



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*

LOT P010122-01

REF PGM-100

Quantity: 100 Tubes

2022-01-01

2024-01-01 (YYYY-MM-DD)

Growth Characteristics

Microorganism	Incubation Temperature	Result
<i>Geobacillus stearothermophilus</i> Cell Line 7953	55° - 65°C	Growth

Growth Promotion Test: Performed in accordance with current USP. Each lot is tested for growth promotion qualities by separately inoculating test tubes of media with 10 to 100 of the above microorganisms and incubating at the above temperature.

Sterility Verification

Incubation Range	Result
Ambient	No Growth
30° - 40°C	No Growth
55° - 65°C	No Growth

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 ASSURANCE APPROVAL

April 19, 2022
DATE



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