STERIS®

VERIFY® ASSERT™ STEAM PROCESS CHALLENGE DEVICE FOR GRAVITY CYCLES (LCB043)

APPLICATION

The VERIFY Assert STEAM Process Challenge Device (PCD) is a single use challenge pack used for qualification, routine microbial monitoring, and cycle monitoring of steam sterilizers. **Table 1** list all cleared steam sterilization cycles.

DESCRIPTION

The VERIFY Assert STEAM Process Challenge Device (PCD) for Gravity cycles is a pre-assembled pack consisting of a clear plastic base and foil lid. Each process challenge device contains a VERIFY® Assert™ Self Contained Biological Indicator (SCBI)[1] and an integrating indicator.

Each SCBI consists of a plastic vial that is inoculated with *Geobacillus stearothermophilus* spores and defined media sealed within the cap. The SCBI vial has a two-ply label on the cap. The removable top label identifies the lot number and expiration date. The label may be adhered to sterilization documentation as a permanent record. The bottom label is imprinted with a process indicator for steam.

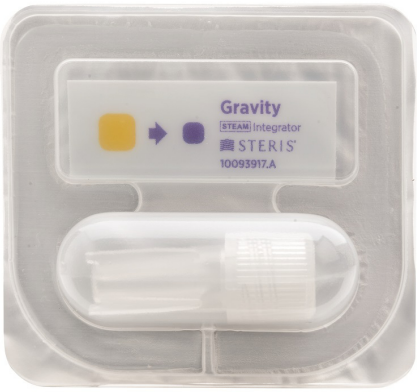
The VERIFY Assert SCBI employs an enzyme detection system. Following the sterilization process, viable indicator spores will begin the germination process upon contact with defined media containing 4-methylumbelliferyl-α-D-glucopyranoside (MUD). The enzyme α-D-glucosidase, reacts with the media substrate MUD to generate a fluorescent signal. An increase in the fluorescent signal detected by the incubator results in a positive growth response.

The final incubation time for the VERIFY Assert SCBI when used in conjunction with the VERIFY Incubator for Assert SCBIs is 40 minutes. The incubation time has been validated using the FDA guidance for validating reduced incubation times of biological indicators.

Performance of the biological indicator 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; the chemical integrator meets the requirements of FDA guidance for chemical indicators and the process indicator on the cap meets the Type 1 chemical indicator requirements of ANSI/AAMI/ISO 11140-1:2014.

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



(Typical - details may vary.)

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

FEATURES

- 40 minute incubation time for fast results and quick device turn-around.
- Compact size requiring minimal shelf space in sterilizer chamber.
- Visibility of integrating indicator through the process challenge device, provides immediate knowledge of sterilization failures without opening the process challenge device.
- Two-ply label on biological indicator allows lot numbers and expiration dates to be easily transferred to documents.
- Equivalent performance to ANSI/AAMI 16-towel biological indicator test pack.
- Biological indicator has a Twist & Flick activation, reduces potential of contamination from “over-activated” vials and also eliminates the need of a second activator.
- Glass-free SCBI design reduces the potential of injury from broken glass.

Ordering Information

❑ **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)_____

_____

1. Tech Data SD1051 provides detail concerning the VERIFY Assert SCBI

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. The PCD is placed in the most challenging location, typically on the bottom rack directly over the drain; and three consecutive test cycles are run for each preprogrammed cycle on the sterilizer.

Routine Monitoring or Load Monitoring

For routine or load monitoring, the process challenge device is placed in a loaded steam sterilization chamber on the lowest rack over the drain.

For each test cycle:

1. Place VERIFY Assert STEAM PCD in the most challenging location, typically on the bottom rack directly over the drain.
2. Run the sterilization cycle.
3. After the sterilization cycle, remove the PCD and allow to cool.
4. Check the integrating indicator strip for passing results (See Figure 1). If passing, open the PCD and remove the SCBI.
5. Remove the top label of the SCBI and adhere it to the cycle printout or other documentation, as applicable.
6. Evaluate the process indicator for a passing result. The process indicator starts pink and turns brown after exposure to steam.
7. Seal and activate the SCBI by twisting the cap clockwise. Media releases with one quick shake of the sealed SCBI.
8. Incubate the SCBI for 40 minutes using the VERIFY Incubator for Assert SCBIs.

