



Technical Data

Spore Strips (Steam Sterilization Monitor Strips)

DD032

Steam Sterilization Monitor Strips are used for evaluating sterilization process. These indicators which are specified by the U.S. military specification MIL-S- 36586 are GMP requirements of U.S. FDA.

Directions

Place indicators in the areas of the pack or load least accessible to steam. Places such as the geometrical center, and the upper and lower regions of both front and rear of the load to be sterilized are considered suitable areas for placement of these indicators. A standard procedure should be established for the routine evaluation of each sterilizer. On completion of the sterilization cycle, remove the indicators from the test loads and deliver them to the laboratory for testing. All sterility tests should be performed in a clean dust free transfer area, preferably under positive air pressure, using rigid aseptic technique throughout the test procedure.

Using sterile scissors, cut open one end of the envelope. Thereafter remove the indicator with sterile tweezers and aseptically transfer it to a tube of sterile Soyabean Casein Digest Medium w/ Yeast Extract and Ferric pyrophosphate (M207) or Soyabean Casein Digest Medium (M011). Incubate the tubes for seven days at 55 - 60°C. Observe the tubes daily. If turbidity develops, failure of the sterilization process is indicated.

Precautions

The spore strips or broth cultures of *Bacillus stearothermophilus* must be autoclaved at 121°C for at least 30 minutes prior to discarding.

Each spore strip is individually packaged in a steam-permeable envelope.

Principle And Interpretation

Bacillus stearothermophilus is a thermophilic bacteria which can grow at 65°C and above. The spores are highly heat resistant and are used to monitor autoclave performance (1).

Sterilisation is the freeing of an article from all living organisms including viable spores(1). Sterilization quality control can only be achieved through the use of calibrated biological indicators (endospores). These indicators consist of *Bacillus stearothermophilus* spores impregnated on chromatography paper strips, individually placed into envelopes. Number of spores present per strip : 10^6 . These organisms are difficult to destroy because they are more resistant to heat than other vegetative bacteria and viruses. Therefore, if they are destroyed during sterilization, it is assumed that all other life forms are also destroyed. This test is considered the most sensitive check of the autoclaves efficiency.

Precautions :

The spore strips or broth cultures of *Bacillus stearothermophilus* must be autoclaved at 121°C for at least 30 minutes prior to discarding.

Each spore strip is individually packaged in a steam-permeable envelope.

Quality Control

Appearance

Filter paper strip impregnated with spores of standard culture of *B.stearothermophilus*

Number of spores

1000000 spores/strip

Cultural response

Sterility checking of the autoclave was carried out using Spore strip. After autoclaving, strip was inoculated in 100ml of st. Soyabean Casein Digest Medium(M011) and incubated at 55°C upto 7 days. An unexposed spore strip was also inoculated separately in 100ml M011

Growth	Unexposed Spore Strip	Exposed Spore Strip	Positive control	Negative control
<i>Growth in M011</i>	Luxuriant	No growth	Luxuriant	No growth

Storage and Shelf Life

Store at 2 - 8°C. Use before expiry date on the label.

Reference

1. Mackie and McCartney, 1996, Practical Medical Microbiology, 14th ed., Vol. 2, Collee J. G., Fraser A. G., Marmion B, P., Simmons A (Eds.), Churchill Livingstone, Edinburgh.

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Spore Strips - Biological Indicator

LA414, LA415 & LA416.

Spore strips for sterility testing in various sterilization environments for both Healthcare and Industrial applications.

Product Name	Product Code	Description	No. of Spores per strips	Pack Size (nos/pack)
Spore Strips - Biological Indicator	LA414	<i>B.stearothermophilus</i>	10 ⁵	100
	LA415	<i>B.stearothermophilus</i>	10 ⁶	100
	LA416	<i>B.subtilis (B.atrophaeus)</i> - For ETO and steam sterilization at 115°C.	10 ⁶	100

B. stearothermophilus – (*Geobacillus stearothermophilus*) For use in steam sterilization.

B. subtilis – (*Bacillus atrophaeus*) For use in Ethylene Oxide (600 mg/L), Dry Heat Sterilization (D value calculated at 160°C), and formaldehyde fumigation. For **Ethylene oxide** sterilization 54% RH, 60°C is recommended.

Principle :

Each Spore Strips contains a population of 1x10⁵ (LA414) / 1x10⁶ (LA415) of *B. stearothermophilus* spores and 1x10⁶ (LA416) of *B. subtilis* spores . Each spore strips as recommended for respective use act as sterilization indicators. The spores after exposure as specified use, gets killed indicating the efficiency of sterilization process. This is determined by studying the growth of treated spore strips in nutrient media like Soyabean casein digest medium.

Directions :

1. Place the spore strips while sterilization to check efficiency of the process (applicable for each as above).
2. Inoculate the treated spore strips in Soyabean casein digest medium at 55°C (For LA 414/LA415) and at 35°C (for LA416) upto 7 days. Observe for growth after every 24 hours and record the results.
3. Check for presence/ absence of growth. Growth is indicated by turbidity.

Interpretation:

Turbidity – Improper sterilization

No turbidity – Proper sterilization

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