

INSTRUCTIONS FOR USE: Biological Indicators

STERILIZATION

1. Place Biological Indicators (minimum of 10 recommended) inside representative materials to be sterilized. Package or wrap as usual.
2. Locate test packages in areas of sterilizer most difficult to sterilize, as outlined in your specific sterilization validation protocol (usually four corners front, four corners rear, center-center and center-top). NAMSA can assist with the development of your sterilization validation process. Identify test packages as to location in sterilizer.
3. After sterilizing, forward sufficient BIs and products overnight to NAMSA or other appropriate sterility test laboratory along with at least one non-sterilized BI marked POSITIVE CONTROL.

STERILITY TEST LABORATORY

1. All sterility testing should be performed in a controlled environment which is clean, dust free and within the confines of a class 5 laminar flow hood. Personnel within the test area should be garbed in sterile gowns, masks, hoods, gloves and boots. All transfers and manipulations must be conducted with rigid aseptic technique.
2. *Procedure:*
 - a. As soon as possible after exposure, aseptically open glassine envelopes, withdraw each BI with sterile forceps and transfer to individual tubes containing 10 ml sterile Soybean Casein Digest Broth or equivalent. Identify tubes.
 - b. Incubate spores 7 days or appropriate validated incubation period at:
30-35°C for *Bacillus atropheus* and *Bacillus pumilus*
55-60°C for *Geobacillus stearothermophilus*
 - c. Observe tubes daily for growth.
Medium Turbidity = growth = non-sterile
Clear Medium = no growth = sterile
3. *Controls:*
 - a. Positive: one or more positive controls should be included in each test series. Transfer a non-sterilized BI representative of the manufacturing lot being utilized to culture medium and incubate with test series. Turbidity and growth indicates that the BI's contain viable spores.
 - b. Negative: at least one unused tube of culture medium from the same batch/lot should be incubated with test series. Absence of growth (clear) indicates that the medium was sterile prior to testing.