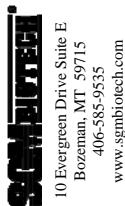


Releasat®

BIOLOGICAL INDICATOR CULTURING SET

For Industrial Use Only

CERTIFICATE OF ANALYSIS



Reorder No: RG/100

Bacillus atrophaeus 9372⁽¹⁾

Biological Indicator for: Ethylene Oxide/Dry Heat Sterilization

Culture: 36 to 38°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Purity: No evidence of contaminants using standard plate count techniques.

Spore Strip Lot No: RGS-

Media Lot No: RM-

Manufacture Date:

Expiration Date: 12 months from Manufacture Date.

Heat Shocked Population: $\times 10^6$ Spores / Unit

Assayed Resistance:	D-Value ⁽²⁾	Survival	Kill
Ethylene Oxide (600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C)		(3)	(3) min
Dry Heat (160°C)		(4)	(4) min
Z-value			°C

D-value reproducible only when exposed in an AAMI BIER vessel and cultured under the exact conditions used to obtain results reported here. MPN method used.

Units are manufactured in compliance with SGM Biotech's quality standards, USP, and ISO 11138 guidelines and all appropriate subsections.

⁽¹⁾Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

⁽²⁾D-value calculated using the Limited Holcomb-Spearman-Karber method.

⁽³⁾Survival/Kill values are calculated according to a formula in USP and ISO 11138. SGM uses a D-value rounded to four decimal places in this calculation.

⁽⁴⁾Empirically derived data.

Certified By: _____

Complete Quality Control testing results available upon request.

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INSTRUCTIONS

Sterilization:

1. Place spore strips inside representative materials to be sterilized. Package or wrap as usual.
2. Locate test packages in areas of sterilizer most difficult to sterilize. Identify test packages as to location in sterilizer.
3. After sterilizing, forward sufficient spore strips **and** products to test laboratory along with at least one non-sterilized spore strip marked POSITIVE CONTROL.

Test Laboratory:

1. All testing should be performed in a clean, dust-free room and within confines of a laminar flow hood. All transfers and manipulations must be conducted with rigid aseptic techniques to avoid "false positive" samples.
2. Procedure:
 - a. Aseptically open glassine envelopes and withdraw spore strips with sterile forceps then transfer to individual Releasat® media tubes. Identify tubes.
 - b. Incubate spore strips in Releasat® medium for 72 hours at $37 \pm 1^\circ\text{C}$.⁽¹⁾
 - c. Observe tubes daily for growth. Yellow = growth = non-sterile
Red-orange = no growth = sterile

⁽¹⁾Reduced incubation time confirmed using FDA Protocol.

Test Strip cultures should show no growth if sterilization has been achieved. A yellow color and/or turbidity indicates bacterial growth occurred in test strip culture tubes. Tubes can be sub-cultured if identification of positive growth is desired. Recommended sub-culturing procedure techniques are available from SGM Biotech.

3. Controls:
 - a. **Positive:** One or more positive controls should be included in each test series. Transfer a non-sterilized spore strip to Releasat culture medium and incubate with test series. Yellow color and turbidity indicates that the medium possesses suitable growth promoting qualities and that the spore strips contain viable spores. If positive control does not grow, do not use the lot.
 - b. **Negative:** One or two tubes of Releasat culture medium incubated with test series. Absence of color change to yellow indicates that the medium was sterile prior to sterility testing.

Storage:

1. Store **Releasat Culturing Set** biological indicators at room temperature. Protect from light. Do not desiccate.
2. Do not store these indicators near sterilants or other chemicals.
3. **Releasat Culturing Set** biological indicators have a 12 month shelf life which is clearly designated on each box. Rotate your stock accordingly.
NOTE: Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving the strips at 121°C for not less than 30 minutes. Dispose of unused culturing media by pouring liquid down drain and placing the tubes in the proper disposal receptacle.