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

GB/T 45743-2025

Biomaterial - General requirements for transportation of cells

生物样本 细胞运输通用要求

(English Translation)

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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 was drafted with reference to ISO 21973:2020 "General requirements for the transport of cells for biotechnology therapeutics" and the degree of consistency is non-equivalent.

1 Scope

This document specifies the general requirements for cell transportation, including basic requirements, transportation service management requirements, transportation containers and labels, cell transportation Operations, temporary storage facility requirements, organizational requirements, documentation and record requirements.

This document applies to the shipment of cells for research and testing purposes.

This document does not apply to the transportation of cells within the same site or the transportation of cells for clinical use.

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/T 37864 General requirements for quality and capability of biobanks

3 Terms and definitions

The following terms and definitions apply to this document.

Cell products celproducts Products containing cells as active substances.

Examples. cells, tissue engineering products.

Note 1: In this document, "cells" refers to cells and cell-containing tissues of human or non-human animal origin.

NOTE 2 In this document, the term includes cells collected as starting material and cultured as intermediate material.

Note 3: The use of cells in this document includes research and detection, and is not applicable to clinical research, testing and treatment.

[Source. ISO 21973:2010, 3.1, modified] 3.2 Transportation the process starts when the sender transfers the packaged cells to the transport service provider and ends when the cells are delivered to the recipient at the destination.

process.

Chain of custody

From collection to research and testing, record the data on product-related operation

content, date, and time.

NOTE: In this document, "chain of custody" refers to all related processes from the transfer of cells from the sender to the transport service provider until the cells are delivered to the recipient at their destination.

Data and records.

Client

Entities that sign an agreement with a transportation service provider and require cell transportation services, including receivers and senders.