

## Thioglycollate Broth U.S.P. – DM221

### Introduction

MAST® Thioglycollate Broth U.S.P. is used for sterility testing as recommended by the United States Pharmacopoeia (U.S.P.). MAST® culture media is supplied in a dehydrated powder form, allowing the end-user to prepare a suitable medium for bacterial & fungal culture. It is suitable to be prepared in a variety of receptacles and at volumes that conform to the end-users desired purpose. The culture of bacterial and fungal species are essential for routine laboratory purposes.

FOR IN VITRO USE ONLY  
NOT FOR USE IN DIAGNOSIS OF HUMAN DISEASE

### Intended Purpose

Thioglycollate Broth U.S.P. is a multipurpose, enrichment, differential growth medium used to determine the oxygen requirements of microorganisms. When prepared in accordance with the instructions for use it produces a liquid medium for the non-selective enrichment of aerobic and anaerobic organisms. Thioglycollate Broth is recommended by the U.S.P. as a recovery medium for sterility testing in the pharmaceutical industry.

Thioglycollate Broth U.S.P. is intended to be used in conjunction with other *in vitro* tests. It is intended to be used by professional, trained, laboratory users for *in vitro* use and is not intended for use in the diagnosis of disease or other conditions in humans or as the basis of treatment or case management decisions.

### Principle of the test

Culture media remains the gold standard for the growth and isolation of viable bacterial and fungal cells. The liquid culture medium is inoculated by sampling 3-5 independent colonies using a sterile loop and suspending in the prepared broth (broth suspension). Broth suspensions should be incubated under the appropriate atmospheric conditions and temperature for the target organisms(s), after which time the medium will become turbid as an indication of growth

These methods should be used in conjunction with other *in vitro* devices in the aid of diagnosis.

Once prepared a single aliquot of culture media broth is only for single use and cannot be re-used.

### Components

MAST® culture media is supplied in a dehydrated form for reconstitution by the end-user. The formulation of the product is described in Table 1.

Table 1. Formulation of DM221\*

Material	Concentration in medium
Casein hydrolysate, enzymic	15.0 g/L
Yeast extract	5.0 g/L
D-Glucose	5.5 g/L
Sodium chloride	2.5 g/L
L-Cystine hydrochloride	0.5 g/L
Sodium thioglycollate	0.5 g/L
Resazurin	0.001 g/L
Agar	0.75 g/L

\*Formulation may change to meet performance criteria.

The formulation is illustrative of the DM221 product range. The product is manufactured within an ISO:9001 and ISO:13485 environment. Inter-batch variation is expected to be minimal with no direct impact on the product.

### Stability and storage

The expiry date applies to unopened containers of MAST® dehydrated culture media when stored in the primary container and in accordance with the manufacturer's instructions. The expiry date and batch number are indicated on each pack label.

- Store packs in a dry environment.
- Store packs at room temperature (10°C to 25°C).
- Avoid sources of moisture such as autoclaves, CO<sub>2</sub> incubators and water-baths.
- Limit the time a pack remains open whilst in use.
- This product is hygroscopic, avoid prolonged exposure to ambient moisture.
- For opened packs of dehydrated culture media ensure lid is firmly closed after every use.
- Before use ensure the appearance of the media conforms to the expected colour and texture i.e. free flowing, no excessive lumps. Media that is discoloured or lumpy should be further examined for performance against the recommended QC organism panel.

### Warnings and precautions

1. Thioglycollate Broth U.S.P. is for *in vitro* use only, and must be used by trained professional laboratory staff.
2. All microbiological cultures and equipment used to transfer and manipulate them should be treated as infectious. Autoclave sterilise all biohazard waste before disposal in accordance with local regulations.

3. On receipt, store MAST<sup>®</sup> dehydrated culture media at the recommended storage temperature and conditions stated on the pack.
4. Do not store near sources of moisture or within high humidity environments.
5. Do not use if media powder is discoloured and/or lumpy, examine against recommended QC organism panel before continuing use. Discolouration could be a sign of degradation and must be examined further.
6. When handling the device ensure that local and regulatory health and safety advice is followed.
7. When handling the sterilised solution, beware of the temperature, use thermal resistant gloves where appropriate.
8. When preparing culture media after sterilisation, ensure that this is performed in an aseptic manner.

MAST<sup>®</sup> dehydrated culture media are supplied in a sealed primary container, which helps to prevent moisture ingress from the environment. The nature and frequency of use of the device is conducive to an end-user re-entering the container. When the product is not in use, the primary container should remain sealed.

### Materials Provided

Mast<sup>®</sup> dehydrated culture media is supplied in a powder form contained within a re-usable primary container for end-user reconstitution.

### Materials required but not provided

Standard microbiological supplies and equipment such as petri dishes, bottles, tubes, laminar flow cabinet, water bath, autoclave, balance, weigh boats, spatulas, thermometer, timer, additives such as defibrinated blood, deionised water, or suitable control strains of microorganisms.

### Procedure

1. Refer to pack label for quantities and volumes required. Prepare MAST<sup>®</sup> Thioglocollate Broth U.S.P. by suspending the powder in distilled or deionised water.
2. Boil to dissolve the agar, mix well and distribute into suitable final containers.
3. Sterilise the solution in an autoclave at 121°C (15 p.s.i) for 15 minutes.
4. Resazurin is an oxidation-reduction indicator so reboil before use if more than one third of the column has turned pink on storage. Do not reheat more than once.

Refer to local Health and Safety handling procedures for infectious waste disposal guidelines.

### Technical Guidance

Observe the powder before use. If the powder is discoloured or lumpy, this could be a sign of degradation and must be further examined.

### Interpretation of results

Following incubation, the inoculated broth will become turbid as an indication of growth.

### Limitations of use

MAST<sup>®</sup> media are not intended to be used as the sole, and primary isolation medium in instances where a failure to detect a pathogenic infection would result in death, serious illness or possible transmission of infectious disease.

### Quality Control

Check for signs of deterioration. Quality control must be performed with at least one organism to demonstrate expected performance. Do not use the product if the result with the control organism is incorrect. The list below illustrates a range of performance control strains which the end user can easily obtain.

Table 2. Suggested organisms for QC

Test Organism	Result
<i>Enterococcus faecalis</i> ATCC <sup>®</sup> 29212	Growth
<i>Pseudomonas aeruginosa</i> ATCC <sup>®</sup> 27853	Growth
<i>Clostridium perfringens</i> ATCC <sup>®</sup> 13124	Growth
<i>Bacteroides fragilis</i> ATCC <sup>®</sup> 25285	Growth

### References

Bibliography is available on request.