



International

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ISO 8934-1

**Biotechnology — Cell viability
analytical methods —**

**Part 1:
General requirements and
considerations**

*Biotechnologie — Méthodes d'analyse de la viabilité cellulaire —
Partie 1: Exigences générales et considérations*

**First edition
2026-05**



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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

Published in Switzerland

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Foreword	v
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Symbols and abbreviated terms	9
5 General concepts of cell viability	9
5.1 General	9
5.2 Cell viability analytical methods	10
5.2.1 General	10
5.2.2 Count-based cell viability analytical methods	11
5.2.3 Non-count-based cell viability analytical methods	12
5.3 Cell viability as a measurand	12
5.3.1 General	12
5.3.2 Measurand charts for cell viability analytical methods	13
6 Design of fit for purpose cell viability analytical methods	15
6.1 General	15
6.2 Intended use	15
6.3 Viable state attributes and measurement principles	16
6.4 Sample considerations and recommendations	18
6.5 Measurement process	19
7 Design of a matrix of cell viability analytical methods	20
8 Managing sources of variability in a cell viability analytical method	20
8.1 General	20
8.2 Pre-analytical phase considerations	21
8.2.1 General	21
8.2.2 Presence of contamination (biological)	23
8.3 Analytical phase considerations	23
8.3.1 General	23
8.3.2 Test sample preparation	23
8.3.3 Test sample stability	24
8.3.4 Analytical reagents	24
8.3.5 Environmental conditions	25
8.3.6 Instrumentation and data collection	26
8.3.7 Data analysis	27
8.4 Post-analytical phase considerations	30
8.4.1 General	30
8.4.2 Measurement uncertainty	30
8.4.3 Reporting of cell viability	31
8.4.4 Metadata documentation	31
8.4.5 Interpretation of cell viability results	32
9 Cell viability analytical method qualification, validation, and continued verification	33
9.1 General	33
9.2 Qualification	33
9.2.1 Qualification characteristics	33
9.2.2 Accuracy	33
9.2.3 Repeatability	34
9.2.4 Specificity and Selectivity	34
9.2.5 Sensitivity	34
9.2.6 Linearity and Proportionality	35
9.2.7 Range	35

This is a preview of ISO 8934-1:2026. [Click here to purchase the full version from the ANSI store.](#)

9.3.2	Intermediate precision	36
9.3.3	Limit of detection (LoD) and limit of quantitation (LoQ)	36
9.3.4	Robustness and Ruggedness	37
9.4	Continued verification	37
9.5	Quality control materials for cell viability measurements	37
Annex A (Informative)	Examples of cell viability analytical methods and their viable state attributes	39
Annex B (Informative)	Example measurand chart for the luminescent cell viability analytical method	41
Annex C (Informative)	Sources of cell stress that can affect the viable state of the cell	43
Annex D (Informative)	Considerations for viability testing by pre-analytical treatment	46
Annex E (Informative)	Considerations for cell viability as a quality attribute in the testing and characterization of cellular therapeutic products	49
Annex F (Informative)	Conceptual process for Cell Viability Analytical Method Development	51
Bibliography		53

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This document was prepared by Technical Committee ISO/TC 276, *Biotechnology*, Subcommittee SC 1, *Analytical methods*.

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Evaluation of cell viability is a fundamental measurement in biotechnology. Cell viability measurements are widely and routinely used in basic research, drug discovery, toxicity testing, manufacturing control and release testing for cell banks, biological products, and cellular therapeutic products. Cell viability can be important in ensuring the safety and efficacy of cellular therapeutic products, in determining cell dose and product potency in cellular therapeutic products, and in the manufacturing and control of cell-based products and products derived from cells.

A quantity value for cell viability can be determined through a broad range of analytical methods evaluating different attributes related to the viable state of the cell(s). Several biological properties, or attributes, serve as the targets for identifying the viable state of the cell(s), and can be used to determine the viability status of cells. Examples include observations of the cell's membrane integrity, metabolic activity, nuclear morphology, and a cell's ability to replicate. Cell viability can also refer to different quantities related to viable and non-viable cells including percent cell viability, viable cell concentration, and signals related to the viable state. There is also a wide range of instrumentation used in the measurement of cell viability, including image based, flow cytometry based, spectrophotometric, and electrical signal-based approaches. Given the wide range of analytical methods associated with cell viability, it is often challenging to compare cell viability results from different analytical methods without additional knowledge regarding the viable state attribute investigated or the analytical method that was conducted. In addition, different applications require the use of different cell viability analytical methods that are compatible with or relevant to the intended use. Although cell viability standards exist, these standards are either test method specific, test article specific, sector specific or region specific. Existing standards do not address the general need of establishing common terminology for cell viability, considerations for fit for purpose cell viability analytical method development and the reporting of cell viability measurement results.

This document establishes a common approach for defining fit for purpose cell viability analytical methods to facilitate common understanding between users of the standard. This document provides general concepts and terminology for cell viability measurements, provides considerations for measurement control strategies and validation strategies, and considerations for establishing cell viability analytical method standard operating procedures. This document also includes the establishment of a common framework for reporting cell viability measurements.

This document is intended for a broad and worldwide industry where the quality and viability of cells are critical for research and product development.

This part of the ISO 8934 series is focused primarily on mammalian cells.