Certificate of Analysis

Apex Biological Indicator (Reorder # HMV-091)
for Gaseous Hydrogen Peroxide

Lot #: **H0000**
Expiration: YEAR MONTH DAY
Indicator: *Geobacillus stearothermophilus* 12980[(1)]
Mean population: 0.0 x 10^6 CFU per stainless steel carrier[(2)]
Storage conditions: 2 - 8°C; less than 50% RH; move to ambient conditions ≥ 1 hr before use.
Shipping conditions: Ambient temperatures; cold pack and desiccant may be used to moderate conditions during shipping.

Resistance Characteristics:

D-value[(3)]: 0.0 minutes in 2mg/L gaseous H_2O_2

D-value is reproducible only when exposed and cultured under identical conditions used to obtain results reported here. MPN method used. Units are manufactured in compliance with Mesa Laboratory, Bozeman Manufacturing Facility's quality standards and ISO 11138-1 guidelines and all appropriate subsections.

Incubation Time:
24-hours at 55 – 60˚C when using Mesa Releasat Medium (PM/100)
7-days at 55 – 60˚C if using generic Trypticase Soy Broth

This product is for Industrial Use Only.

Disposal: Treat as non-pathogenic material and sterilize (steam, EtO, etc) or incinerate before discarding.

(1) Culture is traceable to a recognized culture collection identified in USP and ISO 11138.
(2) Heat shock population determined at 95-100°C for 15 minutes
(3) D-value calculated using the Stumbo-Murphy-Cochran method

Certified By:_____
Quality Representative

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BIOLOGICAL INDICATOR INSTRUCTIONS -- HMV-091/KCD-404

PROCESS EVALUATION

•Place biological indicators in locations previously determined to be the most difficult to sterilize. Areas experiencing minimal gas flow or poor gas distribution include enclosure corners, areas in and around equipment, and locations among disposable materials to be used in the enclosure. Note that the inoculated side of the carrier faces the printed label on the Tyvek pouch, therefore **the printed side should face outward during a process cycle**.

•Validation and mapping processes generally require multiple indicators at numerous sites in an enclosure.

•Conduct the sterilization and aeration cycle.

•Remove the indicators and deliver them, plus one or more unexposed control indicators, to the laboratory for sterility testing. Culturing of exposed indicators should be conducted as soon as possible following removal from the enclosure being tested.

CULTURING PROCEDURES

•Culture in a laminar flow hood. Observe strict aseptic technique at all times. Minimally, sterile gloves should be worn. Include donning hoods, masks, and gowns as appropriate for the facility and circumstances.

•Aseptically open the Tyvek pouch by cutting with sterile scissors or peeling apart at the end with the package offset.

•Using sterile forceps, withdraw the carrier and place in a tube containing sterile Soybean Casein Digest Medium (SCDM) / Tryptic Soy Broth (TSB).

•Aseptically culture the control carrier(s) last.

•Select one or more tubes of the same lot of culture medium to serve as negative controls.

•Incubate test and control tubes for 7 days at 55-60°C. Observe daily for evidence of growth (turbidity).

INTERPRETATION

•Turbidity:
For test indicators, turbidity suggests that the sterilization was incomplete and that at least one spore survived the process.
For positive control indicators, turbidity indicates that viable spores were present and capable of outgrowth in the culture medium used.
In negative control tubes, turbidity indicates that viable organisms may have been present in the growth medium. Contact your supplier.

•No turbidity:
For test indicators, lack of turbidity indicates sterilization was complete and no spores survived the process.
In negative control tubes, lack of turbidity indicates no other viable organisms were present in the culture medium.
For positive control indicator, no turbidity suggests no viable organisms were present on the carrier or that the media may be inhibiting the outgrowth of the test organism. Contact your supplier.