ETIGAM
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SELF CONTAINED BIOLOGICAL INDICATOR
for vaporized Hydrogen Peroxide

CERTIFICATE OF ANALYSIS

Reorder no.	NSC-H6
Organism:	*Geobacillus stearothermophilus* ATCC #7953
Lot:	####
Expires:	YYYY, MM DD
Population[1]:	## x 10^6 per 0.25 inch (6.4 mm) disc

Vaporized Hydrogen Peroxide Performance Data

D-value[2]	Survives[3]	Killed[3]
## sec.	## sec.	## sec.

[1] After a preliminary heat treatment of 95-100ºC for 15 minutes.
[2] Determined at the time of manufacture using fraction negative procedures (e.g. Stumbo Murphy Cochran) in a BIER vessel at 50°C, 2.5 mg/L H_2O_2. The D-value is reproducible only under the exact conditions under which it was determined. The user may not obtain the same result and therefore should determine the suitability of the biological indicator for its particular use.
[3] Survival/Kill times are reproducible only under the exact conditions under which they were determined.

Each NSC-H6 VH_2O_2 BI meets the manufacturer's applicable quality control specifications and enclosed performance characteristics.

This document certifies that the biological indicators are produced for supplier in compliance with the manufacturer's Quality Assurance specifications and suggested performance parameters published in the current United States Pharmacopeia (USP). There are currently no performance standards in regards to Vaporized Hydrogen Peroxide BIs other than AAMI ST58 which describes frequency of use.

Certified by: _____

Quality Assurance Manufacturer's Representative

Complete Quality Control testing results are available upon request with supplier.

INSTRUCTIONS FOR USE

Exposure:
Record the sterilizer number, load number and processing date on the BI label. Place the BI inside a test pack or area within the package to be deemed as the most difficult area to achieve sterilization. Test the most challenging area in the sterilizer as indicated in the sterilizer's instruction manual (e.g. the middle of the sterilizer chamber) using an appropriate number of BI's. Process the load according to the sterilizer manufacturer's instructions. Remove the BI and confirm the chemical indicator printed on the label has turned blue.

Activation:
Activate the processed BI following exposure by gently crushing the inner glass media tube using a vial crusher. Assure that the growth medium has saturated the spore carrier. Prevent over crushing to ensure the culture medium does not come into contact with the filter in the cap. Place the activated biological indicator in the incubator rack or well and incubate within 24 hours. It is recommended that gloves be worn when handling sterilized items due to the potential for peroxide burns.

Incubation:
Incubate at 55-60ºC for 24 hours checking for spore growth (visual color change from purple to yellow or turbidity) at regular intervals (e.g. 6, 12 and 18 hours). Record results of all processed and unprocessed BI's after full incubation.

Test Results and Interpretation:
No color change in the purple media indicates the spores were inactivated and the sterilization process was lethal. Record (no growth) results after full incubation according to your standard operating procedures. The appearance of a yellow color and/or turbidity indicates bacterial growth and should be reported immediately to a supervisor and the sterilizer taken out of service until resolved. Always retest the sterilizer with additional NSC BI's within the test load. NSC BI's can be sub-cultured to verify organism when desired.

Use of Controls:
As a control, an unprocessed BI (from the same lot) should be gently crushed using a vial crusher and incubated each day the sterilizer is tested and in each incubator used. The positive control shall turn yellow within 24 hours of activation and incubation. Once the control turns yellow, it should be recorded and then autoclaved and discarded according to the instructions for use. The control is intended to ensure that viable spores are present on the BI and the incubator performs properly. Positive controls are for verifying biological viability, they are not intended to be used for comparing test results. Incubation of positive controls should be read after 24 hours but no later than 48 hours.

Storage:
Store at controlled room temperature as defined by USP. USP-controlled room temperature is thermostatically controlled to 20-25°C (68-77°F) while allowing for excursions between 15-30°C (56-86°F). Reference the USP for the complete definition. Protect from light, chemicals and sterilants, excessive heat and moisture. Optimal humidity range for long term storage is 20 to 70%. Do not desiccate.

Disposal:
To reduce the possibility of contaminating your test area, it is recommended that all positive cultures be autoclaved at 121°C for not less than 30 minutes. Any indicators on hand after the expiration date should be handled in the same manner.

Technical Datasheet:
Reference the technical datasheet for more detailed information.