

KBT400

Spore Strips Biological Indicator Kit

For Liquid Peracetic Acid High Level Disinfection processes.



Usage

Monitoring the sporicidal activity of Liquid Peracetic Acid in High Level Disinfection processes.

Applicable Regulation

ISO 11138-1:2006 and IRAM 37102-1:1999.

Classification

Class 1, according to risk.

Authorization

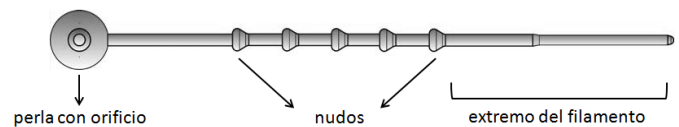
Designed under Quality Management System standards ISO 13485:2003/NS-EN ISO 13485:2012. ANMAT (Argentinean National Administration of Drugs, Food and Medical Technology) PM 1614-1.

Characteristics

25 mm x 70 mm package of non-absorptive material. Turquoise code. 6 mm x 25 mm Tyvek® fiber strip.

10⁶ *Geobacillus stearothermophilus* ATCC 7953 spores per strip.

Silicone fastener: 80 mm long. Pearl end: 5.6 mm diameter. Color: turquoise.



Upon completion of the sterilization cycle, the spore strip should be tested in a suitable culture medium at 60°C. We suggest the use of BIONOVA® MC1020 culture media to final reading in 24 hours. For conventional culture media like TSB, is recommended incubation for 7 days at 60 °C.

D-value: at 50°C, 3.500 ppm of Peracetic Acid.

MC1020-2. Culture medium with pH indicator for growth of *Geobacillus stearothermophilus* ATCC 7953, *Bacillus subtilis* DSM 5230 and *Bacillus atrophaeus* ATCC 9372 bacterial spores.

Growth medium color: red.

Plastic tube: 68 mm high, 10 mm diameter

Medium volume: 2 ml

Medium turns to yellow when spores grow.

Environmental conditions during manufacture

Room temperature 15-30 °C, RH 30-80 %. Sterility conditions are necessary only during the inoculation process performed in laminar flow.

Storage conditions

T = 10-30 °C, RH 30-80 %, keep in a dark place.

Transportation conditions

Storage conditions should be strictly followed.

Products should be transported in closed and reinforced boxes in order to avoid damages. Product transportation does not represent any risk for human health.

Shelf-life

Packing

100 spore strips envelopes + 100 culture medium tubes per box.
Packing information: product code and description, process for intended use, classification according to regulation, manufacturer information and data on box's label.

Information on product's package: product description, process for intended use, batch number and expiration date.

Labelling

On product's box: batch number, manufacture date and expiration date.

Possible target markets

Healthcare and Industry.

Other important information (optional)

It is advisable to incubate at 60 °C in BIONOVA® IC10/20 incubator.
Read product's directions for use thoroughly before use.

NOTE: When necessary, limits of each product's parameters should be specified.

Description of identified and/or predictable risks which could represent a risk for the product

Do not store the product near sterilizing agents.

Do not expose this product to radiation, EO or any processes other than Liquid Peracetic Acid.

Note: Spore strips can be incubated in BIONOVA® MC1020 culture media or other culture medium made up of soybean casein and yeast extract.