

ISO 20391-1:2018-01 (E)

Biotechnology - Cell counting - Part 1: General guidance on cell counting methods

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General concepts of cell counting	4
4.1	General	4
4.2	Total cell counting	5
4.3	Differential cell counting	5
4.4	Direct cell counting	5
4.5	Indirect cell counting	5
5	Considerations for cell counting measurements	5
5.1	Selection of a cell counting method	5
5.2	Considerations for selecting a cell counting method	6
5.3	Sampling of cells for counting	6
5.4	Preparation of cell samples for counting	7
5.4.1	Environmental factors	7
5.4.2	Procedures	7
5.4.3	Quality and stability of reagents	7
5.5	Performing a measurement	8
6	Qualification, validation, and verification	8
6.1	Instrument qualification	8
6.2	Method validation and verification	8
6.3	Reference materials	9
6.3.1	Certified reference materials	9
6.3.2	In-house reference materials	9
6.3.3	Uses of reference materials	9
7	Data processing, analysis, and reporting	10
7.1	Data processing and analysis	10
7.1.1	General	10
7.1.2	Image processing and analysis	10
7.1.3	Gating	10
7.1.4	Coincidence correction	10
7.2	Reporting	10
Annex A (informative) Description of common cell counting methods		11
Annex B (informative) Common cell counting methods for various measurement purposes		14
Bibliography		15