



Fluid Thioglycollate Medium

Liquid medium for sterility test and cultivation of fastidious anaerobic and aerobic microorganisms, according to Harmonized USP/EP/JP and ISO 7937.

DESCRIPTION

Fluid Thioglycollate Medium is a general purpose liquid enrichment medium used for sterility control of pharmaceutical products and for cultivation and isolation of fastidious anaerobic and aerobic microorganisms.

The composition is in accordance with the requirements of the Harmonized US, European and Japanese Pharmacopoeia as well as with ISO 7937 for isolation of *Clostridium perfringens*.

TYPICAL FORMULA*	(g/l)
Enzymatic Digest of Casein	15.0
Yeast Extract	5.0
Glucose	5.5
Sodium Chloride	2.5
Sodium Thioglycollate	0.5
L-Cystine	0.5
Resazurin	0.001
Agar	0.75

Final pH 7.1 ± 0.2 at 25°C

*Formula may be adjusted and/or supplemented as required to meet performance specifications;
Grams per litre of purified water.

METHOD PRINCIPLE

Enzymatic digest of casein provides amino acids, nitrogen, carbon, vitamins and minerals for organisms growth. Yeast extract is a source of vitamins, particularly of B-group. Glucose is a source of energy. Sodium chloride maintains the osmotic balance of the medium. Sodium thioglycollate and L-cystine are included to reduce the redox potential of the medium and create an anaerobic atmosphere. These reducing agents also neutralize the bacteriostatic effects of mercury and other heavy metal compounds in the preparation to be tested for sterility. Resazurin is an oxidation-reduction indicator being pink when oxidized and colorless when reduced. The small amount of agar assists in the maintenance of a low redox potential by stabilizing the medium against convection currents, thereby maintaining anaerobiosis in the lower depths of the medium.

PREPARATION

<u>Dehydrated medium</u>	Suspend 29.8 g of the powder in 1 liter of distilled or deionized water. Mix well. Heat to boil shaking frequently until completely dissolved. Dispense into appropriate containers. Sterilize in autoclave at 121°C for 15 minutes.
<u>Medium in tubes/bottles</u>	If the medium exhibits more than 20% pink color (due to oxidation), the medium may be reheated once for 5 minutes with cap slightly loosened in steam or boiling water in order to expel the oxygen.

TEST PROCEDURE

The medium can be directly inoculated with the test sample (the amount of the inoculated sample material should not be exceed 10% volume of the medium). Incubate at 30-35°C for up to 14 days. Growth of strictly aerobic bacteria can be improved by slightly loosening the cap.

According to ISO 7937 for confirmation of *Clostridium perfringens* inoculate each black colony from Sulfite Cycloserine Agar (ref. 402700) into Fluid Thioglycollate Medium. Incubate at 37 ± 1°C for 18-24 hours. Subsequently, transfer 5 drops of the enrichment culture into Lactose Sulfite Medium (ref. 610358) and incubate at 46 ± 1°C for 18-24 hours.

INTERPRETING RESULTS

Turbidity of the medium indicates microbial growth. Obligate anaerobic microorganisms such as *Clostridium sporogenes* are growing in the lower, yellowish part of the broth medium. The growth of facultative anaerobic microorganisms such as *Staphylococcus aureus* is distributed throughout all the medium. Aerobic microorganisms such as *Pseudomonas aeruginosa* are able to grow in the upper slightly pink layer (oxidized part) of the medium.

STORAGE

The powder is very hygroscopic, store the powder at 10-30°C, in a dry environment, in its original container tightly closed. Store bottles and tubes at 10-25°C away from light. Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration.

SHELF LIFE

Dehydrated medium: 4 years.

Medium in bottles or tubes: 2 years.

QUALITY CONTROL

Appearance of Dehydrated Medium: Free-flowing, homogeneous, light beige.

Appearance of Prepared Medium: Slightly opalescent, light amber (20% or less of upper layer may be pink).

Expected Cultural Response:

Control strain		Inoculum	Incubation	Specification
<i>Bacillus subtilis</i> ^a	WDCM 00003 (ATCC 6633; NCTC 10400)	≤100 CFU	24 h 32.5 ± 2.5°C	Visible turbidity
<i>Clostridium sporogenes</i> ^a	WDCM 00008 (ATCC 19404; NCTC 532)			
<i>Escherichia coli</i> ^a	WDCM 00012 (ATCC 8739; NCTC 12923)			
<i>Pseudomonas aeruginosa</i> ^a	WDCM 00026 (ATCC 9027; NCTC 12924)			
<i>Staphylococcus aureus</i> ^a	WDCM 00032 (ATCC 6538; NCTC 10788)			
<i>Clostridium perfringens</i> ^b	WDCM 00007 (ATCC 13124; NCTC 8237)		18-24 h 37 ± 1°C	Slight to good turbidity
<i>Candida albicans</i> ^a	WDCM 00054 (ATCC 10231; NCPF 3179)		48 h 22.5 ± 2.5°C	
<i>Aspergillus brasiliensis</i> ^a	WDCM 00053 (ATCC 16404; NCPF 2275)		72 h 22.5 ± 2.5°C	

^a Pharmacopoeia Growth Promotion Test

^b EN ISO 11133

Please refer to the actual batch related Certificate of Analysis (CoA).

WARNING AND PRECAUTIONS

For *in-vitro* diagnostic use (see the product list the next page). For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

Disposal of waste must be carried out according to national and local regulations in force.

BIBLIOGRAPHY

See the references at the end of this document.

TABLE OF SYMBOLS

See the table of symbols at the end of this document.

The product is available in the various configurations listed on the next page. There may be additional product ref. numbers as well. For an updated listing of available products, visit liofilchem.com

Product	Format	Packaging	Ref.
Fluid Thioglycollate Medium	Tube	100 x 9 ml	26493 •
Fluid Thioglycollate Medium	Tube	20 x 10 ml	24124 •
Fluid Thioglycollate Medium	Tube	100 x 10 ml	26124 •
Fluid Thioglycollate Medium	Tube	10 x 20 ml	21241 •
Fluid Thioglycollate Medium	Tube	20 x 20 ml	24241 •
Fluid Thioglycollate Medium	Bottle (screw cap)	25 x 90 ml	452110
Fluid Thioglycollate Medium	Bottle (screw cap)	6 x 100 ml	452060 •
Fluid Thioglycollate Medium	Bottle (screw cap)	25 x 100 ml	453060
Fluid Thioglycollate Medium	Bottle (flip-off cap)	6 x 100 ml	400020
Fluid Thioglycollate Medium	Bottle (flip-off cap)	25 x 100 ml	453020
Fluid Thioglycollate Medium	Bottle (crimp cap)	6 x 100 ml	495020
Fluid Thioglycollate Medium	Bottle (perforable cap)	6 x 100 ml	493000
Fluid Thioglycollate Medium	Bottle (wide neck)	6 x 500 ml	470300
Fluid Thioglycollate Medium	Bottle (screw cap)	6 x 900 ml	463100
Fluid Thioglycollate Medium	Dehydrated medium	100 g	620050
Fluid Thioglycollate Medium	Dehydrated medium	500 g	610050
Fluid Thioglycollate Medium	Dehydrated medium	5 kg	6100505

- CE-marked product for *in-vitro* diagnostic use

All the other above listed products are not CE-IVD marked.

This IFU document and the SDS are available from the online Support Center:

lioilchem.com/ifu-sds