

STRIP Control GST E6 (Strips)

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

DESCRIPTION

STRIP Control GST E6 (Strips) 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 (Strips) consist of paper strips 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.

PRINCIPLE

Spores are completely killed off after the sterilization at 121°C. If no spores survive, there is no growth during the subsequent incubation in a growth medium. A failure in the sterilization process (lower temperature and/or shorter sterilization time) causes spores survival and proliferation of bacteria in the medium.

TECNIQUE

- 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.
- 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 either a tube of Tryptic Soy Broth (REF 24113) or Steri Test Medium (REF 20199).
- 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.
- Incubate, at the same conditions of time and temperature, a tube of the medium with a strip not submitted to the sterilization cycle and belonging to the same batch, as spore growth control (positive control).
- Examine the medium and interpret the result as per EVALUATION TABLE: Turbidity in the medium indicates microbial growth and therefore an unsuccessful sterilization. For strips incubated in Steri Test Medium, microbial growth is also observed as a colour change of the pH indicator from violet/clear to yellow/turbid. On the contrary, no turbidity and the persistence of the initial colour of the medium 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: Tryptic Soy Broth remains clear while Steri Test Medium 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: The TSB tube shows turbidity while Steri-Test Medium turns yellow/turbid after incubation at 55-60°C (131-140°F) for 7 days or 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 show the growth of the spores after incubation. On the contrary, the test must be repeated after having investigated the causes of the negative result.

EVALUATION TABLE

Tryptic Soy Broth (TSB)	Steri Test Medium	SPORE	STERILIZATION
Clear	Violet / Clear	Killed off	Successful
Turbid	Yellow / Turbid	Vital	Unsuccessful

Note: Any colour change of the Steri Test Medium 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.



LIOFILCHEM® S.r.l.

Via Scozia, Zona Ind.le - 64026, Roseto degli Abruzzi (TE) - ITALY
Tel +39 0858930745 Fax +39 0858930330 Website: www.liofilchem.com

PRODUCT SPECIFICATIONS

NAME

STRIP Control GST E6 (Strips)

PRESENTATION

Paper strips inoculated with *Geobacillus stearothermophilus* ATCC 7953 spores in predefined concentrations

STORAGE

10-25°C

PACKAGING

REF	CONTENT	PACKAGING
91155	100 strips 1 Instruction Sheet 1 Certificate of Performance	100 strips in thermally soldered envelope

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: $1 \times 10^6 - 5 \times 10^6$ 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

USE

Biological indicators STRIP Control GST E6 (Strips) 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










QUALITY CONTROL

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

SHELFLIFE

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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