



BIOLOGICAL INDICATOR MONITORING SYSTEM

CERTIFICATE OF ANALYSIS

Reorder No.: SRSP6/25BI

Geobacillus stearothermophilus 7953(1)

Biological Indicator for: Steam Sterilization.

Culture: EZTest Media, 58-62°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

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

Lot No: SR-478 Manufacture Date: 2015 May 20

Expiration Date: 2017 May 20

Heat Shocked Population: 2.2 x 10^6 Spores / Unit

Carrier size: 1/4" x 3/4" (6 mm x 19 mm)

Assayed Resistance:

Table with 5 columns: Steam Temperature, D-Value(2), Survival, Kill, and min. Rows include Steam 121°C, 132°C, 134°C, and 135°C.

Z-value: 17.1°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 Mesa Laboratories, Bozeman Manufacturing Facility'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. (4) Empirically derived data.

Certified By: [Signature] Quality Representative

Complete Quality Control testing results available upon request.



Bozeman Manufacturing Facility 10 Evergreen Drive Bozeman, MT 59715 T: 303/987-8000 F: 406/585-9219 www.mesalabs.com



Instructions for Use

US Healthcare Intended Use:

Smart-Read EZTest is a Self-contained Biological Indicator (SCBI) intended for use in determining the efficacy of steam sterilization processes. The SCBI may be used in the following steam sterilization cycles:

Table with 3 columns: Cycle Type, Cycle Temperature, and Cycle Exposure Time. Rows include Gravity, Flash Gravity, Pre-Vac, and Unwrapped nonporous devices only.

Smart-Read EZTest has a validated reduced incubation time of 10 hours. NOTE: Should one observe yellow media in the biological indicator upon removal from the product box, this unit should be killed and discarded.

Smart-Read EZTest\* Biological Test Pack with Instant Readout Integrator is designed specifically for biological testing of 132° - 134°C (270° - 273° F) pre-vacuum steam sterilizers. The test pack consists of a self-contained biological indicator containing Geobacillus stearothermophilus inside a small package of porous and nonporous materials, simulating the biological indicator 16 towel test packs defined by AAMI ST79.

After sterilization, the contents of the Smart-Read 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.

- 1. Load the sterilizer as normal. 2. Place the biological test pack flat on the lowest shelf near the door. 3. Process the load, normal cycle. 4. Remove the pack from the sterilizer and allow to cool at room temperature for 10 minutes. 5. Open the pack and remove the Smart-Read EZTest indicator. Activate and incubate in the Smart-Well Incubator for 10 hours for final sterilization verification (meets the USFDA/RIT protocol). 6. Remove and examine the Instant Readout Integrator card. 7. When the chemical integrator 'PASS' changes color from purple to green, it indicates correct exposure conditions of temperature, time and steam. Biological spores should be killed under the same exposure conditions.

Incubation:

Smart-Read EZTest biological indicators are designed to be used with the Smart-Well incubator which is calibrated to maintain 60°C ± 2°C. To activate the media, place the indicator in an upright position in the crushing chamber located on the Smart-Well incubator. Slowly pull forward to break the glass ampoule and release the media. Immediately place the exposed activated indicator in an incubator cell, 1-10. The "C" cell is intended for an unexposed positive control BI (see also Use of Controls).

Interpretation:

- 1. LEDs located in front of each cell display the current status of the cell; Amber = testing BI, Red = detection of yellow BI, Green = BI still purple at end of incubation cycle. 2. The appearance of a yellow media color indicates a positive test (sterilization failure). No media color change, negative test, indicates adequate sterilization. 3. Biological growth from sterilization failures is detected in three to five hours. The positive test can be immediately confirmed by visually observing the yellow color change. 4. Act on a positive test (yellow BI) as soon as it is observed. Notify appropriate personnel. Smart-Read biological indicators can be subcultured if identification of positive growth is desired. Recommend subculturing procedure techniques are available upon request from Mesa Labs. 5. The recommended incubation time is 10 hours (meets the USFDA/RIT protocol). 6. A printout containing test results will be generated from the Smart-Well incubator printer. Review and sign the printed report and store it in the Smart-Well Record Book. 7. Dispose of all used Smart-Read biological 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 Smart-Read EZTest biological indicator in the Smart-Well incubator for each autoclaved load. B. LEDs located in front of each cell display the current status of the cell; amber = test in progress, red = test positive, green = test negative. The appearance of a yellow color indicates bacterial growth. A yellow BI is the desired result for the positive control. A positive control is to be used anytime a load is being verified or at least once per day. C. If the positive control does not grow, do not use the units from this box. Contact Mesa Labs.

Storage and Disposal:

- A. Store Smart-Read biological indicators at room temperature. Do not desiccate. B. Do not store these indicators near sterilants or other chemicals. C. Smart-Read biological indicators have a shelf life which is clearly designated on each box. Rotate your stock accordingly.

NOTE: Do not use Smart-Read BIs after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes.