



BIOLOGICAL INDICATOR

CERTIFICATE OF ANALYSIS

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GAS

Monitoring Frequency:

For optimum control of hospital sterilized goods, we recommend that EZTest biological indicators be used to monitor every load of ethylene oxide sterilized supplies.

Instructions for Use:

A. Exposure:

- 1. Remove an appropriate number of EZTest units from the box and identify the indicators by labeling with pertinent process information.
2. Place an EZTest indicator in a suitable test pack which is representative of the load.
3. Place this test pack in the most challenging area of the sterilizer, generally on the bottom shelf near the door.
4. Process the load as usual.
5. After sterilization, do either a or b:
a. Open the sterilizer door according to the manufacturer's instructions, transfer the load to the aerator and remove the test pack.
6. The chemical indicator on the label changes from blue to brown when exposed to ethylene oxide.

B. Incubation:

Any microbiological incubator that is adjusted for 35 to 39°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, 24, 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 indicators throughout the test load.
3. The recommended incubation time is 48 hours. More information on incubation time is located in the Technical Report.
4. Record the results.
5. Dispose of all used EZTest indicators in accordance with your institution's policy.

Use of Controls:

- A. As a positive growth control, place an activated, non-sterilized EZTest 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.
C. If the positive control does not grow, do not use the units from this box.
D. Reversion may occur from a yellow positive with extended incubation time or on an underexposed unit.

Storage:

- A. Store EZTest indicators at room temperature conditions. Do not desiccate.
B. Do not store these indicators near sterilants or other chemicals.
C. EZTest indicators have a 24 month shelf life which is clearly designated on each box.

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.

Reorder No: EZG/6

Bacillus atrophaeus 9372(1)

Biological Indicator for: Ethylene Oxide Gas Sterilization.

Culture: EZTest Media, 35-39°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

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

Lot No: G-0000 Manufacture Date: YEAR MONTH DAY

Expiration: 24 months from Manufacture Date.

Heat Shocked Population: 0.0 x 10^6 Spores / Unit

Table with 4 columns: Assayed Resistance, D-Value(2), Survival(3), Kill(3). Row 1: Ethylene Oxide (600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C), 0.0, 00.0, 00.0 min

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 the formula in USP and ISO 11138. SGM uses a D-value rounded to four decimal places in this calculation.

Certified By: _____