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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 42076.1-2022

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

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foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for Standardization Work Part 1. Structure and Drafting Rules for Standardization Documents" drafting.

This document is Part 1 of GB/T 42076 "Biotechnology Cell Counting". GB/T 42076 has issued the following parts.

--- Part 1. General rules for cell counting methods.

This document is equivalent to ISO 20391-1:2018 "Cell Counting in Biotechnology Part 1. General Rules for Cell Counting Methods".

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

This document was proposed and managed by the National Biochemical Testing Standardization Technical Committee (SAC/TC387).

Introduction

Cell counting is a fundamental measurement that broadly impacts many aspects of biotechnology, from biomanufacturing to advanced medicine. This

The number of cells (or number of discrete cells) is usually expressed as the concentration of cells in suspension (ie, the number of cells per unit volume) and the number of cells adhered to a certain surface

Bulk density (that is, the number of cells per unit area). Cell counts are critical in assessing the efficacy and efficacy of cell-based therapies. Bioreactor

The concentration of cells in can be used as an indicator for quality assurance in the cell-based manufacturing process. Many cell-based bioassays require

Normalize the respective cell count results to ensure that the data are comparable to each other.

GB/T 42076 is proposed to be composed of two parts.

--- Part 1. General rules for cell counting methods. Part 1 provides the theoretical basis for Part 2, which aims to provide cell counts

General principles and considerations to be followed.

--- Part 2. Experimental design and statistical analysis to quantify the performance of counting methods. Part 2 is the expansion and specific operation of Part 1 and implementation details.

Biotechnology Cell Counting

Part 1. General rules for cell counting methods

1 Scope

This document defines terms related to cell counting in the field of biotechnology, and describes cell counts (usually cell concentrations) and viscose counts in suspension.

Cell counts attached to the matrix (usually cell area density), providing cell counting methods (including total and differential counts, direct counts

and indirect counting), as well as key considerations for the choice of method and measurement process, specify the guidelines for data processing, analysis, and reporting.

Require.

This document is applicable to the enumeration of all cell types, including mammalian and non-mammalian (e.g. bacteria, yeast) cell counts.

This document is not intended for cell counting in tissue sections or biomaterial matrices.

There are international and national standards related to cell counting in different fields/specific application scenarios. If applicable, the user can operate within its range

Reference to existing standards within the scope (specific measurement technique and/or application scenario).

2 Normative references

This document has no normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1

Accuracyaccuracy

The degree of agreement between the measured value of a measurand and its true value.

Note 1. "Measurement accuracy" is not a quantitative concept, nor is it a quantitative value. When a measurement gives a smaller measurement error, it indicates that the measurement is more accurate.

Note 2 to entry. "Measurement accuracy" is sometimes understood as giving the degree of agreement between measured values to be measured.

[Source. ISO /IEC Guide 99:2007, 2.13, with modifications]

3.2

Cell mass agglomerate

Two or more cells are faintly clustered together and detected as one larger object.

NOTE. Cell clumps can often be dissociated into individual cells without significant damage to the cells.

3.3

cell aggregate aggregate

Two or more cells come together (closely or loosely) and are detected as larger objects.

NOTE. Cell aggregates are generally more difficult to separate into individual cells.

3.4

area density

The number of adherent cells per unit surface, usually expressed as the number of cells per unit area.

3.5

attribute attribute

Physical, chemical, biological or microbiological properties or characteristics.