

EZTest®

BIOLOGICAL INDICATOR
CERTIFICATE OF ANALYSIS

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.

Lot No: **G-243** Manufacture Date: 2023-05-02

Expiration: 2025-05-02

Heat Shocked Population: 3.6×10^6 Spores / Unit

Carrier size: $\frac{1}{4}'' \times \frac{3}{4}''$ (6 mm x 19 mm)

Assayed Resistance:	D-Value ⁽²⁾	Survival ⁽³⁾	Kill ⁽³⁾	
Ethylene Oxide 100% (600 ± 30 mg/l, 60 ± 10% RH, 54 ± 1°C)	2.4	10.92	25.29	min

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⁾ Resistance was determined in an AAMI BIER vessel and calculated using the Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.

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

Certified by:


Quality Representative

12 Jun 2023
Date



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EZTest®

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:

NOTE: Should one observe yellow media in the biological indicator upon removal from the product box, this unit should be killed and discarded.

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. Remove the biological indicators from the test pack. Return the remainder of the test pack to the load for aeration according to the health care facility's policy.
 - b. If the sterilizer/aerator combination does not allow the test pack to be removed, then at the end of the aeration cycle, remove the biological and chemical indicators from the test pack. Dispose of the remaining test pack as soon as the aeration is complete.
6. The chemical indicator on the unit label changes from blue to a green color upon exposure to ethylene oxide. Extended exposure will result in further change to a brown color. The purpose of the chemical indicator is to distinguish exposed from unexposed units.
NOTE: A brown color does not indicate acceptable sterilization.

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 to 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. **EZTest** indicators can be subcultured if identification of positive growth is desired. Recommended subculturing procedure techniques are available upon request from Mesa Labs.
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. Incinerate or autoclave any positive cultures at 250°F (121°C) for not less than 30 minutes.

D. Use of Controls:

1. As a positive growth control, place an activated, non-sterilized **EZTest** indicator in each incubator on a daily basis.
2. 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.
3. If the positive control does not grow, do not use the units from this box. Contact Mesa Labs.
4. Reversion may occur from a yellow positive with extended incubation time or on an underexposed unit. The color will be a fuchsia red color and turbid. Reversion will only occur if living spores are present on the spore strip.

E. Storage:

1. Store **EZTest** indicators at room temperature conditions. Do not desiccate.
2. Do not store these indicators near sterilants or other chemicals.
3. **EZTest** indicators have a 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.