

ICS 11.100.10

CCS C44



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

GB/T 21415-2025

Replacing GB/T 21415-2008

**In vitro diagnostic medical devices - Requirements for
establishing metrological traceability of values assigned to
calibrators, trueness control materials and human samples**

体外诊断医疗器械 建立校准品、正确度控制物质和人体样品赋值的计量溯源性要求

(English Translation)

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Foreword

GB/T 21415-2025 is a recommended national standard (GB/T) of the People's Republic of China, issued on 29 August 2025 by the State Administration for Market Regulation and the Standardization Administration of China, with effect from 1 March 2026.

This edition replaces GB/T 21415-2008.

The document adopts an international standard (ISO or IEC).

It is under the responsibility of the National Medical Products Administration.

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1 Scope

Results from in vitro diagnostic tests are only comparable between laboratories and over time if the values assigned to calibrators and control materials can be traced to a recognised reference. This document sets out requirements for establishing that metrological traceability for the values assigned to calibrators, trueness control materials and human samples used with in vitro diagnostic medical devices.

The primary readers are manufacturers of diagnostic reagents and calibrators, developers of reference materials, clinical laboratories that assign values to patient samples, and regulatory affairs staff who must document traceability in technical dossiers submitted to the authorities. External quality assessment providers and reference measurement laboratories will also find it relevant.

The standard was issued on 29 August 2025 and takes effect on 1 March 2026, replacing GB/T 21415-2008. It is a recommended national standard, so it is voluntary unless referenced by a regulation, registration requirement or contract. Companies whose quality systems still cite the 2008 edition should review their procedures against the new text.