaged

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