



STRIP CONTROL BAT E2

Biological indicators of dry heat or ethylene oxide sterilization processes containing *Bacillus atropheus* (ATCC 9372) spores inoculated on special filter paper strips

DESCRIPTION

Biological indicators **STRIP CONTROL BAT E2** are produced under strictly controlled conditions in order to satisfy the requirements indicated in the USP current edition and in accordance with ISO 11138 and EN 866 standards.

These biological indicators are special filter paper strips, inoculated with *Bacillus atropheus* (ATCC 9372) spores in predefined concentrations and contained in a special envelope.

Each package contains a culture medium, STERI-TEST MEDIUM, in glass test tubes with screw cap closures. The medium is validated for use with strips and meets the U.S. Pharmacopoeia Revision XXII growth promotion guidelines.

Each package contains also a Certificate of Performance that indicates a certified population, D-value, survival time, kill time, species, lot number and expiration date.

COMPOSITION

Strips contain *Bacillus atropheus* (ATCC 9372) spores in concentrations: $1-5 \times 10^2$ CFU/strip.

Each strip is contained in an envelope. Each envelope is printed with product name, lot number and expiration date.

STERITEST MEDIUM is a sterile modified soybean casein digest broth with a pH indicator.

Each tube is printed with product name, lot number and expiration date.

PRINCIPLE

Spores in the strips are completely killed off during dry heat or ethylene oxide sterilization process, if the process has been efficient. In this case the aspect of STERI-TEST MEDIUM (included in the package), inoculated with the strips and incubated for a suitable time will remain unchanged: violet/clear.

On the contrary, if the sterilization process has not been efficient, spores partially survive and STERI-TEST MEDIUM turns from violet/clear to yellow/turbid.

TECHNIQUE

- Take one or more strips from the kit leaving them inside their original envelope.
- Put envelopes with strips on the bottom, in the centre, inner sides and on the critical points of the sterilizer.
- For sterilizers with capacity up to 250 litres put two envelopes for each selected point of the sterilizer. For sterilizers with capacity higher than 250 litres put six or more envelopes in each selected point.
- Remove envelopes after sterilization/aeration cycle and open them aseptically with sterile scissors or by tearing the edges.
- Transfer aseptically each strip from its envelope to a STERI-TEST MEDIUM tube, included in the package.
- Incubate tubes containing strips at 30-35°C (86-95°F) for 7 days or for a shorter time validated by user.
- Incubate, at the same conditions of time and temperature, a strip contained in the envelope not submitted to the sterilization cycle, belonging to the same batch, as spore growth control (positive control).
- Examine tube medium's colour and interpret results as per **EVALUATION TABLE**: a change of medium's colour from violet/clear to yellow/turbid indicates a microbial growth and therefore an unsuccessful sterilization. On the contrary, the persistence of the medium's initial colour (violet/clear) indicates absence of microbial growth and therefore a successful sterilization.

INTERPRETATION OF RESULTS

Bacillus atropheus (ATCC 9372) spores are killed off if the sterilization cycle has been efficient: in this case the medium's colour remains violet/clear even after incubation at 30-35 °C (86-95 °F) for the selected time.

If the sterilization cycle has not been efficient, spores partially survive and the tube's content turns yellow/turbid after incubation at 30-35 °C (86-95 °F) for the selected time. The tube inoculated with the strip contained in the envelope, not submitted to the sterilization cycle and used as spore growth control, has to turn yellow/turbid after incubation. On the contrary, the test must to be repeated after having investigated causes of the negative result.

EVALUATION TABLE		
MEDIUM COLOUR	SPORE	STERILIZATION
Violet / Clear	Killed off	Successful
Yellow / Turbid	Vital	Unsuccessful

STORAGE

Store the product at 2-8 °C: in these conditions it maintains its validity until the expiry date indicated on the label.

WARNING and PRECAUTIONS

The product is not classified as hazardous by current legislation and does not contain harmful substances in concentrations of $\geq 1\%$. The product must be used only by properly trained operators.

DISPOSAL of WASTE

After use, sterilize the positive tubes (yellow/turbid) in autoclave at 121 °C for at least 30 minutes and eliminate them in accordance with the procedures of the laboratory.

REFERENCES

- United States Pharmacopoeia latest edition.
- Deutsches Arzneibuch latest edition.
- European Pharmacopoeia latest edition.
- ISO 11138 and EN 866 latest edition.



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PRODUCT SPECIFICATIONS

NAME STRIP CONTROL BAT E2

PRESENTATION

Strips inoculated with a predefined concentration of *Bacillus atropheus* (ATCC 9372) spores
STERITEST MEDIUM: tubes containing 4 +/- 0.5 mL fo medium.

STORAGE

2-8°C.

PACKAGING

CODE	CONTENT	PACKAGING
91069	20 strips	Each strip in thermically soldered envelope 20 envelopes in thermically soldered envelope
	20 STERI-TEST MEDIUMtubes (4 mL x 20)	20 envelopes + 20 tubes in cardboard boxes
	1 Instruction sheet	
	1 Certificate of Performance	

TECHNICAL PROPERTIES

STRIPS

Primary packaging: Envelope composed by medical paper and plastic laminate.

Spore carrier: Paper strip (approximately 38 mm x 6 mm)

Species: *Bacillus atropheus* ATCC 9372

Mean Population Recovery: 1×10^2 - 5×10^2 spores/ strip

Purity: Bacterial contaminates less than 1 percent 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).

Resistance data: decimal reduction time (D-Value); survival time and kill time.

STERI-TEST MEDIUM

pH: 7, 4 +/- 0.1

Fill volume: 4,0 +/- 0,5 mL

Cap dimensions: approximately 15+/- 1 mm (screw cap)

Tube height: approximately 61 +/-1 mm

Growth promotion: meets U.S.Pharmacopoeia Revision XXIII guidelines

Color : violet (color change to yellow and/or turbidity indicates bacterial growth)

USE

Biological indicators **STRIP CONTROL BAT E2** are used for validation, re-validation and process monitoring of dry heat and ethylene oxide sterilizers.

TECHNIQUE

Refer to technical sheet of the product.

APPEARANCE

Strips are white in colour. The medium is violet, clear.

QUALITY CONTROL

1. Control of general characteristics, label and print
2. Purity: < 1 % contamination. No moulds
3. Heat shocked population: $1-5 \times 10^2$ Spores / strip
4. D_{EO} 600 ± 30 mg/L, 60% \pm 10% RH, 54 ± 1 °C) = 2,6-4,5 minutes
5. D_{DH} (160 ± 1 °C) = 1,0-3,0 minutes
6. Growth in Steri Test Medium 30-35 °C for 18-24 hours; medium change color from violet/clear to yellow/turbid

SHELFLIFE

3 year

TABLE OF SYMBOLS

Manufacturer	Contains sufficient for <n> tests	Temperature limitation
Catalogue number	Fragile, handle with care	Caution, consult accompanying documents
Use by	Batch code	Do not reuse



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