

BioReliance

Toxicology Services



Genetic and Mammalian Toxicology Services

Introduction

BioReliance provides specialty toxicology services that can speedily move your product from discovery to market. We have been a scientific leader in toxicology for more than 65 years – from safety testing the first polio vaccines in the 1950's to validating new transgenic mouse models for carcinogenicity testing.

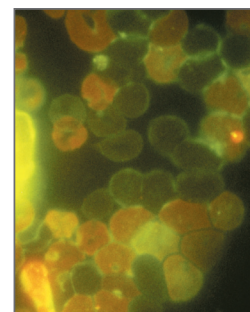
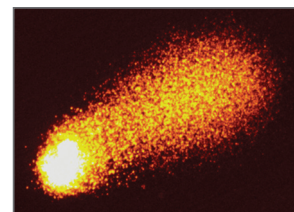
BioReliance services include a broad spectrum of in vitro and in vivo toxicology testing assays designed in accordance with international guidelines and are conducted in full compliance with GLP regulations. Our expertise uniquely qualifies us to custom design testing strategies even when they involve new or novel products. These services are provided to producers of traditional pharmaceuticals, biopharmaceuticals, medical devices, gene therapies, industrial chemicals and consumer products.

Genetic Toxicology

BioReliance offers comprehensive genetic toxicology services for the detection of toxic, mutagenic, clastogenic, and morphological transforming activity in a number of well-characterized test systems.

Non-GLP Approaches/Assays for Discovery, Early Development and Screening

Testing Type	Assay Category	Assays	Purpose of Testing/Detection
Structure-Activity Relationship (SAR)	in silico Testing	qSAR	Linking chemical structure to a chemical property
High Throughput Screening Assays	DNA/Chromosome Damage	CAN FlowScreen GreenScreen	Mode of Action Determination
	Ames	Ames II	Bacterial Mutations
Predictive Screening Assays	Ames	Mini Ames, Micro Ames, Abbreviated Ames	Bacterial Mutations
	In Vitro Mammalian Mutation	Mouse Lymphoma	Mutagenic Potential
	In Vitro Mammalian Cytogenetics	Chromosome Aberration Micronucleus	Clastogenic Potential
	DNA Damage	Comet	DNA Damage
	Cell Transformation	Bhas	Morphological Transforming Activity
	Cytotoxicity	Neutral Red Uptake (NRU)	Cytotoxicity



GLP Assays for Regulatory Submission

Testing Type	Assays	OECD TG	Purpose of Testing/Detection
Bacterial Mutation	Ames	471	Bacterial Mutations
In Vitro Mammalian Cell Gene Mutation	Mouse Lymphoma Assay	490	Mutagenicity
	HPRT Assay	476	
In Vitro Mammalian Cell Cytogenetics	Chromosome Aberration	473	Clastogenicity
	Micronucleus	487	
In Vivo Cytogenetics	Micronucleus	474	Clastogenicity
	Chromosome Aberration	475	
DNA Damage and Repair	Comet	489	DNA Damage and Repair
In Vivo Gene Mutation	Big Blue® TGR	488	Mutagenicity
	Pig-a	N/A	

BioReliance Toxicology

Toxicology Services

Mammalian Toxicology

BioReliance has extensive experience in the development and application of toxicological methodologies using animal models.

Transgenic Carcinogenicity Studies

- 5-Day Range Finder in C57Bl/6 Mice
- 28-Day Toxicity Study in C57Bl/6 Mice*
- 26-Week Carcinogenicity Study with Tg.rasH2 Transgenic Mice*

*Studies with p53+/- Transgenic Mice available upon request

General Toxicity Studies

- 28-Day Repeated-Dose Toxicity Study in Rodents and Rabbits (*), (**)
- 13-Week Subchronic Toxicity Study in Rodents

*Genotoxicity endpoints can be added to in-house 28-Day Studies

- Chromosome Aberration
- Micronucleus
- Comet
- *Pig-a*
- Big-Blue®

**A Mobile team is also available to process samples for Genotoxicity assessment after off-site studies

- Comet
- Big-Blue®
- Inhalation Studies

Analytical Services

BioReliance offers analytical services in support of toxicology studies including, method validation, formulation analysis, homogeneity and stability testing. Pharmacokinetic and Toxicokinetic analyses are also offered through Mass Spectrometry.

Formulation Support

- Analytical Method Validation
- Dosing Solution Analysis
- Stability

Toxicokinetics/Pharmacokinetics (TK/PK)

- Bioanalysis
- TK Analysis Report
- Plasma Sample Collection

Technology

- Liquid Chromatography-Mass Spectrometry (LC/MS)
- High-Performance Liquid Chromatography (HPLC)
- Gas Chromatography (GC)
- Ultraviolet-Visible Spectroscopy (UV/Vis)

Industries, Guidelines and Compliance

Pharmaceuticals, Industrial Chemicals, Agricultural Chemicals, Consumer Products, Flavors & Fragrances, Veterinary Medicine, Medical Devices

FDA, EMA, JPMA, EPA, ECHA, EFSA, METI

OECD, ICH S2(R1), REACH, ISO 10993

M7, ICH S1



Our 50,000 square foot, state-of-the-art facility and dedicated staff continue to lead and advance the field of toxicology with the implementation of the latest technologies that help clients register products internationally.

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 **BioReliance**[®]
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