

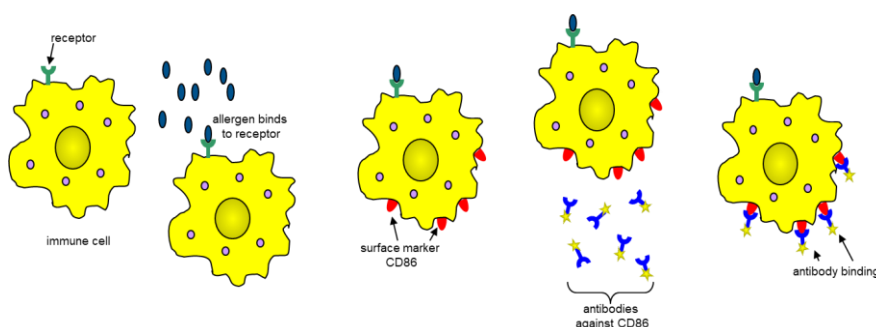
# Sensitization

In this cell culture test, the allergy potential (sensitization potential) of substances that may leach out of the sample material is determined with the help of immune cells (so-called "sentry cells"). The Sensitization Test thus permits the sample material under investigation to be assessed in terms of their potential to trigger allergies. This potential is recorded as a summation parameter. The test is no analysis for single allergens.

## Description

The Sensitization Test is a screening test for the exclusion of a sensitizing effect and a useful pretest to the standard DIN EN ISO 10993-10. The technical prerequisite for the Sensitization Test is that the Cytotoxicity Test has been passed.

An extract is prepared for the test from the sample material and this, in diluted form, is incubated for 24 hours with immune cells. By means of sensitizing substances, the cells are stimulated to form surface markers that bond to the specific fluorescently labeled antibodies. The percentage of positive cells is determined from the fluorescence intensity in the flow cytometer.



## This test is particularly suitable for

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

## Customer benefit

- Product optimization
- Consumer safety
- Advertising impact
- Minimization of complaints

## Marketing Instruments – Labels and Certificates

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

## Test sample requirements

### General

- Technical prerequisite: Samples have to pass the Cytotoxicity Test
- Test samples can cover an entire group of articles. Please contact us for further information
- 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 or size of A3, respectively

### Duration of the test

- Between two and three weeks; the date will be confirmed upon receipt of the test sample

### Test criteria

- Samples with an RFI of 120 % and above are assessed as potentially sensitizing