



Spore Strips (Radiation Sterilization Monitor Strips)

DD039

Radiation Sterilization Monitor Strips are used for evaluating radiation 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 radiation. 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 & Ferric Pyrophosphate (M207) or Soyabean Casein Digest Medium (M011). Incubate the tubes for seven days at 35-37°C. Observe the tubes daily. If turbidity develops, failure of the radiation sterilization process is indicated.

Precautions

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

Principle And Interpretation

Bacillus pumilus is a radiation resistant species. The spores are highly radiation resistant and are used to monitor radiation sterilization (1).

Sterilisation is the freeing of an article from all living organisms including viable spores(1). Radiation sterilization quality control can only be achieved through the use of calibrated biological indicators (endospores). These indicators consist of *Bacillus pumilus* spores impregnated on chromatography paper strips, individually placed into envelopes. Number of spores present per strip : 10^6 . These organisms are difficult to destroy since they are more resistant to radiation 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 efficiency of radiation sterilization.

The spore strips or broth cultures of *Bacillus pumilis* must be autoclaved at 15lbs pressure (121°C) for atleast 30 minutes prior to discarding.

Quality Control

Appearance

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

Number of spores

1000000 spores/strip

Cultural response

Spore strip exposed to 2.5Mrad of radiation was inoculated in 100ml of sterile SCD Medium(M011)&incubated at 35°C upto 7days. Simultaneously unexposed spore strip was inoculated in another 100ml of M011

Growth	Unexposed Spore Strip	Exposed Spore Strip	Positive control	Negative control
Growth in M011	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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