

Application

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 strip 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 55°C and above. The spores are highly heat resistant and are used to monitor autoclave performance (1).

Sterilization 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 autoclave's efficiency.

Quality Control

Appearance

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

Number of spores

10^6 spores/strip

Cultural Response

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

	Unexposed Spore Strip	Exposed Spore Strip	Positive control	Negative control
Growth of Spore strips in M011	luxuriant	no growth	luxuriant	no growth

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.

Storage and Shelf-Life

Store between 15-27°C. Use before expiry date on the label.