



BIOLOGICAL INDICATOR

CERTIFICATE OF ANALYSIS

SGM BIOTECH, INC.
 10 Evergreen Drive Suite E
 Bozeman, MT 59715
 406-585-9535



Steam

Reorder No. EZS/6

Geobacillus stearothermophilus (*Bacillus stearothermophilus*) ATCC 7953

For: Steam Sterilization.

Culture: **EZTest Media**, 55-60°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Storage: Controlled room temperature. Store away from sterilants. Do not desiccate.

Disposal: Incinerate or autoclave at 121°C for not less than 30 minutes.

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

Lot No.: S-317

Manufacture Date: 2005 FEBRUARY 10

Expiration: 18 months from Manufacture Date.

Heat Shocked Population: 2.5×10^6 Spores/Unit

Assayed Resistance:

Temperature	D-value ⁽¹⁾	Survival	Kill	
121°C	1.8	7.92 ⁽²⁾	18.72 ⁽²⁾	minutes
132°C	0.4	2.0 ⁽³⁾	4.5 ⁽³⁾	minutes
134°C	0.3	1.5 ⁽³⁾	3.0 ⁽³⁾	minutes
135°C	0.3	1.0 ⁽³⁾	2.5 ⁽³⁾	minutes

Z-value 16.8 °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, EN 866 and ISO 11138 guidelines and all appropriate subsections.

⁽¹⁾ D-value calculated using the Spearman-Kärber method.

⁽²⁾ Survival/Kill values are calculated according to USP and ISO 11138.

⁽³⁾ Empirically derived data.

Certified By: _____

Garrett Krusheski
Laboratory Manager

Complete Quality Control testing results available upon request.

Monitoring Frequency:

For optimum control of hospital sterilized goods, we recommend that an EZTest biological indicator be used to monitor every load of steam sterilized supplies containing implantable products or at least once a day for each steam autoclave.

Instructions For Use:

CAUTION: After sterilization, the contents of the EZTest biological indicator are hot and under pressure. Always allow to cool at least 10 minutes. Failure to cool at least 10 minutes may cause the glass ampoule to burst and may result in injury from hot liquid.

A. Exposure:

1. Remove an appropriate number of EZTest units from the box.
2. Identify the indicators by labeling pertinent process information.
3. Place an EZTest biological indicator in a suitable test pack which is representative of the load (e.g., a linen pack for the load of linen, a tray of instruments for metal goods may be used).
4. Place this test pack in the most challenging area of the sterilizer, generally on the bottom shelf near the door over the drain. NOTE: If a test pack is not being used, the EZTest unit should be oriented in a horizontal position during load processing.
5. Process the load as usual.
6. Remove from the sterilizer and allow the pack to cool for a sufficient time to cool the indicator, at least 10 minutes.
7. Retrieve the EZTest biological indicator from the test load.
8. The chemical indicator on the label changes from blue to black when exposed to steam. This distinguishes exposed from unexposed units. NOTE: A black color does not indicate acceptable sterilization.

B. Incubation:

Any microbiological incubator that is adjusted for 55 to 60°C will satisfy the incubation conditions for the EZTest. To activate the media, place the indicator in an upright position in a plastic crusher. Gently squeeze the crusher to break the glass ampoule. Place the activated indicator in the incubator rack, and incubate immediately.

C. Interpretation

1. Examine the indicator at regular intervals for any color change (i.e. 18 hours, 24 hours, 48 hours). The appearance of a yellow color indicates bacterial growth. No color change indicates adequate sterilization.
2. Act on a positive test (a color change of yellow) as soon as the color change is noted. Notify appropriate hospital personnel (i.e. Infection Control). Always retest the sterilizer with several EZTest biological indicators throughout the test load. EZTest biological indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from SGM Biotech.
3. The recommended incubation time is 48 hours.
4. Record the results.
5. Dispose of all used EZTest indicators in accordance with your institution's policy. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

Use of Controls:

- A. As a positive growth control, place an activated, unsterilized EZTest biological indicator in each incubator on a daily basis.
- B. Examine the positive indicator at regular intervals such as 18 and 24 hours. The yellow color is evidence of bacterial growth. Record the results. Remove all positive indicators as the yellow color is noticed, and dispose of as mentioned above.
- C. If the positive control does not grow, do not use the units from this box. Contact SGM Biotech.

Storage:

- A. Store EZTest biological indicators at controlled room temperature conditions (15°C to 30°C) and 20 to 70 percent relative humidity.
- B. Do not store these indicators near sterilants or other chemicals.
- C. EZTest biological indicators have an 18 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 at 121°C for not less than 30 minutes.

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