ICS 11.040.01
CCS C30

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# PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

# YY/T 0870.8-2024

## Test for genotoxicity of medical devices - Part 8: In vivo mammalian liver cell unscheduled DNA synthesis test

医疗器械遗传毒性试验 第8部分：体内哺乳动物肝细胞程序外DNA合成试验

**Issued on: July 8, 2024** **Implemented on: July 20, 2025**

**Issued by: National Medical Products Administration**

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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 is part 8 of YY/T 0870 "Genetic Toxicity Testing for Medical Devices". YY/T 0870 has been published in the following parts.

1.Bacterial reverse mutation test;

2.In vitro mammalian cell chromosome aberration test;

--- Part 3: TK gene mutation test using mouse lymphoma cells;

4.Mammalian bone marrow erythrocyte micronucleus test;

5.Mammalian bone marrow chromosome aberration test;

6.In vitro mammalian cell micronucleus test;

7.In vivo alkaline comet test in mammals;

8.In vivo unscheduled DNA synthesis test in mammalian hepatocytes. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Biological Evaluation of Medical Devices (SAC/TC248). This document was drafted by: Shandong Medical Device and Drug Packaging Inspection Institute, Shanghai Ninth People's Hospital Affiliated to Shanghai Jiaotong University School of Medicine Institute, Beijing Institute of Medical Device Inspection (Beijing Medical Biological Protection Equipment Inspection and Research Center). The main drafters of this document are. Wang Luanluan, Liu Xin, Song Wei, Sun Jiao, Zhang Ao, Chu Xiangyu and Che Guoxi.

The test method for detecting potential genotoxic substances given in GB/T 16886.3 does not provide detailed test steps and is therefore not suitable for Directly used for testing medical devices. YY/T 0870 provides detailed test steps based on the characteristics of medical devices and can be used as Supplementary method standard for genetic toxicity test in GB/T 16886.3. This document provides a method for evaluating the genotoxic effects of medical devices on mammals to determine the potential The resulting DNA damage and repair. YY/T 0870 aims to establish specific test methods for genetic toxicity of medical devices and is intended to consist of 8 parts.

1.Bacterial reverse mutation test. The purpose is to provide detailed test results for bacterial reverse mutation test of medical devices/materials method.

2.In vitro mammalian cell chromosome aberration test. The purpose is to give the in vitro mammalian cell chromosome aberration test of medical devices/materials. Detailed test method for cell chromosome aberration test.

--- Part 3: TK gene mutation test using mouse lymphoma cells. The purpose is to provide medical devices/materials using mice Detailed test method for TK gene mutation test performed on lymphoma cells.



## 1 Scope

YY/T 0870.8 is Part 8 of the Chinese series on genotoxicity testing of medical devices, covering the in vivo unscheduled DNA synthesis test in mammalian liver cells. Unscheduled DNA synthesis is repair replication: DNA being rebuilt outside the normal replication cycle because something damaged it, which makes it a direct readout of genotoxic injury in a whole animal rather than in culture. In device testing it belongs to the second tier, used when the in vitro battery has raised a question that has to be resolved before a material can contact the body long-term. The 2024 edition takes effect on 20 July 2025. For a manufacturer whose biological evaluation has produced an equivocal in vitro genotoxicity result, this is the method a Chinese reviewer expects the follow-up study to use.

This document describes a test method for in vivo unscheduled DNA synthesis in mammalian hepatocytes in medical devices. This document is applicable to the evaluation of whether medical devices have the potential to cause unplanned DNA damage in mammalian liver cells by measuring the unplanned DNA damage caused by medical devices. Has potential genotoxic effects. NOTE. In vivo mammalian hepatocyte ex vivo DNA synthesis assays of nanomaterials may require specific revisions to the methods in this document, but this document No description given.

## 2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date,

only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB 14925 Experimental Animal Environment and Facilities

GB/T 16886.2 Biological evaluation of medical devices Part

## 3 Terms and definitions

The terms and definitions defined in GB/T 16886.3 and GB/T 16886.12 and the following apply to this document.

3.1 DNA synthesis that occurs outside the semiconservative DNA program during the S phase of the cell cycle.

## 4 Test Principle

The in vivo mammalian hepatocyte UDS test is an in vivo somatic cell genetic toxicology test conducted using mammals. Compared with "short-range repair" (1 to 3 base pairs), UDS test can effectively remove and replace the bases in the damaged DNA. The UDS test can detect the entire genome and has a high sensitivity. DNA damage is not repaired, mismatch repair or misreplication leads to mutations that cannot fully and accurately reflect the DNA repair process. There is some compensation. The genetic endpoint of the UDS test is DNA damage in hepatocytes and its subsequent repair. Freshly isolated mammalian hepatocytes are placed in Culture the cells in a medium containing 5-ethynyl-2'-deoxyuridine (EdU) for a period of time. If the test substance causes DNA damage in the cells, During the repair process, EdU is integrated into the DNA chain and reacts with the fluorescent probe under the action of Cu. The labeled azide compound undergoes a click reaction (i.e., a copper-catalyzed covalent reaction of an azide group with an alkyne terminal), and the newly synthesized DNA Labeled with fluorescent probes, the amount of EdU incorporated is observed by fluorescence intensity to evaluate the potential mutagenicity of medical devices.