

Certificate of Analysis

Apex Biological Indicator (Reorder # SBC-327)
for Gaseous Hydrogen Peroxide

Lot #: **S0715**

Manufacture: 2015 March 12 Expiration: 2015 December 31

Indicator: *Geobacillus stearothermophilus* 12980 ⁽¹⁾

Mean population: 1.5×10^6 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⁾: 0.7 minutes in 2mg/L gaseous H₂O₂

Units are manufactured in compliance with Mesa Labs, Bozeman Manufacturing Facility's quality standards and ISO 11138-1 guidelines and all appropriate subsections.

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

Incubate at 55-60°C for 7 days. The recommended growth medium is Soybean Casein Digest Medium (SCDM) / Tryptic Soy Broth (TSB).

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

Certified By: _____

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BIOLOGICAL INDICATOR INSTRUCTIONS - SBC-327

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 area on the carrier is visible and is at the opposite end of the stainless steel (SST) strip that projects from the Tyvek pockets. The flexible nature of the SST carrier gives the user several options for placement in the test enclosure. The investigator can use tape at the uninoculated end to attach the BI to a surface. Alternatively, the uninoculated end may be bent into a hook to permit hanging from selected locations. **The inoculated area should be placed to 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.

•Using aseptic technique, remove the indicators and deliver them, plus one or more unexposed control indicators, to the laboratory for sterility testing. Sterile transfer pockets (Reorder #BMWK-750) may be used for this purpose, or the indicators may be cultured at the test site using strict aseptic technique. 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.

•Using sterile forceps, aseptically remove the exposed indicator from the test site (or withdraw it from the Sterile Transfer Pocket, if used). Use sterile scissors to cut the inoculated end of the stainless steel indicator and allow it to drop into 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.

LIMITATION OF LIABILITY AND INDEMNITY: In no event, whether as a result of breach of contract, warranty or tort (including negligence and strict liability) shall Mesa Labs or its suppliers be liable for any consequential or incidental damages including, but not limited to loss of profits or revenues, loss of use of the Products or any associated equipment, loss of the Buyer's Products, damage to associated equipment, cost of capital, cost of substitute products, facilities, service or replacement power, downtime cost, caused by such Products, or claims of the users for such damages. Buyer for itself, its successors and assigns, hereby agrees to indemnify Mesa Labs and to hold Mesa Labs harmless from any and all liability for such consequential or incidental damages. The responsibility of Mesa Labs for damages due to injuries to employees of the Buyer or ultimate user of the Product, caused by the Product, shall be limited to repair or replacement of the item, at the option of Mesa Labs. The Buyer agrees to indemnify Mesa Labs and hold Mesa Labs harmless from any further damages, indemnity or contribution. Mesa Labs liability for any claim of any kind, including performance or breach thereof, or from the Products to Services furnished hereunder, shall in no case exceed the price of the specified Product, system, component or service which gives rise to the claim.