Genetic and Alternative Toxicity Testing for Compound Screening, Derisking and Selection

Aragen has almost three decades of experience testing a wide variety of molecules including pharmaceuticals, agrochemicals and industrial chemicals.

Genotoxicity and mutagenicity both involve damage to genetic material. Genotoxicity refers to the capacity for a substance to damage genetic information within cells. Mutagenicity refers to the capacity for a substance to cause permanent, transmissible changes to genetic structure or amount of genetic material.

Testing at Aragen will identify genotoxicity as well as mutagenicity potential of your test article. We will provide reliable, efficient data as you screen libraries of multiple compounds for derisking your portfolio and candidate selection. Additionally we will also support your OECD safety and toxicology testing as you move towards regulatory filing.

Our toxicology and safety testing protocols are designed by technical experts in their respective fields and validated by regulatory bodies. It is important to note that study design will vary based on the type of molecule, its intended application and regulatory requirements. It is crucial to consult with toxicology and regulatory experts to create an appropriately tailored testing strategy.

The Aragen Advantage:

- OECD GLP compliant and AAALAC accredited facilities
- DABT and ACVP board-certified toxicologists and pathologists
- Complete GLP safety and toxicology programs for many compound types
- Bioanalytical, pathology and histopathology performed onsite
- Comprehensive bioanalytical support from early method development to clinical bioanalysis
- Over 16,000 GLP studies performed to date

Aragen'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 month
4.	*In Vitro* Chromosomal Aberration Test	OECD 473	Human Peripheral Blood Lymphocytes	1.5 months
5.	*In Vitro* Mammalian Cell Gene Mutation Tests Using Thymidine Kinase Gene	OECD 490	L5178Y/Tk+/--3.7.2C mouse lymphoma cell line	1 month
6	*In Vitro* Mammalian Cell Gene Mutation Tests Using Hprt or Xprt Genes	OECD 476	CHO-K1 Cell Line	1 month
7	*In Vitro* Micronucleus Test (Micronuclei enumeration using automated FACS technique for rapid TAT)	OECD 487	Human Peripheral Blood Lymphocytes, TK6 Human Lymphoblastoid Cell line	2 weeks
8.	*In Vitro* Skin Corrosion: Transcutaneous Electrical Resistance Test Method (TER)	OECD 430	Rat *(Rattus norvegicus)*	2 weeks
9.	*In vitro* phototoxicity	OECD 432	BALB/c 3T3, clone A31, (ATCC) CCL163 Mouse Fibroblast cell line	2 weeks
10.	Mammalian Erythrocyte Micronucleus Test	OECD 474	Mice (Swiss albino)	1 month
11.	*In Vivo* Chromosomal Aberration Test	OECD 475	Mice (Swiss albino)	1.5 months
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 Institue Rabbit Cornea Cell Line (SIRC)	3 weeks
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.