

ICS 07.080
CCS B 04



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

GB/T 46526-2025

**Biotechnology - Analytical methods - Risk-based approach for
method selection and validation for rapid microbial detection in
bioprocesses**

生物技术 分析方法 生物制造过程中基于风险考虑的微生物快速检测方法选择与
确认

(English Translation)

Issued on: October 31, 2025

Implemented on: May 1, 2026

Issued by: State Administration for Market Regulation

Table of Contents

Preface	
1 Scope	
2 Normative References	
3 Terms and Definitions	
4 General considerations	5.
5 Microbial contamination risk management	6.
5.1 Risk Management in the Production Process	
5.2 Risk Management of Microbial Testing	
6 Choose a suitable testing method.	7.
6.1 General Rules	
6.2 Selection of Measurement	
6.3 Reagent Kit or System Selection	
6.4 Precautions for various test types	
6.5 User Requirements Specification	
7 Confirm	
7.1 General Concepts	
7.2 Selection of Microorganisms	
7.3 Quality Design for Method Validation	
7.4 Re-confirmation of the method	
7.5 System Confirmation	
7.6 Use of reference materials/standard samples	12 in validation
7.7 Acceptance Criteria for Target Verification Parameters	
7.8 Precision	
7.9 Detection limit	
7.10 Accuracy	
7.11 Robustness	
7.12 Durability	
8 Use and Application of Rapid Microbial Detection	
8.1 Quantity and Type of Samples	
8.2 Test Environment	
8.3 Sensitivity	
8.4 Analytical Specificity (Microbial Detection)	

8.5 Comparable test data

9 Investigation of positive sterile results

10 Training sessions

11 Document

12 Test Report

Appendix A (Informative) A Paradigm Framework for Identifying Microbial Contamination

Appendix B (Informative) Donor Selection in Risk Analysis of Input Materials Related to Cell Therapy Products

Appendix C (Informative) Risk Analysis of Input Materials Related to Cell Therapy Products. Cell Transformation and Expansion

Appendix D (Informative) Risk Analysis of Input Materials Related to Cell Therapy Products. Packaging, Storage, and Management

Appendix E (Informative) Risk Classification of Cell Therapy Product Manufacturing Monitoring Practices

Appendix F (Informative) Validation of Rapid Microbial Detection Methods

F.1 Overview

F.2 Detection limit

F.3 Robustness

Appendix G (Informative) 24 Microorganisms Used to Confirm Rapid Microbial Detection Methods

Appendix H (Informative) Rapid Detection Methods for Microorganisms

H.1 Sequence-based methods

H.2 Solid-phase cell analyzer

H.3 Tilted Nanoarray

H.4 Spectral Analysis and Partial Least Squares Method

H.5 Bioluminescence-based testing

H.6 Mass Spectrometry

H.7 Flow cytometry

H.8 Liquid Chromatography-Mass Spectrometry

H.9 Binding affinity determination

Appendix I (Informative) Environmental Monitoring

References

Foreword

This document conforms to GB/T 1.1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents".

Drafting is scheduled.

This document is equivalent to ISO 24190:2023 "Analytical methods for biotechnology - Risk-based microbial analysis in biomanufacturing processes".

Selection and Validation of Rapid Detection Methods for Substances.

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/TC 387).

1 Scope

This document provides guidance, a framework, and risk-based considerations for the selection and validation of rapid microbial detection methods in biomanufacturing processes.

The method.

This document provides a flexible, risk-based framework for detecting microbial contamination in biomanufacturing processes.

This document outlines the general requirements and risks associated with the manufacture of cell therapy products, while also providing flexibility to adapt to each unique cell type.

Differences in the specific manufacturing processes of therapeutic products.

This document applies to sterility testing in the production of cell therapy products, and also to the production of other cell-derived therapeutic products.

This document focuses on rapid microbial testing methods (RMTM) for use in process and final product testing.

This document does not apply to virus testing in the production of cell therapy products.

2 Normative references

This document does not contain any normative references.

3 Terms and Definitions

The following terms and definitions apply to this document.

The URLs for the terminology databases maintained by ISO and IEC for standardization are as follows.

Acceptance criteria

Numerical limits, ranges, or other properties or variables that satisfy the predefined performance of the determination.

Note: Acceptance criteria are specified in User Requirements Specification (3.30).

accuracy

Measurement accuracy the consistency between the measured value and its true value.

Note 1: The concept of "measurement accuracy" is not a quantity, nor is a numerical value given. When the measurement error is small, the measurement is considered relatively accurate.

Note 2: The term "measurement accuracy" is not used to refer to the correctness of a measurement, and the term "measurement precision" is not used to refer to "measurement accuracy." However, it is related to both of these concepts.

Related to the concept.

Note 3: "Measurement accuracy" is sometimes understood as the degree of consistency between the measured values of the measurand.

[Source. ISO 16140-1:2016, 2.2]