

STERICOLOR-TEST

Biological indicator of steam sterilization process 121°C – 134°C

TEST SUMMARY

Stericolor-Test is a biological indicator containing *Bacillus stearothermophilus* ATCC 7953 spores in suspension with an indicator of colour change in cultural medium.

The heat resistance of spores, allows them to survive after a treatment in an autoclave for 6 minutes at 121° ± 1° C (1 Atm), while they die after 15 minutes at 121° ± 1°C (1 Atm).

The Stericolor-test is used to control the sterilizing capacity of a sterilization process by autoclaving at 121°C - 134°C. as described in the monograph 5.1.2. European Pharmacopoeia 6.0.

The *Bacillus stearothermophilus* ATCC 7953 is considered a biological indicator of absolute tranquillity and security due to its bacteriological and biological characteristics.

This strain is not pathogenic, is not toxic, has not pyrogens activity and, compared with other microorganism, doesn't give any contamination of laboratory.

Product manufactured according to Italian Official Pharmacopoeia and European Pharmacopoeia.

HOW USE

To control the sterilization process, place the stericolor test where the sterilization conditions are more critical (in the middle of package or baskets of gauze, etc.).

To control the sterilization process of material sterilized in containers, the vials, for best results, have to put into the same container (bottle, etc).

The number of vials to be used depends by conditions of the autoclave viability and reliability of analytical results required. It is advisable to utilize not less than two vials for autoclaves up to 200 lt, and not less than six vials for autoclaves above 200 lt.

After the process of sterilization, the Stericolor-test vials should be recovered and incubated at 55 ° C (the optimum temperature is between 55 and 60 ° C for 24-48 hours, using one unsterilized vial for control).

To avoid breakage of the Stericolor-test vials, with consequent contamination of the environment, they must be adequately protected. It is therefore advisable to use special aluminium containers to protect, supplied on request.

REAGENT

Vial: Medium with suspension containing spores of *Bacillus stearothermophilus* ATCC 7953, an indicator of pH, carbohydrate.

RESULTS INTERPRETATION

The absence of strain growth with the original color after the incubation indicates that sterilization is occurred.

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

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

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

WARNING

The vials of Stericolor-test, showing growth of bacteria and turning of medium must be sterilized before being eliminated to avoid dispersion of spores into the environment.

STORAGE

Keep the Stericolor-test at 4-30°C.

PACKAGING

CODE AT00100 (10 vials)

Stericolor-test vials 10 x 1 ml

CODE AT00110 (24 vials)

Stericolor-test vials 24 x 1 ml

REFERENCES

Brewer J.H., McLaughlin C.B. . Bact. Proc. Am. Soc. Micr., 54th General Meeting – Pitsburg, May 2-7-1954, pag. 28.

Brewer J.H., Mckayghlin C.B.: J. Pharm. Sc., 50, 171, 1961.

Developments in Biological Standardization vol. 23 – International Symposium on Sterilization and sterility testing of biological substances – Editors: R.H. Ragamey (Geneva), F.P. Gallardo (Madrid) and W. Hennessen (Marburg/Lahn).








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

USP XX, 1038, 1979.

MANUFACTURER

LTA s.r.l.
Via Milano 15/F
20060 Bussero (Milan) ITALY
tel. +39 02 95409034
fax. +39 02 95334185
e-mail. info@LTAonline.it
website. http://www.LTAonline.it

SYMBOLS

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

Mod. 01.06 (ver. 1.7 – 26/06/2017)