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GB/T 47145-2026

**Recombinant protein reagents - Method for the determination of
affinity**

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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: China Jiliang University, BGI Engineering Biology Changdanghu Institute, and Beijing Baipusaisi Biotechnology Co., Ltd. The company, China Academy of Testing Technology, China National Institutes for Food and Drug Control, Shanghai Institute of Metrology and Testing Technology Co., Ltd., and Zhejiang Kangbai. Yu Biotechnology Co., Ltd., Jiangsu Baiying Biotechnology Co., Ltd., China National Research Institute of Food Fermentation Industries Co., Ltd., Changzhou Xinyisheng Life Technology Co., Ltd., Hangzhou Huasai Disi Entropy Technology Co., Ltd., Beijing Huafang Tianshi Biopharmaceutical Co., Ltd., Beijing Tide Pharmaceutical Co., Ltd., Beijing Solarbio Technology Co., Ltd., Guojian Pharmaceutical (Shenzhen) Group Co., Ltd., Yunnan Normal University, China China Institute of Metrology and Testing, Institute of Biology, China Academy of Testing Technology. The main drafters of this document are: Zhang Yafen, Wang Meiniang, Chen Yiding, Ye Zihong, Zhou Lihua, Miao Jingyun, Li Junfang, Guo Shifu, and Li Lanying. Yang Wenjun, Xiang Lu, Gao Bo, Ge Pingju, Shi Xiaojuan, Jiang Wanlong, Fei Qi, Zheng Yue, Xiong Sichi, Liu Qian, Zhu Yanze, Wang Ran, Wu Juncheng, Chen Yichen, Yang Yunyun, Sun Liqin, Kong Xue, Li Wei, Ma Yuling, Dai Jihai, Li Fuchang, Yang Yangzhongfu, Wang Yujie, Liu Hechun. Recombinant protein reagent affinity assay method

1 Scope

GB/T 47145-2026 is the Chinese national standard covering measuring how tightly a recombinant protein binds its target - the association and dissociation rates and the resulting constant, measured by surface plasmon resonance or interferometry, which is the number that defines the reagent. First edition, in force since 1 May 2026. It was issued on

28 January 2026 and has been in force since 1 May 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 2026 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 describes an enzyme-linked immunosorbent assay (ELISA) method for determining the affinity of recombinant protein reagents. This document applies to the affinity determination of recombinant protein reagents such as cytokines, antibodies, and antigens.

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

GB 19489 General Requirements for Laboratory Biosafety

GB/T 40265 General Rules for Enzyme Immunoassay and Antibody Detection

3 Terms and definitions, abbreviations

3.1 Terms and Definitions The following terms and definitions apply to this document.

3.1.1 Reagents prepared by purifying proteins expressed in a host expression system using technologies such as recombinant DNA.

Note. Recombinant protein reagents, such as cytokines, antibodies, and antigens, are widely used in research, diagnostics, and industrial applications. Host expression systems include *Escherichia coli*, yeast... Mother, insect cells, mammalian cells, or other cells.

3.1.2 affinity The strength of the interaction between a recombinant protein and its target at a single binding site under specific conditions.

Note. Affinity is usually expressed as the equilibrium dissociation constant (K_D), with units of moles per liter (mol/L).

3.1.3 target A molecule that can be specifically recognized and bound by recombinant proteins under specific conditions.

3.2 Abbreviations The following abbreviations apply to this document. BSA. Bovine serum albumin