



BIOLOGICAL INDICATOR – SPORE AMPULES + NEGATIVE CONTROLS

This lot of product meets the accepted performance criteria recommended in the USP and ISO 11138-1.

Product Name: Spore Ampule

For use in Monitoring: Steam

Organism: *Bacillus subtilis* ATCC® 35021

LOT B50-0

REF AB5-06

Volume: 0.7 mL

2020-12-21

2022-12-21

Quantity: 100 Ampules + 10 Negative Controls

Negative Controls **LOT** NC080220-01

2020-08-05

2022-08-05

Soybean Casein Digest Broth (SCDB) for Spore Ampules and Negative Controls **LOT** 0079964

Performance Characteristics				
Population:	1.0 x 10 ⁶ per ampule			
Parameters:	110°C	115°C	118°C	121°C
D value:	2.9 minutes	1.0 minutes	0.6 minutes	0.3 minutes
Survival:	11.6 minutes	4.0 minutes	2.4 minutes	1.2 minutes
Kill:	29.0 minutes	10.0 minutes	6.0 minutes	3.0 minutes
<p>The D value was determined per the fraction negative method and are reproducible only when exposed and cultured under the exact conditions used to obtain results reported above. The user would not necessarily obtain the same results, therefore, should determine the suitability for their particular use.</p> <p>Survival-Kill times calculated using USP and ISO survival time and kill time formulae.</p>				
z value:	11.6°C	Based in D value determinations at 110°C, 115°C and 118°C.		
Purity:	Shall not contain any contamination that would adversely affect the performance or the stability characteristics of the product.			

Storage and Shelf Life			
	Refrigerate (2° - 8°C)		Keep away from sunlight
	Protect from heat, radioactive sources, and sterilizing agents	Shelf Life	24 Months from the date of manufacture

Disposal: Autoclave, steam at 121°C for not less than 30 minutes or incinerate (standard microbial waste; non-pathogenic species).

Quality Approval

August 24, 2022
Date



Exposure:

Spore Ampules may be placed inside representative materials (containers of liquid) or within the chamber directly. Package or wrap product as usual, if applicable. Locate product or Spore Ampules in most difficult location to sterilize, as outlined in your specific sterilization validation protocol or according to standard operating procedure. Run the cycle.

Handle Spore Ampules with care as the contents are extremely hot post-exposure. Always employ proper PPE when handling hot materials; remove Ampules from sterilizer as quickly and safely as possible post-exposure. Leaving the Spore Ampules in the sterilizer post-exposure may have a negative impact on the product's performance. As such, Spore Ampules left in the chamber for extended periods of time (24 hours) post-exposure should be discarded.



After sterilization or exposure, remove Spore Ampules or product from sterilizer. Allow product or Spore Ampules to cool to the touch. No activation is required.

Controls:

A Negative Control Ampule may be used in conjunction with the Spore Ampules, where a negative control is required. If a Positive Control is needed, label one unprocessed Spore Ampule as "Positive Control".

Incubation:

Place the processed Spore Ampules, the Negative Control and the Positive Control in a vertical position in an incubator at 37°C to 40°C for a minimum of 72 hours.

Monitoring:

Examine the Spore Ampules daily, whenever possible during incubation. Record observations. All positive Spore Ampules should be disposed of immediately. Do not continue to incubate a positive Spore Ampule. Continued incubation of positive Ampules may result in metabolism of amino acids in the absence of sugars, causing the pH to rise and result in color reversion that is visibly darker than a sterile unit. These should be considered as positive for growth (turbidity and sediment in the Ampule will be present).

Interpretation:

Negative Control: The Negative Control Ampule should remain Orange and not exhibit a color change to Yellow and/or demonstrate turbidity. Utilize the Negative Control as a color comparison for the exposed Spore Ampules, where applicable.

Positive Control:

The Positive Control Spore Ampule should exhibit a color change to Yellow and/or demonstrate turbidity. Utilize the Positive Control as a color comparison for the exposed Spore Ampules, where applicable. If the positive control does not demonstrate a Yellow color and/or turbidity, the results for test Spore Ampules should not be considered valid. Verify incubation conditions were met throughout the incubation period.

Test Spore Ampules:

A passing sterilization cycle is indicated by a test Spore Ampule remaining Orange in color and is free from turbidity. A failed sterilization cycle is indicated by turbidity and/or a color change to Yellow.