

GENETIC TOXICOLOGY

Pharmaceuticals • Chemicals • Agrochemicals • Consumer Products

Genetic toxicology studies are required for any new drug in early development to identify compounds that can potentially cause genetic damage. These studies are also required for the registration of new chemicals for the European Union REACH (Registration, Evaluation, Authorization and Restriction of Chemical Substances) regulation.

IITRI has been providing genetic toxicology services to the pharmaceutical, biotechnology, chemical and consumer products industries for over 20 years. We offer the standard battery of *in vitro* and *in vivo* genetic toxicology tests required for new pharmaceuticals or for the testing of new chemicals. Our protocols meet ICH and OECD guidelines to support US EPA and FDA regulatory submissions. Our validated and GLP-compliant assays include dose analysis performed by our on-site analytical laboratory.

ASSAY	GENOTOXICITY TYPE	STRAINS/ SPECIES	IN VITRO/ IN VIVO
Ames Bacterial Mutation Test (OECD 471)	Bacterial reverse gene mutation	<i>E. coli</i> , <i>Salmonella</i>	<i>In vitro</i>
Mammalian Cell Mutation Test (OECD 476)	Gene mutations at the thymidine kinase (Tk) locus	Mouse lymphoma L5178Y tk+/-3.7.2C	<i>In vitro</i>
Mammalian Structural Chromosome Aberration Assay (OECD 473)	Chromosomal abnormalities	CHO, HPBL*	<i>In vitro</i>
Mammalian Cell Micronucleus Assay	Micronuclei in cells that have undergone mitosis	Mouse or rat 1 or 2 sex assays	<i>In vivo</i>
Micronucleus Assay	Micronuclei in cells that have undergone mitosis	CHO, HPBL*	<i>In vitro</i>
Neutral Red Cytotoxicity Assay (OECD 432)	Cell viability due to cytotoxicity	BALB/c-3T3 mouse fibroblasts	<i>In vitro</i>

*CHO, Chinese hamster ovary; HPBL, human peripheral blood lymphocyte.

THE IITRI ADVANTAGE

- Direct interaction with expert study directors
- Highly experienced and tenured scientific staff, providing a seasoned and stable project team
- Collaborative approach to solving challenges and optimizing performance of your program
- Flexible programs to meet your specific needs, from complete GLP test battery to individual test options
- Technical advisory and support regarding interpretation of study results and IND-enabling program design



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