

Altogen
Labs

Provider of Preclinical Research Services (GLP/non-GLP) for Drug Discovery
Efficacy and Pharm/Tox IND contract research studies (clients worldwide)
100+ Xenograft Models (validated in-house) and IND-enabling Toxicology studies
100% IP belongs to client, experienced IACUC-regulated barrier facility

Biocompatibility Testing

Contact us: info@altogenlabs.com | Read more at AltogenLabs.com
ALTOGEN® 11200 Menchaca Road 203 • Austin • TX • 78748 • USA 512-433-6177

Frequent Testing

- Altogen Labs regularly conducts testing of all medical devices to ensure that safety standards are kept at their highest standard.
- Employees are trained to maintain regularly scheduled testing in order to ensure biocompatibility.



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What is biocompatibility testing?

- **Biocompatibility testing:** The evaluation of the interaction and compatibility between a medical device and a biological system.
- This type of testing is important to do on a routine basis to ensure that medical devices are always prepared to use without the possible risk of the device having any adverse effects on its subject. This risk assessment is essential to maintain safe operation of medical devices.

ISO 10993

- Also known as: International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"
- Altogen Labs follows all guidelines posed by ISO 10993 & US FDA and keeps all medical devices to standard.
- To date, there are 12 standards created to identify potential risks and analyze information to mitigate possible risks.

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Sensitization Tests

- **Local lymph node assay (LLNA):** An *in vivo* method used to identify and analyze skin sensitization potential hazard of chemicals.
- **Beuhler Test:** An *in vivo* test that flags substances for human skin irritants/potential sensitization potential before proceeding with trials to ensure safety.

Irritation Tests

- **Primary skin irritation test:** This type of test is a mandatory SIAA test item and analyzes the presence of dermal reaction on *in vivo* animal models by administering a substance on a small scar.
- **Ocular irritation test:** Assesses any potential hazard a substance may have on a consumer's eye when it is used.

Genotoxicity tests

- **Mouse lymphoma assay (MLA):** The most commonly used cell gene mutation assay. Used for regulatory means and essential in genotoxicity testing for registration of pharmaceuticals.
- **Ames mutagenicity test:** This type of test assesses any potential mutagenic activity.

Cytotoxicity tests

- Neutral red uptake
- Colony formation
- MEM elution
- Agar overlay

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Routine Toxicity Tests

- Acute toxicity tests
- Sub-acute toxicity tests
- Chronic toxicity tests
- Sub-chronic toxicity tests

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Contact Us

- Altogen Labs provides a variety of preclinical and oncology services available at: altogenlabs.com
- All medical devices used for all projects are regularly tested for biocompatibility under the guidelines posed by ISO 10993 and US FDA.



Contact us to discuss details, timeline estimates, and price!

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