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Biotechnology — Biobanking — Requirements for human neural stem cells derived from pluripotent stem cells

Biotechnologie — Biobanque — Exigences relatives aux cellules souches neuronales humaines dérivées de cellules souches pluripotentes

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by ISO/TC 276, *Biotechnology*.

Any feedback or questions on this document should be directed to the user’s national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

Neural stem cells (NSCs) are the adult stem cells in the central nervous system (CNS). NSCs have self-renewal ability and multipotency. NSCs can differentiate into various neurons and glial cells including astrocytes and oligodendrocytes. NSCs play a major role in embryonic development and adult neurogenesis. According to the hypothesis by Alvarez-Buylla, there are several types of cells can be called NSCs, including neuroepithelium – epithelial cells of the ventricular zone (VZ) of the neural tube[1], radial glial cells (RGCs) and basal (intermediate) progenitor cell (IPC)[2-4]. In the adult, NSCs are restricted to specific brain regions, such as the subventricular zone (SVZ) of the lateral ventricles and the subgranular zone (SGZ) of the dentate gyrus (DG) of the hippocampus[5].

NOTE The term "neural" refers to any type of nerve cell, including a mixture of brain cells, whereas "neuronal" is specifically related to neurons.

Despite these advances, substantial ambiguities persist regarding the nomenclature, nature, identity, function, mode of isolation and experimental handling of these cells. NSCs are not fully defined by the initial minimal criteria proposed out, and as such require careful characterization by a matrix of functional assays.

NSCs have been isolated from human fetal CNS (brain or spinal cord), cerebrospinal fluid, biopsy and autopsy material, or differentiated from pluripotent stem cells (PSCs), which are widely used for animal and clinical research[6]. NSCs generated from different sources or differentiation protocols have different properties. Different institutions use different practices for isolating, processing and biobanking these NSCs, making it difficult to compare data and results across institutions. Thus, there is a need for standardized approaches to isolate, process, expand and cryopreserve these NSCs.

The aim of this document is to provide general guidance for biobanking of human NSCs derived from pluripotent stem cells (hPSC-NSCs) for research purposes. This document is applicable for academic centers, public and private institutions performing a biobanking service of hPSC-NSCs for R&D (Research and Development) and preclinical studies, not for clinical use.

Importantly, this document is focused on hPSC-NSCs that have been isolated, manipulated and/or propagated from hPSCs in culture for research purposes.

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Biotechnology — Biobanking — Requirements for human neural stem cells derived from pluripotent stem cells

1 Scope

This document specifies requirements for the biobanking of human neural stem cells (hPSC-NSCs) derived from human pluripotent stem cells (hPSCs), including the requirements for the differentiaton, culture, characterization, quality control (QC), storage, thawing and transport of hPSC-NSCs.

Requirements for the collection of biological source material, the transport to and reception of biological source material and hPSCs at the biobank, as well as the establishment, expansion and QC of hPSCs are covered in ISO 24603.

This document is applicable to all organizations performing biobanking of hPSC-NSCs used for research and development in the life sciences.

This document does not apply to hPSC-NSCs for the purpose of in vivo application in humans, clinical applications or therapeutic use.

NOTE International, national or regional regulations or requirements or multiple of them can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 8601-1, *Date and time — Representations for information interchange — Part 1: Basic rules*

ISO 20387:2018, *Biotechnology — Biobanking — General requirements for biobanking*

ISO 21709:2020, *Biotechnology — Biobanking — Process and quality requirements for establishment, maintenance and characterization of mammalian cell lines*

ISO 24603:2022, *Biotechnology — Biobanking — Requirements for human and mouse pluripotent stem cells*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387, ISO 21709 and the following apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

3.1
authenticity
quality of being genuine or true

[SOURCE: ISO/TS 22859:2022, 3.1]

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