



Biological Indicators for Monitoring Steam Sterilization of Liquids

INSTRUCTIONS FOR USE

Sterilization:

1. Place **SterilAmp® II** inside representative liquid containers to be sterilized. Package or seal as usual. AAMI recommends a minimum of 10 BIs per cycle.
2. Locate test samples in areas of the load considered most difficult to sterilize or in convenient areas that have been validated. Identify test samples as to location in sterilizer.
3. After sterilizing, send **SterilAmp II** and products to test laboratory along with at least one non-sterilized **SterilAmp II** marked POSITIVE CONTROL.

Test Laboratory:

1. All **SterilAmp II** are fully self-contained BIs which do not require subculture.
2. Procedure:
 - a. **SterilAmp II** may be left in the sterilized container or transferred to a rack or container which allows visual observation during incubation.
 - b. Incubate **SterilAmp II** for 48 hours at 55-60°C.
 - c. The 48 hour incubation meets the criteria established in the FDA protocol for validation of reduced incubation time (RIT).
 - d. Observe daily for growth.

Yellow and/or turbid = growth = non-sterile

Purple = no growth = sterile

SterilAmp II should show “no growth” if sterilization has been achieved.

If color change to yellow or presence of turbidity occurs in **SterilAmp II** cultures, it indicates that the spores have survived the sterilization process and are non-sterile.

Controls:

- a. **Positive:** At least one positive control should be included in each test series. Incubate a non-sterilized **SterilAmp II** with test series. Color change from purple to yellow or presence of turbidity indicates that the medium possesses suitable growth promoting qualities and that the **SterilAmp II** contains viable spores. If positive control does not grow, do not use the units from that package. Contact Mesa Labs.

Storage and Disposal:

1. Refrigerate at 2 – 8°C. Protect from light.
2. Incinerate or autoclave at 121°C for not less than 30 minutes.
3. **SterilAmp II** biological indicators have a shelf life of 18 months which is clearly designated on each package. Rotate your stock accordingly.

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