



Technical Data Sheet

INOCULATED CARRIER SPORE DISCS For Monitoring Ethylene Oxide (EO) & Dry Heat

True Indicating Code: DA-06 and DA3-06

Product Description

Spore Discs for monitoring EO or Dry Heat processes consist of:

- An inoculated carrier, 3mm or 6mm paper disc of *Bacillus atrophaeus* Cell Line 9372
- Primary packaging is in bulk, 100 discs per re-sealable pouch



Physical Properties

| | |
|-----------------|----------------------------|
| Process | EO or Dry Heat |
| Disc Dimensions | DA-06: 6 mm DA3-06: 3mm |
| Packaging | 100 / Pouch |

Monitoring Frequency

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

Indications for Use

The Spore Discs are utilized to monitor EO or Dry Heat sterilization process efficacy. The Spore Discs may be used for equipment or process validation or routine monitoring. The Spore Discs are labelled for laboratory or industrial use only.

Instructions for Use

Place Spore Discs (a minimum of 10 per exposure is recommended) inside representative materials to be sterilized or within the device directly. Package or wrap product or device 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, centre-centre and centre-top) or according to standard operating procedure. Run the cycle.

After exposure to EO or Dry Heat, 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 Disc 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 standard SCDB.

Transfer one Spore Disc which has not been exposed to an EO or Dry Heat process to a tube of growth medium as a Positive Control.



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PRODUCTS

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Incubation: At least one tube of growth medium containing no Inoculated Carrier from the same lot used for culture of the Spore Discs should be incubated with the test series as a Negative Control. Place the cultured Spore Discs, the Positive Control and the Negative Control in an incubator set at 30°C to 40°C.

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

Spore Discs cultured in modified growth medium True Indicating Product Code GGM-100 should be incubated for a minimum of 48 hours.

Monitoring: Examine the Spore Discs daily, when 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 Product 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 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: 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 in the Cultured Spore Discs.

Compliance

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

ISO 11138-2 Sterilization of health care products – Biological indicators – Part 2: Biological indicators for ethylene oxide sterilization processes

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 outlining the methodology.

USP Biological/Official Monographs



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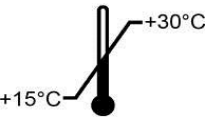






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Performance Characteristics

| | |
|-----------------------|--|
| Population | $\geq 1.0 \times 10^6$ per Disc |
| Purity | No evidence of contamination present in sufficient numbers to adversely affect the finished product. |
| EO Resistance | D value at $54^\circ\text{C} \pm 1^\circ\text{C}$, 600 mg/L \pm 30mg/L, 60% RH \pm 10%RH ≥ 2.0 minutes The EO D value range is based on the requirements outlined in the USP, ISO 11138-2. The EO D value is determined using 100% EO. |
| Dry Heat Resistance | D value at $160^\circ\text{C} \pm 1^\circ\text{C}$ ≥ 2.0 minutes Z value: $\geq 20^\circ\text{C}$ 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. |
| Survival – Kill Times | Survival – Kill Times Calculated based on the formulations outlined in the USP, ISO 11138-1 |
| Post Market Criteria | Population: 50% to 300% of certified population D value: $\pm 20\%$ of the certified D value Survival Time: All Spore Discs result in growth at the certified survival time Kill Time: All Spore Discs 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 | 24 months from the date of manufacture | | |
|  | 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.



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