

Cytotoxicity

(Exclusion of cell damage)

In this cell culture test skin cells are used to detect cell damaging substances that may leach out of the sample material. Therefore, the test allows the evaluation of the potential for cell damage. This potential is recorded as a summation parameter.

The test is no analysis for single cell damaging substances.



This test is particularly suitable for

- Medical devices made from all types of material
- Textiles in health care system

Description

The test on cytotoxicity according to **DIN EN ISO 10993-5** is the basis of numerous tests for biocompatibility under the standard series DIN EN ISO 10993 and is accredited by DAkkS at the Hohenstein Laboratories.

For this purpose an extract of the test material is prepared, which is cultivated with L 929 skin cells for several days. The cell viability respectively potential cell-toxic effect is quantitatively determined for the treated cell culture in comparison with untreated control cultures.

Customer benefit

- Requirement of CE marking
- Requirement for approval as medical product
- Product optimization
- Consumer safety

Marketing Instruments – Labels and Certificates

On passing the test the product may be awarded the certificate “Biological Safety”.

Test sample requirements

General

- When dyestuffs, auxiliaries or reviving agents are used in different quantities articles which use the highest quantity must be selected (worst-case)
- Send assembled samples as total products
- In the event of complaints, provide the product under claim for testing wherever possible (please do not send retain sample)
- Test samples must be packed individually, e.g. in plastic bags, to avoid contamination during transport
- Please indicate adequate names and specific denotations of the sample (composition of material, article number, etc.)

Quantity of material

- At least 40 g of the test sample of size of DIN A3, respectively

Duration of the test

- Normally 5 working days; the date will be confirmed upon receipt of the test sample

Test criteria

- A growth inhibition of more than 30 % in comparison with the extracting agent control is assessed as a clear cell-toxic effect