

Genetic Toxicology

Eurofins Medical Device Testing network of laboratories has more than 30 years of experience performing biological safety and activity testing, including a broad range of Genetic Toxicology Studies. Our certified team has great experience in testing medical devices, pharmaceuticals, chemicals, agrochemicals and mixtures.

Eurofins Medical Device Testing provides the scientific resources and expertise you need, with the most reliable and timely results possible. Our laboratory team has extensive experience, not only in serving the testing needs of diverse clients, but also in conducting *in vitro* assay validation studies.

Our tests comply with the current international guidelines (e.g. ICH, US-FDA, ISO, EMEA, OECD) and are performed in accordance with GLP to ensure their acceptability worldwide. We also offer *in silico* QSAR models to aid in the identification of potentially hazardous substances.

Choose Eurofins Medical Device Testing to help you:

- Increase the success of your product development and avoid the risk of genetic damage by choosing the right test design according to ISO 10993-3.
- Rely on our expertise with different *in vitro* test systems with regard to specific safety and efficacy questions.

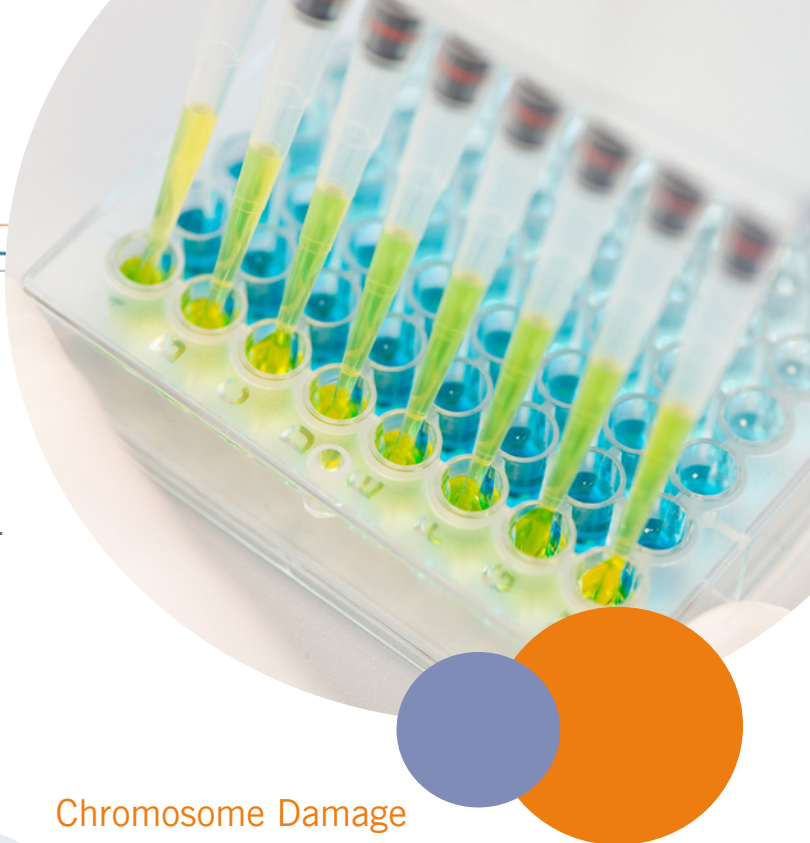
Customised Test Design

The increasing number of newly synthesised molecules demands the use of assays providing rapid results and requiring only small amounts of test material.

To respond to these market requirements, Eurofins Medical Device Testing offers miniaturised screening tests, allowing us to screen a large number of substances.

Gene Mutation

- Bacterial Mutation - Ames mutagenicity (OECD 471) [ISO 10993-3]
- Mammalian mutation assay: mouse lymphoma assay (OECD 490) [ISO 10993-3]
- HPRT-test (OECD 476) [ISO 10993-3]
- Pig-a assay



Chromosome Damage In vitro Cytogenetics

- Micronucleus assay (chinese hamster cell) (OECD 487) [ISO 10993-3]
- Micronucleus assay (human lymphocyte) (OECD 487) [ISO 10993-3]
- Chromosome aberration test (chinese hamster cells) (OECD 473) [ISO 10993-3]
- Chromosome aberration test (human lymphocytes) (OECD 473) [ISO 10993-3]
- Unscheduled DNA synthesis (UDS) test (mammalian liver cells) (OECD 482) [ISO 10993-3]

In vivo Cytogenetics

- Micronucleus assay (peripheral blood) (rat or mouse) (OECD 474) [ISO 10993-3]
- Micronucleus assay (bone marrow) (rat or mouse) (OECD 474) [ISO 10993-3]
- Chromosome aberration test (mammalian bone marrow) (OECD 475) [ISO 10993-3]
- Comet assay (Lung, Stomach Intestine, Liver, Blood) (OECD 489) [ISO 10993-3]

Additional Tests

- Embryonic stem cell test
- Syrian hamster embryo (SHE) cell transformation assay
- Drug uptake *in vitro*
- *In vitro* hepatocytes proliferation assay (mouse, rat, dog, human)
- Sponsor specific assay establishment

*All *in vivo* assays are performed by our partner lab

Testing Services

Biocompatibility & Toxicology • Cleaning & Reprocessing Validations
Chemical & Physical Analysis • Distribution & Package Integrity
Performance Testing • Human Factors & Usability • Microbiology &
Sterility Mechanical & Functionality • Viral Safety

Flexible Models

Fee For Service (FFS)
Full-Time-Equivalent (FTE)
PSS Outsourcing Solutions®

Contact Us

North America: Medical-Device@MDS.EurofinsUS.com
Europe: Medical-Device@MDS.EurofinsEU.com
APAC: Medical-Device-Asia@EurofinsAsia.com
www.Eurofins.com/Medical-Device