

PREPARED GROWTH MEDIUM For Use With *Bacillus atrophaeus*

Excelsior Code: GMBTB-100E

Product Description



The prepared growth media consists of an exclusively formulated Tryptic Soy Broth (TSB) modified with pH indicator. The pH indicator causes a transition in media colour from green to yellow when *Bacillus atrophaeus* bacterial growth is present, allowing for a reduced incubation when used in conjunction with Excelsior Scientific's Biological Indicators (BIs) and Inoculated Carriers.

Indications for Use

The GMBTB growth medium is designed to be utilised in conjunction with BIs containing *Bacillus atrophaeus* to monitor Ethylene Oxide (EO), Dry Heat & Vaporised Hydrogen Peroxide (VH₂O₂) processes.

Instructions for Use

Transfer: Using aseptic technique, typically in a laminar flow hood, transfer one processed (exposed) BI or inoculated carrier to each tube of growth medium.

Controls: A tube of growth medium, without an inoculated carrier, may be incubated as outlined below as a negative control. Label the tube as Negative Control.

When a positive control is needed, aseptically transfer an unprocessed (unexposed) inoculated carrier into a tube of growth medium. Label the tube as Positive Control.

Incubation: Place the tube(s) in a vertical position in an incubator set at 30°C to 40°C.

Monitoring: Examine the tubes daily during incubation as outlined below and record observations. All positive tubes should be recorded and disposed of immediately. Do not continue to incubate positive tubes. Continued growth may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in colour reversion that is visibly darker than a sterile unit. These should be considered a positive for growth (turbidity will be present).

Sterilisation Process	Minimum Incubation Time
EO or Dry Heat	48 Hours
VH ₂ O ₂	7 days

Interpretation:

Negative Control: The Negative Control should not exhibit a colour change to yellow and should remain clear with no signs of turbidity. If the control shows signs of growth, consider the test invalid.

Positive Control: The Positive Control should exhibit a colour change to yellow and/or demonstrate turbidity. If the positive control does not show signs of growth, consider the test invalid.

Test: A passing sterilisation cycle is indicated by the initial colour of the growth medium not transitioning to yellow and the media remaining clear with no signs of turbidity. Failed cycle is indicated by a colour change to yellow and the /or presence of turbidity.

Physical Properties

Tube Dimensions	16.7mm x 62.8mm
Fill Volume	6.5 mL \pm 0. 5mL
Packaging	100 Tubes / Pack

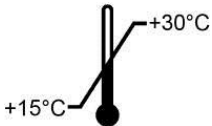






Monitoring Frequency

For greatest control of sterilised goods, it is recommended that one or more BIs be included with every load. To maximize efficiency and reduce incubation time, use modified growth medium in conjunction with the BIs

Performance Characteristics

Sterility	Pass
Growth Promotion Capabilities	Growth of <i>Bacillus atrophaeus</i> , cell line 9372 within 48 hours

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	20% to 80% Relative Humidity		Keep dry
	Do not freeze		Do not use after expiration date
Shelf-Life	12 Months from the date of manufacture		Protect from heat & radioactive sources

Disposal

Prior to disposal, Autoclave all positive units at 121°C for not less than 30 minutes.