



For Industrial Use Only
CERTIFICATE OF ANALYSIS

SGM BIOTECH
 10 Evergreen Drive
 Bozeman, MT 59715
 406-585-9535
 www.sgmbiotech.com



Hydrogen peroxide

Monitoring Frequency:

For optimum control of sterilized goods, we recommend that an **EZTest** biological indicator be used to monitor every sterilizer load. Monitoring use is the responsibility of each institution or end user.

Instructions for Use:

A. Exposure:

1. Remove an appropriate number of **EZTest** units from the box.
2. Identify the indicators by labeling pertinent process information.
3. It is recommended that duplicate BI's be used per cycle.
4. Place **EZTest** biological indicators in a horizontal position with representative materials to be sterilized. These materials should be located in the "worst case" (least lethal location) in the load.
5. Select the appropriate cycle and process the load.
6. Remove from the sterilizer.
7. Retrieve the **EZTest** biological indicator from the test load.

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.

NOTE: For the 10⁵ EZTest place a clear cap (included) over the purple cap after activation but BEFORE incubation. This will prevent excess evaporation of the media.

C. Interpretation

1. Examine the indicator at regular intervals for any color change (i.e. 12, 18, and 24 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 quality 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 incubation time is 24 hours. (Meets the US FDA/RIT protocol)
4. Record the results.
5. Dispose of all used **EZTest** 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 **EZTest** biological indicator in each incubator on a daily basis.
- B. Examine the positive indicator at regular intervals (i.e. 12, 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 package. Contact SGM Biotech.

Storage:

- A. Store **EZTest** biological indicators at room temperature. Do not desiccate.
- 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 package. 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.

Reorder No: EZH/

Geobacillus stearothermophilus 7953⁽¹⁾

Indicator for: Hydrogen Peroxide Sterilization.

Culture: 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: H-

Manufacture Date: YEAR MONTH DAY

Expiration Date: 18 months from Manufacture Date.

Heat Shocked Population: 0.0 x 10 Spores / Unit

Assayed Resistance: Hydrogen Peroxide Vapor at 45°C, 2.0 mg/L

D-Value⁽²⁾
 0.0 min

D-value reproducible only when exposed to the exact sterilization conditions and cultured under the exact conditions used to obtain results reported here.

Units are manufactured in compliance with SGM Biotech's quality standards.

⁽¹⁾ Culture is traceable to a recognized culture collection identified in USP and ISO 11138.

⁽²⁾ D-value calculated using the Stumbo-Murphy-Cochran method.

Certified By: _____