

## THIOGLYCOLLATE BROTH (USP) THIOGLYCOLLATE (Fluid) MEDIUM ALTERNATIVE

**IVD in Class A, EU Reg. 2017/746**

 For in vitro diagnostic use **IVD**

Thioglycollate Broth is used for cultivation and isolation of obligate and facultative anaerobic and microaerophilic bacteria and for aseptic process simulations.

### DESCRIPTION

The culture media complies with the recommendations of the United States Pharmacopeia XXVI (2003), the European Pharmacopeia II (2003) and APHA (1992). This medium is suggested as an alternative to Thioglycollate (Fluid) Medium for media fill application in the Sterility Testing chapters of EP and USP. In contrast to Thioglycollate (Fluid) Medium it does not contain agar-agar and Resazurin.

### PRINCIPLE

Thioglycollate Broth is formulated as described in the N.I.H. memorandum. It is used for the sterility testing of certain biological products which are turbid or viscous. Both the media have similar composition, except agar and resazurin that are not included in Thioglycollate Broth. This deletion makes it suitable for sterility testing of viscous products. Tryptone serves as a source of nitrogen and carbon compounds, long chain amino acids and other essential nutrients. Yeast extract serve as source of essential nutrients to the contaminants, if present. Dextrose serves as the energy source. Sodium chloride maintains the osmotic equilibrium of the medium whereas L-cystine, an amino acid, also serves as source of essential growth factors. Sodium thioglycollate and L-cystine lower the oxidation-reduction potential of the medium by removing oxygen to maintain a low Eh. Sodium thioglycollate also helps to neutralize the toxic effects of mercurial preservatives.

### COMPOSITION

|                             | g/L   |
|-----------------------------|-------|
| Pancreatic digest of casein | 15,00 |
| Yeast Extract               | 5,00  |
| Dextrose                    | 5,50  |
| Sodium chloride             | 2,50  |
| Sodium thioglycolate        | 0,50  |
| L-cystine                   | 0,50  |

**Final pH 7,1 ± 0,2 at 25°C**

### WARNING AND PRECAUTIONS

#### For in vitro diagnostic use.

Observe the precautions normally taken when handling laboratory reagents.

**Dehydrated medium: HIGHLY HYGROSCOPIC.** During the handling, wear dust protection mask. Avoid the eye contact. Do not use beyond the expiration date or if the product shows signs of deterioration, an altered color or has compacted.

**Prepared Medium:** The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous.

**Safety Data Sheet** is available on request for professional users.

All waste must be disposed of according to local directives.

### STORAGE AND STABILITY

|                           |         |
|---------------------------|---------|
| <b>Dehydrated medium:</b> | 10-30°C |
| <b>Prepared medium:</b>   | 10-25°C |

THIOGLYCOLLATE BROTH (USP) is stable until the expiration date indicated on the label under the recommended storage conditions.

### PREPARATION

**Dehydrated medium:** Suspend 29 g Thioglycollate Broth/l. Dispense into tubes or bottles. Autoclave 15 min at 121 °C.

**Prepared medium (bottles, tubes):** ready to use.

### PROCEDURE

Inoculate the culture medium with the sample material taking care that the sample reaches the bottom of the tubes. In order to ensure anaerobiosis, the medium can then be overlaid with 1 cm of sterile liquid paraffin or agar solution. Incubation: several days at the optimal incubation temperature (30-35 °C). Anaerobes grow in the lower part of the culture.

### RESULTS

Turbidity indicates microbial growth.

### QUALITY CONTROL

**Dehydrated medium:** Straw coloured, free-flowing powder.

**Prepared medium:** Straw coloured solution.

**Typical response after incubation at 30-35°C for 24-72 hours**

| MICROORGANISM                     | GROWTH         |
|-----------------------------------|----------------|
| Clostridium sporogenes ATCC 19404 | Good/Turbidity |
| Clostridium sporogenes ATCC 11437 | Good/Turbidity |
| Staphylococcus aureus ATCC 25953  | Good/Turbidity |
| Bacteroides vulgatus ATCC 8482    | Good/Turbidity |
| Bacillus subtilis ATCC 6633       | Good/Turbidity |
| Kocuria rhizophila ATCC 9341      | Good/Turbidity |
| Pseudomonas aeruginosa ATCC 9027  | Good/Turbidity |

### REFERENCES

1. Isenberg, H.D. Clinical Microbiology Procedures Handbook. 2 nd 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. Lapage S., Shelton J. and Mitchell T., 1970, Methods in Microbiology, Norris J. and Ribbons D., (Eds.), Vol. 3A, Academic Press, London.
4. MacFaddin J. F., 2000, Biochemical Tests for Identification of Medical Bacteria, 3rd Ed., Lippincott, Williams and Wilkins, Baltimore
5. N.I.H. Memorandum, 1955: Culture Media for Sterility Tests, 4th Revision.
6. Nungester, Hood and Warren, 1943, Proc. Soc. Exp. Biol. Med., 52: 287
7. Portwood, 1944, J. Bacteriol., 48: 255
8. The United States Pharmacopoeia, 2019, The United States Pharmacopoeial Convention, Rockville, MD.

### PRESENTATION

**Packaging**
**REF.**

#### Dehydrated medium:

#### THIOGLYCOLLATE BROTH (USP)

|              |              |
|--------------|--------------|
| <b>100 g</b> | <b>11064</b> |
| <b>500 g</b> | <b>10064</b> |

#### Prepared medium:

#### THIOGLYCOLLATE BROTH

|                          |                 |
|--------------------------|-----------------|
| <b>100 x 4 mL tubes</b>  | <b>5280</b>     |
| <b>20 x 10 mL tubes</b>  | <b>5268</b>     |
| <b>100 x 10 mL tubes</b> | <b>5068/100</b> |

### SYMBOLS

|  |   |  |                          |
|--|---|--|--------------------------|
|  | <b>Read the instructions</b>  |  | <b>Biological hazard</b> |
|  | <b>CE Mark (product complies with the requirements of Regulation (EU) 746/2017)</b> |  |                          |
|  | <b>Temperature limitation</b>   |  | <b>Use by</b>            |
|  | <b>For in vitro diagnostic use</b>  |  | <b>Manufacturer</b>      |