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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 1161-2009

Tumor Associated Antigen CA125 Quantitative Detection Reagent (Kit) (Chemiluminescent Immunoassay)

肿瘤相关抗原 CA125 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 tumor associated antigen CA125 quantitative determination reagent (kit) (chemiluminescence immunoassay) product quality.

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

This Standard is centralized by the National Medical Clinical Testing Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC 136).

This Standard is drafted by: Beijing Institute of Medical Device Testing, Beijing Chemclin Biotech Co., Ltd, Beijing Yuande Biomedical Engineering Co., Ltd, Beckman Coulter Co., Ltd, Siemens Diagnostics Medical (Shanghai) Corporation.

The main drafter of this Standard: Zhang Xinmei, Cheng Yinghao, Sun Xudong, Hu Guomao, Ying Xitang, Zhang Jinwen, Zhu Weizan.

Tumor Associated Antigen CA125 Quantitative Detection Reagent (Kit) (Chemiluminescent Immunoassay)

1 Scope

This Standard specifies the terms and definitions, classification, requirements, test methods, inspection rules, identification, labels, instructions, packaging, transportation and storage of tumor associated antigen CA125 quantitative determination reagent (kit) (chemiluminescence immunoassay).

This Standard is applicable to quantitative detection of tumor associated antigen (CA125) reagent (kit) [hereinafter referred to as “CA125 reagent (kit)”] based on the principles of chemiluminescence immunoassay. It includes the enzymatic and non-enzymatic chemiluminescence immunoassay detection reagent (kit) with carriers of microplates, tubes, magnetic particles, microbeads and plastic beads.

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

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 21415-2008In 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 standard, the following terms and definitions shall apply.

3.1

Chemiluminescence, CL

Because that the chemical reaction can generate the substances of electronic energy level to be in the excited state, the latter can generate photon by transition release energy,

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