GENERAL DESCRIPTION

The Verify Biological Ethylene Oxide (EO) Test Pack (S3070/S3071) is a preassembled test pack. The Verify Biological EO Test Pack consists of a clear plastic tray sealed with a Tyvek lid. The tray contains a chemical EO sterilization indicator card, which can be used as a test record, and a plastic syringe (20cc) containing a Verify Self-Contained Biological Indicator (SCBI) and blue foam.

Each Verify SCBI consists of a plastic vial which contains a disc inoculated with *Bacillus atrophaeus* (NRRL #B4418) spores and an ampule of specifically modified soybean casein digest growth medium with pH indicators. The Verify SCBI vial is designed to be sealed after processing, reducing the risk of contamination (and consequent false positives) or growth medium evaporation. Following incubation of the SCBI, a vivid color change of the growth media from deep blue/purple to yellow and/or turbidity gives unmistakable evidence of microbial growth. If no microbial growth occurs, the media remains deep blue and without turbidity. A chemical indicator is also present on the SCBI vial label.

The Verify Biological EO Test Pack is lightweight and compact in size. The approximate overall dimensions are 9.0” L x 2.5” W (230 mm L x 64 mm W). Each box of Verify Biological EO Test Packs contains 20 test packs (S3070 contains 20 test packs and 5 controls; S3071 contains 20 test packs and 20 controls).

APPLICATION

The Verify Biological EO Test Pack is a single use test pack designed and validated for monitoring the effectiveness of EO processing of each sterilizer load. The test pack provides a high level of resistance to ethylene oxide sterilization, making it suitable for use as a process challenge device that exhibits the same biological resistance pattern as the properly assembled Association for the Advancement of Medical Instrumentation (AAMI) ethylene oxide test pack. The test pack also contains chemical indicators for EO to provide immediate proof of processing.

FEATURES | BENEFITS
---|---
Comparable to AAMI biological EO test pack | Exhibits the same biological resistance pattern as the properly assembled AAMI biological EO test pack
The test pack is preassembled | Consistent quality is maintained, and no material or labor resources are required to prepare the test pack at the point of use
The test pack is lightweight and compact Disposable | Eliminates the need for bulky towels
Verify SCBI includes the BI, media, and pH indicator | No maintenance or storage of test pack components
Closed system after the Verify SCBI cap is pressed down | Self-contained system reduces chances for false positives due to aseptic transfer technique
Vivid color change of pH indicator during incubation to indicate microbial growth | Prevents contamination of vial contents and media does not evaporate if incubated for seven days
Chemical indicator for EO in the test pack and on the SCBI vial label | pH indicator makes positives easier to identify
Lot number and expiration on the test pack label | Provides an immediate verification of exposure to sterilant
Convenient dispenser box | Traceable results and valuable documentation

Ease of use
**TECHNICAL PROPERTIES**

**Test pack dimensions:** approximately 9.0" L x 2.5" W (230 mm L x 64 mm W)

**SCBI spore carrier type:** filter paper

**SCBI spore carrier:** 1/4" (6.35 mm) diameter disc

**Species:** Bacillus atrophaeus

**Mean population recovery:** 1.0 x 10⁶ to 5.0 x 10⁶ cfu/disc Bacillus atrophaeus

**pH indicators:** Two pH indicators with a yellow acid coloration and a blue/purple base coloration

**Growth media:** Specially modified soybean casein digest

**D-value of the Verify SCBI for ethylene oxide (Dₑ₀):** greater than or equal to 2.8 minutes

The D-value is reproducible only when the biological indicator is exposed and cultured under the same conditions which were used by STERIS to determine the D-value.

**Incubation temperature:** 35°-39°C

**Shelf life:** 12 months from the time of manufacture; the expiration date is printed on the Verify Biological EO Test Pack and the certification card that accompanies the product.

**DIRECTIONS FOR USE**

Lay the Verify Biological EO Test Pack on its long edge in the center of a loaded sterilizer, and run the standard sterilization cycle. After the cycle has been completed, the Verify Biological EO Test Pack can be opened immediately upon removal from the chamber if appropriate EO exposure control measures are taken to minimize operator exposure. If these measures are inadequate or not available, the EO Test Pack should be aerated with the remainder of the load and then opened. Upon opening the test pack, remove the Verify SCBI from the inside of the syringe. If desired, fill out the indicator record card with appropriate information. Discard all other components. If the chemical process exposure indicator on the vial label changed to the proper color and the Verify SCBI has cooled to the touch, firmly seal the Verify SCBI by the recommended technique shown in the instructions included in the Verify Biological EO Test Pack box. The indicator is properly sealed when the cap is pushed down to the second black bar on the vial label.

To activate, push or pull the Verify SCBI completely through the restricted space on the Verify Vial Activator (S3075). The Verify SCBI is properly activated when the growth medium is released from the crushed ampule and is in contact with the spore disc. It is not necessary to shake or invert the activated indicator after removal from the Verify Vial Activator.

The activated SCBI should then be placed into the Verify Dual Temperature Incubator* utilizing the green color-coded block heated to 35°-39°C. Check the Verify SCBI at 48 hours of incubation. If the media in the Verify SCBI begins to show turbidity and/or color change from deep blue to yellow, sterility has not been achieved. Sterilization of the Verify SCBI is evidenced by an absence of turbidity and the lack of color change in the blue medium after the full incubation period. Although the Verify SCBI is validated for a 48-hour reduced incubation period, the SCBIs contain adequate growth medium for incubation up to seven days, if desired. See the instruction sheet enclosed in the Verify Biological EO Test Pack (S3071/S3071) box for detailed instructions.

*A specially designed incubator is available for use with the Verify SCBI. Please contact STERIS for more information.

**STORAGE INSTRUCTIONS**

Verify Biological EO Test Packs (S3070/S3071) should be stored at a controlled room temperature [20-25°C; 30-60% R.H.]. Do not store in close proximity to steam or ethylene oxide (EO) processing areas. Avoid contact with, or storage near, sterilants or chemicals; e.g., any oxidizing or reducing agents such as formaldehyde, bleach, ammonia, etc.

Do not use after expiration date printed on the packaging.

**DISPOSAL**

Before discarding, treat the SCBI, as appropriate, for standard microbiological waste, nonpathogenic species.
SERVICE

Sales
Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical
STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

ORDERING INFORMATION

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<tr>
<th>Description</th>
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