INSTRUCTIONS -- Tri-Scale Biological Indicator (LOG-456) for Hydrogen Peroxide

The Tri-Scale Biological Indicator (BI) for hydrogen peroxide gas is uniquely suited for preliminary evaluations of enclosures or test sites where a single biological test will be beneficial in demonstrating areas of low concentrations of hydrogen peroxide. The Tri-Scale BI also aids in ensuring adequate gas distribution in chambers with large volumes or unique configurations that may compromise gas homogeneity.

PROCESS EVALUATION

•Place biological indicators throughout the enclosure to be tested. 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**.

•Conduct the sterilization process 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

•Culturing is preferably conducted in a laminar flow hood. Alternatively, a clean, dust free area in the laboratory with no air circulation may be used. 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 offset tab. Most users will find it easier to separate the three compartments of each BI by carefully cutting along each sealed seam and then individually opening and culturing the 1E4, 1E5, and 1E6 carriers.

•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.