Cat. No. SCG-100 Quantity: 100 SCBIs
Cat. No. SCG-025 Quantity: 25 SCBIs

BIOLOGICAL INDICATOR CERTIFICATE OF PERFORMANCE

Organism: *Bacillus atrophaeus* 9372
Lot: 5243
Expires: 2022-01-31
Population[1]: 2.5 x 10^6 per 0.25 inch (6.4mm) disc

Ethylene Oxide Performance Data

Temperature	D value[2]	Survives[4]	Killed[4]
54.0 ± 1.0 °C	2.8 min.[3]	12.4 min.	29.1 min

[1] After a preliminary heat treatment of 80-85°C for 10 min.
[2] Determined at 54 ± 1.0°C, 600 ± 30 mg/L EO, 50 -70% relative Humidity using 100% ethylene oxide.
[3] Determined at the time of manufacture using fraction negative procedures in an AAMI/ISO compliant test vessel.
[4] Calculated using USP, AAMI, and ISO survival/kill time formulas.

The D value is reproducible only under the exact conditions under which it was determined. The user may not obtain the same result, and therefore the user is responsible for determining the suitability for their particular use.

This document certifies that these biological indicators meet our Quality Assurance specifications and suggested performance parameters published in the current United States Pharmacopeia and AAMI/ISO 11138.

07/14/2020

Quality Assurance Approval

CROSSTEX® A CANTEL MEDICAL COMPANY
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Use:

These self-contained biological indicators are recommended for use in evaluating ethylene oxide sterilization processes.

Purity:

No evidence of contamination using standard plate count techniques.

Incubation:

48 hours at 35-39°C. See Instructions for use.

Storage:

Store at controlled room temperature as defined by the United States Pharmacopeia*. * Reference the USP for the complete definition.

Protect from light, chemicals and sterilants (e. g. ethylene oxide), excessive heat and moisture. Optimal humidity range for long term storage is 20 – 70%. Do not desiccate.

Disposal:

To reduce the possibility of contaminating your test area, it is recommended that all positive cultures be autoclaved at 121°C for not less than 30 minutes before discarding. Any indicators on hand after the expiration date should be handled in the same manner.

Instructions for Use

1. Record the sterilizer number, load number and processing date on the BI label.
2. Place the BI inside a test pack or area within the package to be deemed as the most difficult area to achieve sterilization.
3. Test the most challenging area in the sterilizer as indicated in the sterilizer's instruction manual (ie. the middle of the sterilizer chamber).
4. Process the load according to the sterilizer manufacturer's instructions.
5. Remove the BI and confirm the chemical indicator printed on the label has turned **orange**.

Activation and Incubation

1. Activate the processed BI after processing by gently crushing the inner glass media tube using a vial crusher.
2. Incubate at 35-39°C for 48 hours checking for spore growth (visual color change from purple to yellow) at regular intervals (i.e. 12, 24 and 36 hours). Results should be read no later than 72 hours after incubation.

Test Results

1. Record negative (no growth) results after full incubation in a Sterilizer Record Notebook. No color change in the purple media indicates proper sterilization.
2. Any positive (growth indicated by purple to yellow color change) result, should be reported immediately to a Supervisor and the sterilizer taken out of service until resolved

Use of Controls

1. As a control, an unprocessed BI (from the same lot) should be gently crushed using a vial crusher and incubated each time the sterilizer is tested.