Genetic Toxicology and Alternative Toxicity Testing

Intox, a subsidiary of Aragen, has almost three decades of experience testing a wide variety of molecules including pharmaceuticals, nutraceuticals, medical deivces, pesticides and industrial chemicals.

Genotoxicity refers to the capacity for a substance to damage genetic material within cells through interactions with the DNA sequence and structure. Mutagenicity refers to the capacity for a substance to cause permanent, transmissible changes to genetic structure or amount of genetic material.

Intox offers a broad array of genotoxicity/mutagenicity studies, both in vivo and in vitro. Robust historical control data developed in our laboratories for various vehicles and positive controls convincingly supports the outcome of the experiments. We will provide you with reliable, efficient data as you screen libraries of multiple compounds for derisking your portfolio and candidate selection. Further, we will also support you with GLP safety studies as you move towards regulatory filings.

The genotoxicity testing protocols at Intox are developed and validated by our experts in regulatory toxicology. The study reports have been accepted by regulatory agencies across the globe. While experimental designs for various test items will vary with their type, the intended application and the regulatory requirements, a consultation with our toxicology and regulatory experts will create the most appropriately tailored testing strategy for your product.

The Intox- Aragen Advantage:

- OECD GLP compliant and AAALAC accredited facilities
- Experienced Cell Biologist and Cytogeneticists
- DABT and DACVP board-certified toxicologists and pathologists
- GLP toxicology solutions available across various product classes
- Capabilities of bioanalysis, chemical analysis and pathology/histopathology available onsite
- Comprehensive bioanalytical support from early method development to clinical bioanalysis
- Over 17,000 GLP studies performed to date

Intox's portfolio of Genotoxicity and Alternative Toxicity Testing:

S. No.	Name of the test	Test guideline	Test system	TAT
1.	*In Silico* tools to predict genotoxicity- Vega Software	ICHM7	Mutagenicity (Ames test) CONSENSUS model 1.0.2 Mutagenicity (Ames test) model (CAESAR) 2.1.13, (SarPy/IRFMN) 1.0.7, (ISS) 1.0.2, (KNN/Read-Across) 1.0.0	1 week
2.	Mini Ames- Non GLP	-	*Salmonella typhimurium* TA98, TA100, TA1535, TA1537 and E. coli WP2 uvrA, E. coli WP2 [pKM101]	1 week
3.	Bacterial reverse mutation test *(Ames Test)*	OECD 471	*Salmonella typhimurium* TA97a, TA98, TA100, TA102 and TA1535	1.5 months
4.	*In Vitro* Chromosomal Aberration Test	OECD 473	Human Peripheral Blood Lymphocytes	2 months
5.	Mammalian Erythrocyte Micronucleus Test (Micronuclei enumeration using automated FACS technique for increased accuracy and rapid TAT)	OECD 474	Mouse	1.5 month
6	*In Vivo* Chromosomal Aberration Test	OECD 475	Mouse	2 months
7	*In Vitro* Mammalian Cell Gene Mutation Tests Using Hprt or Xprt Genes	OECD 476	CHO-K1 Cell Lin	month
8.	*In Vitro* Micronucleus Test (Micronuclei enumeration using automated FACS technique for increased accuracy and rapid TAT)	OECD 487	Human Peripheral Blood Lymphocytes, TK6 Human Lymphoblastoid Cell line	3 weeks
9.	*In Vitro* Mammalian Cell Gene Mutation Tests using Thymidine Kinase Gene	OECD 490	L5178Y/Tk+/--3.7.2C mouse lymphoma cell line	1.5 month
Alternative Toxicity Testing				
10.	*In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)	OECD 430	Rat	3 weeks
11.	*In vitro* phototoxicity – non-GLP screening and GLP	OECD 432	BALB/c 3T3, clone A31, (ATCC) CCL163 Mouse Fibroblast cell line	3 weeks
12.	Short Time Exposure In Vitro Test Method for Identifying i) Chemicals Inducing Serious Eye Damage and ii) Chemicals Not Requiring Classification for Eye Irritation or Serious Eye Damage	OECD 491	Statens Serum Institute Rabbit Cornea Cell Line (SIRC)	1 month
13.	*In Vitro* Skin Irritation: Reconstructed Human Epidermis Test Method,	OECD 439	Reconstructed Human Epidermis	2 weeks
14.	Biological evaluation of medical devices - Tests for In Vitro cytotoxicity	ISO10993-5,12	L929 Mouse Fibroblast Cell line	2 weeks

Aragen Life Sciences is a leading contract research, development, and manufacturing organization offerings end-to-end integrated and standalone solutions for pharmaceutical, biotechnology, crop protection and industrial chemical industries. To learn more about Aragen's services or to discuss your safety assessment program with one of our experts, write to us at bd@aragen.com.

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