BIOLOGICAL INDICATOR SPORE STRIPS
For Monitoring Dry Heat

Excelsior Code: STN-06DHE

Product Description

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

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

Indications for Use

The Spore Strips are utilised to monitor Dry Heat sterilisation process efficacy. The Spore Strips are labelled for industrial use only.

Instructions for Use

Place Spore Strips (a minimum of 10 per exposure is recommended) inside representative materials to be sterilised 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 sterilise, as outlined in your specific sterilisation validation protocol (usually four corners front, four corners rear, centre-centre and centre-top) or according to standard operating procedure. Run the cycle.

After sterilisation or exposure, remove Spore Strips or product from steriliser

Aseptically transfer the Spore Strip from the primary packaging and transfer to 10-15 mL of Soybean Casein Digest Broth (SCDB). Conversely, modified growth medium, Excelsior code GMBTB-100E may be used in place of the SCDB.

Transfer one Spore Strip which has not been exposed in a sterilisation 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 Excelsior code GMBTB-100E should be incubated for a minimum of 48 hours.

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

Interpretation:

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

Where modified media, Excelsior code GMBTB-100E was used:
Tubes which transition in colour from green to yellow and/or demonstrate turbidity are considered positive for growth. Tubes which remain green in colour 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 coloured pellicle or demonstrate a colour 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 colour where modified medium was utilised. If the Negative Control results in growth, there is a potential for false positives

Physical Properties

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

Monitoring Frequency

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

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 The Dry Heat *D* value range is based on the requirements outlined in ISO 11138-4. 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. Excelsior 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

Compliance

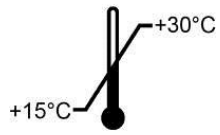
ISO 11138-1 Sterilization of health care products – Biological Indicators- Part 1: General Requirements

ISO 11138-4 Sterilization of health care products – Biological indicators – Part 4: Biological indicators for dry heat sterilization processes

Excelsior Scientific has a validated method for Total Viable Spore Count. Please inquire for the Technical data sheet entitled “Population Verification for Biological Indicator Strips” to ensure consistent methodologies when performing verification testing.

USP Biological/Official Monographs

Storage and Shelf Life

	15°C to 30°C		Keep away from sunlight
	20% to 80% relative humidity		Keep Dry
Shelf Life	24 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 Strips. Do not use damaged 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.

For additional product information:
Please visit us at
www.excelsiorscientific.com
Email us at sales@excelsiorscientific.com

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