

ISO 23511:2026-07 (E)

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

Contents

Page

Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Principles of cell line authentication	4
4.1 General	4
4.2 Cell line identification	5
4.3 Detection of cross-contamination	6
4.3.1 Detection of cell line inter-species cross-contamination	6
4.3.2 Detection of cell line intra-species cross-contamination	6
4.4 Confirmation of cell line-specific characteristics	6
4.4.1 General	6
4.4.2 Detection of cell line heterogeneity	7
4.4.3 Detection of cellular differentiation	7
4.5 Best practice in cell culture	7
4.5.1 General	7
4.5.2 Aseptic technique	7
4.5.3 Equipment and reagents	8
4.5.4 Regular cleaning	8
4.5.5 Proper handling	8
4.5.6 Correct labelling	8
4.5.7 Monitoring	8
4.5.8 Quarantine new cell lines	8
4.5.9 Regular stocking of cells in culture	8
5 Application scenarios of cell line authentication	9
6 Detection method for cell line identification and cellular cross-contamination	9
6.1 General	9
6.2 DNA-based cell line identification methods	9
6.2.1 Short tandem repeat profiling for human cell lines	9
6.2.2 STR profiling for non-human cell lines	12
6.2.3 Single nucleotide polymorphism profiling	13
6.2.4 DNA barcoding	14
6.2.5 Species-specific Multiplex PCR	14
6.2.6 Whole genome sequencing	15
6.3 Related methods for cell line authentication	15
7 Method selection for different purposes	16
7.1 General	16
7.2 Method selection for verification of cell identity	16
7.2.1 Confirmation of cell line identification	16
7.2.2 Identification of cell line genetic profile	16
7.2.3 Identification of cell line gene mutations	16
7.2.4 Authentication for co-cultured cells	16

7.2.5	Authentication for ex vivo cell culture	17
7.3	Method selection for cell line cross-contamination	17
7.3.1	Cell line inter-species cross-contamination	17
7.3.2	Cell line intra-species cross-contamination	17
7.4	Authentication purpose	18
8	Quality control	18
8.1	Personnel training	18
8.2	Instruments and equipment	18
8.3	Reagents	19
8.4	Validation and verification of methods	19
8.4.1	General	19
8.4.2	Validation	19
8.4.3	Verification	19
8.5	Control of laboratory operation	19
9	Report	20
Annex A (informative)	Detection methods for cell line identification and cell line cross-contamination	21
Bibliography		23