Bacterial Reverse Mutation Assay or Ames assay (OECD 471)

Now offered in compliance with the principles of Good Laboratory Practice (GLP)

The **Bacterial reverse mutation assay (Ames assay)** is the most widely used initial screen to determine the mutagenic potential of new chemicals and drugs. The bacterial mutagenicity data also represent a core component of the chemical safety assessment data required by regulatory agencies for registration or acceptance of numerous chemicals and products, including drugs, pesticides, biocides, food additives etc.

Principle of the assay:
The test employs essential amino acid deficient *Salmonella typhimurium* and *Escherichia coli* strains carrying different mutations in various genes of the histidine and tryptophan operon, respectively. These mutations act as hot spots for mutagens that cause DNA damage leading to mutations via different mechanisms. Gene mutations are detected when they cause restoration of the capability of the bacteria to synthesize the essential amino acid that are then able to grow in the absence of the amino acid required by the parent test strain.
The assay is performed according to the OECD Guideline 471. Bacterial cells are exposed to test chemical in the presence and absence of metabolic activation, either by plate incorporation or by pre-incubation prior to plating out. Mutations are determined by scoring bacterial growth (revertant colonies) on selective agar plates lacking the essential amino acid.

Tester strains:
The assay can be performed with *S. typhimurium* strains TA97a, TA98, TA100, TA102, TA1535, TA1537 and TA1538, and *E. coli* strains WP2 and WP2urvA. Sponsor can choose the number and set of strains according to the regulatory requirements for the tested chemical or product or sponsors own requirements.
The Bacterial Reverse Mutation Assay is offered as GLP or as non-GLP screening assay.

GLP process:
For GLP study, the sponsor has to provide the test item characterisation and formulation information. NIB-GEN prepares a draft study plan that is reviewed by the sponsor and NIB-GEN quality assurance (QA) group. After the approval of the study plan the sponsor supplies the test item and the study can begin.
In case that no toxicity or solubility information has been provided, a range-finding test is carried out before the main assay is performed.

The sponsor is notified of the results of the study. NIB-GEN prepares a draft report that is reviewed by the sponsor, and NIB-GEN QA group. After the final approval, a QA statement is added to the final report.

Pricing for GLP studies:
between € 1500 and 3200 per sample depending on the number of strains and replicates.

Pricing for studies performed under non-GLP conditions:
between € 1200 and 2400 per sample depending on the number of strains and replicates.

Turn Around Time:

Normally: 4- 6 weeks after the approval of the study plan, but this mostly depends on the number of strains and the number of samples.

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