NOTICE: This standard has either been superceded and replaced by a new version or discontinued.
Contact ASTM International (www.astm.org) for the latest information.

Designation: E 1202 – 87 (Reapproved 1998)

Standard Guide for Development of Micronucleus Assay Standards[1]

This standard is issued under the fixed designation E 1202; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This guide covers minimal criteria which should be met by a micronucleus assay system prior to the development of an ASTM Standard or Guide for the conduct of that assay.

1.2 *This standard does not purport to address all of the safety concerns, if any, associated with its use. It is the responsibility of the user of this standard to establish appropriate safety and health practices and determine the applicability of regulatory limitations prior to use.*

2. Significance and Use

2.1 Micronucleus assays for genetic damage have been developed in many types of eucaryotic cells, both *in vitro* and *in vivo.* The occurrence of micronuclei is indicative of chromosomal damage or mitotic spindle dysfunction.

3. Criteria

3.1 *Biology*:

3.1.1 The biology of the system should be well understood in terms of (*a*) cell cycle, (*b*) metabolic capabilities, (*c*) culture or growth conditions, and (*d*) other factors of importance in maintaining a reproducible experimental situation. There should be evidence that micronuclei arise from chromosomal aberrations or chromosome loss or both, and not apoptosis or any other mechanism.

3.2 *Time Response*:

3.2.1 The "expression time" for micronuclei should be characterized for (*a*) direct-acting genotoxins and (*b*) genotoxins requiring metabolic activation.

3.3 *Dose Response*:

3.3.1 The dose response curves for several classes of genotoxins, over a dose range including both toxic and nontoxic doses, should be known. A rational method for determining the upper and lower doses to be tested should be available.

3.4 *Spontaneous Frequency*:

3.4.1 The spontaneous frequency of micronuclei should be well characterized and should be stable under the test conditions employed. Major factors affecting the spontaneous incidence of micronuclei should be defined.

3.5 *Statistics*:

3.5.1 The following statistical criteria should be met:

3.5.1.1 There should be sufficient data to define the major sources of experimental variability (for example, slide to slide, animal to animal), in order to permit rational experimental design,

3.5.1.2 Appropriate statistical methods for analyzing the data should be available,

3.5.1.3 Sufficient data and adequate statistical methods should be available to permit determination of the sample sizes required for adequate statistical power, and

3.5.1.4 The quantitative reproducibility of experimental results between and within experiments should be known.

3.6 *Transportability*:

3.6.1 There should be sufficient experience with the system in order to know how well the characteristics of the assay are maintained in different laboratories. It should be known whether observer-dependent effects, such as scoring and sample preparation, have been sufficiently controlled among laboratories to ensure uniform interpretation of test data. The influence of factors, such as source of test organism and materials, on experimental outcome should be known. A written description of the techniques required for the conduct of the assay that is adequate to permit a new laboratory with normal experience in genetic toxicology testing to carry out the assay should be available.

[1] This guide is under the jurisdiction of ASTM Committee F04 on Medical and Surgical Materials and Devices and is the direct responsibility of Subcommittee F 04.16 on Biocompatibility Test Methods.

Current edition approved Sept. 25, 1987. Published November 1987.

Copyright © ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States.

NOTICE: This standard has either been superceded and replaced by a new version or discontinued.
Contact ASTM International (www.astm.org) for the latest information.

ASTM International takes no position respecting the validity of any patent rights asserted in connection with any item mentioned in this standard. Users of this standard are expressly advised that determination of the validity of any such patent rights, and the risk of infringement of such rights, are entirely their own responsibility.

This standard is subject to revision at any time by the responsible technical committee and must be reviewed every five years and if not revised, either reapproved or withdrawn. Your comments are invited either for revision of this standard or for additional standards and should be addressed to ASTM International Headquarters. Your comments will receive careful consideration at a meeting of the responsible technical committee, which you may attend. If you feel that your comments have not received a fair hearing you should make your views known to the ASTM Committee on Standards, at the address shown below.

This standard is copyrighted by ASTM International, 100 Barr Harbor Drive, PO Box C700, West Conshohocken, PA 19428-2959, United States. Individual reprints (single or multiple copies) of this standard may be obtained by contacting ASTM at the above address or at 610-832-9585 (phone), 610-832-9555 (fax), or service@astm.org (e-mail); or through the ASTM website (www.astm.org).