

GENERAL DESCRIPTION

The Spordex Strip NA141/NA139 Biological Indicator (BI) is produced from filter paper inoculated with a single spore species (*Geobacillus stearothermophilus*, ATCC 7953) and enclosed in a glassine envelope. The strips are produced under controlled conditions to meet suggested performance parameters published in the current U.S. Pharmacopeia. The Spordex Strip NA139 BI is identical to the Spordex Strip NA141 BI except for the quantity per box. Spordex NA139 BI has 100 biological indicators per box and Spordex NA141 BI has 500 biological indicators per box.

APPLICATION

The Spordex Strip NA141/NA139 BI is used to validate and re-qualify steam sterilizers and to monitor the effectiveness of the steam sterilizing process.

FEATURES

Geobacillus stearothermophilus
 single species E6 population

Lot number and expiration on each glassine envelope and data card

Easy-peel glassine pouch

Packaged in plastic boxes; two sizes available

BENEFITS

E6 may be used in applications requiring a 6-log reduction

Traceable results and valuable documentation

Facilitates aseptic transfer

Conveniently sized boxes help to protect the product integrity

TECHNICAL PROPERTIES

Primary packaging: glassine envelope approximately 3 x 1"

Spore carrier: filter paper strip approximately 1-1/2 x 1/4"

Species: *Geobacillus stearothermophilus* (ATCC 7953)

Mean population recovery: 1.0 x 10⁶ to 5.0 x 10⁶ cfu/strip

Purity: Bacterial contaminants less than 1% of the labeled population; this is the detection limit using the pour plate method with an aliquot that yields at least 100 colony forming units (cfu).

D-value for saturated steam (D₁₂₁): 2.0-2.5 minutes

D₁₂₁ is determined by MPN method utilizing 121° ± 0.5°C exposure temperature.

The D-value is reproducible only when the biological indicator is exposed and cultured under the same conditions which were used by STERIS to determine the D-value.

Incubation temperature: 55-60°C (131-140°F)

Shelf life: 18 months from time of manufacture. The expiration date is printed on the glassine envelope and on the data card that accompanies the box.

DIRECTIONS FOR USE

After sterilization processing has been completed, remove the Spordex Strip NA141/NA139 BI from the test pack. Aseptically open the glassine envelope by cutting the glassine with sterile scissors or peeling apart the glassine at the indicated end. Aseptically transfer each strip from its envelope to a tube of sterile Spordex® Culture Media NA114. Incubate the tubes at 55-60°C (131-140°F) for seven days or for a customer-validated reduced incubation time. Examine the media containing the biological indicators during the incubation period. A color change from red to yellow and/or the presence of turbidity indicates microbiological growth. See the instruction card enclosed in the Spordex Strip box for detailed use directions.

STORAGE CONDITIONS

The Spordex Strip NA141/NA139 Biological Indicators should be stored at a temperature of 2-24°C (36-75°F) and a relative humidity of 30-80%. Avoid contact with, or storage near, sterilants or chemicals; e.g., any oxidizing or reducing agents such as formaldehyde, bleach, ammonia, etc. Do not use after the expiration date printed on the packaging.

DISPOSAL

Before discarding, treat as appropriate for standard microbiological waste, nonpathogenic species; e.g., steam autoclave at 121°C (250°F) for not less than 30 minutes, incinerate, or use other suitable means.

SERVICE

Sales

Service is one of the most important ways to verify consistent quality of the facility's performance and operation. A tailored service program by STERIS provides effective, trouble-free operations.

Technical

STERIS is pleased to provide a completely staffed and equipped technical service laboratory capable of performing needed tests and providing both telephone and on-site assistance when needed. More details on how this service can benefit a facility's particular situation can be provided upon request.

ORDERING INFORMATION

Description	Quantity Per Box	Reorder Number
Spordex Strip NA141 Biological Indicator	500	NA141
Spordex Strip NA139 Biological Indicator	100	NA139

For further information, please contact:

STERIS[®]



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