

# 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 a potential for cell damage. This potential is recorded as a sum parameter. The test is not an analysis for individual 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 the test, 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” and/or the quality label “Medically tested”.

## Test sample requirements

### General

- If dyestuffs, auxiliaries or avivages are used in different quantities, articles which use the highest quantity must be selected (worst-case)
- For ready-made samples, send the complete product
- In the event of complaints, provide the product in question for testing, if possible (please do not provide retain samples)
- Test samples must be packed individually to avoid contamination during transport, i.e. pack them separately e.g. in plastic bags
- Provide sufficiently precise designations of the test sample (material composition, item number, etc.)

### Quantity of material

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

### Duration of the test

- Usually 5-10 working days; date confirmation after receipt of 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