

ICS 07.080  
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**NATIONAL STANDARD OF THE  
PEOPLE'S REPUBLIC OF CHINA**

**GB/T 46661-2025**

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**Magnetic beads performance detection methods for cell  
separation**

细胞分选用磁珠性能检测方法

**Issued on: October 31, 2025**

**Implemented on: May 1, 2026**

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**Issued by: State Administration for Market Regulation;  
Standardization Administration of the PRC**

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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 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 Biochemical Testing (SAC/TC387). This document was drafted by: Beijing Academy of Science and Technology Analysis and Testing Institute (Beijing Physical and Chemical Analysis and Testing Center), Jilin University, Institute of Biology, China Academy of Testing Technology; Lanzhou Baiyuan Gene Technology Co., Ltd.; Nanjing Genscript Biotech Co., Ltd.; Beijing Science and Technology Research Institute, Suzhou Beaver Biomedical Engineering Co., Ltd., Beijing Qinbang Technology Co., Ltd., Peking University, Changchun Medical College Colleges and universities, Beijing NiuNiu Gene Technology Co., Ltd., Sichuan University, Yantai Zhigong Biomedical Technology Co., Ltd., and Mike Biotechnology Co., Ltd. Limited Liability Company, Shenzhen Eray Bio-Tech Co., Ltd., Tsinghua University, Ruifudi Biomedical (Shanghai) Co., Ltd., LeadHealth Technology (Guangzhou) Co., Ltd. The main drafters of this document are. Du Meihong, Hong Tian,

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## 1 Scope

GB/T 46661-2025 is the Chinese national standard covering testing the magnetic beads used to sort cells - the particle size and magnetisation, the antibody coupling and its capacity, the non-specific binding that contaminates the sorted fraction, and the yield and purity achieved on a reference cell population. Bead-based separation is a step in every CAR-T manufacturing process. First edition, in force from 1 May 2026. Issued on 31 October 2025, it has been in force since 1 May 2026.

This document describes a method for testing the performance of magnetic beads used in cell separation. This document applies to the selection of magnetic beads for cell differentiation that possess superparamagnetic properties and have bioactive molecules such as antibodies or streptavidin immobilized on their surface. Performance testing.

## 2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 16886.5-2017 Biological evaluation of medical devices - Part

## 3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 Cell viability The percentage of live cells out of the total number of cells.

3.2 Set gate gating The process of selecting a specific cell population during flow cytometry analysis.

3.3 celpurity The percentage of target cells out of the total number of cells.

3.4 Cell yield celyield The percentage of target cells obtained after sorting compared to the number of target cells before sorting.

4. Abbreviations The following abbreviations apply to this document.

## 5 In vitro cytotoxicity tests

GB/T 19077 Particle size analysis by laser diffraction GB /Z 26082 Measurement Method of DC Magnetic Susceptibility (Magnetic Moment) of Nanomaterials

GB/T 29022 Dynamic Light Scattering (DLS) Method for Particle Size Analysis

GB/T 30902 Determination of impurity elements in inorganic chemical products by inductively coupled plasma optical emission spectrometry (ICP-OES)

GB/T 38506-2020 Methods for the determination of biochemical parameters during animal cell culture

GB/T 39729 General requirements for cell purity determination - Flow cytometry method

GB/T 40268-2021 Test methods for the properties of immunomagnetic materials