



This lot of product meets the accepted performance criteria recommended in the USP and ISO 11138-1, ISO 11138-2 and ISO 11138-4.

Product Name: Modified Growth Medium

For Use with: *Bacillus atrophaeus*

LOT

101718-02

REF

GGM-100



2020-10-17 (YYYY-MM-DD)



2018-10-17

Quantity: 100 Tubes

### Instruction for Use

After exposure to the sterilization process, aseptically transfer each carrier to an individual tube of the modified growth medium. Controls: A tube of growth medium containing no BI/Inoculated Carrier may be utilized as a Negative Control. A tube of growth medium containing a BI/Inoculated Carrier which has not been exposed to a sterilization process may be utilized as a Positive Control.

Incubate tubes containing exposed BIs/Inoculated Carriers and control tubes at 30° - 40°C for the minimum incubation period outlined below based on the exposure process.

Organism	Process	Minimum Incubation Period
<i>Bacillus atrophaeus</i>	Ethylene Oxide (EO)	48 Hours
	Dry Heat	
	Vaporized Hydrogen Peroxide (VH <sub>2</sub> O <sub>2</sub> )	

Examine tubes for growth, daily or as frequently as possible. Tubes which transition from green to yellow and/or become turbid are positive for bacterial growth. Typical growth of *Bacillus atrophaeus* will display a cream-orange colored pellicle.

### Result Interpretation:

Media Type	Media Remains Green	Media Transitions to Yellow
Tubes Containing Test BI/Inoculated Carrier	Effective Sterilization	Process did not kill all spores present on the BI/Inoculated Carrier
Negative Control	Test Valid	Test Invalid -indicates the growth medium was not sterile and false positives may be detected
Positive Control	Test Invalid – indicates: <ul style="list-style-type: none"><li>the incubation temperature was not correct</li><li>length of incubation was not sufficient</li><li>the BI/Inoculated Carrier did not contain spores</li><li>the growth medium is not capable of supporting growth</li></ul>	Test Valid

### Storage and Shelf Life

	Room Temperature (15° - 30°C)		Keep away from sunlight.
	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents.
Shelf Life	24 Months from the date of manufacture		



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PRODUCTS

## Certificate of Analysis

Disposal: Autoclave medium tubes positive for growth, at 121°C for not less than 30 minutes. Media within processed tubes of growth medium and tubes which were negative for growth may be discarded as standard waste; tubes may be recycled as glass.

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Quality Approval

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Date