



Spore Strips (*B. pumilus*)

DD039

Intended use

Recommended as radiation sterilization monitor strips for evaluating radiation sterilization process.

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 Tryptone Soya Agar w/Yeast Extract and Hemin w/o Dextrose (M207) or Tryptone Soya Agar (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).

Sterilization 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 : 106. 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.

Type of specimen

Isolated micro-organism

Specimen Collection and Handling:

For microbial specimens, follow appropriate techniques for handling specimens as per established guidelines. After use, contaminated materials must be sterilized by autoclaving before discarding.

Warning and Precautions:

Read the label before opening the container. Wear protective gloves/protective clothing/eye protection/ face protection. Follow good microbiological lab practices while handling specimens and culture. Standard precautions as per established guidelines should be followed while handling specimens. Safety guidelines may be referred in individual safety data sheets.

Limitations:

1. Other biochemical and serological tests must be performed to identify the organism accurately.

Quality Control

Appearance

Filter paper strip impregnated with spores of standard culture of *Bacillus pumilis*.

Number of spores

1000000 spores/strip

Cultural response

Spore strip exposed to 2.5Mrad of radiation was inoculated in 100ml of sterile Tryptone Soya Broth (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 between 15-27°C.. Use before expiry date on the label. Product performance is best if used within stated expiry period.

Disposal

User must ensure safe disposal by autoclaving and/or incineration of used or unusable preparations of this product. Follow established laboratory procedures in disposing of infectious materials and material that into contact comes with sample must be decontaminated and disposed of in accordance with current laboratory techniques (2,3).

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.
- 2.Isenberg, H.D. Clinical Microbiology Procedures Handbook 2nd Edition.
- 3.Jorgensen, J.H., Pfaller, M.A., Carroll, K.C., Funke, G., Landry, M.L., Richter, S.S and Warnock., D.W. (2015) Manual of Clinical Microbiology, 11th Edition. Vol. 1.

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