

# **Technical Data**

# **NIH Agar**

## **M194**

## **Intended Use:**

Recommended for sterility testing and for cultivation and maintenance of isolates from sterility testing of biological products.

#### **Composition\*\***

Ingredients	Gms / Litre
Tryptone	15.000
Yeast extract	5.000
Dextrose (Glucose)	5.500
Sodium chloride	2.500
L-Cystine	0.050
Agar	15.000
Final pH ( at 25°C)	7.1±0.2
**Formula adjusted, standardized to suit performance parameters	

Directions

Suspend 43.05 grams in 1000 ml purified/distilled water. Heat to boiling to dissolve the medium completely. Dispense into test tubes or flasks as desired. Sterilize by autoclaving at 15 lbs pressure (121°C) for 15 minutes. As per USP, it is recommended to add 0.05% sodium thioglycollate or 0.03% Thioglycollic acid for neutralization of bacteriostatic effect of mercuric compounds.

## **Principle And Interpretation**

NIH Agar is formulated according to the agar medium specified by USPHS sterility test (7). This medium can be used for sterility testing and also for cultivating the isolates from biological products tested for sterility. This medium is also recommended by the National Institute of Health (NIH) for sterility testing of turbid appearing biological products (3). NIH Medium has a similar composition as Fluid Thioglycollate Medium, except sodium thioglycollate and resazurin. Also the agar concentration is more in NIH Medium than in Fluid Thioglycollate Medium.

NIH medium is a nutritious medium containing nutrients like Tryptone, yeast extract and the amino acid L-cystine. It contains the fermentable carbohydrate dextrose and sodium chloride for maintaining osmotic equilibrium. NIH Medium is devoid of sodium thioglycollate. U.S. Pharmacopoeia (6) has recommended using this medium with sodium thioglycollate (0.05%) or thioglycollic acid (0.03%) for the sterility testing of biological products containing mercurial preservatives, since sodium thioglycollate neutralizes the bacteriostatic effect of mercuric compounds (4, 5).

## Type of specimen

Pharmaceutical samples for sterility testing

## **Specimen Collection and Handling**

For pharmaceutical samples, follow appropriate techniques for sample collection, processing as per guidelines (3,6,7). 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 clinical specimens. Safety guidelines may be referred in individual safety data sheets.

## Limitations

1. Further biochemical and serological tests must be carried out for complete identification.

## **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 & Clarity of prepared medium** Light amber coloured clear to slightly opalescent gel forms in Petri plates **Reaction** Reaction of 4.3% w/v aqueous solution at 25°C. pH : 7.1±0.2 **pH** 6.90-7.30

#### **Cultural Response**

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

Organism	Inoculum	Growth	Recovery
Escherichia coli ATCC 25922 (00013*)	50-100	good-luxuriant	>=70%
Streptococcus mitis ATCC 9895	50-100	good-luxuriant	>=70%
Staphylococcus aureus subsp. aureus ATCC 25923 (00034*)	50-100	good-luxuriant	>=70%
Streptococcus pyogenes ATCC 19615	50-100	good-luxuriant	>=70%

Cultural characteristics observed after an incubation at 35-37°C for 18-24 hours with addition of sodium thioglycollate.

<i>Bacillussubtilis</i> subsp. <i>spizizenii</i> ATCC 6633 (00003*)	50-100	good-luxuriant >=50%
Bacteroides vulgatus ATCC 8482	50-100	good-luxuriant >=50%
Candida albicans ATCC 10231 (00054*)	50-100	good-luxuriant >=50%
<i>Micrococcus luteus</i> ATCC 9341	50-100	good-luxuriant >=50%
Clostridium sporogenes ATCC 11437	50-100	good-luxuriant >=50%

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 (1,2).

#### Reference

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.

2. 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.

3. MacFaddin J. F., 1985, Media for Isolation-Cultivation-Identification-Maintenance of Medical Bacteria, Vol. 1, Williams and Wilkins, Baltimore.

4. Nungester, Hood and Warren, 1943, Proc. Soc. Exp. Biol. Med. 52: 287

5. Portwood, 1944, J. Bacteriol., 48 : 255.

- 6. The United States Pharmacopoeia, 2006, USP29/NF24. The United States Pharmacopoeial Convention, Rockville, MD.
- 7. USPHS Reg., 73, 730: Federal Register, 1970, Vol. 35, No. 0171, p. 13:930.

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#### Disclaimer :

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