

STERICOLOR-TEST

Biological indicator of steam sterilization process

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 Stericolor test is used to monitor the effectiveness of autoclave steam sterilization cycles (usually at 121 ° C to 134 ° C).

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 the Stericolor-test must be placed inside the autoclave in the sites where the sterilization conditions are considered critical (for example: on the bottom of the autoclave where air pockets are suspected, all inside of packages of clothes, racks, etc.)

For the control of the sterilization process of material contained in recipients with dimensions greater than the indicator vials, the best method of use is by inserting the Stericolor-test inside the containers (bottle, bottle, etc.).

The number of vials to be used is at the discretion of the operator based on the size of the autoclave, its characteristics and the reliability of the required analytical result.

At the end of the sterilization process the Stericolor-test vials should be recovered and incubated at 57°C (55°C - 60°C) for 24-48 hours, using an unsterilized vial as a control.

Handle with Care To avoid breakage of the Stericolor-test vials, with consequent contamination of the environment.

REAGENT

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

RESULTS INTERPRETATION

After 24 hours, check the growth of the strain with the color change from violet to yellow. This is an indication of lack of sterilization.

In the absence of color change, incubate for up to 48 hours.

The absence of growth of the strain, after incubation, with maintenance of the initial violet color is an indication of sterilization.

The control vial can become turbid and the medium must turn yellow.

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

Mod. 01.06 (ver. 1.8 – 13/12/2018)