

Providing Sterilisation & Laboratory Services for the world's most innovative healthcare companies.

From the Blog

An Overview of Cytotoxicity Analysis

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At Medistri, we recognize the critical importance of cytotoxicity testing in the development and approval of medical devices. These tests are not merely regulatory checkboxes but are fundamental to ensure that materials used in medical devices are biocompatible and safe for direct human contact. This blog delves into the sophisticated methodologies we employ and the standards we adhere to, ensuring the highest level of safety and compliance.

Defining Cytotoxicity Testing

Cytotoxicity testing specifically measures the toxic effects that a material may exert on cellular structures, distinguishing it from broader toxicity evaluations that assess general biological harm. In the realm of medical devices, where materials often come into direct contact with human tissues, understanding these interactions at the cellular level is paramount. Our goal is to anticipate any cellular damage or death that might translate into adverse clinical outcomes.

Methodologies Employed in Cytotoxicity Testing

Medistri employs both qualitative and quantitative cytotoxicity testing methods, adapted to the specific requirements of each device and material type:

Cytotoxicity tests fall into two categories: qualitative and quantitative.

Qualitative Cytotoxicity Testing:

Qualitative tests are used to observe visible effects on cells, such as changes in growth, structure, or morphology. The three main methods are:

Agar Diffusion Test: our use of a semi-permeable agar layer allows for the diffusion of cytotoxic substances without direct contact, mimicking conditions where only diffusible components of materials pose a risk.

Direct Contact Test: applied to materials that contact body tissues directly, such as surgical implants and contact lenses, this test provides a direct assessment of material-cell interaction, offering crucial insights into immediate cytotoxic responses.

Quantitative Cytotoxicity Testing:

XTT Assay: A cornerstone of our quantitative testing, the XTT assay provides precise measurements of cell viability. This colorimetric assay involves the reduction of XTT by mitochondrial dehydrogenase of viable cells to form a purple formazan product. The intensity of this product, quantitatively measured via spectrophotometry, correlates directly with the number of metabolically active cells, providing a robust measure of cytotoxicity.



Regulatory and Standard Compliance of Cytotoxicity Testing for Medical Devices

Our testing protocols comply with the most rigorous international standards:

ISO 10993-5: This standard guides our in vitro cytotoxicity testing methods, ensuring consistency and reliability in our test results.

10993-12: This standards cover the extraction methods used for various biocompatibility tests.

FDA's Biocompatibility Guidance on Use of ISO 10993-1 : This guide highlights all FDA specific requirements for biocompatibility testing and the current interpretation of the ISO 10993 series.

Medistri's Laboratory's advanced cytotoxicity testing services are designed to support the innovation and safety of medical devices. By partnering with us, medical device manufacturers ensure not only regulatory compliance but also the highest standards of patient safety. Our expert team is equipped to handle the complex challenges of biocompatibility testing, making Medistri a trusted partner in the medical device industry.

Learn more about our cytotoxicity testing services. To discover how Medistri ensures the safety and regulatory compliance of your medical devices, visit our website [here](#) or contact our dedicated team at contact@medistri.com.

— The Medistri Team

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