



BSI Standards Publication

Biotechnology — General requirements and considerations for cell line authentication

National foreword

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Biotechnology — General requirements and considerations for cell line authentication

*Biotechnologie — Exigences et considérations générales relatives à
l'authentification de la lignée cellulaire*



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Foreword

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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

Cell line authentication is a critical quality control (QC) procedure, which aims to verify a cell line's identity and show that it is free of contamination from other cell lines. It has been estimated that a considerable proportion of the cell lines stored in the United States, Europe and Asia are misidentified or cross-contaminated, which results in potentially misleading or non-repeatable data, causing tremendous waste of time and effort.^[13] To facilitate proper utilization of a cell line, the standardization of procedures used for cell line authentication is urgently needed. This document elaborates on general requirements for cell line authentication based on the existing national standards and state-of-the-art methods, aiming to represent and provide guidance to stakeholders in life science, biomedicine and other related fields.

Biotechnology — General requirements and considerations for cell line authentication

1 Scope

This document defines terms related to cell line authentication in the field of biotechnology. It describes the general principles, detection strategies and analytical methods for cell line authentication. It specifies requirements and key considerations for method selection, quality control parameters, data analysis and reporting.

This document is applicable to routine inspection of cell lines in culture and in storage in the fields of basic research, translational studies and product manufacturing. It is also applicable to cell line origin validation in academic and industrial laboratories, cell banks and manufacturing sites. It is primarily applicable to mammalian cells, including human cells.

This document does not apply to non-animal cells (e.g. microbial contamination, plant cells), nor to cells in complex matrices (e.g. tissues, organs, organoids, plants).

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/IEC 17025](#), *General requirements for the competence of testing and calibration laboratories*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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

cell bank

collection of appropriate containers, whose contents are of uniform composition, stored under defined conditions, and where each container represents an aliquot of a single pool of cells

[SOURCE: ICH Q5D^[14]]

3.2

cell line

defined population of cells that has been passaged from a primary culture, and can be maintained in culture for an extended period of time, retaining stability of certain initial phenotypes and functions for its intended use

Note 1 to entry: A primary culture is a culture started from cells, tissues or organs taken directly from an organism, and before the first subculture, propagation and consecutive passages *in vitro*.