

STERITEST-STRIP

Biological indicator on inoculated strips of steam sterilization process

TEST SUMMARY

Steritest-strip is a biological indicator based on strips inoculated with *Geobacillus stearothermophilus* ATCC 7953 spores for the control of steam sterilization process at 121°C / 134°C.

The strip is inserted in an autoclave and, at the end of the sterilization cycle, it is incubated in a TSB test tube or in another suitable cultural medium which allows the growth of *Geobacillus stearothermophilus*. By verifying the strain growth it is therefore possible to determine if the sterilization cycle was successful.

The thermoresistance of the spores inoculated on the strips is such that they survive after a treatment in autoclave for 6 minutes at 121° ± 1°C (1 Atm), while they die after 15 minutes at 121° ± 1°C (1 Atm).

Geobacillus stearothermophilus ATCC 7953 is considered a biological indicator of absolute tranquillity and security due to its bacteriological and biological characteristics. This strain isn't pathogenic nor toxic, does not show any pyrogenic activity and compared to other microorganisms, it doesn't cause any contamination in laboratories.

This product is manufactured according to Italian Official and European Pharmacopeia.

HOW TO USE

To control the sterilization process, pick a strip taking care that the external slipcover is not opened, and place it in an autoclave where the sterilization conditions are more critical (f. e. on the bottom of the autoclave where air sacks can develop or in the middle of garments packages or in the baskets).

To control the sterilization process of the material sterilized in containers bigger than the ones of the strips, the best results are obtained inserting the strip and its external slipcover inside these containers (vials, bottles, etc.).

The number of strips to be used depends on the autoclave viability and reliability of the required analytical results. It is advisable to utilize not less than two strips for autoclaves up to 200 lt. and not less than six strips for autoclaves over 200 lt.

After the sterilization process, the strip should be recovered by means of sterile tweezers in asepsis conditions, taken out of its external slipcover and put into a vial/bottle containing suitable cultural medium for the growth of *Geobacillus stearothermophilus* and closed.

Incubate at 55°C (the best temperature is between 55 and 60°C) for 24-48 hours, using as a control a strip not subject to sterilization put in a vial/bottle with medium, and then check eventual strain growth.

RESULTS INTERPRETATION

Absence of a strain growth in the vial/bottle after incubation indicates that sterilization has occurred.

Presence instead of a strain growth in the vial/bottle after incubation indicates a sterilization failure.

The vial/bottle with the medium and the control strip must show a strain growth. In case of no strain growth, the test must be redone.

REAGENT

Strip: paper strip inoculated with a standardised quantity of *Geobacillus stearothermophilus* ATCC 7953 spores in a slipcover.

WARNING

- Use only with steam autoclaves, do not use with other sterilization systems (dry, ethylene oxide, gas-plasma, etc...).
- Sterilize all used material before disposing of it in order to avoid dispersion of spores in the environment.

STORAGE

Keep the strips at 4-30°C.

REAGENTS REQUIRED BUT NOT SUPPLIED

Test tubes/bottles with suitable liquid cultural medium (f.e. TSB) for the growth of *Geobacillus stearothermophilus*.

PACKAGING

CODE AT00190 (100 test)
Strips 100 pieces

REFERENCES

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


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USP XX, 1038, 1979.

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SYMBOLS

-  Lot of manufacturing
-  Code number
-  Storage temperature interval
-  Expiration date (year - month)
-  Warning, read enclosed documents
-  Read the directions
-  Biological risk

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