



GENERAL DESCRIPTION

The Spordex Strip NA005/NA004 Biological Indicator (BI) is produced from filter paper inoculated with a single spore species (*Bacillus atrophaeus*, NRRL#B4418) and enclosed in a glassine envelope. The strips are produced under controlled conditions to meet the suggested performance parameters published in the current United States Pharmacopeia (USP), American National Standards Institute/Association of the Advancement of Medical Instrumentation/International Standards Organization (ANSI/AAMI/ISO) 11138 and EP Standards.

The Spordex Strip NA004 BI is identical to the Spordex Strip NA005 BI except for the quantity per box. Spordex NA004 has 100 biological indicators per box and Spordex NA005 has 500 biological indicators per box.

APPLICATION

The Spordex Strip NA005/NA004 BI is used to validate and re-qualify ethylene oxide (EO) gas or dry heat sterilizers and to monitor the effectiveness of common EO gas or dry heat sterilizing processes.

FEATURES

Bacillus atrophaeus single species E6 population
Tested in accordance with ISO 11138-2

Lot number, organism name 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

Allows for harmonization of biological indicators between global Customer sites

Traceable results and valuable documentation

Facilitates aseptic transfer

Conveniently sized boxes help to protect the integrity of the product

TECHNICAL PROPERTIES

Primary packaging: glassine envelope approximately 3 x 1"

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

Species: *Bacillus atrophaeus*, NRRL#B4418

Mean population recovery: 1.0×10^6 to 5.0×10^6 cfu/strip

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

D-value for ethylene oxide (D_{EO}): 2.6-4.5 minutes

D_{EO} is determined by MPN and SC methods with a 600±30 mg/L ethylene oxide concentration, 54°±1°C, 50-70% R.H.

D-value for dry heat (D_{DH}): 1.0-3.0 minutes

D_{DH} is determined by MPN utilizing 160°±2°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. The labeled D-value was determined utilizing the E6 population strip and Spordex® Culture Media NA114.

Incubation temperature: 30-35°C (86-95°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.

Quantity: 500 per box, Spordex Strip NA005 Biological Indicator
100 per box, Spordex Strip NA004 Biological Indicator

DIRECTIONS FOR USE

After sterilization and aeration processing have been completed, remove the Spordex Strip NA005/NA004 BI from the test pack. Aseptically open the glassine envelope. This can be accomplished 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 30-35°C (86-95°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 NA005/NA004 BIs 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	Reorder Number
Spordex Strip NA005 Biological Indicator	500 per box	NA005
Spordex Strip NA004 Biological Indicator	100 per box	NA004

(NA004 is identical to NA005 except for the quantity per box.)

For further information, please contact:

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