
**Biotechnology — Biobanking —
Requirements for human and mouse
pluripotent stem cells**

*Biotechnologie — Biobanking — Exigences relatives aux cellules
souches pluripotentes humaines et murines*



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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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 documents 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).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT), see www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee 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.

Introduction

Pluripotent stem cells (PSCs), including embryonic stem cells (ESCs) and induced pluripotent stem cells (iPSCs), have been extensively studied in scientific research in order to improve the understanding of developmental biology and diseases, to create organoids for drug screening, and to be applied in cell-based therapies. In just a few years, thousands of PSC lines have been established in laboratories around the world. PSC lines hold unique characteristics and behaviour due to their capability for both self-renewal and differentiation into multiple cell types. However, the stem cell phenotype can be changed by suboptimal cell culture technique, prolonged passage or changing the culture conditions. Clearly the consequences of using adversely affected cells would be wasted time and resources but, even more seriously, the generation of erroneous data in the literature which could both confuse and delay scientific progress in this area. Accordingly, mouse PSCs have been used to establish our fundamental understanding of PSC biology and these discoveries have been translated into human PSC research to drive the development of new human-cell-based *in vitro* assays and potential regenerative medicines. Mouse PSCs and human PSCs have become the most widely studied species in this field and many significant scientific advances have been made by using PSCs from these two species. Of course, PSC lines have been established from other species such as rat, porcine, canine, bovine, primate, etc. and those from primates in particular have provided understanding of the biology of these cells which can be more relevant to human stem cell biology than data from mouse PSCs. However, PSCs from these species are much less used in research laboratories than mouse and human and are therefore not described specifically in this document although much of this document will be relevant to them.

Human PSCs developed in research environments will give the clues to the development of cell therapies, thus ensuring that cell lines used in this dynamic field have been prepared and documented appropriately and have the correct identity and characteristics, which is critical to help ensure reproducibility in PSC-based research. This document aims to meet the current demand for standardized PSC procedures of biobanks and builds on international consensus agreed by PSC resource centres^[9]. This document specifies the establishment, maintenance, characterization, storage and distribution requirements for mouse and human PSCs, providing a general guideline for both biobanking and fundamental research of PSCs.

Biotechnology — Biobanking — Requirements for human and mouse pluripotent stem cells

1 Scope

This document specifies requirements for the biobanking of human and mouse pluripotent stem cells (PSCs), including the collection of biological source material and associated data, establishment, expansion, characterization, quality control (QC), maintenance, preservation, storage, thawing, disposal, distribution and transport.

This document is applicable to all organizations performing biobanking with human and mouse PSCs used for research and development.

This document does not apply to cell lines used for *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/TS 20388:2021, *Biotechnology — Biobanking — Requirements for animal biological material*

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 20387:2018 and the following apply.

ISO and IEC maintain terminological 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

biobank

legal entity or part of a legal entity that performs *biobanking* (3.2)

[SOURCE: ISO 20387:2018, 3.5]