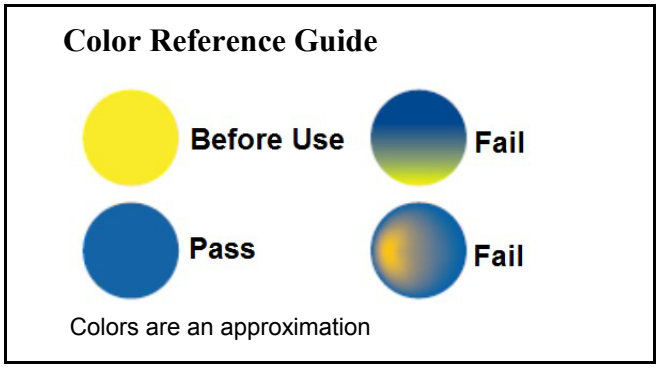


Figure 1. Interpretation Guide for Integrating Indicator Strips

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

TECHNICAL DATA

The performance of the VERIFY Assert STEAM PCD is equivalent to the 16-towel biological indicator test pack as defined in ANSI/AAMI ST79. **Table 2** compares the performance of the VERIFY Assert STEAM PCD for Gravity Cycles against that of the ANSI/AAMI ST79 16-towel biological indicator test pack when exposed to two common gravity steam sterilization cycles.

Performance of VERIFY Assert SCBIs was tested per the methods for biological indicators for steam sterilization processes as defined in ASNI/AAMI/ISO 11138-1 and 11138-3.

The PCD chemical indicator strip is an integrating indicator and meets all performance specifications as defined by FDA guidance for chemical integrators.

TECHNICAL PROPERTIES

Components:

- Foil cover
- Clear polypropylene housing
- VERIFY Assert SCBI
- Chemical Integrator

PCD Dimensions: 3 x 3 ¼ x ¾ inches (76.2 x 82.6 x 19 mm)
Bacterial species: *Geobacillus stearothermophilus* NRRL B-1172

Mean population recovery: 1.0×10^6 to 4.0×10^6 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 (of the VERIFY Assert SCBI) 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.*

Incubation time (for the VERIFY Assert SCBI): 40 minutes
PCD Shelf life: Shelf life is established at the time of manufacture, as indicated by the expiration date on the lot label.

TABLES

Table 1. List of Validated Steam Sterilization Cycles

Preconditioning Cycle Type	Exposure Temperature	Exposure Time
Gravity	250°F (121°C)	30 minutes
	270°F (132°C)	15 minutes

Table 2. Comparison of VERIFY Assert STEAM Process Challenge Devices to the ANSI/AAMI ST79 16-Towel Biological Indicator Test Pack

Exposure Conditions	16-Towel Test Pack # Positive / # Tested			Process Challenge Device* # Positive / # Tested		
	Integrator # Fail	SCBI Fluorescence	SCBI Growth	Integrator # Fail	SCBI Fluorescence	SCBI Growth
ABORTED CYCLE						
250°F (121°C) Gravity 30 minutes	18/18	18/18	18/18	73/73	72/72	72/72
270°F (132°C) Gravity 15 minutes	18/18	18/18	18/18	72/72	72/72	72/72
FULL CYCLE						
250°F (121°C) Gravity 30 minutes	0/18	0/18	0/18	0/72	0/72	0/72
270°F (132°C) Gravity 15 minutes	0/18	0/18	0/18	0/72	0/72	0/72

** Results for PCDs are combined for three lots of test articles.*

STORAGE CONDITIONS

Prior to use, PCDs should be stored at 60-75°F (16-24°C) with a relative humidity of 30-60% (RH) and away from direct sunlight.

Do not store near strong acid or alkaline products such as cleaning/disinfecting agents and sterilants.

DISPOSAL

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.

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.

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

THIS DOCUMENT IS INTENDED ONLY FOR USE IN NORTH AMERICA.

For further information, contact:

STERIS Corporation
5960 Heisley Road
Mentor, OH 44060-1834 • USA
440-354-2600 • 800-548-4873
www.steris.com