

Specialized Toxicology Services

Introduction

BioReliance® services provides specialty toxicology testing that can speedily move your product from discovery to market. We have been a scientific leader in toxicology for more than 70 years – from safety testing the first polio vaccines in the 1950s, to validating new and novel genotoxicity assays.

Our 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, industrial and agricultural chemicals, medical devices, and consumer products including tobacco, flavors & fragrances.

Genetic Toxicology

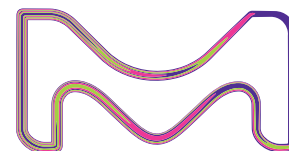
We offer comprehensive genetic toxicology services for the detection of toxic, mutagenic, clastogenic, and morphological transforming activity in a number of well-characterized test systems.

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 MultiFlow™	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

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	
Cell Transformation	Syrian Hamster Embryo (SHE)	N/A	Cell Transformation
In Vitro Mammalian Cell Cytogenetics	Chromosome Aberration	473	Clastogenicity
	Micronucleus	487	
In Vivo Cytogenetics	Micronucleus	474	Clastogenicity
	Chromosome Aberration	475	



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GLP Assays - Tier II Follow Up Assays

Testing Type	Assays	OECD TG	Purpose of Testing/Detection
DNA Damage and Repair	Comet	489	DNA Damage
	Unscheduled DNA Synthesis (UDS)	N/A	DNA Repair
In Vivo Gene Mutation	Big Blue® TGR	488	Mutagenicity
	<i>Pig-a</i>	N/A	

In Vitro Alternative Assays

Testing Type	Assays	Purpose of Testing / Detection
In Vitro Mammalian Cell Cytogenetics	3D Skin Micronucleus (RSMN)	Clastogenicity
DNA Damage and Repair	3D Skin Comet	DNA Damage

Alternative Assays for ICH M7

Testing Type	Assays	Detection	Justification
Structure-Activity Relationship (SAR)	qSAR	"Linking chemical structure to a chemical property"	Hazard Assessment
Bacterial Mutation	Mini Ames, Micro Ames, Abbreviated Ames	Bacterial Mutations	Follow up on a structural alert
	Ames II™		
In Vivo Gene Mutation	Big Blue® TGR	Mutagenicity	For any bacterial mutagenicity positive
	<i>Pig-a</i>		For direct acting mutagens
In Vivo Cytogenetics	Micronucleus	Clastogenicity	For direct acting mutagens and compounds known to be clastogenic
DNA Damage and Repair	Rat Liver Unscheduled DNA Synthesis (UDS)	DNA Repair	For any bacterial mutagenicity positive with S9
	Comet	DNA Damage	Justification Needed

Other Testing Services

- 28-Day Repeated-Dose Toxicity Study in Rodents and Rabbits*†
- 13-Week Subchronic Toxicity Study in Rodents

Genotoxicity Endpoints

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

*Assessments of genotoxicity can be added to 28-Day Repeat-Dose studies

For additional information, please visit www.bioreliance.com

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Mobile Processing

- Comet
- Big-Blue®
- Inhalation Studies

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

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 globally.

