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

GB/T 46938-2025

**General principles for the detection technology of biological
enzymes**

生物酶检测技术通则

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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. 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). This document was drafted by: Institute of Biology, China Academy of Testing Technology; Shenzhen Second People's Hospital; and Shenzhen Yirui Biotechnology Co., Ltd. Limited Liability Company, Nanjing Novizan Biotechnology Co., Ltd., Nanning Pangbo Biotechnology Co., Ltd., Wuhan Xinhua Yang Biotechnology Co., Ltd. Limited Company, The First Affiliated Hospital of Chengdu Medical College, Sinopharm Group Weichida Pharmaceutical Co., Ltd., North Sichuan Medical College, Sichuan Wovente Biotechnology Co., Ltd. Limited Company, Qingdao University of Science and Technology, Shenzhen Gufang Traditional Chinese Medicine Pieces Co., Ltd., Guangzhou Heshi Biotechnology Co., Ltd., Guangzhou Minte Biotechnology Limited Liability Company, Jiangsu Boyang Biological Products Co., Ltd., Taizhou Lingfeng Biotechnology Co., Ltd., Ningbo LinYE Biotechnology Co., Ltd., Jiangsu Snow Leopard Daily Chemical Co., Ltd., Zhuhai Langjian Biotechnology Co., Ltd., Hubei Tianshu Pharmaceutical Co., Ltd., and Sichuan Zhenxing Testing Technology Co., Ltd. Limited Liability Company, Xihua University. The main drafters of this document are. Ye Deping, Zhou Lihua, Gu Dayong, Xu Ying, Wang Bingzhi, Lei Jiahong, Wang Cui, Liu Hanling, Xu Li, and Yang Deqian. Wang Shuishu, Yi Huimin, Liu Yan, Yan Yiyong, Zhang Yongqin, Dai Jiyang, Chen Huayun, Peng Lisheng, Dong Zheqing, Cai Qingfeng, Fan Weiwei, Ge Chengqing, Chen Lei Zhou Xipeng, Su Xiaoyi, Liang Yuling, Zhang Yuanyuan, Luo Xiaojun, Liu Hong. General Rules for Bioenzyme Detection Technology

1 Scope

GB/T 46938-2025 is the Chinese national standard covering measuring enzyme activity - the substrate and conditions, the definition of a unit, the linearity and the controls, and the reporting, on measurements that are meaningless unless everyone states the conditions they were made under. First edition. It was issued on 31 December 2025 and has been in force since 1 July 2026, as a first edition. The document is under the responsibility of the Standardization Administration of China. This page is published from the official record of the 2025 edition; the clause text of a standard this recent is not yet in circulation, and the figures, limits and tables it contains are those of the document itself, delivered in full with the English translation.

This document specifies the general requirements, method validation or verification, experimental records and reports, and hazardous waste disposal for bio-enzyme detection technologies. The requirements describe a method for detecting biological enzymes. This document applies to the detection of bioenzyme activity, purity, and impurities during scientific research, production, and application.

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 document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 6682 Specifications and test methods for water used in analytical laboratories

3 Terms and Definitions

The following terms and definitions apply to this document.

3.1 bio-enzyme Biomolecules that have the function of catalyzing specific chemical reactions.

Note. See Appendix A for the classification of biological enzymes.

3.2 bio-enzyme activity The ability of a biological enzyme to catalyze a specific chemical reaction.

Note. It is usually expressed as the reaction rate of a chemical reaction under certain conditions. [Source: GB/T 37966-2019, 3.1.2, with modifications]

3.3 Purity of bio-enzyme The percentage of the target bioenzyme in the total protein or components of the sample.

Note. Ribozymes are not included. [Source: GB/T 40174-2021, 3.1, with modifications]

4.1 Environment

4.1.1 Laboratory facilities and environment shall meet the requirements of the analytical system.

4.1.2 All test operations shall be carried out in a clean environment.

4.2 Reagents or Materials

4.2.1 The water used should meet or exceed the Class II water requirements specified in GB/T 6682. Unless otherwise specified, such as if the prepared reagents need to be stored for a long period of time.