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CERTIFICATE OF ANALYSIS

Reorder No: STP/25

Geobacillus stearothermophilus 7953⁽¹⁾

Biological Indicator for: Steam Sterilization.

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

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

Lot No: S-355

Manufacture Date: 2006 DECEMBER 21

Expiration Date: 24 months from Manufacture Date.

Heat Shocked Population	2.1x10 ⁵	Spores / Unit	Kill
Assayed Resistance:	D-Value ⁽²⁾	Survival	
Steam 121°C	1.8	5.90 ⁽³⁾	16.56 ⁽³⁾ min
Steam 132°C	0.7	2.00 ⁽⁴⁾	5.00 ⁽⁴⁾ min
Steam 134°C	0.3	1.00 ⁽⁴⁾	3.00 ⁽⁴⁾ min
Steam 135°C	0.5	2.00 ⁽⁴⁾	3.50 ⁽⁴⁾ min
Z-value	12.3°C		

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

EZTest biological indicators are manufactured in compliance with SGM Biotech's quality standards, USP, 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-Hotcomb-Sperman-Karber method.

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

(4) Empirically derived data.

Certified By: 
Garrett Krushofski
Laboratory Manager

INDICATIONS FOR USE

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 ST46.

INSTRUCTIONS FOR USE

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 15 minutes.
5. Open the pack and remove the EZTest indicator. Activate and incubate at 55-60°C for 24 hours for final sterilization verification (meets the USPDA/RII 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

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

DISPOSAL

Dispose of all exposed EZTest indicators in accordance with your institution's policy. Incubate or autoclave any positive cultures at 121° C (250° F) for not less than 30 minutes.

INTERPRETATION

-Instant Readout Integrator Card: An integrator card printed with a chemical indicator is contained within the test pack to demonstrate that the test pack has been exposed to the proper sterilization conditions of steam, time and temperature. If the chemical integrator "PASS" is PURPLE, it has not been exposed to the proper conditions. If the indicator is GREEN, the pack has been exposed to proper sterilization conditions and therefore, biological kill should be achieved. Record data on the Integrator card.

-Biological Indicator: Examine the EZTest biological test indicator at regular intervals (i.e. 12, 18 and 24 hours) for signs of color change. If biological indicator medium changes to YELLOW, the biological spores have survived and the load is NOT sterile. If the indicator growth media remains PURPLE, the spores were exposed to proper sterilization conditions.

-Use of Controls: EZTest biological indicators are supplied with each case of test packs to be used as controls. Activate and incubate an unexposed control biological indicator with every sixth test pack run if 3 controls are included or 1 control for every test pack run if 25 controls are included. Examine the positive biological indicators at 18 and 24 hours. The yellow color is evidence of bacterial growth. Record the results, dispose of biological indicators in accordance with your institution's policy for handling microbial waste. It is recommended that as soon as a biological indicator shows a positive result (yellow color), it should be discarded. Autoclave any positive biological indicators at 250°F/121°C for at least 30 minutes.

STORAGE

- Store at room temperature. Do not desiccate.
- EZTest Biological Indicator Test Packs have a shelf life of 24 months from the date of manufacture.
- The expiration date is supplied on the front of the box.

Caution:

- Do not store near sterilants or other chemicals.
- Do not use after expiration date.
- Dispose of expired biological indicators as mentioned above.

DECLARATION OF CONFORMITY

The EZTest Biological Test Pack is equivalent in function and performance to the standard AAMI Challenge Test Pack as outlined in the AAMI ST46 "Good Hospital Practice: Steam Sterilization and Sterility Assurance". All biological indicators used in the EZTest Biological Test Packs are manufactured according to SGM Biotech's quality systems and in compliance with USP, ISO 11138 and all appropriate subsections.