Steril Control BAS E6

Biological indicator ampoule with spores of *Bacillus subtilis*
for monitoring Low Temperature Steam Sterilization processes.

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

DESCRIPTION

Steril Control BAS E6 ampoule is a biological indicator (BI) used for monitoring the efficacy of low temperature (110-118°C) steam sterilization cycles.

Each BI unit consists of 10^6 *Bacillus subtilis* (ATCC 35021) spores suspended in a sterile culture medium with pH indicator. The spore/medium suspension is contained in a thin-walled, pharmaceutical-grade glass ampoule.

Steril Control BAS E6 complies with ISO 11138-1, ISO 11138-3, EP and USP.

PRINCIPLE

After 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 red-orange 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 BI units in the most challenging location of the steam sterilizer such as on the bottom shelf, near the door, and over the drain. Ampoules may be placed inside representative materials or within the sterilize chamber directly. Run the cycle.
2. After sterilization (exposure), remove the ampoules from the sterilizer and allow to cool down at least to incubation temperature.
3. Incubate the BIs including the Positive Control, i.e. an ampoule that has not been exposed in a sterilization process (in a vertical position), at 35-39°C for at least 72 hours or for a different time validated by the user.

   NOTE 1 Ampoules can be incubated in either a water bath or standard bacteriological incubator.

   NOTE 2 The Positive Control is intended to ensure that viable spores are present on the BI lot.

   NOTE 3 A Negative Control (ref. 91043 only), i.e. an ampoule the contains the medium without spores, may be placed in the sterilizer load along with the other BI units. It is used to determine if color changes are caused by thermal degradation. Following incubation, the ampoule that contains the spore/medium suspension is compared to the negative control ampoule. If there is not a significant change in the color of the two ampoules, the result is recorded as negative. On the contrary, the result is recorded as positive.

INTERPRETING RESULTS

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

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

STORAGE

Store refrigerated at 2-8°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. Short excursions outside the recommended range of temperature will not impact the product performance.

NOTE Any temperature between 15°C and 57°C may cause spores of *Bacillus subtilis* to germinate.

SHELF LIFE

2 years.

TECHNICAL PROPERTIES

Species: *Bacillus subtilis*.

Growth Medium: Sterile modified soybean casein digest broth.

pH Indicator: Phenol red.

pH: 7.3 ± 0.2

Glass Ampoule (ref. 91011): 13 / 70 mm (diameter/height), 4 ml filled volume.

Glass Ampoule (ref. 91043): 10 / 58 mm (diameter/height), 1 ml filled volume.

PERFORMANCE CHARACTERISTICS

Mean Population Recovery: 1.0 x 10^6 to 5.0 x 10^6 CFU per ampoule.

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

Steam Resistance Assessment testing is performed by exposing Steril Control BAS E6 at 110°C ± 0.5°C, 118°C ± 0.5°C and 121°C ± 0.5°C in saturated steam. D-value is determined using Fraction Negative method.

Z-value is calculated using 110°C, 118°C and 121°C D-values.

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.
Steril Control BAS E6 ampoule	10^6	50 ampoules x 4 ml	91011
Steril Control BAS E6 ampoule	10^6	50 ampoules x 1ml + 10 negative controls	91043

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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