

SELF-CONTAINED BIOLOGICAL INDICATOR (SCBI)

Geobacillus stearothermophilus (Steam)



PHYSICAL PROPERTIES	
Organism	<i>Geobacillus stearothermophilus</i>
Description	Vial containing spore disc and culture medium encased in a glass ampule with bromocresol purple functioning as a pH indicator.
SCBI Dimensions	0.4" x 2.4" (1.05 cm x 6.0 cm)
GUIDELINES FOR USE	
Application	Steam sterilization at 121°C
Shelf Life	Labeled with the shorter shelf life of the two components, inoculated discs and media ampule, which have independent expiration periods.
Activation	Following exposure, seal the cap by pressing down firmly until the media ampule is crushed.
Incubation	Place activated SCBIs into 55–60°C incubator for a minimum of 24 hours. Examine for growth (turbidity or color change), discard SCBIs immediately, prolonged incubation may have adverse positive effects.
Growth Indicator	The acid production associated with bacterial growth causes a shift in the color of the culture medium from purple to yellow.
Storage Conditions	Room temperature 15-30°C. Protect from sterilizing agents and direct sunlight. Do not refrigerate or freeze.
Clean Up/Disposal	Autoclave SCBIs for 30 minutes at 121°C or per validated disposal cycle prior to discard.
PERFORMANCE CHARACTERISTICS	
Population	1.0 to 4.0 x 10 ⁶ per 6 mm spore disc
Steam D-value (121°C)	1.5 to 3.0 minutes
Compliance	ANSI/AAMI/ISO/EN and USP where applicable.
Result Availability	24 Hours

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