

## STRIP CONTROL PUM E6

Biological indicators of irradiation sterilization processes containing *Bacillus pumilus* (ATCC 27142) spores inoculated on special filter paper strips

### DESCRIPTION

Biological indicators **STRIP CONTROL PUM E6** are produced under strictly controlled conditions in order to satisfy the requirements indicated in the USP current edition and in accordance with ISO 11138 and EN 866 standards.

These biological indicators are special filter paper strips, inoculated with *Bacillus pumilus* (ATCC 27142) spores in predefined concentrations and contained in a special envelope.

Each package contains a culture medium, STERI-TEST MEDIUM, in glass test tubes with screw cap closures. The medium is validated for use with strips and meets the U.S. Pharmacopoeia Revision XXII growth promotion guidelines.

Each package contains also a Certificate of Performance that indicates a certified population, D-value (121°C), survival time, kill time, species, lot number and expiration date.

### COMPOSITION

Strips contain *Bacillus pumilus* (ATCC 27142) spores in concentrations: 1-5 x10<sup>6</sup>CFU/strip.

Each strip is contained in an envelope. Each envelope is printed with product name, lot number and expiration date.

STERI-TEST MEDIUM is a sterile modified soybean casein digest broth with a pH indicator.

Each tube is printed with product name, lot number and expiration date.

### PRINCIPLE

Spores in the strips are completely killed off during irradiation sterilization process, if the process has been efficient. In this case the aspect of Steri-Test Medium (included in the package), inoculated with strips and incubated for a suitable time will remain unchanged: violet/clear. On the contrary, if the sterilization process has not been efficient, spores will partially survive and STERI-TEST MEDIUM turns : from violet/clear to yellow/turbid.

### TECHNIQUE

- Take one or more strips, from the package leaving them inside their original envelope.
- Put a suitable number of envelopes with the strips on the critical points of material to sterilize.
- Remove envelopes after sterilization cycle and open them aseptically with a steril scissors or by tearing the edges.
- Transfer aseptically each strip from its envelope to STERI-TEST MEDIUM tube included in the package.
- Incubate tubes containing strips at 30-35 °C (86-95 °F) for 7 days or for a shorter time validated by user.
- Incubate, at the same conditions of time and temperature, a strip contained in the envelope not submitted to sterilization cycle, belonging to the same batch, as spore control growth (positive control).
- Examine tube medium's colour and interpret results as per **EVALUATION TABLE**: a change of medium's colour from violet/clear to yellow/turbid indicates a microbial growth and therefore an unsuccessful sterilization. On the contrary the persistence of medium's initial colour (violet/clear) indicates absence of microbial growth and therefore a successful sterilization.

### INTERPRETATION OF RESULTS

*Bacillus pumilus* (ATCC 27142) spores are killed off if the sterilization cycle has been efficient : in this case medium's colour remains violet/clear even after incubation at 30-35 °C (86-95 °F) for the selected time.

If the sterilization cycle has not been efficient, spores partially survive and tube's content turns yellow/turbid after incubation at 30-35 °C (86-95 °F) for the selected time.

The tube inoculated with the strip contained in the envelope not submitted to the sterilization cycle and used as spore control growth, has to turn to yellow/turbid after incubation. On the contrary, the test must be repeated after having investigated about causes of the negative result.

| EVALUATION TABLE |            |               |
|------------------|------------|---------------|
| MEDIUM COLOUR    | SPORE      | STERILIZATION |
| Violet / Clear   | Killed off | Successful    |
| Yellow / Turbid  | Vital      | Unsuccessful  |

### STORAGE

Store the product at 2-8 °C: in these conditions it maintains its validity until the expiry date indicated on the label.

### WARNING and PRECAUTIONS

The product is not classified as hazardous by current legislation and does not contain harmful substances in concentrations of ≥1%. The product must be used only by properly trained operators.

### DISPOSAL of WASTE

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.

### 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** Bacteriology Products

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## PRODUCT SPECIFICATIONS

### NAME

STRIP CONTROL PUM E6

### PRESENTATION

Strips inoculated with a predefined concentration of *Bacillus pumilus* spores.  
STERI-TEST MEDIUM: tubes containing 4 +/- 0.5 mL of medium.

### STORAGE

2-8°C.

### PACKAGING

| CODE  | CONTENT                                 | PACKAGING                                                                                    |
|-------|-----------------------------------------|----------------------------------------------------------------------------------------------|
| 91072 | 20 strips                               | Each strip in thermically soldered envelope<br>20 envelopes in thermically soldered envelope |
|       | 20 STERI -TEST MEDIUM tubes (4 mL x 20) | 20 envelopes + 20 tubes in cardboard boxes                                                   |
|       | 1 Instruction sheet                     |                                                                                              |
|       | 1 Certificate of Performance            |                                                                                              |

### TECHNICAL PROPERTIES

#### STRIPS

**Primary packaging:** Envelope composed by medical paper and plastic laminate (approximately 50 mm x 100 mm)

**Spore carrier:** Paper strip (approximately 38 mm x 6 mm)

**Species:** *Bacillus pumilus* ATCC 27142

**Mean Population Recovery:**  $1 \times 10^6$  -  $5 \times 10^6$  spores/ strip

**Purity:** Bacterial contaminates less than 1 percent of the labeled population; this is the detection limit using the pour plate method with an aliquot that yields at least 100 colony forming units (CFU).

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

#### STERI-TEST MEDIUM

**pH:** 7, 4 +/- 0.1

**Fill volume:** 4,0 +/- 0,5 mL

**Cap dimensions:** approximately 15 +/- 1 mm (screw cap)

**Tube height:** approximately 61 +/- 1 mm

**Growth promotion:** meets U.S. Pharmacopoeia Revision XXIII guidelines

**Color:** violet (color change to yellow and/or turbidity indicates bacterial growth)

### USE

Biological indicators **STRIP CONTROL PUM E6** are used for validation, re-validation and process monitoring of irradiation sterilizers.

### TECHNIQUE

Refer to technical sheet of the product.

### APPEARANCE

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

### 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 : 1,0-2,0 kGy
5. Growth in STERI -TEST MEDIUM 30-35°C for 18-24 hours; medium change color from violet/clear to yellow/turbid

### SHELF LIFE

1 year

### 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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