

ICS 07.080
CCS A 40



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

GB/T 33411-2025

Replacing GB/T 33411-2016

Guidelines for enzyme immunoassays kit

酶联免疫分析试剂盒通则

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Foreword

This document was issued on 25 April 2025 by the State Administration for Market Regulation and the Standardization Administration of the People's Republic of China, and has been in force since 25 April 2025.

It replaces GB/T 33411-2016.

The document is under the responsibility of the Standardization Administration of China.

Classification: ICS 07.080, CCS A 40.

1 Scope

GB/T 33411-2025 is the Chinese national standard covering the ELISA kit as a finished product - the appearance and the components from coated solid phase and antibody to enzyme conjugate and substrate, the detection limit, the specificity, the linearity of the standard curve, the agreement of the positive and negative controls, the accuracy, precision and stability, the test method behind each of those figures, and the instruction manual and label that carry them to whoever runs the plate. It replaces GB/T 33411-2016, adding specificity, control agreement and stability to the performance requirements and dropping the limit of quantification. In force from 25 April 2025. It was issued on 25 April 2025 and has been in force since 25 April 2025, replacing GB/T 33411-2016. 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.

About this edition

GB/T 33411-2025 is the current edition. It was issued on 25 April 2025 and has been in force since 25 April 2025, replacing GB/T 33411-2016.

GB/T 33411-2016 has been superseded: a specification that still cites it is citing a withdrawn edition.

The interval between issue and effect is the transition period. It exists so that producers, laboratories and buyers can requalify products, revise procedures and use up documentation before the new text becomes the one that applies. The date on this page is the official one from the record of the Standardization Administration.

Classification and status

GB/T 33411-2025 is classified under ICS 07.080, in the field of natural and applied sciences. ICS is the International Classification for Standards, the same scheme used by ISO and by the national bodies of most countries, which is what allows a Chinese standard to be placed beside its foreign counterparts on subject rather than on number.

Its Chinese Standard Classification code is CCS A 40. CCS is the domestic scheme, a letter for the sector and two digits for the subject within it, and it is the code by which the standard is filed and searched in China.

The GB/T prefix marks a recommended national standard. It is not, in itself, law: it becomes binding when a contract names it, when a regulation or a mandatory standard refers to it, or when a producer declares conformity with it. In practice that covers most of the cases in which it will be read - a purchase specification, an inspection agreement or a certification scheme.

The document is under the responsibility of the Standardization Administration of China, which is the body that maintains it and that will answer a formal question about its interpretation.

How a Chinese national standard is set out

Chinese national standards are drafted to the rules of GB/T 1.1, which fixes the order in which a standard is set out. The document opens with a foreword recording the issuing bodies, the relationship to any previous edition and the technical committee responsible for it. Clause 1 is the scope. Clause 2 lists the normative references - the other standards that have to be applied together with this one, and without which its requirements cannot be met. Clause 3 gives the terms and definitions. The technical clauses follow: the requirements themselves, the test or measurement methods by which conformity is established, the inspection rules that say how a lot is sampled and judged, and, for a product standard, the provisions on marking, packaging, transport and storage. Annexes, normative or informative, come last.

What is delivered is the complete document in that order: every clause, every table, every figure and every annex of the Chinese original, with the same numbering, so that a reference to a clause number in a contract or a test report points to the same place in both

languages.

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