STERILtest GST E6/E5

Self-Contained Biological Indicators (SCBIs) with spores of *Geobacillus stearothermophilus* for monitoring Steam Sterilization processes.

Instructions **F**or **U**se
ENGLISH

DESCRIPTION

STERILtest GST E6/E5 are self-contained biological indicators (SCBIs) used for monitoring the efficacy of steam sterilization cycles at 121°C (250°F).

Each SCBI unit consists of a paper disc inoculated with 10^5 or 10^6 *Geobacillus stearothermophilus* (ATCC 7953) spore and a crushable glass ampoule with a sterile culture medium with pH indicator. The carrier (disc) and medium (ampoule) are contained in a thermoplastic vial with a cap permeable to steam.

STERILtest GST E6/E5 comply with ISO 11138-1, ISO 11138-3, EP and USP.

PRINCIPLE

After activation and incubation (see TEST PROCEDURE), if viable spores are present a color change to yellow and/or turbidity of the medium will result as consequence of bacterial growth. If no microbial growth occurs (no viable spores), the medium remains violet and without turbidity, indicating a successful sterilization cycle.

NOTE If prior to use, an ampoule shows signs of a visual color change or turbidity, it should be autoclaved and discarded.

TEST PROCEDURE

1. Place one or more SCBI units in the most challenging location of the steam sterilizer such as on the bottom shelf, near the door, and over the drain. SCBIs may be placed inside representative materials or within the sterilize chamber directly. The number of vials to be used will depend on the size of the 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 vials are used for each selected point of the autoclave. For autoclaves with volume higher than 250 litres, six or more vials can be used per point. Run the cycle.
2. After sterilization (exposure), remove the SCBIs from the sterilizer and allow to cool down for at least 10 minutes. To activate, compress the plastic vial until the glass ampoule is broken allowing the spores to mix with the growth medium. Ensure the disc is immersed in the medium.
3. Activate one SCBI which has not been exposed in a sterilization process as a Positive Control. That is intended to ensure that viable spores are present on the SCBI lot.
4. After activation, incubate the SCBIs including the positive control (in a vertical position), at 55-60°C (131-140°F) for at least 24 hours or for a different time validated by the user.

INTERPRETING RESULTS

A color change of the medium from violet/clear to yellow/turbid indicates microbial growth and therefore an unsuccessful or inadequate sterilization (positive test).

No color change (violet/clear) indicates the spore were killed in the sterilization process, which means that the sterilization was achieved (negative test).

STORAGE

Store at room temperature (10-25°C). Do not use the product beyond its expiry date on the label or if product shows any evidence of contamination or any sign of deterioration. Do not refrigerate. Short excursions outside the recommended range of temperature will not impact the product performance.

SHELF LIFE

2 years.

TECHNICAL PROPERTIES

Spore Carrier: 6 mm diameter paper disc.

Species: *Geobacillus stearothermophilus*.

Growth Medium: Sterile modified soybean casein digest broth.

pH Indicator: Bromocresol purple.

pH: 7.4 ± 0.1

Glass Ampoule: 8 / 45 mm (diameter/height), 0.7 ml filled volume.

Thermoplastic Vial: 10 / 47 mm (diameter/height); 12 mm diameter cap with three holes and inner Tyvek disc.

PERFORMANCE CHARACTERISTICS

Mean Population Recovery: 1.0 x 10^5 to 5.0 x 10^5 CFU per disc (**E5**); 1.0 x 10^6 to 5.0 x 10^6 CFU per disc (**E6**).

Purity: No evidence of contaminations present in sufficient numbers to adversely affect the finished product.

$D_{121°C} \geq$ 1.5 minutes.

Z-value $\geq$ 6°C.

Steam Resistance Assessment testing is performed by exposing STERILtest GST E6/E5 at 121°C ± 0.5°C in saturated steam. Additional D-value assessment at 115°C ± 0.5°C and 124°C ± 0.5°C are performed for calculation of Z-value.

Each pack is accompanied by a Certificate of Analysis (CoA) which provides the lot-related information including strain, population, purity, resistance (D-value), survival time, kill time and expiration date.

WARNING AND PRECAUTIONS

For professional use only. Operators must be trained and have certain experience in the laboratory methods. Please read the instructions carefully before using this product. Reliability of assay results cannot be guaranteed if there are any deviations from the instructions in this document.

Consult the Safety Data Sheet (SDS) for information regarding hazards and safe handling practices.

DISPOSAL OF WASTE

Autoclave for not less than 30 minutes at 121°C or per validated disposal cycle prior to discard. Disposal of waste must be carried out according to national and local regulations in force.

REFERENCES

1. ISO 11138-1 Sterilization of health care products - Biological indicators - Part 1: General requirements.
2. ISO 11138-3 Sterilization of health care products - Biological indicators - Part 3: Biological indicators for moist heat sterilization processes.
3. EP chapter 5.1.2 Biological indicators and related microbial preparations used in the manufacturer of sterile products.
4. USP <55> Biological indicators - Resistance Performance Tests.

Product	Population	Packaging	Ref.
STERILtest GST E5	10^5	100 units	91101
STERILtest GST E6	10^6	100 units	91100

There may be additional product ref. numbers as well. For an updated listing of available products, visit **liofilchem.com**

TABLE OF SYMBOLS

LOT Batch code	Use by	Contains sufficient for <n> tests
REF Catalogue number	Fragile, handle with care	Consult Instruction For Use
Manufacturer	Temperature limitation	Do not reuse

This IFU document and the SDS are available from the online Support Center:

liofilchem.com/ifu-sds

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