

ISO/TS 22859:2022-07 (E)

Biotechnology - Biobanking - Requirements for human mesenchymal stromal cells derived from umbilical cord tissue

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	Abbreviated terms and symbols	5
5	General requirements	10
5.1	General	10
5.2	Personnel, facilities and equipment	10
5.3	Reagents, consumables and other supplies	11
5.4	Management of information and data	11
6	Collection of umbilical cord and associated data	11
6.1	Information about the umbilical cord donor	11
6.2	Collection procedure	12
7	Transport of umbilical cord or hUC-MSCs and associated data to the biobank	13
8	Reception and traceability of umbilical cord tissue or hUC-MSCs and associated data	13
9	Isolation and expansion of hUC-MSCs	13
9.1	Processes	13
9.2	Unique identification	13
9.3	Testing for infectious agents	14
9.4	Isolation of hUC-MSCs and primary culture	14
9.5	Subculture and limited expansion	14
10	Characterization of hUC-MSCs	14
10.1	General	14
10.2	Viability	15
10.3	Morphology	15
10.4	Population doubling time and subculture/passage	16
10.4.1	PDT	16
10.4.2	Subculture/passage	16
10.5	Cell population purity	16
10.6	In vitro self-renewal assessment	17
10.7	Proliferation	17
10.8	Differentiation capability -- In vitro multilineage differentiation	17
10.8.1	General	17
10.8.2	In vitro adipogenic differentiation	17
10.8.3	In vitro chondrogenic differentiation	18
10.8.4	In vitro osteogenic differentiation	18
10.9	Immunophenotyping by flow cytometry	18
10.10	Paracrine secretion/expression (protein-based assay of secretome)	20
10.11	Immunoregulation (modulation of immune cells)	20

10.12	Microbial contamination	21
11	Quality control	21
12	Storage	22
13	Thawing	23
14	Disposal	24
15	Distribution of hUC-MSCs -- Information for users	24
16	Transport of hUC-MSCs	24
16.1	General	24
16.2	hUC-MSCs frozen in ampoules or cryovials	25
16.3	Living hUC-MSC cultures	25
Annex A (informative) Exemplary quality control test procedure for biobanking of hUC- MSCs		27
Annex B (informative) Examples for suitable methods for the isolation and primary culture of hUC- MSCs		28
Annex C (informative) Exemplary methods for characterization of hUC-MSCs		30
Bibliography		32