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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 1160-2009

Carcinoembryonic Antigen Quantitative Detection Reagent (Kit) (Chemiluminescent Immunoassay)

癌胚抗原（CEA）定量测定试剂（盒）（化学发光免疫分析法）

Issued on December 30, 2009 **Implemented on June 1,2011**

Issued by China Food and Drug Administration

Contents

Foreword

The preparation of this Standard follows the basic regulations of the GB/T 1.1-2000 *Directives for Standardization, Part 1: Rules for the Structure and Preparation of Standards*, which is the basis for evaluation of carcinoembryonic antigen quantitative determination reagent (kit) (chemiluminescent immunoassay) product quality.

This Standard is proposed by the China Food and Drug Administration.

This Standard shall be under the jurisdiction of the National Medical Clinical Testing Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC 136).

Participating drafting organizations of this Standard: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd, Beijing Yuande Biomedical Engineering Co., Ltd, Roche Diagnostic Products (Shanghai) Co., Ltd and Beckman Coulter Co., Ltd.

Main drafters of this Standard: Zhang Xinmei, Cheng Yinghao, Sun Xudong, Hu Guomao, Ying Xitang, Cai Xiaorong and Zhang Jinwen.

Carcinoembryonic Antigen Quantitative Detection Reagent (Kit) (Chemiluminescent Immunoassay)

1 Scope

This Standard specifies the terms and definitions, classification, requirements, test methods, inspection rules, marks, labels, operating instructions, packaging, transportation and storage of carcinoembryonic antigen (CEA) quantitative determination reagent (kit) (chemiluminescent immunoassay).

This Standard applies to the quantitative determination of human carcinoembryonic antigen (CEA) quantitative detection reagent (box) (hereinafter referred to as "CEA reagent (kit)") based on the principle of chemiluminescent immunoassay, including microplates, pipes, magnetic particles, microbeads and plastic beads as the carrier of enzymatic and non-enzymatic chemiluminescent immunoassay detection reagent (box).

The Standard is not applicable to the requirements of calibration products and quality control products in the kit.

2 Normative references

The articles contained in the following documents have become this Standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard.

GB/T 21415-2008In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials (ISO 17511:2003, IDT)

3 Terms and definitions

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

3.1

Chemiluminescence, CL

It means that the chemical reaction can generate the substances of electronic energy level to be in the excited state, and the latter can generate photon by transition release energy, thereby causing the luminescence phenomenon.

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