



Genetic and Molecular Toxicology

For more than three decades, SRI International has been a leader in the fields of genetic toxicology and mechanisms of carcinogenesis. Many of the widely used genotoxicity tests were either developed or validated at SRI. Our staff members have been involved in the writing of many of the international guidelines for genotoxicity test methods.

Major portions of the current databases of the Environmental Protection Agency (EPA) and the National Toxicology Program were developed at SRI. We have considerable experience in solving unusual genetic toxicology problems related to pharmaceuticals, biotechnology products, chemicals such as dyes and inks, agrochemicals, and medical devices for commercial and government sponsors.

Genetic Toxicology Test Systems

SRI offers the following array of genetic toxicology test systems, all in compliance with GLP regulations:

- Microbial mutagenesis assays including the Salmonella/microsome (Ames test) and E. coli mutation assays
- Mouse lymphoma gene mutation assay
- Chromosome aberrations in Chinese hamster ovary (CHO) cells, human lymphocytes, rodent bone marrow, and spermatogonial cells
- Micronucleus assays in rodent bone marrow and peripheral blood.
- Transgenic rodent mutagenesis assays (Big Blue®)
- Sister-chromatid exchange assays, in vitro and in vivo
- Unscheduled DNA synthesis (UDS) in isolated hepatocytes from a variety of species, with in vitro or in vivo treatment.



Bridging the drug development gap

Molecular Toxicology

SRI offers a wide range of molecular toxicology services including mutation analysis, quantitative PCR and RT-PCR, and microarray analysis. We offer comprehensive biodistribution, persistence, and integration services to determine the tissue distribution and/or expression levels of preclinical DNA or viral based vaccines or therapeutics. Everything from dose administration to quantitative PCR analysis can be performed at SRI. Moreover, we can conduct these studies in compliance with GLP regulations if required.

Our scientists can develop and qualify a robust and sensitive quantitative PCR assay specific to your target of interest. We have extensive experience in primer and probe design, PCR optimization, and data analysis and interpretation. For real-time quantitative PCR, we use the Lightcycler® 2.0 and 480 systems with fluorescently labeled hydrolysis or hybridization probes. We typically achieve results that are more sensitive than the FDA recommended <100 copies per 1 µg of genomic DNA.

Capabilities

- Isolation and purification of DNA and RNA from biological samples
- Purification of high molecular weight DNA for integration analysis
- Detection of DNA and RNA sequences for biodistribution, persistence, integration, and target gene expression studies using custom designed primers and probes specific to your product
- Analysis of DNA and RNA copy number by real-time quantitative PCR
- Complete biodistribution and/or integration study design and implementation (from animal dosing to quantitative PCR analysis)
- GLP compliance

You Make the Call

For further information, contact our Client Services Team:

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