

GENERAL DESCRIPTION

The Verify S3111 Self-Contained Biological Indicator (SCBI) is for use in monitoring common steam sterilization processes. The Verify S3111 SCBI is tested in accordance with ISO 11138 and EN 866.

Each indicator is completely self-contained, combining a disc inoculated with a single spore species (*Geobacillus stearothermophilus*) and an ampule of specifically modified soybean casein digest growth medium with pH indicators. The Verify S3111 SCBI is designed to be sealed after processing, reducing the risk of contamination (and consequent false positives) or of growth medium evaporation.

Steam chemical indicators on each vial provide immediate proof of processing. Following incubation, a vivid color change from deep blue to bright yellow and/or turbidity gives unmistakable evidence of microbial growth. If no microbial growth occurs, the vial remains deep blue and without turbidity.

The customer can perform a reduced incubation time validation study and shorten holding time for product release. (All testing to determine reduced incubation time must be performed according to the FDA Guide for Validation of Biological Incubation Time.) Sufficient growth medium is provided for incubation up to seven days, if desired.

APPLICATION

The Verify S3111 SCBIs are designed and validated for use in monitoring the effectiveness of common steam sterilizing processes, including 250°F (121°C) gravity steam, 270°F (132°C) prevacuum steam, and 270°F (132°C) gravity steam. The Verify S3111 SCBI is for scientific applications and international use and is not approved for use in healthcare facilities in the United States.

FEATURES

- Geobacillus stearothermophilus* single species E6 population
- Complies with performance requirements of ISO 11138-3 and EN 866-3
- Manufactured to meet the current USP
- Reduced incubation time
- Chemical indicator on label
- Closed system after activation
- Vivid color change of pH indicator during incubation to indicate microbial growth
- Complete system is self-contained, including BI, media, and pH indicator
- Convenient dispenser box

BENEFITS

- E6 population meets the current ISO/AAMI/EN requirement of 6-log reduction
- Allows for harmonization of biological indicators between global customer sites
- Compliance with current guidelines
- A reduced incubation time study may be performed by the customer to shorten holding time for product release
- Provides immediate proof of processing
- Prevents contamination of vial contents; media does not evaporate if incubated for seven days
- pH indicator makes positives easier to identify
- Reduces chances for false positives from aseptic transfer technique
- Ease of use

TECHNICAL PROPERTIES

Spore carrier type: filter paper

Spore carrier: 1/4" diameter (6.35 mm) disc

Species: *Geobacillus stearothermophilus*

Mean population recovery: 1.0×10^6 to 5.0×10^6

pH indicators: bromthymol blue and bromocresol purple

Growth media: specially modified soybean casein digest growth medium

D-value for saturated steam (D_{121}): 1.5-3.0 minutes

– D_{121} is determined with a $121^\circ\text{C} \pm 0.5^\circ\text{C}$ exposure temperature utilizing a prevacuum cycle.

Incubation temperature: $55\text{-}59^\circ\text{C}$ ($131\text{-}138^\circ\text{F}$)

Shelf life: 12 months from time of manufacture. The expiration date is printed on the certification card that accompanies the Verify S3111 SCBI.

Quantity: 100 count box

DIRECTIONS FOR USE

After sterilization processing has been completed, allow the test packs to cool until they are safe to handle and open. Remove the Verify S3111 SCBI from the test pack and allow to cool an additional 10-15 minutes. Observe the chemical process indicator on the vial label to verify the steam process indicator has turned brown. If the chemical indicator is unchanged, exposure to the sterilization process may not have occurred. If the chemical process indicator on the vial label changed to the proper color and the Verify S3111 SCBI is cool to the touch, firmly seal the Verify S3111 SCBI by the recommended technique shown in the instructions included in the Verify S3111 SCBI box. The Verify S3111 SCBI 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 S3111 SCBI completely through the restricted space on the base of the Verify® Vial Activator (S3075). The Verify S3111 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 Verify S3111 SCBI after removal from the activator.

The activated SCBI is ready for placement into the $55^\circ\text{-}59^\circ\text{C}$ ($131^\circ\text{-}138^\circ\text{F}$) incubator. Examine the biological indicator during the incubation period. If the media in the Verify S3111 SCBI begins to show turbidity and/or color change from deep blue to bright yellow, sterility has not been achieved. If sterilization of the indicator was achieved, the Verify S3111 SCBI shows no change during the incubation period; i.e., there is no turbidity and the growth media remains deep blue.

See the instruction card enclosed in the Verify S3111 SCBI box for detailed use directions.

A specially designed incubator is available for use with the Verify Self-Contained Biological Indicators. Please contact STERIS for more information.

STORAGE CONDITIONS

Verify S3111 SCBIs should be stored at controlled room temperature $20\text{-}25^\circ\text{C}$ ($68\text{-}77^\circ\text{F}$) as defined by the United States Pharmacopoeia and a relative humidity of 30-80%. 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 the expiration date printed on the packaging.

DISPOSAL

Before discarding, treat 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

Description	Quantity Per Box	Reorder Number
Verify S3111 Self-Contained Biological Indicator	100	S3111
Verify Vial Activator Set	1	S3075

For further information, please contact:

STERIS®



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