



SELF-CONTAINED NEGATIVE CONTROL AMPULES For Monitoring Liquid Steam Processes



True Indicating Code: AT-10-NC

Product Description

Negative Control Ampules are hermetically sealed glass ampules which contains modified Tryptic Soy Broth (TSB) with a pH indicator and a glass bead to designate the ampule as a control. The modified TSB will transition from the initial Purple color to Yellow and/or demonstrate turbidity in the presence of bacterial growth. The Negative Control Ampules serve as a color comparison after incubation of processed Spore Ampules.

Indications for Use

Negative Control Ampules may be utilized with Spore Ampules that are intended for use in monitoring Steam sterilization processes at 121°C to 137°C in liquid steam sterilization cycles but may also be utilized in monitoring dry loads. The Negative Control Ampules serve as a comparison to processed Spore Ampules as the Negative Control Ampules retain a Purple color expected for Spore Ampules which are negative for growth.

Negative Control Ampules are labeled for laboratory/industrial use only.

Physical Properties

Process	Steam as a Control
Dimensions	47 mm x 10.6 mm
Packaging	10 per box
Volume	1mL

Monitoring Frequency

For greatest control of sterilized goods, it is recommended that one Negative Control Ampule be included with every load.

Instructions for Use

Exposure: Negative Control Ampules may be placed inside representative materials (containers of liquid) or within the chamber directly with or adjacent to Spore Ampules. 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 Negative Control and 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 as safely possible post-exposure. Leaving the Ampules in the sterilizer post-exposure may have a negative impact on the product's performance. As such, Ampules left in the chamber for extended periods of time (24 hours) post-exposure should be discarded.

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





Technical Data Sheet

Incubation: Place the processed Ampules and a Positive Control (unexposed Spore Ampule) in a vertical position in an incubator at 55°C to 65°C for a minimum of 48 hours.

Monitoring: Examine the Ampules daily, whenever possible during incubation. Record observations. All positive Ampules should be disposed of immediately. Do not continue to incubate a positive 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 (Dark Purple-Brown) 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 Purple 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.

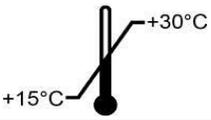
Positive Control: The Positive Control Spore Ampule should exhibit a color change to Yellow and/or demonstrate turbidity. Utilize the Positive Control as a color comparison for the exposed Spore Ampules, where applicable. If the positive control does not demonstrate a Yellow color and/or turbidity, the 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 Purple in color and is free from turbidity. A failed sterilization cycle is indicated by turbidity and/or a color change to Yellow.

Performance Characteristics

Purity	No evidence of contamination (Ampule is clear and Purple in color)
--------	--

Storage and Shelf Life

	15°C to 30°C		Keep away from Sunlight
	Do not freeze		Protect from heat, radioactive sources and sterilizing agents
Shelf Life	24 months from the date of manufacture		
	Do not use damaged Ampules or Ampules which demonstrate turbidity or have transitioned to a Yellow color. 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.

