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# PROFESSIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

# 中华人民共和国医药行业标准

YY/T 1175-2010

# Quantitative detection reagent (kit) for tumor markers - Chemiluminescent immunoassay

# 肿瘤标志物定量测定试剂（盒）化学发光免疫分析法

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## Foreword

This Standard is drafted in accordance with the rules specified in GB/T 1.1-2009.

Please note that some contents in this file may involve patents. The issued institution of this file should not bear the responsibility to identify these patents.

This Standard is proposed by the China Clinical Laboratory Testing and In vitro Diagnostic Test System of Standardization Administration of China (SAC/TC 136).

This Standard is under the jurisdiction of the China Clinical Laboratory Testing and In vitro Diagnostic Test System of Standardization Administration of China (SAC/TC 136).

This Standard is drafted by: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd., Beijing Yuande Bio-Medical Engineering Co., Ltd, Roche Diagnostic Products (Shanghai) Co., Ltd and Siemens Healthcare Diagnostics (Shanghai) Co., Ltd.

The main drafters of this Standard: Zhang Xinmei, Cheng Yinghao, Yang Xiaolin, Du Haiou, Cai Xiaorong and Zhu Weizan.

# Quantitative detection reagent (kit) for tumor markers - Chemiluminescent immunoassay

## 1 Scope

This Standard stipulates the terms and definition, classification, requirements, test method, marks, labels, instructions, packaging, transportation and storage etc. of quantitative detection reagent (kit) [herein after referred to as “reagent (kit)”] for tumor markers (chemiluminescent immunoassay).

This Standard applies to the reagent (kit) used for quantitative detection of human tumor markers taking the chemiluminescent immunoassay as principle, including the enzymatic and non-enzymatic chemiluminescent immunoassay detection reagent (kit) in the carrier of microplates, pipes, magnetic particles, microbeads and plastic beads.

This Standard does not apply to:

a) The calibration product and quality control product of tumor markers intended for separate sale;

b) Biochip in the principle of chemiluminescent immunoassay.

## 2 Normative references

The articles contained in the following documents have become this document when they are quoted herein. For the dated documents so quoted, all the modifications (Including all corrections) or revisions made thereafter shall be applicable to this document.

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

## 3 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

**3.1**

**Tumor marker, TM**

During the tumorigenesis and reproduction, it is generated or secreted by tumor cells or other cells and then released into the blood, body fluids, cells or tissues, which will reflex

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