



STRIP CONTROL BAT E8/E7/E6/E5/E4/E3

ENGLISH

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

DESCRIPTION

USP (United States Pharmacopoeia), EP (European Pharmacopoeia) and DAB (Deutsches Arzneibuch) standards, recommend to use bioindicators during dry heat and ethylene oxide sterilization processes.

Biological indicators **STRIP CONTROL BAT E8/E7/E6/E5/E4/E3** are special filter paper strips, inoculated with *Bacillus atropheus* (ATCC 9372) spores in predefined concentrations and contained in a special envelope. These bioindicators are used for validation, re-validation and process monitoring of dry heat and ethylene oxide sterilizers.

Biological indicators **STRIP CONTROL BAT E8/E7/E6/E5/E4/E3** 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.

PRINCIPLE

STRIP CONTROL BAT E8/E7/E6/E5/E4/E3 contain *Bacillus atropheus* (ATCC 9372) spores in predefined concentrations: E8=1-5x10⁸UFC/strip; E7=1-5x10⁷CFU/strip; E6=1-5x10⁶CFU/strip; E5=1-5x10⁵CFU/strip; E4=1-5x10⁴ CFU /strip; E3=1-5x10³ CFU /strip.

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.

INSTRUCTIONS FOR USE

- 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.

EVALUATION

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

TREATMENT OF STERILTEST MEDIUM TEST TUBES AFTER USE

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.

STORAGE

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

BIBLIOGRAPHY

See the references at the end of this document

TABLE OF SYMBOLS

See the table of symbols at the end of this document.

PRESENTATION

PRODUCT	CODE	PACKAGING	Spores: CFU/strip	D _{EO} (600 ± 30 mg/L, 60% ± 10% RH, 54 ± 1 °C)	D _{DH} (160 ± 1 °C)
STRIP CONTROL BAT E8	91059	20 envelopes + 20 Steri-Test Medium tubes	1-5x10 ⁸	2,6-4,5 minutes	> 2.5 minutes
STRIP CONTROL BAT E7	91062	20 envelopes + 20 Steri-Test Medium tubes	1-5x10 ⁷	2,6-4,5 minutes	> 2.5 minutes
STRIP CONTROL BAT E6	91063	20 envelopes + 20 Steri-Test Medium tubes	1-5x10 ⁶	2,6-4,5 minutes	> 2.5 minutes
STRIP CONTROL BAT E5	91064	20 envelopes + 20 Steri-Test Medium tubes	1-5x10 ⁵	2,6-4,5 minutes	> 2.5 minutes
STRIP CONTROL BAT E4	91065	20 envelopes + 20 Steri-Test Medium tubes	1-5x10 ⁴	2,6-4,5 minutes	> 2.5 minutes
STRIP CONTROL BAT E3	91066	20 envelopes + 20 Steri-Test Medium tubes	1-5x10 ³	2,6-4,5 minutes	> 2.5 minutes

D value for ethylene oxide (D_{EO}) is calculated with the MPN and SC methods with 600±30 mg/L of ethylene oxide, at a temperature of 54±1°C, with 50-70% humidity.
D value for dry heat (D_{DH}) is calculated with MPN method at a temperature of 160±1°C.