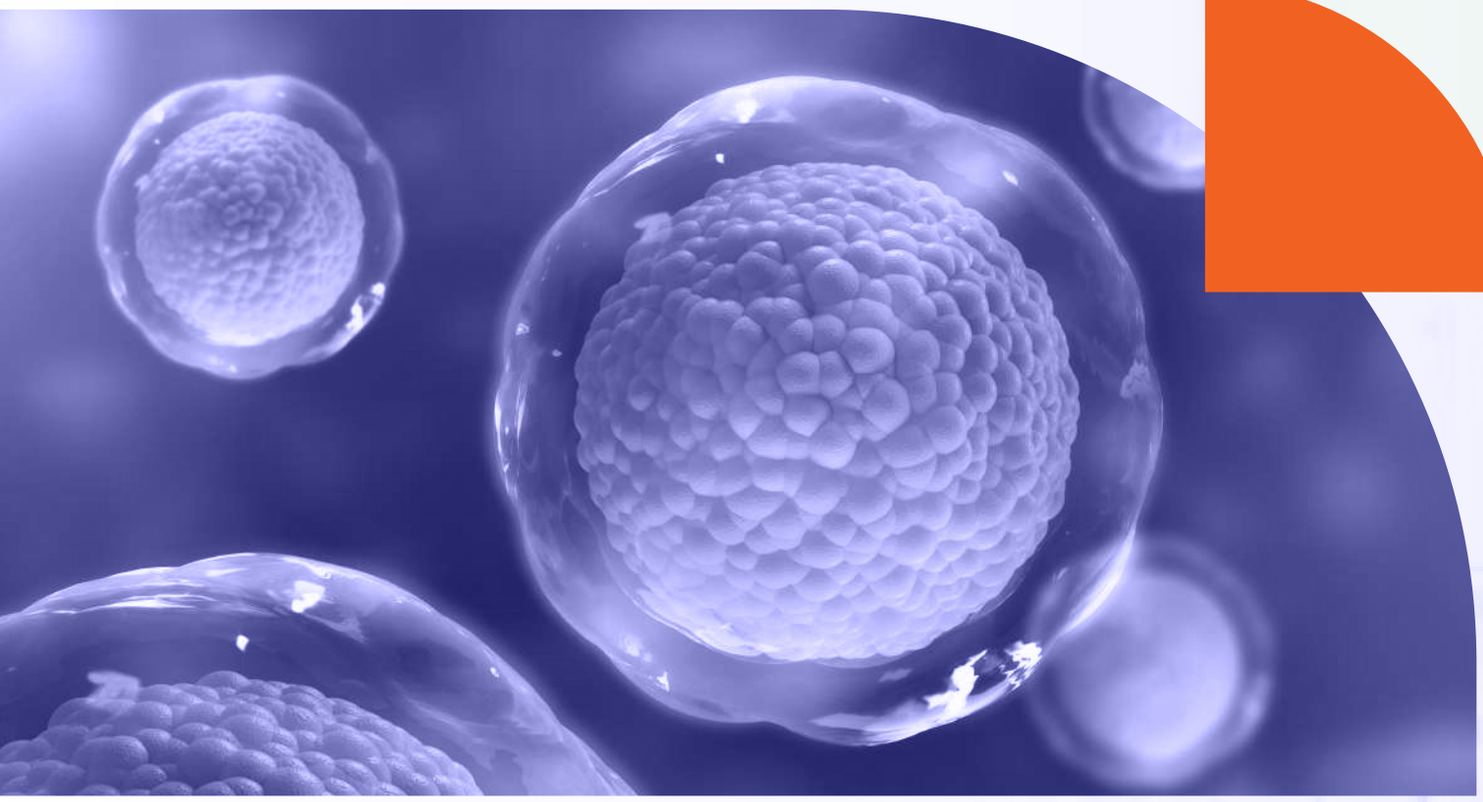
CMDC Labs

CYTOTOXICITY
(TISSUE CULTURE)



In vitro cell culture assays using isolated cells can be used to evaluate the biocompatibility of a material or leachable These procedures assess material toxicity and irritancy. They can also be used screen materials before in vivo experiments. At CMDC Labs, we can handle all of your Cytotoxicity testing needs.

Making the Unknown Known...

QUALITATIVE CYTOTOXICITY TESTS

Medical devices undergo three qualitative cytotoxicity evaluations. For low density materials like contact lens plastics, Direct Contact tests are used. This method places test material directly on cultured cells. Incubation follows. During incubation, leachable compounds from the test material can reach the cell layer. Malformation, degeneration, and lysis of test-sample cells suggest reactivity. Agar Diffusion tests are used for high-density materials like elastomeric closures. In this procedure, cultivated cells are covered with nutrient-rich agar. The test material (or a dried extract) is placed on the agar layer, and the cells are incubated. A zone of deformed, degenerative, or lysed cells implies cytotoxicity. MEM Elution assay uses diverse extracting media and extraction settings to test devices under real-world or extreme situations. The cytotoxicity of extracts can be semi-quantified. After preparation, extracts are incubated on cells. Following incubation, cells are evaluated for deformity, degeneration, and lysis. Each device component should be tested for cytotoxicity.

MTT CYTOTOXICITY TEST

Recent regulatory modifications (ANSI/AAMI/ISO 10993-5:2009) on biocompatibility for devices say qualitative cytotoxicity tests (direct contact, MEM elution, agar diffusion) are appropriate for screening, but quantitative evaluation is preferred.

ISO 10993-5:2009 Annex C refers to the MTT cytotoxicity assay, which can quantify as little as 950 cells. MTT measures mitochondrial succinate dehydrogenase's reduction of 3-(4,5-dimethylthiazol-2-yl)-2,5-diphenyl tetrazolium bromide which directly relates to cell viability. Because only living cells catalyze cellular reduction, the fraction of living cells in a solution may be quantified.

QUALITATIVE CYTOTOXICITY TESTS

- **Toxins**
- **Environmental toxins**
- **Growth-inhibiting antibodies**
- **Medical device extractables**

MTT's quantitative capabilities, diverse sample requirements, ability to use extracts or direct contact, and interpretation-free results are its main features. MTT can be done on 96-well microplates in a conventional microplate reader for quick and high throughput sample screening.

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