

ICS 11.100



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

GB/T 21415-2008

**In vitro diagnostic medical devices - Measurement of quantities
in biological samples - Metrological traceability of values
assigned to calibrators and control materials**

体外诊断医疗器械 生物样品中量的测量 校准品和控制物质赋值的计量学溯源性

(English Translation)

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Table of Contents

Foreword	1
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Foreword

This Standard equivalently adopts ISO 17511:2003 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials.

For ease of use, the editorial modifications have been made in this Standard as follows.

- Modify the "international standard" to "this Standard";
- Replace the comma "," with decimal point ".";
- Delete the foreword of international standard.

The Standard was proposed by China Food and Drug Administration.

The Standard shall be under the jurisdiction of National Technical Committee (SAC/TC 136) on System of Medical Clinical Test Lab and in Vitro Diagnostic System of Standardization Administration of China.

The responsible drafting organizations of this Standard. Beijing Institute of Medical Device Testing, and Roche Diagnostics (Shanghai) Co., Ltd.

The chief drafting staffs of this Standard. Zong Yulong, Feng Renfeng, Zhang Xinmei, Hu Dongmei, Tao Yuan, and Kang Juan.

32) Stockl D, Franzini C, Kratochvila J, Middle J, Ricos C, Siekmann L, Thienpont LM.

Analytical specifications of reference methods. Compilation and critical discussion (From the members of the European EQA-organizers Working Group B) [Review].

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33) Velapoldi RA, Paule RC, Schaffer R, Mandel J, Machlan LA, Gramlich JW. A reference method for the determination of potassium in serum (Special Publication 260-60). Gaithersburg. National Bureau of Standards;1979.

34) WHO. Guidelines for the preparation, characterization and establishment of international and other standards and reference reagents for biological substances.

Techn Rep Ser 1990;No.800 (Annex 4).181-214.