

APPLICATION

The VERIFY Assert Self-Contained Biological Indicator is a single use biological indicator used to qualify steam sterilizers following installation, relocation and major repairs. It is also used to microbially challenge steam sterilizers and for monitoring steam sterilization loads.

Table 1 lists all cleared steam sterilization cycles.

DESCRIPTION

The VERIFY Assert Self-Contained Biological Indicator (SCBI) is a biological indicator used for monitoring steam sterilization processes. It provides a final read within 40 minutes of incubation in the VERIFY™ Incubator for VERIFY Assert SCBIs.*

Each biological indicator consists of a plastic vial that is inoculated with *Geobacillus stearothermophilus* spores. Specialized defined media is sealed within the cap.

Each biological indicator has a two-ply label located on the cap. The removable top label identifies the lot number and expiration date. This label may be adhered to sterilization documentation as a permanent record. The bottom label is imprinted with a process indicator for steam and is used to distinguish between a processed and unprocessed SCBI.

Performance of the VERIFY Assert SCBI was tested per methods described in American National Standards Institute, Association for the Advancement of Medical Instrumentation, and the International Organization of Standards (ANSI/AAMI/ISO) 11138-1:2006 and 11138-3:2006; and the process indicator located on the cap meets Type 1 chemical indicator requirements of ANSI/AAMI/ISO 11140-1:2014.

The self contained biological indicator has an intrinsic activation system. No separate activator is required to use this product.

FEATURES:

- 40 minute incubation time for fast results and quick device turn-around.
- Two-ply label on biological indicator allows lot numbers and expiration dates to be easily transferred to documents.



(Typical - details may vary.)

- Biological indicator has a Twist & Flick activation, reducing the potential of contamination from “over-activated” vials and also eliminating the requirement for a second activator.
- Glass-free SCBI vial and cap design reduces the potential of injury from broken glass.

STANDARDS

ANSI/AAMI/ISO 11138-1:2006 Sterilization of health care products- Biological indicators – Part 1: General requirements. Association for the Advancement of Medical Instrumentation; 2006

ANSI/AAMI/ISO 11138-3:2006 Sterilization of health care products- Biological indicators – Part 3: Biological indicators for moist heat sterilization processes. Association for the Advancement of Medical Instrumentation; 2006

ANSI/AAMI/ISO 11140-1:2014 Sterilization of health care products- Chemical indicators - Part 1: General requirements. Association for the Advancement of Medical Instrumentation; 2014

ANSI/AAMI ST79:2012 Comprehensive guide to steam sterilization and sterility assurance in health care facilities. Association for the Advancement of Medical Instrumentation; 2012

Ordering Information

- LCB031** - VERIFY Assert SCBI; Quantity: 25 per Box
- LCB032** - VERIFY Assert **STEAM** Process Challenge Device for Dynamic Air Removal; Quantity: 25 Test Packs plus 5 Controls
- LCB033** - VERIFY Assert **STEAM** Process Challenge Device for Dynamic Air Removal; Quantity: 25 Test Packs plus 25 Controls

- LCB043** - VERIFY Assert **STEAM** Process Challenge Device for Gravity Cycles; Quantity: 25 Test Packs plus 25 Controls
- LCB030** - VERIFY Incubator for VERIFY Assert SCBI; Quantity 1

Item _____
 Location(s) _____

*Tech Data SD1052 provides detail concerning VERIFY™ Incubator for Assert SCBIs.

PERFORMANCE DATA

Performance of VERIFY Assert SCBIs was tested per methods described in ANSI/AAMI/ISO 11138-1 and 11138-3. **Table 2** and **Table 3** show the performance testing completed on three lots of SCBIs. The biological indicators employ an enzyme detection system. Following the sterilization process, viable indicator spores begin to germinate upon contact with a defined media containing 4-methylumbelliferyl- α -D-glucopyranoside (MUD). The enzyme, α -Glucosidase, reacts with the media substrate MUD to generate a fluorescence signal. An increase in the fluorescence signal (by the incubator) indicates a positive growth response.

The final incubation time for the VERIFY Assert SCBI, when used in conjunction with the VERIFY Incubator for VERIFY Assert SCBIs, is 40 minutes. The incubation time has been validated following the FDA guidance for submission of biological indicators and validation requirements for reduced incubation times of biological indicators.

DIRECTIONS FOR USE

IMPORTANT:

This section enables the Customer to have a good understanding of directions for use. It is never to be used in place of actual instructions or in place of information provided on product packaging or labeling. Always refer to the directions that come with the product and adhere to all applicable warnings and cautions.

Qualification Testing

For Qualification Testing, all tests are performed in an empty steam sterilization chamber. Three consecutive test cycles are run for each preprogrammed cycle on the sterilizer.

Routine Monitoring or Load Monitoring

For routine monitoring or load monitoring, a user-constructed challenge pack is placed in a loaded steam sterilization chamber on the lowest rack over the drain.

Product Testing

For product testing, SCBIs are placed within the items to be sterilized, that have been determined by the user to represent the greatest challenge to the sterilization process.

