



Technical Data Sheet

PREPARED MODIFIED GROWTH MEDIUM For Use With *Bacillus subtilis*

True Indicating Codes: RGM-100 and RGM-50R

Product Description

The prepared growth media consists of an exclusively formulated Tryptic Soybean Broth (TSB) modified with pH indicator. The pH indicator causes a transition in media color from Orange to Yellow when *Bacillus subtilis* bacterial growth is present, allowing for a reduced incubation when used in conjunction with True Indicating Biological Indicators (BIs) and Inoculated Carriers.



Physical Properties

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|-----------------|--|
| Tube Dimensions | 16.7 mm x 62.8 mm |
| Fill Volume | 5 mL ± 0.5mL |
| Packaging | RGM-100: 100 Tubes / Pack RGM-50R: 50 Tubes + Transport Rack |

Indications for Use

The RGM growth medium is designed to be utilized in conjunction with BIs containing *Bacillus subtilis* Cell Line 35021 (formerly 5230) to monitor Steam processes.

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: Incubate the tube(s) in a vertical position at 30°C to 40°C for a minimum of 72 hours.





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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 exhibit a Orange color and should remain clear with no signs of turbidity. If the control transitions to Yellow or shows signs of growth, consider the test invalid.

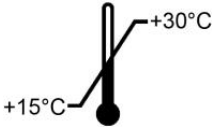






Positive Control: The Positive Control should exhibit a color change to Yellow and/or demonstrate turbidity. If the positive control does not show signs of growth, consider the test invalid.

Test: A passing cycle is indicated by the color of the growth medium remaining Orange and the media remaining clear with no signs of turbidity. Failed cycle is indicated by a color change to Yellow and the /or presence of turbidly.

Performance Characteristics

| | |
|-------------------------------|--|
| Sterility | Pass |
| Growth Promotion Capabilities | Growth of <i>Bacillus subtilis</i> cell line 35021 within 48 hours |

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.

