



WHERE
insights LEAD TO
answers



Annual Genotoxicity Workshop

Inotiv Technical Seminar April 10-11, 2025

Welcome and Opening Remarks

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Annual Genotoxicity Workshop April 10-11, 2025



Drug Discovery & Development Services

Bioanalysis
Biomarkers
Biotherapeutics
Carcinogenicity Studies
Cell and Molecular Biology
Clinical Pathology
Computational Toxicology

DART & JAS
Digital Pathology
Disease Pharmacology
DMPK
Exploratory Toxicology
General Toxicology
Genetic Toxicology

Histology
Medical Device Pathology
Medical Device Testing
Pathology
Proteomics
Safety Pharmacology
Toxicogenomics

Research Models, Diets & Services

Antibody Production Services
Biospecimen Services
Contact Bedding
Contract Breeding Services
Custom Research Diets

Enrichment Products
GEMS
Genetic Testing Services
Health Monitoring Services
Medicated Diets

Research Models
Standard Diets
Surgical Services
Tumor Models and Services

Inotiv Genetic Toxicology Services Overview

- Discovery and Safety Assessment (DSA)
 - > Greater than 850 employees
- Genetic Toxicology
 - > Two sites (RTP, North Carolina and Rockville, Maryland)
 - > More than 75 dedicated Genetox employees
 - > 11 Scientists/Study Directors
- Facility Space (~ 41,000Ft)
 - > ~11Ft² in RTP and ~30Ft² in RKV



Site Overview – Rockville, Maryland

- About 30,000 Ft² Facility Supporting Genetic Toxicology
 - > Assets of BioReliance Genetic Toxicology division acquired July 2021
 - > Retention of BioReliance technical and ops staff
 - > Historical Control Data
 - > More than 45 dedicated Genetox employees - 6 Genetox Study Directors
- Supporting Non-GLP and GLP Genetox
 - > *In vitro* Genetic Toxicology Assays
 - Ames
 - *In vitro* Micronucleus (MN)
 - Chromosome Aberration
 - Mammalian Mutation Assays
 - Secondary Assays – NRU, Bhas cell transformation
- *In Vivo* Endpoints
 - > Comet
 - > *In vivo* MN
 - > RTP Primary Vivarium

Nitrosamine testing, NRU Phototox*, Thiazole Blue (MTT)*

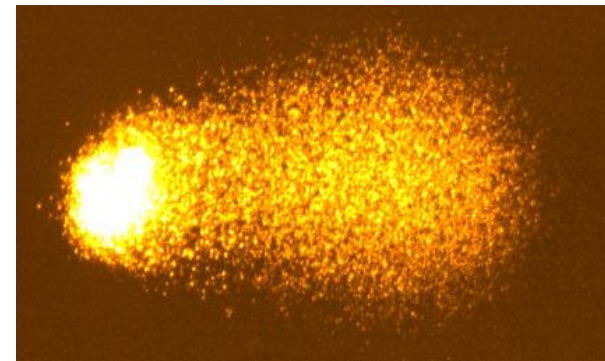
*Coming soon



What's new?

Site Overview – Research Triangle Park, NC

- Inotiv acquired ILS in Jan 2022; GLP lab
- Areas of Scientific Focus
 - > *In vitro/in vivo* toxicology
 - > Genetic Toxicology
 - > About 30 Genetox employees - 5 Genetox Study Directors
 - Ames
 - *In vitro* Micronucleus TK6 – Flow Based
 - *In vivo* Micronucleus
 - Comet Assay
 - Pig-a
 - Duplex Sequencing
 - > QSAR
 - > Multiflow Assay
 - > Computational biology and data science
- State of the Art Facilities with more than 100 staff
 - > Specific pathogen free (SPF) facility: 12,000 sq. ft.
 - > AAALAC accredited since 1993
 - OLAW assured
 - Fully constituted IACUC



Most Experienced Scientific Team in Genetic Toxicology

- Participation in International Validation Programs
 - > JaCVAM – Comet Assay
 - > EFPIA/PhRMA – Comet Assay
 - > NEDO – Bhas Transformation Assay
 - > Litron / ILSI-HESI Pig-a *in vivo* Gene Mutation Assay
 - > Cosmetics Europe (CosEU) – 3D Reconstructed Skin Micronucleus
 - > EPA ToxCast Program: High throughput in vitro Genetox Assays
 - > HESI Enhanced Ames Nitrosamines Ring Trial
 - > Litron – Liver Micronucleus Validation Ring Trial

How Do We Differentiate Ourselves?



Objectives of the Genetic Toxicology Workshop

- **Understand Genetic Toxicology Testing:**
 - Provide background on principles of genetic toxicology, including the mechanisms by which test substances can interact with DNA and cause mutations or chromosomal aberrations
- **Testing Methodologies:**
 - Learn practical application of the various genetic toxicology assays, such as:
 - Bacterial Reverse Mutation Assay (Ames test)
 - *In vitro* and *in vivo* Cytogenetics (Micronucleus and Chromosome Aberration Assays)
 - Cytotoxicity and Cell Transformation Assays
 - Mammalian Mutation Assays
 - Comet Assay
 - Demo of how the various assays are performed
- **Interpret Data:**
 - How to accurately interpret the results of genetic toxicology tests
 - Understand regulatory guidelines and requirements for genetic toxicology testing
- **Stay Current with Advancements in Genetic Toxicology:**
 - Learn about new testing methods, technologies, and regulatory changes
 - Learn about areas like Duplex Sequencing, Predictive toxicology and QSAR (quantitative structure-activity relationship) analysis



Explore our Genetic Toxicology Services