Common Steps

For each qualification, routine monitoring or load monitoring test cycle:

1. Place the VERIFY Assert SCBI in a challenge pack suitable for the sterilization cycle to be tested.

Note: ANSI/AAMI ST79 provides instructions for assembly of challenge packs found to be suitable for steam sterilization. A chemical indicator strip for steam sterilization may also be included in the pack.

2. Place the challenge pack in the most difficult location to sterilize (typically on the bottom shelf, over the drain).
3. Run the sterilization cycle.
4. After the sterilization cycle, remove the challenge pack and allow it to cool.

5. Open the challenge pack.
6. Check the indicator strip for results. (Refer to the indicator strip instructions provided in the product box). If passing, activate and incubate the SCBIs.
7. Remove the top label of the biological indicator and attach to the cycle printout (or other document).

Note: The process indicator is evaluated for a passing result. The process indicator starts pink and turns brown after exposure to steam.

8. Seal the biological indicator by twisting the cap clockwise. Media is released with one quick shake of the sealed biological indicator.
9. Incubate the biological indicator for up to 40 minutes using the VERIFY Incubator for Assert SCBIs.

The incubator is a fully automated system. At completion of the incubation process (or as soon as a positive biological indicator is identified) the incubator indicates the conclusion of the test. A permanent record of the test results may be printed using an optional printer.

When performing product testing per ANSI/AAMI ST79:

1. Review sterilization cycle load configurations commonly used within the facility. Construct a worst case load using the load configurations and items that are the most difficult to sterilize.
2. Place biological indicators and chemical indicator strips within each item to be sterilized in the test cycle. Following completion of the test cycle, allow the items to cool and then open.
3. Check indicator strips for passing results (Refer to the indicator strips instructions). If passing, activate and incubate the SCBIs as previously described.

NOTES

1. Prior to use, SCBIs should be stored at 60-75°F (16-24°C) with a relative humidity of 30-60% (RH) away from direct sunlight. Do not store near strong acid or alkaline products such as cleaning/disinfecting agents and sterilants.
2. Before discarding, treat unexposed biological indicators and positive biological indicators as appropriate for standard biological waste, nonpathogenic species. All other components and negative biological indicators may be disposed of as regular waste.

TECHNICAL PROPERTIES (SCBI)

Dimensions: Height x Dia.: 1.8 x 0.64" (45.7 x 16.3 mm)

Bacterial species: *Geobacillus stearothermophilus* NRRL B-1172

Mean population recovery: 1.0x10⁶ to 4.0x10⁶ cfu/biological indicator of *Geobacillus stearothermophilus*

Detection system: Reaction of α -Glucosidase with 4-Methylumbelliferyl α -D-glucopyranoside

Fluorogenic substrate:

4-methylumbelliferyl- α -D-glucopyranoside (MUD)

Medium: Defined medium

D-value for saturated steam at 250°F (121°C): ≥ 1.5 minutes

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

Z-value: ≥ 10°C

Incubation time: 40 minutes

Incubation conditions: The VERIFY Assert SCBI is designed to only be used in conjunction with the VERIFY Incubator for VERIFY Assert SCBI.

Shelf life: Shelf life is established at the time of manufacture, as indicated by the expiration date on the lot label.

SERVICE

Technical

STERIS is pleased to provide a completely staffed and well 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.

Education

STERIS University prepares both today's and tomorrow's leaders. With a wide range of learning opportunities, curriculum and expertise; STERIS University provides a tailored accredited education program that fits anyone's busy schedule. Visit <http://university.steris.com/sterisu> to learn more.

TABLES

Table 1. List of Validated Steam Sterilization Cycles

Preconditioning Cycle Type	Exposure Temperature	Exposure Time
Dynamic Air Removal (Prevacuum)	270°F (132°C)	4 minutes
	275°F (135°C)	3 minutes
Dynamic Air Removal (Steam Flush Pressure Pulse)	270°F (132°C)	4 minutes
	275°F (135°C)	3 minutes
Gravity	250°F (121°C)	30 minutes
	275°F (135°C)	15 minutes

Table 2. Population Determination and D-Value / Z-Value Test Results from 3 Lots of VERIFY Assert SCBIs

Lot	Population	250°F (121°C) D-Value	270°F (132°C) D-Value	275°F (135°C) D-Value	Z-Value
1	1.60 x 10 ⁶	2.5	0.9	0.7	20.0
2	1.90 x 10 ⁶	2.3	0.8	0.7	25.0
3	1.70 x 10 ⁶	2.5	0.8	0.8	20.0

Table 3. Survive/Kill Results from 3 Lots of VERIFY Assert SCBIs

Lot	Survival Exposure Time	Test Results (# Positive/# Tested)	Kill Exposure Time	Test Results (# Positive/# Tested)
1	10.42	50/50	25.29	0/50
2	9.81	50/50	23.57	0/50
3	10.57	50/50	25.57	0/50

***CUSTOMER IS RESPONSIBLE FOR COMPLIANCE WITH
APPLICABLE LOCAL AND NATIONAL CODES AND
REGULATIONS.***

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