

Infection Control Division | Biological Indicators

BT97 BioSurf Biological Indicator Super Rapid Readout Fluorescence System



Usage

Bionova® BT97 BioSurf Biological Indicator has been designed for quick and easy monitoring of airborne and surface disinfection processes by hydrogen peroxide.

Applicable regulation

Designed under Quality Management System standards ISO 13485:2016/ EN ISO 13485:2016.

Authorization

ANMAT (Argentinian National Administration of Drugs, Food and Medical Devices) PM 1614-1.

Classification

Class 1, according to risk.

Characteristics

Tubes A and B: Polypropylene, 45.0 mm high x 8.5 mm external diameter. Wall thickness: 0.5 mm

Cap A: Polypropylene, 10.5 mm external diameter, 13.0 mm high. Wall thickness: 1.0 mm. This cap contains a 28.0 mm stem with a slot in which the carrier is located.

Cap B: Polypropylene, 10.0 mm external diameter, 16.5 mm high. Wall thickness: 1.0 mm.

Cap filter: Polyethylene fibers, 17 mm in diameter.

Glass ampoule: 38.0 - 40.0 mm high. External diameter: 6.5 mm. Wall thickness: 0.2 - 0.3 mm.

Culture medium: 0.65 - 0.75 ml, purple color.

Carrier in tube A: Stainless steel 4.9 mm x 15.0 mm x 0.8 mm.

Special filter in tube B: Polypropylene microfibers of 17 mm diameter.

$\geq 10^6$ *Geobacillus stearothermophilus* ATCC®* 7953 spores per vial.

Final fluorescence reading is performed after 1-hour incubation at 60 °C (sensitivity ≥ 97 %).

An optional visual pH color change confirmation could be performed after 48 hours of incubation. If disinfection process has not been successful, culture medium will turn yellow during incubation at 60 °C, thus showing the presence of living spores. If disinfection process is successful culture medium will remain purple after the incubation process.

7-day readout is optional and not intended to be routinely performed; it is an initial validation of the 1-hour reading. Fluorescence results may be compared to the 7-day visual reading. NOTE: If 7-day readout is performed, a humidified environment will be required to prevent medium from drying out.

D-Value: calculated at 50 °C, 2 mg/l H₂O₂.

*ATCC® is a registered trademark of American Type Culture Collection.

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Environmental conditions during manufacture

T = 15-30 °C, RH = 30-80 %. Sterility conditions are necessary only during inoculation and assemble of the biological indicator processes, performed in laminar flow.

Storage conditions

T = 10-30 °C, RH = 30-80 %, keep away from direct sunlight in its original box.

Transport conditions

It is recommended to store it away from sunlight and at a temperature between 10–30 °C.

Products should be transported in closed and reinforced boxes in order to avoid damages. The transport of this product does not represent any risk for human health.

Shelf life

2 years.

Packing

50 units per box. 25 tubes A + 25 tubes B.

Packing information: Product code and description, process for intended use, regulatory and standards information, bacterial strain, storage conditions and manufacturer information.

Labelling

On product's packing: product code and description, batch number, bacterial load, manufacture and expiration date, bar code and Data Matrix.

Possible target markets

Healthcare and Industry.

Other important information

It is advisable to incubate at 60 °C in Bionova® IC10/20FR, Bionova® IC10/20FRLCD or Bionova® MiniBio Auto-Readers incubators.

Read product's Instructions for Use thoroughly before use.

Precautions

Do not store the product near disinfecting agents.

Do not use this product to control ethylene oxide, steam, dry heat, formaldehyde or any disinfection process other than hydrogen peroxide.