

BIOLOGICAL INDICATOR SPORE STRIPS
For Monitoring Dry Heat Processes

True Indicating Code: SA-06DH

Product Description

Biological indicator Spore Strips for monitoring Dry Heat processes consist of:

- An inoculated carrier, 6mm x 30mm strip of *Bacillus atrophaeus* Cell Line 9372
- Primary packaging in a glassine envelope

Indications for Use

The Spore Strips are utilized to monitor Dry Heat sterilization process efficacy in the range of 150° to 180°C. Spore strips can be used for equipment and process validation or routine monitoring. The Spore Strips are labeled for laboratory/industrial use only.

Physical Properties

Process	Dry Heat
Strip Dimensions	6 mm x 30 mm
Glassine Dimensions	Envelope : 30 mm x 38 mm
Packaging	100 / Pack

Monitoring Frequency

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

Instructions for Use

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

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

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

Spore Strips 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 Strips are not transferred to growth medium within 96 hours of exposure, the cycle should be repeated

Aseptically transfer the Spore Strip from the primary packaging and transfer to 5-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, True Indicating Product Code GGM-100 may be used in place of the SCDB.

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946 Kane St. Suite A, Toledo, OH, 43612
United States
@: info@trueindicating.com
www.trueindicating.com

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

Incubation: At least one unused tube of culture medium from the same lot should be incubated with the test series as a Negative Control. Place the cultured Spore Strips, the Positive Control and the Negative Control in an incubator set at 30°C to 40°C.

Spore Strips cultured in SCDB should be incubated for a minimum of 7 days or per a validated reduced incubation period.

Spore Strips cultured in modified growth medium SCDB True Indicating code GGM-100 should be incubated for a minimum of 48 hours.

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

Interpretation:

Where SCDB (standard or unmodified) was used: Tubes which demonstrate turbidity with cream/orange colored pellicle are considered positive for growth of *Bacillus atrophaeus.* Tubes which remain clear and without formation of pellicle are considered negative for growth.

Where modified media, True Indicating code GGM-100 was used: Tubes which transition in color from Green to Yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain Green 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 should demonstrate turbidity with a cream/orange colored pellicle or demonstrate a color transition from Green to Yellow where modified media has been utilised. 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: Tube of media should remain clear and Green in color where modified medium was utilized. If the Negative Control results in growth, there is a potential for false positives

Compliance

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

ISO 11138-4 Sterilization of health care products – Biological indicators – Part 4: Biological indicators for Dry 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 which outlines the recommended methodology.

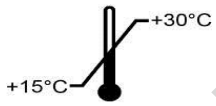
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Performance Characteristics

Population	≥1.0 x 10^6 per Strip
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Dry Heat Resistance	*D* value at 160°C ± 1°C ≥2.0 minutes Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 z value: ≥ 20°C Determined based on three temperatures in the range of 150°C to 180°C. True Indicating typically uses D values determined at 150°C, 160°C and 180°C for z value calculation.
Post Market Criteria	Population: 50% to 300% of certified population *D* value: ± 20% of the certified *D* value Survival Time: All Spore Strips result in growth at the certified survival time Kill Time: All Spore Strips result in no growth at the certified kill time

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% relative humidity		Keep Dry
Shelf Life	36 months from the date of manufacture		Protect from heat and radioactive sources
	Normal fluctuation and excursions outside the range of temperature and relative humidity recommended will not impact the performance of the Spore Strips. Do not use after the expiration date. The Spore Strips 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.

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