ISO 24651:2022-08 (E)

Biotechnology - Biobanking - Requirements for human mesenchymal stromal cells derived from bone marrow

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 Abbreviated terms and symbols 5

5 General requirements 7
5.1 General 7
5.2 Personnel, facilities and equipment 7
5.3 Reagents, consumables and other supplies 8
5.4 Management of information and data 8

6 Collection of bone marrow samples and associated data 8
6.1 Information about the bone marrow donor 8
6.2 Anatomical collection site 9
6.3 Collection volume 9
6.4 Collection procedure 9
6.4.1 General 9
6.4.2 Obtaining bone marrow by puncturing into the intramedullary canal 10
6.4.3 Obtaining bone marrow by aspirate 10

7 Transport of bone marrow samples or hBM-MSCs and associated data to the biobank 10

8 Reception and traceability of bone marrow or hBM-MSCs and associated data 10

9 Isolation and expansion of hBM-MSCs 11
9.1 Processes 11
9.2 Unique identification 11
9.3 Testing for infectious agents 11
9.4 Isolation of hBM-MSCs from bone marrow samples obtained by puncturing into the intramedullary canal and primary culture 11
9.5 Isolation of hBM-MSCs from bone marrow samples obtained by aspirate and primary culture 12
9.6 Subculture and limited expansion 12

10 Characterization of hBM-MSCs 12
10.1 General 12
10.2 Viability 13
10.3 Morphology 13
10.4 Population doubling time and subculture/passage 13
10.4.1 PDT 13
10.4.2 Subculture/passage 14
10.5 Cell population purity 14
10.6 In vitro self-renewal assessment 14
10.7 Proliferation 14

10.8 Differentiation capability -- In vitro multilineage differentiation 15
10.8.1 General 15
10.8.2 In vitro adipogenic differentiation 15
10.8.3 In vitro chondrogeneic differentiation 15
10.8.4 In vitro osteogenic differentiation 16
10.9 Immunophenotyping by flow cytometry 16
10.10 Paracrine secretion/expression (protein-based assay of secretome) 17
10.11 Immunoregulation (modulation of immune cells) 17
10.12 Microbial contamination 18

11 Quality control 19

12 Storage 19

13 Thawing 20

14 Disposal 20

15 Distribution of hBM-MSCs -- Information for users 21

16 Transport of hBM-MSCs 21
16.1 General 21
16.2 hBM-MSCs frozen in ampoules or cryovials 22
16.3 Living hBM-MSC cultures 22

Annex A (informative) Preparation of human bone marrow mononuclear cells (hBM-MNCs) 23

Bibliography 24