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Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

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Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at <https://standardsdevelopment.bsigroup.com/>. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx
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1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex (e.g. 3.1)	Paragraph/ Figure/Table/Note	Type of comment	Comment (justification for change) by the MB	Proposed change by the MB	Secretariat observations on each comment submitted
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	



DRAFT International Standard

ISO/DIS 23511

Biotechnology — General requirements and considerations for cell line identification and cross- contamination testing

ICS: 07.080

ISO/TC 276/SC 1

Secretariat: **ANSI**

Voting begins on:
2025-08-18

Voting terminates on:
2025-11-10

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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

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, free of adventitious agents, and expresses cell-specific characteristics (including phenotype, genotype, and function). Each of these methods are necessary for cell line authentication and are only supportive information on their own. It has been estimated that a considerable proportion of the cell lines stored in the biobanks and laboratories in the United States, Europe and Asia are misidentified or cross-contaminated, which results in potentially erroneous or irreproducible data, causing tremendous waste of time, money and effort.^[13] To facilitate proper utilization of a cell line and ensure the accuracy and validity of the results of cell research and application, the standardization of procedures used for cell line authentication is urgently needed. This document elaborates on aspects of cell authentication and provides general requirements for cell line identification and cell line cross-contamination 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 identification and cross-contamination testing

1 Scope

This document provides terms and definitions, general principles, detection strategies and analytical methods for cell line identification of mammalian cells in the field of biotechnology. It also specifies general requirements and key considerations for method selection, quality control parameters, data analysis and reporting in cell line identification.

This document is applicable to routine cell line cross- contamination testing in the fields of basic research, translational medicine studies and cell therapeutic product manufacturing. It is also applicable to cell line identity confirmation to prevent cell misidentification in academic and industrial laboratories, cell banks and manufacturing sites. It is primarily applicable to mammalian cells.

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

allele

member of two or more alternative forms of a DNA sequence found at a particular locus

[SOURCE: ISO/IEC 19794-14:2022, 3.1.6]

3.2

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]]

3.3

cell line

progeny of a primary culture (3.16) after it has been passaged beyond crises or beyond senescence either spontaneously or after introduction of immortalizing factors.

Note 1 to entry: Note to entry: A cell line is continuous for proliferation.

[SOURCE: ISO 21709:2020, 3.2]

3.4

cell line authentication

process by which the *cell line* (3.3) identity is verified, confirmation of cell line origin, free of cell line cross-contamination, free of adventitious agents, and express cell-specific characteristics (phenotype, genotype, function).

3.5

cell line identification

the process by which a *cell line* (3.3) identity is verified or confirmed.

3.6

cross- contamination detection limit

lowest quantity of cross-contamination cells that can be identified using a specific method

3.7

DNA barcoding

method of identifying organisms at the species level based on short, standardized DNA fragments containing both conserved and variable sequences from a specific region or regions of the genome

Note 1 to entry: The principle of DNA barcoding is that by comparison with a reference database the sequence from these DNA fragments can be used to uniquely identify an organism or link it to a specific taxon.

Note 2 to entry: the mitochondrial cytochrome c oxidase subunit I (CO1) gene is commonly used for species determination in DNA barcoding.

[SOURCE: ISO 16577:2022, 3.7.3]

3.8

inter-species cross-contamination

contamination of a cell line by cells from another species

3.9

intra-species cross-contamination

contamination of a cell line by cells from the same species

Note 1 to entry: include the same type of cells from different individuals or different types of cells from different individuals

3.10

cell line misidentification

incidence where the *cell line* (3.3) identity no longer corresponds to the donor or species from which it was originally established.

Note 1 to entry: Improper naming of newly established cell lines or cell line derivatives (clones) can lead to cell line misidentification

3.11

cell line origin

Cell line origin includes race, sex, age, tissue, and disease and date when cell line was established.

3.12

cell type

classification used to distinguish among distinct cell forms

[SOURCE: ISO 21709:2020(en), 3.5]

3.13

gene mutation

a permanent alteration (as by point mutation or frameshift mutation) in the nucleotide sequence of a gene, referred to as alterations in a single-base pair nucleotide or changes in one or more nucleotides altering the open-reading frame