



This lot of product meets the accepted performance criteria recommended in the USP and ISO 11138-1 and ISO 11138-3.

Product Name: Modified Growth Medium

For Use with: *Geobacillus stearothermophilus*



101718-01



PGM-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 55° - 65°C for the minimum incubation period outlined below based on the exposure process.

Organism	Process	Minimum Incubation Period
<i>Geobacillus stearothermophilus</i>	Steam	24 Hours
	Vaporized Hydrogen Peroxide (VH ₂ O ₂)	24 Hours

Examine tubes for growth, daily or as frequently as possible. Tubes which transition from purple to yellow and/or become turbid are positive for bacterial growth. Typical growth of *Geobacillus stearothermophilus* will display a cream-colored sediment.

Result Interpretation:

Media Type	Media Remains Purple	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: -the incubation temperature was not correct -length of incubation was not sufficient -the BI/Inoculated Carrier did not contain spores -the growth medium is not capable of supporting growth	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		

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.

Quality Approval

Date