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

GB/T 42466-2023

**Biobanking technical requirement for management of
pluripotent stem cells**

生物样本库多能干细胞管理技术规范

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1. Structure and Drafting Rules of Standardization Documents" Drafting. Please note that some content in this document may be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed and coordinated by the National Technical Committee for Standardization of Biological Samples (SAC/TC559). This document was drafted by: Institute of Zoology, Chinese Academy of Sciences, Beijing Institute of Stem Cells and Regenerative Medicine, Chinese Society of Cell Biology, Beijing Technology and Business University, Beijing Zehui Chenxing Biotechnology Co., Ltd., Anhui Zhongshengshuyuan Biotechnology Co., Ltd., China Metrology Science Research Institute of Standardization, China National Institute of Standardization, China National Accreditation Center for Conformity Assessment, Kunming University of Science and Technology, Hunan Guangxiu High-tech Life Technology Co., Ltd., Shanghai Xinchao Biotechnology Co., Ltd., China Medical Biotechnology Association, Zhongshan Hospital Affiliated to Fudan University, Shenzhen BGI Life Sciences Research Hospital, Guangdong Provincial Hospital of Traditional Chinese Medicine. The main drafters of this document. Zhao Tongbiao, Hao Jie, Zhou Qi, Cao Jiani, Hu Baoyang, Wang Lei, Ma Aijin, Liang Lingmin, Wang Liu, Zhang Yu, Wei Jun, Yu Junying, Fu Boqiang, Peng Yaojin, Tan Yuanqing, Ma Juan, Wu Jun, Wang Yukai, Li Xiaoyan, Wang Changlin, Zhai Peijun, Na

Tao, Li Tianqing, Lin Ge, Gao Hengjun, Wu Zhaohui, Li Ka, Li Qiyuan, Zhang Xiaoyan, Chen Qubo. Technical specifications for the management of pluripotent stem cells in biobanks

1 Scope

GB/T 42466-2023 sets the technical requirements for managing pluripotent stem cells in a biobank. These lines - embryonic and induced pluripotent - are the most demanding material a biobank holds: they drift genetically with passage, they differentiate spontaneously if the culture slips, and a line distributed to fifty laboratories carries its defects to all of them, which is why the identity and quality control provisions are the heart of the standard. It sets the general requirements, then collection and reception, the establishment of the line's records and relationships, thawing and culture, cryopreservation and storage, quality control, distribution and transport, with an informative annex listing the quality control tests for human and mouse pluripotent stem cell banks. It took effect on 7 September 2023.

This document specifies the general technical requirements for the management of human pluripotent stem cells and mouse pluripotent stem cells in biobanks, including general principles, raw materials Management and technical requirements for the collection and receipt, establishment, recovery and culture, freezing and storage, quality control, distribution and transportation of materials and related data. This document applies to the management of human pluripotent stem cells and mouse pluripotent stem cells in biobanks. This document does not apply to the management of biological samples intended for clinical treatment.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 7408 Data elements and exchange format information exchange date and time representation

GB/T 16886.2 Biological evaluation of medical devices Part

3 Terms and definitions

The terms and definitions defined in GB/T 40364, ISO 21709 and the following apply to this document.

3.1 stem cellsstemcells A type of cell that is capable of self-renewal and differentiation into one or more functional cell types.

3.2 Pluripotent stem cellspluripotentstemcells A type of stem cell that can self-renew without restriction in vitro and has the potential to differentiate into cells of the three germ layers. Examples. Embryonic stem cells, induced pluripotent stem cells.

Note. Human embryonic stem cells are called human embryonic stem cells.

3.3 Collection collection The process of obtaining biological samples such as tissues and cells from a donor. [Source: GB/T 40364-2021, 3.20, modified]