



# PRODUCT SPECIFICATION SHEET

## Alternative Thioglycollate Medium (NIH Thioglycollate Broth) (DM264)

### Intended Use

Alternative Thioglycollate Medium (NIH Thioglycollate Broth) (DM264) is recommended for sterility testing of turbid or viscous biological products.

### Product Summary and Explanation

Alternative Thioglycollate Medium is formulated as described in the N.I.H. memorandum.<sup>(1)</sup> It is used for the sterility testing of certain biological products which are turbid or viscous and can't be tested using Fluid Thioglycollate Medium. NIH Thioglycollate Broth which is a USP Alternative Thioglycollate Medium, is a Fluid Thioglycollate Medium without the agar or resazurin indicator components. They are used for the same sterility test procedures except that anaerobic incubation is recommended rather than aerobic incubation. This deletion makes it suitable for sterility testing of viscous products. They also meet the requirements of the USP growth promotion test.<sup>(2)</sup>

### Principles of the Procedure

Alternative Thioglycollate Medium contains casein enzymic hydrolysate which provides carbon, nitrogen and a source of essential nutrients to the contaminants, if present. Yeast extract serve as a source of vitamins. Dextrose serves as the energy and carbon 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.<sup>(3,4)</sup>

### Formula / Liter

Ingredients	Gms / Liter
Pancreatic digest of casein	15.00
Yeast extract	5.00
Dextrose (Glucose)	5.50
Sodium chloride	2.50
L-Cystine	0.50
Sodium thioglycollate	0.50
Final pH: 7.1 ± 0.2 at 25°C	
Formula may be adjusted and/or supplemented as required to meet performance specifications	

### Precautions

1. For Laboratory Use only.
2. IRRITANT. Irritating to eyes, respiratory system, and skin.
3. It is preferable to use freshly prepared medium, alternatively it should be boiled and cooled just once prior to use as on reheating, toxic oxygen radicals are formed.

### Directions

1. Suspend 29 grams in one liter of distilled water.
2. Heat, if necessary, to dissolve the medium completely.
3. Autoclave at 121°C, 15 psi pressure, for 15 minutes / validated cycle.
4. Mix well and dispense as desired.





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### Quality Control Specifications

<b>Dehydrated Appearance</b>	Cream to yellow homogeneous free flowing powder
<b>Prepared Medium</b>	Yellow coloured clear solution without any precipitate.
<b>Reaction of 2.9% solution</b>	pH 7.1 ± 0.2 at 25°C
<b>Gel Strength</b>	Not Applicable

**Expected Cultural Response:** Cultural characteristics observed after an incubation at 30-35°C for not more than 3 days.

Sr. No.	Organisms	Results to be achieved	
		Inoculum (CFU)	Growth
1.	<i>Clostridium sporogenes</i> ATCC 19404	50-100	good-luxuriant
2.	<i>Clostridium sporogenes</i> ATCC 11437	50-100	good-luxuriant
3.	<i>Clostridium sporogenes</i> NBRC 14293	50-100	good-luxuriant
4.	<i>Clostridium perfringens</i> ATCC 13124	50-100	good-luxuriant
5.	<i>Bacteroides fragilis</i> ATCC 23745	50-100	good-luxuriant
6.	<i>Bacteroides vulgatus</i> ATCC 8482	50-100	good-luxuriant
7.	<i>Staphylococcus aureus</i> ATCC 25923	50-100	good-luxuriant
8.	<i>Staphylococcus aureus</i> ATCC 6538	50-100	good-luxuriant
9.	<i>Pseudomonas aeruginosa</i> ATCC 27853	50-100	good-luxuriant
10.	<i>Pseudomonas aeruginosa</i> ATCC 9027	50-100	good-luxuriant
11.	<i>Escherichia coli</i> ATCC 25922	50-100	good-luxuriant
12.	<i>Escherichia coli</i> ATCC 8739	50-100	good-luxuriant
13.	<i>Escherichia coli</i> NCTC 9002	50-100	good-luxuriant
14.	<i>Salmonella abony</i> NCTC 6017	50-100	good-luxuriant
15.	<i>Salmonella typhimurium</i> ATCC 14028	50-100	good-luxuriant

The organisms listed are the minimum that should be used for quality control testing.

### Test Procedure

Refer to appropriate references for standard test procedures.

### Results

- After incubation, growth is evidenced by the presence of turbidity compared to an uninoculated control.
- Strict aerobes tend to grow in a thin layer at the surface of the broth; obligate anaerobes will grow only in that portion of the broth below the upper oxidized layer.

### Storage

Store the sealed bottle containing the dehydrated medium at 2 - 30°C. Once opened and recapped, place container in a low humidity environment at the same storage temperature. Protect from moisture and light.

### Expiration

Refer to the expiration date stamped on the container. The dehydrated medium should be discarded if not free flowing, or if the appearance has changed from the original color. Expiry applies to medium in its intact container when stored as directed.





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### Limitations of the Procedure

1. Anaerobes can be overgrown by more rapidly growing facultative organisms.
2. If plating medium reveals no growth examine and Gram stain broth.
3. Never rely on broth cultures exclusively for isolation of anaerobes. Some anaerobes may be inhibited by metabolic products or acids produced from more rapidly growing facultative anaerobes.
4. Consult appropriate texts for detailed information and recommended procedures.

### Packaging

Product Name : Alternative Thioglycollate Medium (NIH Thioglycollate Broth)

Product Code : DM264

Available Pack sizes : 100gm/500gm

### References

1. N.I.H. Memorandum, 1955: Culture Media for Sterility Tests, 4th Revision.
2. United States Pharmacopeial Convention, Inc. 2008. The United States pharmacopeia 31/The national formulary 26, Supp. 1, 8-1-08, online. United States Pharmacopeial Convention, Inc., Rockville, Md.
3. Nungester, Hood and Warren, 1943, Proc. Soc. Exp. Biol. Med., 52: 287.
4. Portwood, 1944, J. Bacteriol., 48: 255.

### Further Information

For further information please contact your local MICROMASTER Representative.



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