Technical Data Sheet

SPORE SUSPENSION
Geobacillus stearothermophilus Cell Line 7953

True Indicating Codes: UT-02, UT-03, UT-04, UT-05, UT-06, UT-07 and UT-08

Product Description

Pure suspension of viable spores with a known population and resistance to Steam sterilization processes.

Indications for Use

True Indicating Spore Suspensions are standardized suspensions of spores appropriate for direct inoculation onto samples for sterility, bio burden and bacteriostasis testing.

Physical Properties

Organism	*Geobacillus stearothermophilus* Cell Line 7953
Suspended Volume	10 mL suspended in Water for Injection (WFI)
Packaging	Pharmaceutical grade glass vial with screw cap and septum

Instructions for Use

1. Perform inoculation operations in a clean area which is remote from the sterility testing area.
2. Samples to be inoculated should be representative of product being sterilized.
3. For most purposes, inoculation of product with targeted population level of spores to provide a suitable challenge. Note: Suspensions are standardized on the basis of number of spores per 0.1 mL of Suspension; a 10 mL vial of Suspension yields 100 doses 0.1 mL.
4. Use a suitable sterile pipette or syringe to accurately measure and deliver the volume of suspension to be utilized.
5. Manually shake or vortex vial before each use.
6. If a syringe is used, disinfect septum surface and pull syringe plunger halfway back. Insert needle through the septum, push the plunger in, and slowly withdraw plunger to fill syringe to desired volume.
7. If a pipette is used, remove cap and septum and insert pipette. Withdraw desired volume.
8. Deposit suspension onto product. The area to be inoculated should be the one most difficult to sterilize. Return vial(s) of remaining suspension to refrigerator storage (2°C to 8°C) after use.
9. Allow product to dry at room temperature (15°C to 30°C) for approximately 24 hours (or until visibly dry). Some devices with small lumens may take longer to dry.
10. Package inoculated product exactly like product being sterilized and identify prominently as “Inoculated Test Samples.”
11. Distribute “Inoculated Test Samples” throughout the sterilizer load, as outlined in associated validation protocol or work instruction specific to your process.

Culture: Aseptically transfer the exposed test samples into Soybean Casein Digest Broth (SCDB) as soon as possible following the exposure.

Incubation: incubate at 55°C to 65°C. for up to 7 days or for a validated incubation period.

Monitoring: Examine the tubes daily, whenever possible during incubation. Record observations.

Turbidity = Growth = non-sterile Clear Medium = no growth = sterile

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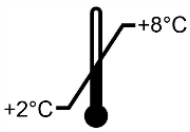
Interpretation: Tubes which demonstrate turbidity with cream-colored sediment are considered positive for growth of *Geobacillus stearothermophilus*. Tubes which remain clear and without sediment formation are considered negative for growth.

Performance Characteristics

Population	≥1.0 x 10^2 - 10^8 spores per 0.1 mL
Saturated Steam (121°C) *D* value	*D* value at 121°C ± 0.5°C ≥1.5 minutes z value: ≥ 6°C The z value is based on *D* values at three temperatures in the range of 110°C to 138°C. True Indicating typically uses *D* values determined at 118°C, 121°C and 130°C.
Post Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value

Storage and Shelf Life

	Refrigerate 2°C to 8°C		Keep away from sunlight
	Do not freeze		Protect from heat and radioactive sources and sterilizing agents
Shelf Life	24 months from the date of manufacture		
	Do not use damaged vials of Spore Suspensions. Do not use after the expiration date. The Spore Suspensions contain live cultures and should be handled with care.		

Compliance

ISO 11138-1 sterilization of healthcare products—Biological indicators—Part 1: General requirements

USP

Disposal

Autoclave for not less than 30 minutes at 121°C or per other validated disposal cycle prior to discard.

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