

D.H.S.C.T. DRY HEAT STERILITY COLOUR TEST

1 - INTENDED USE

Biological indicator for the validation and routine monitoring of dry heat sterilization process.

2 - PRINCIPLE OF THE METHOD AND EXPLANATION OF THE PROCEDURE

D.H.S.C.T. (Dry Heat Sterility Colour Test) is a biological indicator prepared with a paper disk containing *Bacillus atrophaeus* (*Bacillus subtilis* var. *niger*) ATCC 9372 dried spores, and a medium with a pH indicator.

This strain is not pathogenic and is not a toxin producer.

The heat resistance of spores in the bottle allows them to survive after a treatment by dry heat for 10-20 minutes at 160° C, while they die after exposure for longer periods of time and at higher temperatures.

Product manufactured according to Italian Official Pharmacopoeia and European Pharmacopoeia.

3 - MATERIALS PROVIDED - PACKAGING

Product	Type	REF	Pack
D.H.S.C.T.	dried spores on paper disk	9100200	10 vials with paper disk + 10 medium vials (1 mL)

Medium appearance pink colour

4 - TEST PROCEDURE

To control the sterilization process by dry heat put into the corners of the sterilizer one or more vials of D.H.S.C.T. containing the paper disk, where the conditions for sterilization are critical and generally in those areas where sufficient or uniform heat doesn't arrive.

The number of disk-vials to be used is function of the practicability of the sterilizer and the degree of reliability required; it is advisable to utilize 1-2 vials per sterilizer for laboratory use, and utilize not less than 4-5 per sterilizer for industrial use.

NB The medium vials included in the package should not be placed in the sterilizer.

1. After the sterilization process, recover the disk-vial.
 2. By means of a sterile syringe and in aseptic conditions, withdraw the medium contained into a medium-vial not exposed to heat, and discharge it into the disk-vial recovered from the sterilizer after the sterilization process.
 3. Incubate the disk-vial with the addition of medium at 35°C for 48 hours.
 4. As a control use a disk-vial not exposed to heat, with the addition of the culture medium
- Before the addition of medium into the disk-vial verify the colour that must be pink.

5 - READING AND INTERPRETATION

The turning of the medium from pink to pale yellow colour and the presence of turbidity into the disk-vial incubated as described above, shall be interpreted as a failure of the sterilization process.

The maintenance of the original pink colour and the absence of bacterial growth shall be interpreted as a correct sterilisation process.

The control vial, with the paper disk not exposed to heat and filled up with medium, must show a colour change of the medium from pink to yellow and a turbidity.

6 - PRECAUTIONS AND WARNINGS

- D.H.S.C.T. vials showing bacterial growth and/or a colour change of the medium must be sterilized before being eliminated to avoid dispersion of spores into the environment.
- The Certificates of Analysis and the Safety Data Sheets are available on the website www.biolifeitaliana.it.
- The information provided in this document has been defined to the best of our knowledge and ability and represents a guideline for the proper use of the product but without obligation or liability. In all cases existing local laws, regulations and standard procedures must be observed for the examination of samples collected from human and animal organic districts, for environmental samples and for products intended for human or animal consumption. Our information does not relieve our customers from their responsibility for checking the suitability of our product for the intended purpose.













7 - STORAGE CONDITIONS

Store D.H.S.C.T. at room temperature (10-30°C)

8 - REFERENCES

- Biochim. Biophys. Acta, 62, 145, 1962.
- Appl. Microbiol., 14, 732, 1966.
- Principles and Methods of Sterilisation in health sciences, II ed., Perkins, J.J., Springfield, Illinois: Charles C. Thomas, 1969.

TABLE OF APPLICABLE SYMBOLS

 REF or REF Catalogue number	 LOT Batch code	 Manufacturer	 This side up	 Store in a dry place	 Fragile
 Temperature limitation	 Content sufficient for <n> tests	 Consult Instructions for Use	 Use by	 Biological Risk	 For single use only

REVISION HISTORY

Version	Description of changes	Date
Revision 3	Content update	2025/03

Note: minor typographical, grammatical, and formatting changes are not included in the revision history.