ENGLISH

OXI CONTROL E6 12980 SS

Biological indicators of H_2O_2 vapour superficial decontamination processes containing *Geobacillus stearothermophilus* (ATCC 12980) spores inoculated on stainless-steel coupons.

DESCRIPTION

USP (United States Pharmacopoeia), EP (European Pharmacopoeia) and DAB (Deutsches Arzneibuch) standards recommend to use bioindicators during decontamination processes. Biological indicators **OXI CONTROL E6 12980 SS** are used for regular control of H_2O_2 vapour superficial decontamination cycles and validation of sterilizers. These biological indicators use a stainless-steel support (coupon), that is not permeable to hydrogen peroxide. Stainless-steel coupon has been inoculated with *Geobacillus stearothermophilus* (ATCC 12980) spores and has been introduced into a Tyvek®/Polytene envelope. Tyvek® side of the envelope is permeable to hydrogen peroxide vapours, while the Polytene side of the envelope is not permeable to these vapours. Biological indicators **OXI CONTROL E6 12980 SS** 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.

PRINCIPLE

OXI CONTROL E6 12980 SS contain *Geobacillus stearothermophilus* (ATCC 12980) spores in predefined concentrations: E6 = 1-5 x 10^6 CFU/coupon.
Spores are completely killed if the decontamination cycle has been efficient. In this case, during the following incubation in an appropriate broth of growth (Steri-Test Medium tubes, ref. 20199; Tryptic Soy Broth, ref 24513), spores are not able to grow and to modify medium's aspect.
On the contrary, in the case the decontamination 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.

INSTRUCTIONS FOR USE

Before using biological indicators **OXI CONTROL E6 12980 SS,** allow them to reach room temperature (about 1 hour). Coupons are exposed to vapours, during decontamination, inside their original envelope or aseptically removed from their envelope and hanged utilizing the special hole.

Exposure of indicators

Put envelopes containing coupons or coupons without their envelopes inside the decontamination 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 sterilization process.
NOTE 1 (exposure inside the envelope): do not cover the Tyvek® side (white side) of the biological indicator.
NOTE 2 (exposure without envelope): during transfer of coupons without envelope it is essential to operate in asepsis to avoid accidental contaminations which could invalidate results.

Coupons culture

At the end of decontamination/aeration process, remove the biological indicators, with or without envelope, 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 aseptic methods.
Submit to culture the biological indicators, opening the Tyvek®/Polytene envelope with a cooled sterile scissors and carefully transferring both coupons, the exposed ones with envelope and those exposed without envelope, inside an appropriate broth of growth, 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.

Incubation

Incubate the broth tubes, that contain coupons, at 55-60°C (131-140°F) for 7 days or for a shorter time validated by user.

EVALUATION

Geobacillus stearothermophilus (ATCC 12980) spores are killed off if the decontamination cycle has been efficient: in this case the medium's colour remains violet or clear even after incubation at 55-60°C (131-140°F) for the selected time.
If the decontamination cycle has not been efficient, spores partially survive and broth is turbid. Steri-Test 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 decontamination cycle and used as spore growth control (positive control), has to turn yellow or turbid after incubation. On the contrary, the test must be repeated after having investigated the causes of the negative result.

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

1. United States Pharmacopoeia latest edition.
2. Deutsches Arzneibuch latest edition.
3. European Pharmacopoeia latest edition.
4. ISO 11138 and EN 866 latest edition.

PRESENTATION

PRODUCT	REF	PACKAGING	Spore: CFU / coupon	D_{VHP} (1,6 ± 0,5 mg/l, 30 °C)
OXI CONTROL E6 12980 SS	91195	100 coupons	1-5x10^6	1,5-4,0 minutes

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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