



# CYTOTOXICITY – ISO 10993-5 – indirect contact

Title	Assessment of the cytotoxic potential of a test element (medical device) after indirect contact
Reference	ISO 10993-5 (June 2009) and ISO 10993-12 (December 2009)
Objective	To assess quantitatively and qualitatively the cytotoxic potential of a test element after indirect contact with the surface of an agarose gel in contact with cells
Test system	Mouse lung fibroblasts – NCTC L929
Schedule	Duration of the study: 3 days Beginning: 1 week upon receipt of the sample Report: 2-3 weeks after the end of the study
Quantity	To be defined according to the type of medical device
Methodology	Determination of the cytotoxicity after contact of the test element with the surface of an agarose gel in contact with cells by staining the living cells with a vital dye (Neutral Red). Calculation of the range of cell lysis diameter (quantitative evaluation) and appreciation of the morphological aspect of the cells [qualitative evaluation]
Procedure	D-1: <ul style="list-style-type: none"><li>• Cells seeding</li></ul> D1: <ul style="list-style-type: none"><li>• Preparation of the agarose gel</li><li>• Contact of the agarose gel with cells</li><li>• Contact of the test element</li><li>• Incubation for 24 hours</li></ul> D2: <ul style="list-style-type: none"><li>• Preparation of the colouring solution</li><li>• Revelation of the cytotoxicity</li><li>• Reading</li></ul>