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

GB/T 42076.2-2025

**Biotechnology - Cell Counting - Part 2: Experimental design
and statistical analysis to quantify counting method
performance**

生物技术 细胞计数 第2部分：量化计数方法性能的实验设计与统计分析
(English Translation)

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Table of Contents

Preface	
Introduction	
1 Scope	
2 Normative References	
3 Terms, Definitions, Symbols, and Abbreviations	
3.1 Terms and Definitions	
3.2 Symbols and Abbreviations	
4 Principles	
4.1 General Rules	
4.2 Scale	
4.3 Deviation Ratio	
5 Experimental Design	
5.1 General Rules	
5.2 Precautions during cell counting measurement	
5.3 Preparing Samples for Experimental Design	
5.4 Test Sample Label	
5.5 Measurement of Test Samples	
6 Statistical Methods	
6.1 Overview	
6.2 Mean cell count	
6.3 Measurement precision	
6.4 Scaling Model Fitting	
6.5, coefficient of determination	
6.6 Proportional Index (PI)	
6.7 Additional Statistical Analysis and Quality Indicators	
6.8 Explanation of Data	
7 Report	
7.1 Quality Indicator Report	
7.2 Experimental Design Parameters and Statistical Analysis Methods (Document 17)	
7.3 Additional Reporting Elements of the Cell Count Measurement Process	
Appendix A (Informative) Methods for assessing the impact of pipetting errors on dilution integrity	

A.1 Overview

Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting.

This document is Part 2 of GB/T 42076 "Biotechnology - Cell Counting". GB/T 42076 has already published the following parts.

---Part 1: General Rules for Cell Counting Methods;

---Part 2: Experimental Design and Statistical Analysis of the Performance of the Quantization Counting Method this document is equivalent to ISO 20391-2:2019 "Biotechnology - Cell counting - Part 2: Experimental apparatus for evaluating the performance of quantitative counting methods".

"Calculation and Statistical Analysis".

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed and is under the jurisdiction of the National Technical Committee on Standardization of Biochemical Testing (SAC/TC387).

Introduction

Cell counting impacts many aspects of biotechnology, from biomanufacturing to medical diagnostics to advanced therapies. Cell counting can be used as a means of...

Quality control measures used in the process can also be applied to decision-making. Cell count is also an important parameter in many cell-based assays, including...

This includes activity and potency assays-the results of which are typically normalized to cell counts for data comparison.

Cell counts are usually expressed as concentrations, and can reflect either the total number of cells in a cell population (total cell count) or the number of cells in a subpopulation.

Cell count (differential cell count). Advances in instrumentation have spurred the development of various techniques and instruments for total cell counting and/or differential cell counting.

However, due to the lack of readily available standard substances/samples or true values, the accuracy of the measurement method is difficult to determine. And biological samples...

The complexity of this preparation (such as cell type, origin, and preparation process) further exacerbates this problem. Currently, some standards exist for specific...

The use of cell counting or specific measurement systems in industry/applications (see GB/T 42076.1-2022 and reference [16]). Some of these the method employs a comparability approach, that is, by tracing the results of a newer cell counting assay back to those of a more established cell counting assay.

The results are achieved through this approach. While this comparability strategy allows data from the second instrument to be compared with data from the (more established) master instrument used as a benchmark.

In comparison, it does not solve the quality problem of any measurement process. Therefore, in the absence of standard substances/standard samples or reference methods, it is ineffective.

However, relevant strategies still need to be developed to ensure the quality of the cell counting measurement process.

GB/T 42076 is proposed to consist of two parts.

---Part 1: General Principles of Cell Counting Methods. Part 1 provides the theoretical basis for Part 2 and aims to provide methods for cell counting.

General principles and precautions to be followed.

---Part 2: Experimental Design and Statistical Analysis of the Performance of the Quantization Counting Method. Part 2 expands upon and details Part 1.

Details of the work and implementation.

This document provides a method for evaluating quality-related aspects of cell counting procedures using a dilution series experimental design. Based on this...

The experimental design allows for the derivation of a set of quality metrics to evaluate the performance of the cell counting measurement process. Specifically, these quality metrics can assess the precision and proportionality of the cell counting measurement process are assessed. This is especially important when accuracy cannot be determined (i.e., a traceable reference method or traceable...).

This method is particularly useful when using standard substances/standard samples; it is also generally applicable to quality verification and monitoring of cell counting measurement processes.

Control and other aspects.

The information contained in this document will provide credibility to the data generated by the selected cell counting measurement procedure. This method may be helpful for providing specific...

Selecting or optimizing the cell sample preparation process may also provide supporting performance parameters for a specific cell counting measurement procedure.

It can be confirmed.

Biotechnology cell counting Part 2: Experimental Design for Performance of Quantization Counting Methods with statistical analysis

1 Scope

This document describes a method based on dilute-based quality indicators to assess the quality of each step in the cell counting process of a specific cell preparation.

The experimental design and statistical analysis methods were employed. These quality indicators were based on the repeatability of the measurements and the response of the measurement results to the ideal dilution fraction.

The model's fit is evaluated.

This document applies to the measurement of total cell count, differential cell count, and direct and indirect cell count methods, provided that the measurement process is performed correctly.

The experimental design criteria must be met (e.g., cells must be suspended in solution).

This document is most applicable during the development, optimization, validation, evaluation, and/or confirmation of cell counting methods and cell counting measurement processes.

This document is particularly applicable in situations where suitable reference materials/standard samples are unavailable for accuracy assessment. This method does not directly provide cells.

Accuracy of counting.

This document is primarily applicable to eukaryotic cells.

Note: Cell counting is already present in several international and national standards for specific industries/applications. Therefore, referring to existing standards within the applicable scope is advisable.

Very helpful.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this