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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 21773-2025

Replacing GB/T 21773-2008

Chemicals - Test method of in vivo mammalian erythrocyte micronucleus

化学品 体内哺乳动物红细胞微核试验方法

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Foreword

This document is in accordance with GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents". Drafting is scheduled.

This document supersedes GB/T 21773-2008 "Test Method for Micronuclei in Mammalian Red Blood Cells of Chemicals", and is consistent with GB/T 21773- Compared to 2008, aside from structural adjustments and editorial changes, the main technical changes are as follows.

a) The content of the "Basic Principles of Experimentation" has been revised (see Chapter 4, Chapter 3 of the 2008 edition);

b) A new chapter on "Laboratory Proficiency Testing" has been added (see Chapter 5);

c) The sections on "Animal Selection," "Housing Conditions," "Animal Preparation," and "Test Substance Preparation" have been revised (see 6.1, 4.1 of the 2008 edition);

d) The contents of "Solvent/Excipients" and "Control" have been changed (see 6.2, 4.2 of the 2008 version);

e) The content regarding "Animal Number and Sex" (see 6.3.1, 4.3.1 in the 2008 version)

and the content regarding "Dose Level" (see...) have been modified.

6.3.2 (4.3.3 in the 2008 edition), the content of "Limited Quantity Testing" (see 6.3.3, 4.3.4 in the 2008 edition), and the content of "Route of Exposure" The contents of the "Discharge Procedure" (see 6.3.4, 4.3.5 of the 2008 edition) and the "Discharge Procedure" (see 6.3.5, 4.3.2 of the 2008 edition);

f) Added sections on "Observation" (see 6.3.6) and "Target Tissue Exposure" (see 6.3.7);

g) The content of "Bone Marrow/Blood Sample Preparation" (see 6.3.8, 4.3.6 in the 2008 version) and "Analysis (Manual and Automated)" have been changed.

The content of "Analysis" (see 6.3.9, 4.3.7 of the 2008 edition);

h) The content of "Data Processing" has been changed (see 7.1, 5.1 in the 2008 version);

i) Added content on "Quality Control" (see 7.2);

j) The content of "Results Evaluation and Interpretation" (see 7.3, 5.2 of the 2008 version) and the content of "Trial Report" (see 7.4, 2008 version) have been revised. (5.3 of the 2018 edition).

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Hazardous Chemicals Management (SAC/TC251).

This document was drafted by. the National Institute for Environmental Health and Related Product Safety, Chinese Center for Disease Control and Prevention; and the National Institute for Occupational Health and Related Product Safety, Chinese Center for Disease Control and Prevention.

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The release history of this document and the document it replaces is as follows.

- First published in 2008 as GB/T 21773-2008;

- This is the first revision.

Introduction

The in vivo mammalian erythrocyte micronucleus assay is an in vivo genotoxicity test that detects erythrocyte micronuclei in the bone marrow of animals (usually rodents).

Or assess the formation of micronuclei in peripheral blood erythrocytes to determine if chemicals have caused damage to erythroblast chromosomes or mitotic apparatus. Micronuclei The purpose of the experiment is to identify chemicals that can cause cellular genetic damage, leading to the formation of micronuclei, which may contain delayed chromosomes.

Chromosome fragments or entire chromosomes. Micronucleus assays in mammals are of particular significance in assessing the genotoxicity of chemicals, although there may be ... While species differences exist, this experiment can reflect the impact of processes such as metabolism, toxicokinetics, and the body's DNA repair capacity on genetic damage.

The in vivo micronucleus assay can also be used to conduct further research on genotoxic substances detected in in vitro assays.

During the development of erythroblasts in the bone marrow into immature erythroblasts at a specific stage, their nuclei are expelled, and the resulting micronuclei...

They may remain in the cytoplasm. Because these cells lack a nucleus, micronuclei are easier to observe or detect. In animals exposed to chemicals, if...

An increased micronucleated cell rate in immature red blood cells indicates that chemicals induced chromosomal structural or numerical aberrations. Newly formed micronucleated cells...

After staining, red blood cells can be observed and counted manually using a microscope, or automated analysis methods can be used. Automated analysis systems can be used...

The system can significantly improve counting efficiency and can replace manual counting. With proper calibration, the automated analysis method can be used both in-laboratory and inter-laboratory.

The reproducibility and sensitivity are superior to manual counting methods. Automated analytical systems suitable for erythrocyte micronucleus assays include, but are not limited to.

Flow cytometer, image analysis platform, and laser scanning cytometer.

In this experiment, chromosome fragments can be distinguished from whole chromosomes using various criteria, such as identifying the presence of kinetochore or centromere DNA.

Whether or not, both are characteristics of a complete chromosome. If no kinetochore or centromere DNA is detected in the micronucleus, it indicates that it contains only chromosomes.

Fragments; if kinetochore or centromere DNA is detected in the micronucleus, it indicates that an entire chromosome has been lost. It should be noted that the above distinction between chromosome fragments...

Methods involving chromosome fragments and whole chromosomes are typically not included as part of the test. The target tissue for this experiment is juvenile rodents.

The bone marrow is the primary site of red blood cell production. If there is evidence that immature red blood cells in the peripheral blood of certain mammalian species are...

The detection of chemically induced chromosomal structural or numerical aberrations is sensitive enough, and immature red blood cells in peripheral blood can also be used as the detection target.

The micronucleated cell rate of immature erythrocytes in bone marrow or peripheral blood is the primary endpoint. If the spleen of a mammalian species contains micronucleated cells...

If the clearance effect is weak, or if the experimental animals are continuously exposed to the virus for a period exceeding the lifespan of the species' erythrocytes (e.g., mice exposed to the virus for 4 weeks or more), then...

In both cases, the micronucleated cell rate of mature erythrocytes in peripheral blood can be selected as the detection endpoint.

Before obtaining toxicity assessment data for a mixture in accordance with this testing guideline and using it for intended regulatory purposes, it is necessary to assess whether it can provide [the necessary information].

This objective is to provide compliant results while analyzing the reasons that may affect the applicability of the results. If there are regulatory requirements for the testing of mixtures, then...

The above assessment is unnecessary.

Chemicals in mammalian red blood cells Micronucleus test method

1 Scope

This document establishes the basic experimental principles for the in vivo mammalian erythrocyte micronucleus assay, and specifies the laboratory proficiency testing, experimental parameters, and procedures.

The test methods were described in accordance with the requirements of the report.

This document applies to the in vivo mammalian erythrocyte micronucleus assay for chemicals.

This document does not apply to chemicals or their metabolites that have not reached the target tissue.