



Technical Data Sheet

INOCULATED CARRIER SPORE DISCS For Monitoring STEAM Processes

True Indicating Codes: DT-05, DT-06 and DT3-06



Product Description

Inoculated carrier Spore Discs and mini Spore Discs for monitoring steam processes consist of:

- An inoculated carrier, 3mm or 6mm disc of *Geobacillus stearothermophilus* Cell Line 7953
- Primary packaging is in bulk, 100 discs per re-sealable pouch

Indications for Use

The Spore Discs are designed to be placed directly into a device and used to monitor steam sterilization process efficacy. Spore Discs may be used in equipment or process validations and for routine monitoring. The Spore Discs are labeled for laboratory/industrial use only.

Physical Properties

Process	Steam
Disc Dimensions	DT-05 and DT-06: 6 mm DT3-06: 3mm
Packaging	100 / Pack

Monitoring Frequency

For greatest control of sterilized goods it is recommended that a minimum of ten (10) Spore Discs be included with every load.

Instructions for Use

Place Spore Discs (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized. Package or wrap product as usual, if applicable.

Locate the test packages or Spore Discs in areas most difficult to sterilize, as outlined in your specific sterilization validation protocol (usually four corners front, four corners rear, center-center and center-top) or according to standard operating procedure. Run the cycle.

After sterilization or exposure, remove Spore Discs or product from sterilizer.



Spore Discs may be held at room temperature up to 96 hours post-exposure prior to transfer without any impact to the performance. If the processed Spore Discs are not transferred to growth medium within 96 hours of exposure, the cycle should be repeated.

Aseptically transfer the Spore Discs to 5-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, True Indicating Code PGM-100, may be utilized in place of the SCDB.

Transfer one Spore Disc which has not been exposed in a sterilization process as a Positive Control.





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Incubation: At least one unused tube of culture medium (no Spore Disc) from the same lot should be incubated with the test series as a Negative Control. Incubate the cultured Spore Discs, the Positive Control and the Negative Control at 55°C to 65°C as outlined in the following table:

Sterilization Process	Media Type	Min. Incubation Time
Steam	SCDB	7 days
	PGM-100	24 Hours

Monitoring: Examine the Spore Discs daily during incubation. Record observations.

Interpretation:

Where SCDB (standard or unmodified) was utilized: Tubes which demonstrate turbidity with cream-colored sediment are considered positive for growth of *Geobacillus stearothermophilus*. Tubes which remain clear and without sediment are considered negative for growth.

Where modified media, True Indicating Code PGM-100, was utilized: Tubes which transition in color from Purple to Yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain Purple in color and do not demonstrate turbidity are considered negative for growth.

For unexpected positives, it is recommended that a Gram stain be performed. Gram positive rods are indicative for the indicator organism.

Positive Control: Tube(s) should demonstrate turbidity and cream-colored sediment or demonstrate a color transition from Purple to Yellow where modified media has been utilized. If the Positive Control does not result in growth, the exposure is considered invalid. Check the conditions during incubation and verify the capability of the medium to support growth.

Negative Control: Tubes of media should remain clear and Purple in cases where modified medium was utilized. If the Negative Control results in growth, there is a potential for false positive results.

Compliance

ISO 11138-1 Sterilization of health care products – Biological indicators- Part 1: General requirements

ISO 11138-3 Sterilization of health care products – Biological indicators- Part 3: Biological indicators for moist heat sterilization processes

USP <55> Biological Indicators—Resistance Performance Tests

True Indicating has a validated method for Total Viable Spore Count. Please inquire for the Technical Bulletin for recommended methodology.





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Performance Characteristics

Population	$\geq 1.0 \times 10^x$ per disc where x = the log population
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Steam Resistance	<p>D value at $121^\circ\text{C} \pm 0.5^\circ\text{C}$ ≥ 1.5 minutes</p> <p>The Steam D value range is based on the requirements outlined in the USP, ISO 11138-3 and guidance issued by the Food & Drug Administration (FDA).</p> <p>Survival – Kill Times Calculated based on the formulas outlined in the USP, ISO 11138-1 and guidance issued by the FDA.</p> <p>z value $\geq 6^\circ\text{C}$</p> <p>Determined based on three temperatures in the range of 110°C to 138°C. True Indicating typically utilizes D values determined at 118°C, 121°C and 130°C for z value calculation.</p>
Post Market Criteria	<p>Population: 50% to 300% of certified population</p> <p>D value: $\pm 20\%$ of the certified D value</p> <p>Survival Time: All Spore Discs result in growth at the certified survival time</p> <p>Kill Time: All spore Discs result in no growth at the certified kill time</p>

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% Relative Humidity		Keep Dry
Shelf Life	30 months from the date of manufacture		Protect from heat and radioactive sources
	Short excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Discs. Do not use damaged Spore Discs. Do not use after the expiration date. The Spore Discs contain live cultures and should be handled with care.		

Disposal

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

