TRUE INDICATING PRODUCTS

Certificate of Analysis

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*

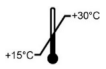
LOT G010122-01 REF GGM-100 Quantity: 100 Tubes

2022-01-01 0224-01-01 (YYYY-MM-DD)

Growth Characteristics		
Microorganism	Incubation Temperature	Result
Bacillus atrophaeus Cell Line 9372	30°- 40°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.

_____ April 19, 2022

QUALITY ASSURANCE APPROVAL DATE

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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
Bacillus atrophaeus	Ethylene Oxide (EO)	48 Hours
	Dry Heat	
	Vaporized Hydrogen Peroxide (VH_2O_2)	

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: • 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