

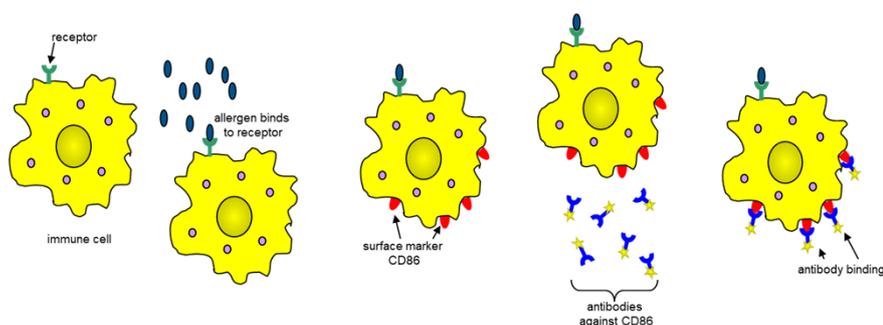
# Sensitization

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 enables an assessment of the tested sample materials regarding their potential to trigger allergies. This potential is recorded as a sum parameter. The test is not an analysis for individual allergens.

## Description

The Sensitization Test is a screening test for the exclusion of a sensitizing effect. The technical prerequisite for the Sensitization Test is that the Cytotoxicity Test has been passed.

An extract of the sample material is prepared for the test and this, in diluted form, is incubated for 48 hours with immune cells. Sensitizing substances stimulate the cells to form surface markers to which specific fluorescence-labelled antibodies are bound. The percentage of labelled cells is determined by means of the fluorescence intensity in a 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” and/or the quality label “Medically tested”.

## Test sample requirements

### General

- Technical prerequisite: Samples must pass the Cytotoxicity Test
- 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 or size of A3, respectively

### Duration of the test

- Usually 10-15 working days; date confirmation after receipt of test sample

### Test criteria

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