



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

Product Name: Modified Growth Medium

For Use with: *Bacillus subtilis*

LOT R010121
 2021-01-01

REF RGM-100
 2022-07-01 (YYYY-MM-DD)

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° - 35°C for the minimum incubation period outlined below based on the exposure process.

Organism	Process	Minimum Incubation Period
<i>Bacillus subtilis</i>	Steam	72 Hours

Examine tubes for growth, daily or as frequently as possible. Tubes which transition from orange to yellow and/or become turbid are positive for bacterial growth. Typical growth of *Bacillus subtilis* will be flocculent (flaky, clumped) and cream-white in color.

Result Interpretation		
Media Type	Media Remains Orange	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			
+15°C to +30°C	Room Temperature (15° - 30°C)		Keep away from sunlight
20% to 80%	20% to 80% Relative Humidity		Protect from heat, radioactive sources, and sterilizing agents
Shelf Life	18 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

May 20, 2021
DATE