

## TM 2043 – CLOSTRIDIUM DIFFICILE MANNITOL TAUROCHOLATE BROTH BASE

### INTENDED USE

For cultivation of *Clostridium difficile* from certain clinical specimens.

### PRODUCT SUMMARY AND EXPLANATION

*Clostridium difficile* Mannitol Taurocholate Broth Base is used for the primary isolation of *C. difficile* from faecal specimens. The spectrum of disease caused by *Clostridium difficile* (a pathogenic *Clostridium* affecting the bowel) ranges from pseudomembranous colitis (PMC) through antibiotic associated colitis (AAC). It also includes chronic inflammatory bowel diseases, post-operative diarrhoea and non-antibiotic associated diarrhoea. Smith and King first reported the presence of *C. difficile* in human infections. The medium composition is designed so as to obtain luxuriant growth of *C. difficile*. The selective agents D-cycloserine and cefoxitin used in the medium inhibit the growth of majority of Enterobacteriaceae and also *Enterococcus faecalis*, gram-negative anaerobic bacilli and *Clostridium* species other than *C. difficile*, which may be found abundantly in faecal samples.

### COMPOSITION

| Ingredients                    | Gms / Ltr |
|--------------------------------|-----------|
| Proteose peptone               | 40.000    |
| Disodium hydrogen phosphate    | 5.000     |
| Potassium dihydrogen phosphate | 1.000     |
| Sodium chloride                | 2.000     |
| Magnesium sulfate              | 0.100     |
| Mannitol                       | 6.000     |
| Neutral red                    | 0.030     |
| Sodium taurocholate            | 1.000     |
| Cysteine                       | 0.500     |

### PRINCIPLE

Proteose peptone provides essential growth factors and trace nutrients. Mannitol is the fermentable carbohydrate, fermentation of which leads to acid production, detected by neutral red indicator. Taurocholate and lysozyme are added as spore germination stimulators. Inorganic salts supply the necessary growth requirements. Sodium chloride maintains the osmotic equilibrium.

### INSTRUCTION FOR USE

- Dissolve 55.63 grams in 1000 ml distilled water.
- Heat if necessary to boiling to dissolve the medium completely.
- Sterilize by autoclaving at 15 psi pressure (121°C) for 15 minutes. Cool to 45-50°C.
- Aseptically add rehydrated contents of 1 vial of *Clostridium difficile* Selective Supplement.
- Mix well and dispense into sterile tubes.

### QUALITY CONTROL SPECIFICATIONS



**Appearance of Powder** : Cream to yellow homogeneous free flowing powder.  
**Appearance of prepared medium** : Red coloured clear solution in tubes.  
**pH (at 25°C)** : 7.3±0.2

### INTERPRETATION

Cultural characteristics observed after incubation under anaerobic condition with added Clostridium difficile Selective Supplement.

| Microorganism                  | ATCC  | Inoculum (CFU/ml) | Growth    | Acid                                | Incubation Temperature | Incubation Period |
|--------------------------------|-------|-------------------|-----------|-------------------------------------|------------------------|-------------------|
| <i>Clostridium difficile</i>   | 11204 | 50-100            | Luxuriant | Positive reaction, yellow colour    | 35-37°C                | 48 Hours          |
| <i>Clostridium sporogenes</i>  | 11437 | ≥10 <sup>3</sup>  | Inhibited | Negative reaction, no colour change | 35-37°C                | 48 Hours          |
| <i>Clostridium perfringens</i> | 12924 | ≥10 <sup>3</sup>  | Inhibited | Negative reaction, no colour change | 35-37°C                | 48 Hours          |
| <i>Staphylococcus aureus</i>   | 25923 | ≥10 <sup>3</sup>  | Inhibited | Negative reaction, no colour change | 35-37°C                | 48 Hours          |
| <i>Bacteroides fragilis</i>    | 25285 | ≥10 <sup>3</sup>  | Inhibited | Negative reaction, no colour change | 35-37°C                | 48 Hours          |
| <i>Streptococcus faecalis</i>  | 29212 | ≥10 <sup>3</sup>  | Inhibited | Negative reaction, no colour change | 35-37°C                | 48 Hours          |
| <i>Proteus mirabilis</i>       | 25933 | ≥10 <sup>3</sup>  | Inhibited | Negative reaction, no colour change | 35-37°C                | 48 Hours          |

### PACKAGING:

In pack size of 500 gm bottles.

### STORAGE

Dehydrated powder, hygroscopic in nature, store in a dry place, in tightly-sealed containers between 25-30°C and protect from direct sunlight. Under optimal conditions, the medium has a shelf life of 4 years. When the container is opened for the first time, note the time and date on the label space provided on the container. After the desired amount of medium has been taken out replace the cap tightly to protect from hydration.

**Product Deterioration:** Do not use if they show evidence of microbial contamination, discoloration, drying or any other signs of deterioration.













### DISPOSAL



After use, prepared plates, specimen/sample containers and other contaminated materials must be sterilized before discarding.

**REFERENCES**

1. Holdeman, L.V., F.P.Cato and W.E.C.Moore.1977.Anaeobe Laboratory Manual. Virginia Polytechnic Institute and State University. Blacksburg, VA24061.
2. Collee J. G., Fraser A. G., Marmion B. P., Simmons A., (Eds.), Mackie and McCartney, Practical Medical Microbiology, 14th Ed., Churchill Livingstone.
3. Smith L. D. S. and King E. O., 1962, J. Bacteriol., 84:65.

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|--|---|--|---|--|---|
| <br>GMP<br>Good Manufacturing Practices Certified | <br>IVD<br>For In Vitro Diagnostic Use   | <br>QTY.<br>Quantity    | <br>LOT/<br>B. NO.<br>Lot / Batch Number | <br>REF<br>Catalogue Number       | <br>Manufacturer |
| <br>Temperature Unit                              | <br>EC REP<br>Authorized Representative<br><small>MedNet GmbH<br/>Barkstrasse 10<br/>48163 Muenster, Germany</small> | <br>European Conformity | <br>QR Code                              | <br>Consults Instructions for Use | <br>Best Before  |

**NOTE:** Please consult the Material Safety Data Sheet for information regarding hazards and safe handling Practices.

\*For Lab Use Only  
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