

STERITEST-PLASMA

Biological indicator of sterilization process using hydrogen peroxide / gas plasma

TEST SUMMARY

Steritest-Plasma is a biological indicator made of a protective bag containing a disk inoculated with *Geobacillus stearothermophilus* ATCC 7953 in a standardized quantity.

The sterilizing agent passes through the protective bag acting on the population of spores inoculated on the disk.

At the end of the sterilization process the disk is transferred on the dedicated medium in order to verify actual sterility.

The used strain is not pathogenic and does not produce toxins..

HOW TO USE

Before performing the sterilization process control, ensure that the protective bag containing the disk is intact.

To control the sterilization process put a bag containing the disk, without opening it, in the sterilizer and perform a normal sterilizing process.

N.B. The vials containing the medium must not be put in the sterilizer.

To verify the effective sterilization follow these instructions:

After the sterilization process take out the bag and using sterile tweezers, in asepsis condition, extract the disk e put it in a vial containing medium and plug it.

Incubate the vial at 55°C (the best temperature is between 55 and 60°C) for 24-48 hours, using as a control a vial containing medium in which a disk not submitted to sterilization has been added.

REAGENTS

Disk: Synthetic disk inoculated with bacterial spores of *Geobacillus stearothermophilus* ATCC 7953, in standardized quantity.

Vial with medium Violet colored specific liquid medium

INTERPRETATION OF RESULTS

The absence of strain growth with the original colour after the incubation indicates that sterilization has taken place.

The growth of strain with the turning of the colour to yellow indicates sterilization failure.

The control vial should become cloudy and the medium must change to yellow.

If the incubation of the vials is continued for more than 72 hours you can obtain a degeneration of yellow back to the original colour; in this case the reading of the result should be based only on the turbidity.

WARNING

After usage and before disposal the Steritest-plasma vials where bacterial growth and colour changing of the medium can be seen must be sterilized in autoclave or in alternative ways in order to avoid spore dispersion.

Product in accordance with UNI ISO 11138 and Italian Official Pharmacopeia XII/European Pharmacopeia 6th edition..

STORAGE

Keep the Steritest-Plasma at 4-30°C.

PACKAGING

CODE AT00650 (10 tests)

Disks 10
Vials containing medium 10 x 1 ml

REFERENCES

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




Lena e coll.: Il farmaco, Ed. Pr., 32, 172, 1977.

USP XX, 1038, 1979.

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SYMBOLS

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

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