Genetic Toxicology Testing

Genetic toxicology testing evaluates the potential of the test material to induce the gene mutation or chromosome damage using a range of bacterial, mammalian cells in vitro and in vivo test systems. **STEMart** offers multiple test types for genotoxicity biocompatibility testing, following the OECD guidelines modified for medical devices and performing under GLP conditions.

Genetic Toxicology Testing for Medical Devices

Bacterial Reverse Mutation Test (Ames)

The Ames Mutagenicity test is used to evaluate the potential mutagenic activity of the materials extracted from a medical device. The Bacterial Reverse Mutation Assay (Ames test) is performed to determine if leachable from a medical device is mutagenic.

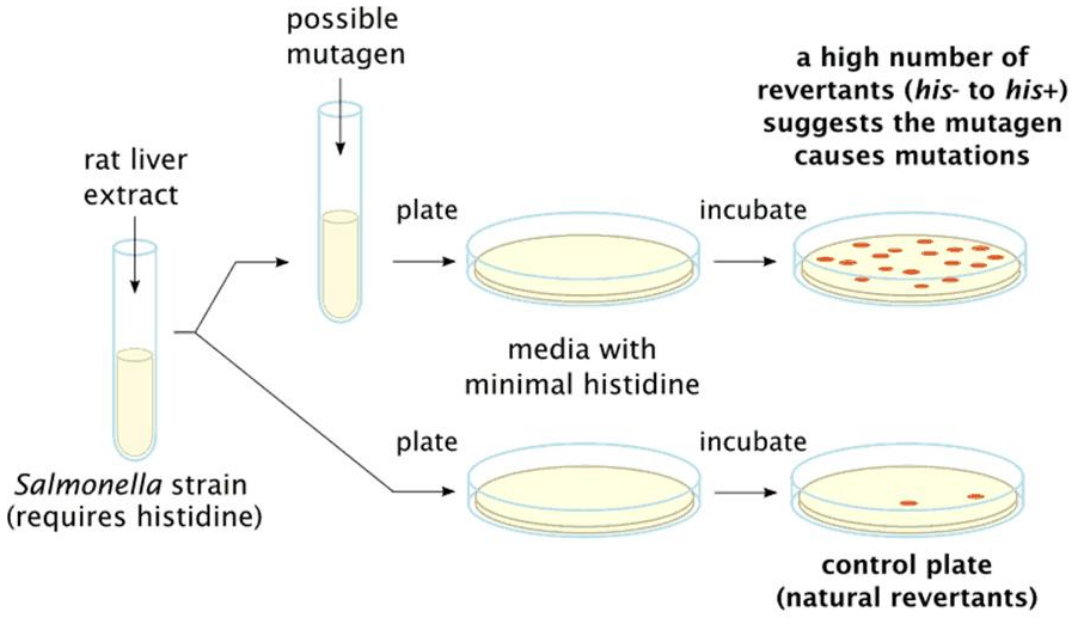

Fig.1 Ames test procedure.

In Vitro Mouse Lymphoma Assay TK

The mouse lymphoma assay is used to detect a battery of cell cultures, usually mammalian, to determine gene mutations, change in chromosome structure, and other gene toxicities induced by medical devices or extracts. This test can help eliminate the risk of eliciting genotoxicity for medical devices that have prolonged contact with patients.

In Vitro Chromosome Aberration Test

The chromosomal aberration test is used to evaluate the potential of a medical device compound to cause structural chromosomal abnormalities, this test can be performed in HPBLs or established cell lines, such as Chinese hamster ovary (CHO) cells. The test is performed on devices that have permanent or prolonged contact with patient, or blood contact.

- **Micronucleus Assay**

The micronucleus test (MNT) is used to evaluate the genetic toxicity of a compound by assessing the presence of micronuclei.

- In vitro micronucleus test

In vitro micronucleus test, incubate cell cultures with several levels of concentrations of the test article for 4 hours in the presence and absence of metabolic activation and for 24 hours in the absence of metabolic activation. Measure the increase in micronucleated cells to determine the genetic toxicity of medical devices.

- In vivo rat micronucleus test

Treat the male and/or female rats with the test compound at three dose levels, the frequency is usually two or three times per 24-hour. After 24 hours of the last dose, collect bone marrow or peripheral blood to assess the frequency of MN-PCEs or MN-RETs, respectively.

- In vivo mouse micronucleus test

In both male and female mice, the positive and negative controls of the test article extract are administered at a dose of 20 mL/kg. Then bone marrow is harvested at 24 and 48 hours after administration and examined for the presence of PCEs. The presence of PCE indicates a mutagenic substance is leachable from the medical device.

If you have additional questions about Genetic Toxicology Testing, or would like to find out more about our services, please feel free to contact us.