



Fluconazole Testing Medium (Twin Pack)

M1209

Intended Use:

Recommended for fluconazole susceptibility testing by using *Candida* species.

Composition**

Ingredients	Gms / Litre
Part A	-
Agar	10.000
Part B	-
Dextrose (Glucose)	19.980
Potassium dihydrogen phosphate	1.990
Ammonium sulphate	4.990
L-Glutamine	0.580
Magnesium sulphate	0.990
Sodium chloride	0.200
Calcium chloride	0.200
L-Lysine hydrochloride	0.073
Valine	0.047
L- Arginine hydrochloride	0.042
L-Histidine	0.023
DL-Methionine	0.0189
Tryptophan	0.020
Nicotinic acid	0.00079
Inositol	0.00397
Pyridoxine hydrochloride	0.00079
Boric acid	0.00099
Calcium D-pantothenic acid	0.00079
Aneurine hydrochloride	0.00079
Manganous sulphate	0.00079
Zinc sulphate	0.0014
p-Amino benzoic acid (PABA)	0.000395
Riboflavin	0.000395
Ferric chloride	0.000395
Cupric sulphate	0.00012
Biotin crystalline	0.000004
Folic acid	0.000395
L-Isoleucine	0.052
Sodium molybdate	0.00047
Potassium iodide	0.0002
L-Leucine	0.052
Threonine	0.0476

**Formula adjusted, standardized to suit performance parameters

Directions

Part A and Part B are sterilized separately as follows:

Part A: - Suspend 2.0 grams of Part A in 100 ml purified / distilled water, add 0.1 ml phosphate buffer to adjust the pH to 7.5. Heat to boiling to dissolve the agar particles completely and then sterilize by autoclaving at 115°C for 10 minutes.

Part B: - Suspend 29.31 grams of Part B in 900 ml purified / distilled water. Mix well, add 2 gram of sodium bicarbonate, after stirring make up the total volume to 1 litre with distilled water. Sterilize by filtration. The medium can be kept at 4°C for two weeks. Complete medium is prepared by aseptically adding equal volume of molten Part A (previously cooled to 50°C) and Part B. Mix thoroughly and dispense.

Principle And Interpretation

To carry out standardization of antifungal drug susceptibility assays as a standard reference method, CLSI had recommended broth macro dilution testing of yeasts. Fluconazole Testing Medium is a chemically defined medium specifically developed for the in-vitro testing of fluconazole by using *Candida* species. Inhibitory concentration values obtained by using this medium correlate well with the clinical outcome (1,2,3). The medium contains dextrose and a variety of amino acids, salts and vitamins to support the growth of *Candida* and other fungi.

Type of specimen

Clinical samples - skin, Palate scrapings, blood sample or scraping from the infected body site.

Specimen Collection and Handling:

The inoculum size varies with different fungi. *Candida* species are grown in Sabouraud Dextrose Broth (M033) at 37°C for 16-18 hours and then diluted with normal saline to give following dilutions:

Candida albicans 10⁵ / ml
Candida tropicalis 10⁵ / ml
Candida krusei 10⁵ / ml
Candida guilliermondii 10⁶ / ml
Candida parapsilosis 10⁶ / ml
Candida pseudotropicalis 10⁶ / ml

Surface inoculate the above diluted cultures and incubate at 28°C for 48 hours to determine MIC value of fluconazole. Dermatophytes are grown in Sabouraud Dextrose Agar (M063) at 28°C for 5-10 days. The mycelial growth is homogenized in 2 ml of 0.85% saline using glass beads. The density of the suspension is adjusted with 0.85% saline to get a 65% light transmission. Inoculate the plates and incubate for about 5-6 days at 28°C.

Check the control plates to ensure that all isolates have grown adequately and determine the Minimum Inhibitory Concentration (MIC).

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. Standard methods should be followed for inoculating the plates.
2. Dilutions should be precise to avoid erroneous results.

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

Part A : Cream to light yellow homogeneous coarse powder Part B : White to light yellow homogeneous free flowing powder

Colour and Clarity of prepared medium

Light yellow coloured, opalescent solution may be with fine precipitate

Cultural Response

Cultural characteristics observed after an incubation at 28-30°C for 48 hours .

Organism	MIC of Fluconazole
<i>Candida albicans</i> ATCC 90028	0.25-1mcg/ml

Storage and Shelf Life

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

Reference

1. Cook R. A., McIntyre K. A. and Galgiani J. N., 1990, Antimicrob. Agents and Chemother., 34:1542.
2. Hoepfich P. D. and Finn. P. D., 1972, J. Infect, Dis., 126: 353
3. Pfaller M. A. et al, 1992, Antimicrob. Agents and Chemother.,36:1805.
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.

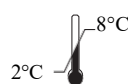
Revision : 03/2022



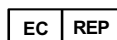
HiMedia Laboratories Pvt. Limited,
Plot No.C-40, Road No.21Y,
MIDC, Wagle Industrial Area,
Thane (W) -400604, MS, India



**In vitro diagnostic
medical device**



Storage temperature



CEpartner4U, Esdoornlaan 13,
3951DB Maarn, NL
www.cepartner4u.eu



CE Marking



**Do not use if
package is damaged**

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.