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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 21794-2025

Replacing GB/T 21794-2008

**Chemicals - Test method of in vitro mammalian chromosome
aberration**

化学品 体外哺乳动物细胞染色体畸变试验方法

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. This document replaces GB/T 21794-2008 "Test method for chromosome aberration of mammalian cells in vitro by chemicals" and GB/T 21794- Compared with.2008, in addition to structural adjustments and editorial changes, the main technical changes are as follows:

a) Added the terms and definitions of "chromatid cleaving", "genotoxicity", "relative cell growth number" and "relative population doubling number" (see 3.1, 3.5, 3.9, 3.10); deleted the term and definition of "cleft" (see

2.4 of the.2008 edition); changed the term "chromatid abnormality" Definitions of "chromosomal aberration", "endoreplication", "mitotic index", "numerical aberration", "polyploidy" and "structural aberration" (see 3.2, 3.3, 3.4, 3.6, 3.7,

3.8 and 3.11, 2.1, 2.2, 2.3, 2.5, 2.6,

2.8 of the.2008 edition);

b) Added the "Abbreviations" section (see Chapter 4);

c) The "Preparation" section has been modified to refine the cell selection conditions and add cell preservation conditions and gas or volatile test conditions. The preparation conditions of the organisms were revised, and the concentration of S9 in the culture medium was revised (see 6.1,

4.1 of the.2008 edition);

d) The solvent selection conditions have been changed to specify the concentration of organic solvents in the final contact concentration (see 6.2.1,

4.2.1 of the.2008 edition);

e) The names and CAS numbers of cyclophosphamide and cyclophosphamide (monohydrate) have been changed (see Table 1,

4.2.3.2 of the.2008 edition);

f) The content of the "Test Procedures" was changed to specify the concentration of colchicine and the time of culture treatment, and to add the required Count the number of metaphase cells (see 6.3,

1 Scope

GB/T 21794-2025 is the Chinese national standard on chemicals - test method of in vitro mammalian chromosome aberration, in the field of environment and health protection, safety. The /T suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 29 August 2025 by the State Administration for Market Regulation; Standardization Administration of China, and has been in force since 1 December 2025. Classification: ICS 13.300, CCS A80. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This document establishes the basic principles of in vitro mammalian cell chromosome aberration testing for chemicals, describes the test methods, and specifies the test Data and report content. This document applies to in vitro mammalian cell chromosome aberration tests for chemicals.

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 chromatid gap A chromatin-free region that appears on a single chromatid and is smaller than the width of the chromatid's cross section.

3.2 chromatid-type aberration It refers to the phenomenon of chromatid breakage or chromosome structural damage caused by breakage and reconnection between chromatids.

3.3 chromosome-type aberration It refers to the phenomenon of chromosome structural

damage in which two chromatids break or rejoin at the same site.

3.4 Endoreduplication After the S phase of DNA replication, the cell nucleus begins another S phase without undergoing mitosis.

Note. The result is that the chromosomes have 4, 8, or 16 fold chromatin.

3.5 genotoxic The ability to damage the genome.

Note. This includes mutagenicity and other various effects caused by toxic effects on the genome.

3.6 Mitotic index The ratio of the number of cells in mitosis to the total number of cells.

Note. This is an indicator used to measure the number of proliferating cells.

3.7 Numerical distortion An alteration in the number of chromosomes that is different from the normal number of chromosomes in the cells being used.