OXI CONTROL E6 STRIP

Biological indicators of H_2O_2 vapour superficial sterilization processes containing *Geobacillus stearothermophilus* (ATCC 7953) spores inoculated on special filter paper

DESCRIPTION

Biological indicators **OXI CONTROL E6 STRIP** are produced under strictly controlled conditions in order to satisfy the requirements indicated in the USP and EP current editions and in accordance with ISO 11138 and EN 866 standards.
These biological indicators use a support (coupon) made by special filter paper. Strip has been inoculated with *Geobacillus stearothermophilus* (ATCC 7953) spores and has been introduced into a Tyvek®/Polytene 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 coupons and meets the U.S. Pharmacoopoeia Revision XXII growth promotion guidelines.
Each package contains also a Certificate of Performance that indicates a certified population , D-value (121°C), survival time, kill time, species, lot number and expiration date.

COMPOSITION

Strips contain *Geobacillus stearothermophilus* (ATCC 7953) spores in concentration:1-5 x10^6CFU/strip.
Each coupon is contained in an envelope. Each envelope is printed with product name, lot number and expiration date.
STERI-TEST 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 are completely killed if the sterilization cycle has been efficient . In this case, during the following incubation in the STERI-TEST MEDIUM tubes, included in the package, spores are not able to grow and to modify medium's aspect.
On the contrary, in the case the sterilization process has not been efficient, spores partially survive and therefore during the following incubation will be able to grow and to modify medium's aspect.

TECNIQUE

- Before using biological indicators **OXI CONTROL E6 STRIP,** allow them to reach room temperature (about 1 hour). Strips are exposed to vapours, during sterilization, inside their original envelope.
- Put envelopes containing coupons inside the sterilization environment in the points considered the most difficult to reach and to sterilize by hydrogen peroxide vapour.
- Follow the operative instructions indicated by sterilizer manufacturer for the sterilizazion process.
  NOTE: do not cover the Tyvek® side (white side) of the biological indicator.
- At the end of sterilization/aereation process, remove the biological indicators and deliver them to the laboratory for the culture together with a not exposed control (positive control), belonging to the same batch
  In optimal conditions all culture procedures have to been performed under a laminar flow cabinet following aseptical methods.
- Submit to culture the biological indicators, opening the Tyvek®/Polytene envelope with a cooled sterile scissors and carefully transferring the coupons inside a STERI-TEST MEDIUM tube, taking them by cooled sterile tweezers and letting them fall into the medium. Ensure that the coupons are completely dipped in the medium gently shaking the tube.
- Incubate the STERI-TEST MEDIUM tubes, that contain coupons, at 55-60 °C (131-140 °F) for 7 days or for a shorter time validated by user.

INTERPRETATION OF RESULTS

Geobacillus stearothermophilus (ATCC 7953) 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 55-60 °C (131-140 °F) for the selected time.
If the sterilization cycle has not been efficient, spores partially survive and medium's colour turns yellow/turbid after incubation at 55-60 °C (131-140 °F) for the selected time.
The tube inoculated with the coupon not submitted to the sterilization cycle and used as spore growth control (positive control), has to turn yellow/turbid after incubation. On the contrary, the test must be repeated after having investigated the 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 ≥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
OXI CONTROL E6 STRIP

PRESENTATION
Strips inoculated with a predefined concentration of *Geobacillus stearothermophilus* spores.
STERI-TEST MEDIUM: tubes containing 4 +/- 0.5 mL fo medium.

STORAGE
2-8°C.

PACKAGING

CODE	CONTENT	PACKAGING
91088	20 strips	Each strip in thermically soldered envelope 20 envelopes in thermically soldered envelope
	20 STERI-TEST MEDIUM tubes (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 Tyvek paper and Polytene paper. (approximately 50 mm x 80 mm).Tyvek® side of the envelope is permeable to hydrogen peroxide vapours, while the Polytene side of the envelope is not permeable to these vapours.
Spore carrier: Paper strip (approximately 38 x 6 mm).
Species: *Geobacillus stearothermophilus* ATCC 7953
Mean Population Recovery: 1 x 10^6 -5 x 10^6 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 **OXI CONTROL E6 STRIP** are used for regular control of H_2O_2 vapour superficial sterilization cycles and validation of 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 x 10^6 Spores/ strip
4. D_{VHP} (1,6 ± 0,5 mg/l, 30 °C)): 1,5-4,0 minutes
5. Growth in Steri Test Medium 55-60°C for 18-24 hours; medium change color from violet/clear to yellow/turbid

SHELFLIFE
1 year

TABLE OF SYMBOLS

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

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