

STRIP Control GST E6

Biological indicators for steam sterilization processes with *G. stearothermophilus* ATCC® 7953 spores inoculated on paper strips.

DESCRIPTION

STRIP Control GST E6 are used to monitor the effectiveness of steam sterilizing process. These biological indicators (BI's) are produced under strictly controlled conditions in order to satisfy the requirements in USP, ISO 11138 and EN 866 standards.

STRIP Control GST E6 contain bacterial spores on special filter paper strips and glass test tubes with screw cap. Each tube contains a validated growth medium with pH indicator. Strips are inoculated with spores of *Geobacillus stearothermophilus* (ATCC 7953) in predefined concentrations.

A Certificate of Analysis including population, strain, D-value (121°C), Z-Value (115°C, 121°C, 124°C), survival time, kill time, lot number and expiration date is inserted in the packaging.

COMPOSITION

Strips contain *G. stearothermophilus* (ATCC 7953) spores in concentrations 1-5 x10⁶ CFU/strip. Each strip is enclosed in an envelope; lot number and expiration date are printed on each envelope.

Tubes contain 4 ± 0.5 mL of a sterile modified soybean casein digest broth with a pH indicator (Steri-Test medium); lot number and expiration date are printed on each tube.

PRINCIPLE

Spores are completely killed off after the sterilization at 121°C. If no spores survive, there is no growth during the subsequent incubation and the medium inside the ampoule remains violet. A failure in the sterilization process (lower temperature and/or shorter sterilization time), is detected by the colour change of the medium to yellow due to spores survival and proliferation of bacteria.

TECHNIQUE

1. Place one or more strips of STRIP Control GST E6 (each in its envelope) in the most challenging location of the steam sterilizer such as on the bottom shelf, near the door, and over the drain. The number of strips to be used will depend on the size of the sterilize chamber and/or regional requirements or load in the sterilizer. Typically, for autoclaves having an internal volume lower than or equal to 250 litres, two strips are used for each selected point of the autoclave. For autoclaves with volume higher than 250 litres, six or more strips can be used per point.
2. Remove the strip (still in its envelope) after sterilization cycle, aseptically open the envelope with sterile scissors or by tearing the edges, transfer the strip to a tube of Steri-Test medium included in the package.
3. Incubate the tube containing the strip at 55-60°C (131-140°F) for 7 days or for a different time validated by the user.
4. Incubate, at the same conditions of time and temperature, a tube of Steri-Test medium with a strip not submitted to the sterilization cycle and belonging to the same batch, as spore growth control (positive control).
5. Examine the Steri-Test medium and interpret the result as per EVALUATION TABLE: a colour change of medium from violet/clear to yellow/turbid indicates microbial growth and therefore an unsuccessful sterilization. On the contrary, the persistence of the initial colour of the medium (violet/clear) indicates absence of microbial growth and therefore a successful sterilization.

INTERPRETATION OF RESULTS

Geobacillus stearothermophilus (ATCC 7953) spores are killed off if the sterilization cycle has been efficient: in this case the broth contained in STRIP Control GST E6 remains violet/clear even after incubation at 55-60°C (131-140°F) for 7 days or for the selected time. If the sterilization cycle has not been efficient, spores partially survive and the Steri-Test medium turns yellow/turbid after incubation at 55-60°C (131-140°F) for 7 days or for the selected time. The Steri-Test medium 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 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

Note: Any colour change with no turbidity (the medium remains clear after incubation) indicates a successful sterilization cycle (no growth).

STORAGE

Store at room temperature (10-25°C). In these conditions the product maintains its validity until the expiry date indicated on the label.

WARNING AND PRECAUTIONS

The product does not contain hazardous substances in concentrations exceeding the limits set by current legislation and therefore is not classified as dangerous. It is nevertheless recommended to consult the safety data sheet for its correct use. The product is designed for professional use only and must be used by properly trained operators.

DISPOSAL OF WASTE

After use, sterilize positive vials (yellow/turbid) in autoclave at 121°C for at least 30 minutes and eliminate them in accordance with the procedures in 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 GST E6

PRESENTATION

Paper strips inoculated with *Geobacillus stearothermophilus* ATCC 7953 spores in predefined concentrations and glass tubes with a growth medium

STORAGE

10-25°C

PACKAGING

REF	CONTENT	PACKAGING
91055	20 unities 1 Instruction Sheet 1 Certificate of Performance	20 unities in thermally soldered envelope 20 envelopes + 20 tubes in cardboard boxes

TECHNICAL PROPERTIES

STRIP

Spore carrier type: filter paper

Spore carrier: approximately 38 x 6 mm paper strip

Species: *Geobacillus stearothermophilus* ATCC 7953

Mean Population Recovery: 1×10^6 - 5×10^6 spores/strip

Purity: Bacterial contaminates less than 1 percent of the labeled population

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

Steri-Test Medium (growth medium)

pH: 7.4 ± 0.1

Fill volume: 4.0 ± 0.5 mL

Tube: glass tube; height approximately 15 ± 1 mm (screw cap)

Growth promotion: meets USP current edition

Colour: violet (colour change to yellow and/or turbidity indicates bacterial growth)

USE

Biological indicators STRIP Control GST E6 are used for regular control of steam sterilization cycles (i.e. 15 minutes at 121°C) and control of any steam autoclave functionality

TECHNIQUE

Refer to technical sheet of the product

APPEARANCE

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










QUALITY CONTROL

- Control of general characteristics, label and print
- Purity: < 1% contamination. No moulds
- Heat shocked population: $1-5 \times 10^6$ Spores/strip
- D-Value (121°C): 1.5-4.5 minutes
- Z-Value (115°C, 121°C, 124°C): $\geq 6^\circ\text{C}$
- Growth: 55-60°C for 18-24 hours; colour change of the medium from violet/clear to yellow/turbid

SHELF LIFE

3 years

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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