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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 1163-2009

Total Prostate Specific Antigen (t-PSA) Quantitative Detection Reagent (Kit) (Chemiluminescent Immimoassay)

总前列腺特异性抗原（t-PSA）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 provisions of GB/T 1.1-2000 *Directives for Standardization, Part 1: Standard Structure and Compilation Rules*, which is the basis for evaluation of total prostate specific antigen (t-PSA) quantitative detection reagent (kit) (chemiluminescent immimoassay) 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 Yuande Medical Engineering Co., Ltd., Beijing Chemclin Biotech Co., Ltd., Roche Diagnostic Products (Shanghai) Co., Ltd., and Shanghai Abbott Laboratories Co., Ltd.

Main drafters of this Standard: Zhang Xinmei, Sun Xudong, Cheng Yinghao, Yang Xiaolin, Cai Xiaorong and Wang Xuefeng.

Prostate Specific Antigen (t-PSA) Quantitative Detection Reagent (Kit) (Chemiluminescent Immimoassay)

1 Scope

This Standard specifies the terms and definitions, classification, requirements, test methods, inspection rules, marks, labels, operating instructions, packaging, transportation and storage of total prostate specific antigen (t-PSA) quantitative detection reagent (kit) (chemiluminescent immimoassay).

This Standard is applicable to the quantitative detection of total prostate specific antigen (t-PSA) quantitative detection reagent (kit) (herein after referred to as “t-PSA reagent (kit)”) of the human blood matrix or other body fluid components based on the principle of chemiluminescent immunoassay. It includes the enzymatic and non-enzymatic chemiluminescence immunoassay detection reagent (kit) with carriers of microplates, tubes, magnetic particles, microbeads and plastic beads and others.

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 21415-2008 In 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

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