Technical Report

Apex® – Packaged Discs and Ribbons

I. Introduction

Apex biological indicators (BIs) are used to monitor the efficacy of vaporized hydrogen peroxide (VH_2O_2) cycles at ambient pressures.

Apex BIs consist of a 9 mm diameter x 0.2 mm thick stainless-steel disc inoculated with varying populations of either *Geobacillus stearothermophilus* strain 12980, *Geobacillus stearothermophilus* strain 7953 or *Bacillus atrophaeus* strain 9372, or a 6.4 mm x 70 mm stainless-steel ribbon inoculated on one end with *Geobacillus stearothermophilus* strain 12980. The discs are packaged in a medical grade Tyvek® pouch which is permeable to H_2O_2 vapor. The ribbons are packaged in a Tyvek sleeve but are removed for exposure.

II. Storage

Apex BIs should be stored at 2-8°C and less than 50% relative humidity (RH). The BIs should not be stored near sterilants or other chemicals

During shipping, ambient temperatures and below 50% RH are acceptable. Cold packs and desiccant may be used to moderate conditions during shipping.

III. Shelf Life

Apex BIs have a 9-month shelf life from the date of manufacture when stored at recommended conditions. The day of expiry is the last day of the month.

Do not use after expiration date printed on package. Dispose of expired indicators by autoclaving at 121°C for not less than 30 minutes or per site procedures.

IV. Medium

The culture medium used for Apex BIs can either be sterile Soybean Casein Digest Medium (SCDM)/Tryptic Soy Broth (TSB) or for carriers inoculated with *Geobacillus stearothermophilus*, Mesa Releasat® Purple Medium (PM/100).

After the Apex BI is cultured into growth medium and incubated for an appropriate amount of time, the medium will either stay clear, indicating all spores were inactivated, or become turbid, indicating growth of viable microorganisms. When using Mesa Releasat Medium, a color change to yellow and/or turbidity indicates growth of microorganisms, and no color change and absence of turbidity indicates all spores were inactivated.

V. Use

1. Remove an appropriate number of Apex BIs from storage approximately one hour before use.

2. Identify the Apex BIs by labeling pertinent process or load location information. Do not write on the face of the packaging, over the inoculated disc, or over the inoculated end of a ribbon. Place BIs in locations previously determined to be the most difficult to decontaminate. Areas experiencing minimal vapor flow or poor vapor distribution include enclosure corners, areas in and around equipment, locations around disposable materials to be used in the enclosure.

NOTE: The inoculated side of the disc faces the printed label on the Tyvek pouch, therefore the printed side should face outward during the cycle. Likewise, the visible inoculum on the ribbon should face outward.

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

4. After processing, remove the BIs and deliver them, plus one or more unexposed control indicators to the laboratory for culturing and incubation.

   NOTE: Do not place the unexposed control in the same container as the processed BIs.

5. Culturing of exposed BIs should be conducted as soon as possible following removal from the enclosure being tested.

6. Culture in a laminar flow hood using strict aseptic procedures.

VI. Incubation and Readout Time

The recommended incubation for Apex BIs containing *Geobacillus stearothermophilus* 12980 or 7953 is not less than 7 days at 55 – 60°C.

The recommended incubation for Apex BIs containing *Bacillus atrophaeus* 9372 is not less than 7 days at 30° – 35°C.

The tubes should be placed in the incubator immediately after the BIs are cultured. Placement in an optimized growth environment is necessary to gain accurate results. It is important the incubation temperature be maintained to achieve accurate results.

VII. Interpretation

The appearance of color change and/or turbid medium indicates bacterial growth. Clear medium or no color change indicates no growth and the spores were killed in the process.

Act on a positive test as soon as it is noted. The medium can be subcultured if identification of positive growth is desired.

A positive control should be prepared periodically or at least weekly. Many users perform a positive and negative control for each cycle tested. The positive control typically turns turbid (or changes color if using Releasat medium) within 24 to 48 hours of incubation. As soon as the control turns positive, it should be appropriately recorded, autoclaved and discarded. The positive control is intended to assure the user that viable spores are present on the BI and the culture medium will support the growth of the test organism.

A positive control that truly has not grown is a serious problem. Fortunately, the causes are few: a grossly malfunctioning incubator; inadvertent sterilization of the positive control BI; or inadvertent “sterilization” of the entire bag of BIs due to improper storage.

A negative control (a tube incubated without a BI) tests the medium for contamination. It should show no signs of growth.

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VIII. Resistance Performance Characteristics

Apex BI resistance assessment is performed in Mesa's test isolator in 1 mg/L gaseous H_2O_2. D-value is determined using the Fraction Negative method and calculated using the Stumbo-Murphy-Cochran procedure. The recommended range of exposures for Apex products is shown in Table 1.

Table 1. Recommended Test Point Intervals for Resistance Testing on Apex BIs

	Exposure Time (minutes)							
BI Type (Lot Prefix)	**1**	**2**	**5**	**8**	**11**	**14**	**17**	**20**
AH		x	x	x	x	x	x	x
AN	x	x	x	x	x	x	x	x
AG	x	x	x	x	x	x	x	x
AP	x	x	x	x	x	x	x	x
AK	x	x	x	x	x	x	x	x
AS		x	x	x	x	x	x	x

IX. Population Determination

Detailed population assay instructions, TS-401 Apex Products, are available on Mesa's website.

X. Compliance

Apex BIs are manufactured in compliance with Mesa Laboratories' quality standards and applicable guidelines of both USP and ISO 11138-1:2017, except for verifying and reporting the survival and kill times.