



Biological Indicators (BIs) For Monitoring Dry Heat Processes ISO 11113-1 and ISO 11138-4 Compliant

Product Code: AAD-06

Product Description

Dry Heat Ampules for monitoring Dry Heat sterilization processes consist of:

- Snap top glass ampule containing silica material inoculated with *Bacillus atrophaeus* Cell Line 9372 Spores with a known population and resistance.
- Tubes of growth medium specially formulated for *Bacillus atrophaeus* modified with a pH indicator that transitions from Green to Yellow and offers a reduced incubation time of 72 hours.
- All materials are compatible with extremely high temperatures such as those in dry heat tunnels or ovens used for sterilization or depyrogenation in manufacturing of aseptically filled pharmaceutical liquids.

Indications for Use

The Ampules are for use in high temperature dry heat sterilizers, ovens and tunnels operating at 160°C (or higher) or depyrogenation processes operating up to 250°C including direct air exposure, submersion in oils and other liquids where traditional BIs of paper are not suitable for use.

The Ampules are labeled for laboratory/industrial use only.

Physical Properties

Process	Dry Heat or Depyrogenation
Dimensions	Ampule: 47 mm x 10.6 mm
Packaging	50 Ampules + 50 Tubes of Growth Medium
Volume of Growth Medium	4.5 mL

Instructions for Use

Identify the Ampule with pertinent process or load location information. Position the Ampule inside the product or product packaging and place in the most difficult to sterilize location. Expose the load to the validated sterilization cycle/conditions.

Following exposure, remove the Ampule from the load and transfer to the laboratory for culturing. Ampules should be aseptically handled within a laminar flow hood.

Open each Ampule by holding the base of the Ampule in one hand and firmly pressing the neck of the Ampule with the other hand to apply pressure to snap it open.



Wear safety goggles.

Avoid scored area of the Ampule once snapped as the Ampule base will be sharp where the neck has been removed.

Transfer contents of the Ampule to a tube of growth medium. Repeat until all Ampules have been transferred.





Technical Data Sheet

Controls: Use of a Positive Control Ampule is recommended. Transfer the contents of an unexposed Ampule (in the same manner as the Test Ampules) to a tube of growth medium. Label the tube as “Positive Control”.

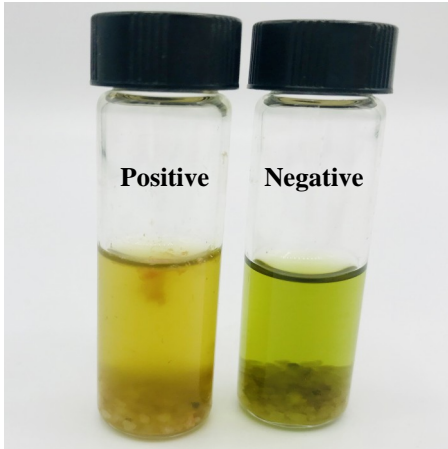
Incubation: Place the tubes containing the contents of the Test Ampules and the Positive Control, if applicable, in a vertical position in an incubator at 30°C - 40°C for a minimum of 72 hours.

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

Interpretation:

Positive Control: The Positive Control should exhibit a color change to Yellow and/or demonstrate turbidity. Utilize the Positive Control as a color comparison for the tubes containing the Test Ampules.

Test Ampules: A passing sterilization cycle is indicated by the color of the growth medium remaining Green and free of turbidity or visible evidence of growth. A failed sterilization cycle is indicated by a color change in the medium to Yellow and/or turbidity.



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

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





Technical Data Sheet

Performance Characteristics

Population	$\geq 1.0 \times 10^6$ Per Ampule
Purity	No evidence of contamination present in sufficient numbers to adversely affect the finished product.
Dry Heat Resistance	<p><i>D</i> value at 160°C ≥ 2.0 minutes</p> <p>The Dry Heat <i>D</i> value is based on the requirements outlined in ISO 11138-4.</p> <p>Survival-Kill Times Calculated based on the formulas outlined in the USP, ISO 11138-1 and guidance issued by FDA.</p> <p><i>z</i> value $\geq 20^\circ\text{C}$</p> <p>Determined based on three temperatures in the range of 150°C to 180°C. True Indicating typically utilizes <i>D</i> values determined at 150°C, 160°C and 180°C for <i>z</i> value calculation.</p>
Post-Market Criteria	<p>Population: 50% to 300% of certified population</p> <p><i>D</i> value: $\pm 20\%$ of the certified value</p> <p>Survival Time: All Ampules result in growth at the certified survival time</p> <p>Kill Time: All Ampules 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	24 months from the date of manufacture; labeled based on the shorter of the two components with individual shelf life (the Ampule and Growth Medium)		
	Keep away from sterilants. Do not use damaged indicators or growth medium which have already transitioned to Yellow. Do not use after expiration date.		

Disposal

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

