



Technical Data Sheet



PREPARED GROWTH MEDIUM

For Use With *Bacillus atrophaeus*, *Bacillus pumilus*, *Bacillus subtilis* or *Geobacillus stearothermophilus*

True Indicating Codes: SGM-100

Product Description

The prepared growth media consists of Trypticase Soybean Broth (TSB). The media is a general purpose broth utilized to detect when bacterial growth is present.

Physical Properties

Tube Dimensions	16.7mm x 62.8mm
Fill Volume	5 mL ± 0.5mL
Packaging	100 Tubes / Pack

Indications for Use

The media may be utilized to detect when bacterial growth of BIs for the following organisms and processes:

Organism	Sterilization Process
<i>Bacillus atrophaeus</i>	Dry Heat, Ethylene Oxide (EO), Vaporized Hydrogen Peroxide
<i>Bacillus pumilus</i>	Radiation, Ultra-Violet (UV)
<i>Bacillus subtilis</i>	Steam
<i>Geobacillus stearothermophilus</i>	Steam, Formaldehyde, Vaporized Hydrogen Peroxide

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one or more BIs be included with every load. To maximize efficiency and reduce incubation time, use modified growth medium in conjunction with the BIs.

Instructions for Use

Transfer: Using aseptic technique, typically in a laminar flow hood, transfer one processed (exposed) BI or inoculated carrier to each tube of growth medium.

Controls: A tube of growth medium, without an inoculated carrier, may be incubated as outlined below as a negative control. Label the tube as Negative Control.

When a positive control is needed, aseptically transfer an unprocessed (unexposed) inoculated carrier into a tube of growth medium. Label the tube as Positive Control.

Incubation: Place the tube(s) in a vertical position in an incubator set at the Indicator organisms growth temperature as follows: *Bacillus atrophaeus*, *Bacillus pumilus*, and *Bacillus subtilis* at 30-40°C and *Geobacillus stearothermophilus* at 55-65°C.

Incubate for a minimum of 7 days or per validated reduced incubation period.



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Monitoring: Examine the tubes daily, whenever possible during incubation as outlined below and record observations.

Interpretation:

Negative Control: The Negative Control should remain clear with no signs of turbidity. If the control shows signs of growth, consider the test invalid.

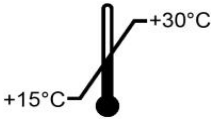






Positive Control: The Positive Control should demonstrate turbidity. If the positive control does not show signs of growth, consider the test invalid.

Test: A passing cycle is indicated by the media remaining clear with no signs of turbidity. Failed cycle is indicated by the presence of turbidity.

Performance Characteristics

Test	Requirement
Sterility	Pass
Growth Promotion Capabilities	Growth of <i>Bacillus atrophaeus</i> cell line 9372, <i>Bacillus subtilis</i> cell line 6633 and <i>Geobacillus stearothermophilus</i> cell line 7953 within 2-3 days

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	20% to 80% Relative Humidity		Keep dry
	Do not freeze		Do not use after expiration date
Shelf-Life	18 Months from the date of manufacture		Protect from heat & radioactive sources

Disposal

Prior to disposal, Autoclave all positive units at 121°C for not less than 30 minutes. Recycle glass tubes whenever possible.

