



PREPARED CULTURE MEDIA For Use With *Bacillus atrophaeus*

Crosstex Code: GMBTB-100

Product Description

The prepared culture 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.

Intended Use

The GMBTB culture media is designed to be utilized in conjunction with BIs containing *Bacillus atrophaeus* for monitoring of Ethylene Oxide (EO), Dry Heat and Vaporized Hydrogen Peroxide (VH₂O₂) sterilization and disinfection processes.

Instructions for Use

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

Controls: A tube of culture 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 unprocessed (unexposed) inoculated carrier into a tube of culture media and incubate as outlined below. Label the tube as Positive Control.

Incubation: Incubate the tubes in a vertical position as outlined in the following table:

Sterilization Process	Incubation Temperature	Minimum Incubation Time
EO	30°C to 40°C	72 hours
Dry Heat	30°C to 40°C	48 hours
VH ₂ O ₂	30°C to 40°C	48 hours

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

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 or disinfection cycle is indicated by the initial color of the culture media not transitioning to yellow and the media remaining clear with no signs of turbidity. A failed sterilization or disinfection 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 ± 0.5mL
Packaging	100 Tubes/Box

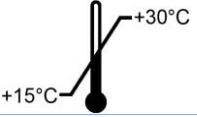





Monitoring Frequency

For greatest control of sterilized goods and disinfection efficacy, it is recommended that one or more BIs be included with every load or disinfection process.

Performance Characteristics

pH	7.3 ± 0.3 at 20°C to 25°C
Sterility	Pass
Growth Promotion Capabilities	Growth of <i>Bacillus atrophaeus</i> , Cell line 9372, within 3 days

Storage and Shelf Life

	20°C to 25°C average Excursions 15°C to 30°C allowed		Keep away from sunlight
	Do not freeze		Keep dry
Shelf life	12 Months from the date of manufacture		Do not use after expiration date
	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.