

TM 2372 – THIOSTARCH BROTH

INTENDED USE

For sterility testing of pharmaceutical or biological products.

PRODUCT SUMMARY AND EXPLANATION

Brewer formulated Fluid Thioglycollate Medium for rapid cultivation of aerobes as well as anaerobes including microaerophiles by adding a reducing agent and small amount of agar. The USP, BP, EP and AOAC have recommended the media for sterility testing of antibiotics, biologicals and foods and for determining the phenol coefficient and sporicidal effect of disinfectants. However, it is intended for the examination of clear liquid or water-soluble materials. Fluid Thioglycollate Medium is also routinely used to check the sterility of stored blood in blood banks. Thiostarch Broth is a slight modification of Fluid Thioglycollate Medium. It additionally contains soluble starch which neutralizes the toxic effects.

COMPOSITION

Ingredients	Gms / Ltr
Casein enzymic hydrolysate	15.000
Yeast extract	5.000
L-Cystine	0.500
Dextrose	5.000
Sodium chloride	2.500
Sodium thioglycollate	0.500
Soluble starch	1.000
Resazurin	0.001
Agar	0.750

PRINCIPLE

Casein, enzymic hydrolysate, yeast extract, L-cysteine provide nitrogen source and growth factor for bacterial growth. Sodium thioglycollate and L-cysteine are reducing agents, maintains low redox potential and support anaerobiosis and thus allows Clostridium to grow in the medium even under aerobic conditions. Resazurin is an oxidation-reduction indicator being pink when oxidized and colourless when reduced. Small amount of agar assists in the maintenance of anaerobiosis in the lower depths of the medium.

INSTRUCTION FOR USE

- Dissolve 30.25 grams in 1000 ml distilled water.
- Heat to boiling to dissolve the medium completely.
- Dispense in test tubes. Sterilize by autoclaving at 15 psi pressure (121°C) for 20 minutes.

QUALITY CONTROL SPECIFICATIONS

Appearance of Powder	: Cream to pink coloured homogeneous free flowing powder
Appearance of prepared medium	: Light straw coloured upper 10% or less medium pink on standing, clear to slightly opalescent.
pH (at 25°C)	: 7.1±0.2

INTERPRETATION



Cultural characteristics observed after incubation.

Microorganism	ATCC	Inoculum (CFU/ml)	Growth	Incubation Temperature	Incubation Period
<i>Bacillus subtilis</i>	6633	50-100	Luxuriant	35 - 37°C	18-48 Hours
<i>Candida albicans</i>	10231	50-100	Luxuriant	35 - 37°C	18-48 Hours
<i>Clostridium sporogenes</i>	11437	50-100	Luxuriant	35 - 37°C	18-48 Hours
<i>Micrococcus luteus</i>	10240	50-100	Luxuriant	35 - 37°C	18-48 Hours
<i>Streptococcus pyogenes</i>	19615	50-100	Luxuriant	35 - 37°C	18-48 Hours

PACKAGING:

In pack size of 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. Brewer, 1940, J. Am. Med. Assoc., 115:598.
2. The United States Pharmacopoeia, 2009, The United States Pharmacopoeial Convention, Rockville, MD. 3. British Pharmacopoeia, 2009, The Stationery office British Pharmacopoeia.
4. European Pharmacopoeia, 2009, European Dept. for the quality of Medicines.
5. Williams H., (Ed.), 2005, Official Methods of Analysis of the Association of Official Analytical Chemists, 19th Ed., AOAC, Washington, D.C.
6. Federal Register, 1992, Fed. Regist., 21:640.2.17.
7. Quastel and Stephenson, 1926, J. Biochem., 20:1125.



 GMP Good Manufacturing Practices Certified	 IVD For In Vitro Diagnostic Use	 QTY. Quantity	 LOT/ B. NO. Lot / Batch Number	 REF Catalogue Number	 Manufacturer
 Temperature Unit	 EC REP Authorized Representative <small>MedNet GmbH Birkstrasse 10 48163 Muenster, Germany</small>	 European Conformity	 QR Code	 Consults Instructions for Use	 Best Before

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

***For Lab Use Only**
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