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## Genotoxicity: Basic aspects and most commonly worldwide employed and validated *in vitro* assays

*In vitro* genotoxicity assays that are commonly used for regulatory purposes can be categorized into two main groups based upon the endpoints analyzed: Gene mutation and chromosome aberration. The single most commonly performed test is the bacterial reverse mutation assay generally referred to as the Ames assay which is often used as the first go/no go decision point in product development. Gene mutation can also be evaluated in mammalian cell test systems such as the mouse lymphoma or CHO/HPRT assays, where the cells become resistant to metabolic poisons after loss of specific gene function. The other main group of assays is based upon cytogenetic analyses that examine changes in chromosome structure or number. Clastogens induce structural changes that can be detected microscopically and may manifest as breaks or rearrangements involving one or both chromatids of one chromosome or multiple chromosomes. While chromosome aberration assays may detect limited types of numerical aberrations (polyploidy and endoreduplication), the micronucleus assay is better suited for that purpose since it can detect aneugens (spindle poisons) that cause more limited changes in chromosome number (i.e., gain or loss of single chromosomes). The basic principles underlying these assays and their basic design will be presented as well as a discussion of the pros and cons of each.

### Biography

Leon F Stankowski, Jr., PhD received BS degrees from The Pennsylvania State University in pre-medicine and biophysics; studied toward a MS in biochemistry at the University of Scranton; and received a PhD in biomedical sciences, specializing in genetics, from the University of Tennessee – Oak Ridge Graduate School of Biomedical Sciences. Since then, he has held various scientific and management positions in contract research organizations and the pharmaceutical industry. He has served a study director for a variety of *in vitro* and *in vivo* genetic toxicology assays, and as a program manager or consultant. He has directed thousands of assays in multiple *in vivo* and *in vitro* test systems; has had a lead role in developing and validating novel mutagenesis, *in vitro* toxicity and biochemistry methods and services; and has published original research results in multiple journals and presented at numerous meetings. He is a member of the Environmental Mutagenesis and Genomics Society and the Genetic Toxicology Association (GTA), and served on the GTA Board of Directors from 2000 to 2003, as the GTA Assistant Treasurer from 2003 to 2006, and as the GTA Treasurer from 2006 to present. He has been a reviewer for several journals in the field, served on numerous industrial workgroups involving *in vitro* and *in vivo* mammalian mutagenesis assays, including ASTM, IWGT, US EPA, and ILSI-HESI, and is a US Delegate to the Expert Working Group for the review of most of the OECD Test Guidelines on Genotoxicity.

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