Millipore®
Preparation, Separation,
Filtration & Monitoring Products

Data Sheet

Fluid Thioglycollate Medium Clear

Ordering number: 1.46456.0010

Fluid Thioglycollate Medium Clear is a universal complex medium for the isolation and cultivation of fastidious anaerobic as well as for aerobic microorganisms. Fluid Thioglycollate Medium Clear is used for sterility control of pharmaceutical products.

The formulation of the Fluid Thioglycollate Medium (FTM) described in EP and USP includes agar, which gives a slightly turbid appearance to the media. Fluid Thioglycollate Medium Clear contains a reduced agar content, supplemented by a clear gelling agent, to offer the same media properties as FTM, with extra clarity.

The Fluid Thioglycollate Medium clear is available in different filling volumes and various locking mechanisms:

- Fluid Thioglycollate Medium clear (article number 146456): 125 mL-bottle with **flip cap**, filling volume 100 mL
- Fluid Thioglycollate Medium clear (article number 146333): 125 mL-bottle with combined **septum and screw cap**, filling volume 100 mL
- Fluid Thioglycollate Medium clear (article number 146387): 1000 mL-bottle with combined **septum and screw cap**, filling volume 750 mL
- Fluid Thioglycollate Medium clear (article number 146590): 1000 mL-bottle with combined **septum and screw cap**, filling volume 900 mL

Mode of Action

Thioglycollate and L-Cystine in the medium reduce the redox potential of the culture medium in order to create an anaerobic atmosphere. In addition, mercury and other heavy metal compounds are inactivated by these agents. The presence of agar and clear gelling agent further reduce a rapid diffusion of oxygen through the medium while offering a clear medium. Resazurin indicates the reduction potential of the medium. An increased concentration of oxygen is indicated by a color change from yellow to pink.

Typical Composition

Casein Peptone	**15 g/L**
Yeast extract	**5 g/L**
Glucose Anhydrous	**5 g/L**
NaCl	**2.5 g/L**
L-Cystine	**0.5 g/L**
Sodium Thioglycollate	**0.5 g/L**
Resazurin	**1 mg**
Agar/Gelling Agent	**0.2 g/L**

The appearance of the medium is clear and yellowish. The pH value is in the range of 6.9-7.3. The medium can be adjusted and/or supplemented according to the performance criteria required.

MERCK

Application and Interpretation

The broth medium should be equilibrated to room temperature before use.

The surface of the containers is not sterile. Therefore, please be aware about a risk of secondary contamination due to handling. In order to reduce the risk of secondary contamination by defect glass containers or handling the following recommendations may be helpful:

- Please control each single container for visible defects or turbidity. Do not use such containers.
- Please avoid the contamination of culture media by contact with skin or body fluids. Such contaminated media cannot be used anymore.
- Due to negative pressure (vacuum generated above media surface during production), the containers should be ventilated by sterile filter-units before usage to avoid aspiration of potential contaminated air. For this, the protective cap should be removed, and the septum surface must be disinfected.
- The risk of transfer of microorganisms from the surface of the containers into the sterile culture medium can be minimized by disinfection of these surfaces followed by handling in sterile environments, e.g. isolators. The inoculation of the containers or the media transfer into membrane filtration units by sterile cannulas is safer than procedures which require opening of media bottles or tubes.

Media which contain ingredients of animal or human origin such as meat extract must be considered potentially infectious. After contact of such media a disinfection of the affected skin area is recommended.

Strictly 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 in the complete medium. Aerobic microorganisms such as *Pseudomonas aeruginosa* are able to grow in the upper, oxidized part of Fluid Thioglycollate Medium indicated by a slight pink color. Usually the incubation is performed under aerobic conditions. To provide enough oxygen for the growth of aerobic microorganisms in bottles, which are filled under vacuum, a sterile ventilation device may be necessary. Not more than the upper half of the medium should have undergone a color change to pink indicative of oxygen uptake at the end of the incubation period.

If a sterile aeration device is not available, ventilation of the bottle must be performed in a sterile environment (isolator, cleanroom class A).

Fluid Thioglycollate Medium is recommended for sterility testing of pharmaceutical products according to the European and US Pharmacopoeia. According to the Pharmacopoeia a membrane filtration method should be performed wherever possible, but also direct inoculation methods are possible.

For membrane filtration application, we recommend the use of our 100 mL Fluid Thioglycollate Medium clear (Ordering information table - page 3). Fluid Thioglycollate Medium clear contains a reduced Agar content, whereby the other part of agar is replaced by a clear gelling agent. This does not influence the growth promoting properties of the medium.

If a standard Fluid Thioglycollate Medium in 100 mL filling volume is required, we offer Fluid Thioglycollate Medium (Ordering information table - page 3).

Note: For direct inoculation, we additionally offer Fluid Thioglycollate Medium clear and standard Fluid Thioglycollate Medium (Ordering information table - page 3), with specific filling volumes and closure system. For direct inoculation the amount of the inoculated sample material should not exceed 10% of the volume of the Fluid Thioglycollate Medium.

Fluid Thioglycollate Medium clear is incubated for 14 days at 30-35 °C and visually inspected for growth.

The sterility test is passed, if no growth is visible at the end of incubation.

It is recommended to identify grown microorganisms in order to find out the origin of contamination and to implement corrective actions

Storage and Shelf life

The product can be used for tests until the expiry date if protected from light and properly sealed at +2 °C to +25 °C.

The testing procedures as described on the CoA can be started up to the expiry date printed on the label.

Disposal

Please mind the respective regulations for the disposal of used culture medium (e.g. autoclave for 20 min at 121 °C, disinfect, incinerate etc.).

Quality Control

Control Strains	ATCC	Inoculum CFU	Incubation	Expected Results
Clostridium sporogenes	**19404**	10-100	20-24 h at 33-35 °C	good growth; pronounced turbidity
	11437	10-100	20-24 h at 33-35 °C	good growth; pronounced turbidity
Staphylococcus aureus	**6538**	10-100	20-24 h at 33-35 °C	good growth; pronounced turbidity
Pseudomonas aeruginosa	**9027**	10-100	20-24 h at 33-35 °C	good growth; pronounced turbidity

Please refer to the actual batch related Certificate of Analysis.

Literature

European Pharmacopoeia 9.0 (2016): 2.6.1. Sterility.

Guidance for Industry (2004): Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice.

United States Pharmacopoeia 41 (2018): <71> Sterility Tests.

Ordering Information

Product	Cat. No.	Pack size
Fluid Thioglycollate Medium Clear	**1.46456.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium Clear	**1.46333.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium Clear	**1.46387.0006**	6 x 750 mL bottles
Fluid Thioglycollate Medium Clear	**1.46590.0006**	6 x 900 mL bottles
Fluid Thioglycollate Medium	**1.46386.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium	**1.46406.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium	**1.46385.0010**	10 x 100 mL bottles
Fluid Thioglycollate Medium	**1.46220.0100**	100 x 9 mL tubes
Fluid Thioglycollate Medium	**1.46139.0100**	100 x 10 mL tubes

To place an order or receive technical assistance

Order/Customer Service:
SigmaAldrich.com/order

Technical Service:
SigmaAldrich.com/techservice

SigmaAldrich.com/sterilitytesting

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt, Germany

Lit. No. MK_DS3908EN Ver. 2.0
2019-22279
11/2021