SterilAmp® II

BIOLOGICAL INDICATOR

FOR INDUSTRIAL USE ONLY

CERTIFICATE OF ANALYSIS

Reorder No: SA/6

Geobacillus stearothermophilus 7953[1]

Biological Indicator for Steam Sterilization of solutions at 121°C.

Culture: 55 – 60°C. The supplied bacteriological medium will meet requirements for growth promoting ability.

Lot No: **SA-749** Manufacture Date: 2024-07-05

Expiration: 2026-01-05

Heat Shocked Population: 2.5×10^6 Spores / Unit

Assayed Resistance:

	D-Value	Survival	Kill	
Steam 121°C	2.4[2]	10.66[3]	25.24[3]	min
F_0		13.00[4]	19.00[4]	min

Z-value: 7.5°C

Units are manufactured in compliance with Mesa Laboratories' quality standards, USP, and ISO 11138 guidelines and all appropriate subsections.

[1] Culture is traceable to a recognized culture collection identified in USP and ISO 11138.
[2] Resistance was calculated using the Fraction Negative method. The D-value is reproducible only when exposed and cultured under the exact conditions used to obtain results reported here.
[3] Survival/Kill values are calculated according to a formula in USP and ISO 11138. A D-value rounded to four decimal places is used in this calculation.
[4] Empirically derived data.

Certified by: Kaggi Hare
Quality Representative

30 Jul 2024
Date

MesaLabs
Bozeman Manufacturing Facility
625 Zoot Way
Bozeman, MT 59718
T: 303/987-8000 ♦ F: 406/585-9219
www.mesalabs.com

SterilAmp® II

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.
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 time was validated according to the CDRH Guidance for Industry and FDA Staff: Biological Indicator (BI) Premarket Notification [510(k)] Submissions, issued October 4, 2007. The CDRH RIT protocol for validation of RIT may or may not meet each user's requirements for regulatory compliance. Users should therefore confirm regulatory requirements for reduced incubation time, or incubate for 7 days.
   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.
3. 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.
   b. **Negative:** The distinguishing characteristic of the negative control is a 2 mm stainless steel bead that is placed in the glass tube before it is sealed. The negative control is placed in the sterilizer load along with units that contain spores. Color changes due to thermal degradation can be observed and compared. This documents the normal shift in color from the process.

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.

Rev.3
Part No. 77026