



PREPARED GROWTH MEDIA For Use With *Bacillus atrophaeus*

Crosstex Code: GMBTB-100

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 color from green to yellow when *Bacillus atrophaeus* bacterial growth is present, allowing for a reduced incubation when used in conjunction with Crosstex's Biological Indicators (BIs) and Inoculated Carriers for EO and Dry Heat sterilization processes.

Intended Use

The GMBTB growth media is designed to be utilized in conjunction with BIs containing *Bacillus atrophaeus* to monitor Ethylene Oxide (EO), Dry Heat and Vaporized Hydrogen Peroxide (VH₂O₂) processes.

Instructions for Use

Aseptically remove the processed inoculated carriers from the primary packaging, if applicable, and transfer to individual tubes of growth media.

Controls: A tube of growth media, 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 unexposed inoculated carrier into a tube of growth media. Label the tube as Positive Control.

Incubation: Place the cultured inoculated carriers, the Positive Control and the Negative Control in a vertical position in an incubator set at 30°C to 40°C.

Monitoring: Examine the tubes daily during the incubation period as outlined below and record observations.

Sterilization Process	Minimum Incubation Time
EO	72 hours
Dry Heat	48 hours
VH ₂ O ₂	7 days

Interpretation:

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

Test Samples: A passing sterilization cycle is indicated by the initial color of the growth media not transitioning to yellow and the media remaining clear with no signs of turbidity. A failed sterilization cycle is indicated by a color change to yellow and/or presence of turbidity.

Physical Properties

Tube Dimensions	13 mm x 100 mm
Fill Volume	5.0 mL ± 0.2 mL
Packaging	100 Tubes/Box

Monitoring Frequency

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

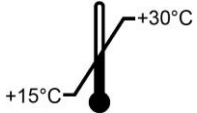

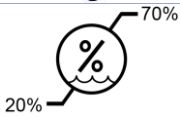




Performance Characteristics

pH	7.3 ± 0.3
Sterility	Pass
Growth Promotion Capabilities	Growth of <i>Bacillus atrophaeus</i> , Cell line 9372, within 48 hours

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators – Part 1: General requirements

Storage and Shelf-Life

	15°C to 30°C		Keep away from sunlight
	20% to 70% Relative Humidity		Keep dry
	Do not freeze		Do not use after expiration date
<p>Shelf life</p>	12 Months from the date of manufacture		Protect from heat and radioactive sources

Disposal

Prior to disposal, sterilize all positive units by steam at 121°C for not less than 30 minutes or by other validated sterilization processes.