

TM 795 – NIH AGAR

INTENDED USE

For cultivation & maintenance of isolates from sterility testing of biological products.

PRODUCT SUMMARY AND EXPLANATION

NIH Agar is formulated according to the agar medium specified by USPHS sterility test. 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. NIH Medium has a similar composition as Fluid Thioglycollate Medium, except sodium thioglycollate and resazurin. The agar concentration is more in NIH Medium than in Fluid Thioglycollate Medium.

COMPOSITION

Ingredients	Gms / Ltr
Tryptone	15.000
Yeast extract	5.000
Dextrose	5.500
Sodium chloride	2.500
L-Cystine	0.050
Agar	15.000

PRINCIPLE

NIH medium is a nutritious medium which contains 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 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.

INSTRUCTION FOR USE

- Dissolve 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 psi 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.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to yellow homogeneous free flowing powder.
Appearance of prepared medium	: Light amber coloured clear to slightly opalescent gel forms in Petri plates.
pH (at 25°C)	: 7.1 ± 0.2

INTERPRETATION



Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
<i>Escherichia coli</i>	25922	50-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours
<i>Streptococcus mitis</i>	9895	50-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours
<i>Staphylococcus aureus subsp. aureus</i>	25923	50-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours
<i>Streptococcus pyogenes</i>	19615	50-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours

Cultural characteristics observed after incubation with addition of sodium thioglycollate.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Recovery	Incubation Temperature	Incubation Period
<i>Bacillus subtilis subsp. spizizenii</i>	6633	50-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours
<i>Bacteroides vulgatus</i>	8482	50-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours
<i>Candida albicans</i>	10231	10-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours
<i>Micrococcus luteus</i>	9341	50-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours
<i>Clostridium sporogenes</i>	11437	50-100	Good-luxuriant	>=50%	35-37°C	18-24 Hours

PACKAGING:

In pack size of 100 gm and 500 gm bottles.

STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.










Product Deterioration: Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.

DISPOSAL

After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

REFERENCES

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.

 Good Manufacturing Practices Certified	 Best Before	 Quantity	 Catalogue Number	 Manufacturer
 Temperature Unit	 Lot / Batch Number	 Consults Instructions for Use	 QR Code	

NOTE: Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

***For Lab Use Only**
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