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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 1155-2009

Automatic Luminescence Immunoassay Analyzer

全自动发光免疫分析仪

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

Issued by China Food and Drug Administration

Contents

Foreword

The Standard is proposed by China Food and Drug Administration.

The Standard is 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 Standard is mainly drafted by Beijing Institute of Medical Device Testing, Abbott Laboratories Ltd, Johnson & Johnson Medical (China) Ltd, Roche Diagnostics (Shanghai) Limited and Beckman Coulter Commercial Enterprise (China) Co., Ltd.

The main drafters of the Standard: Wang Jun, Wang Xuefeng, Zhang Zhang, Cai Xiaorong, Zhang Jinwen and Zhang Xinmei.

Automatic Luminescence Immunoassay Analyzer

1 Scope

This Standard specifies the requirements, test methods, marks, labels and instructions, packaging, transportation and storage of automatic luminescence immunoassay analyzer.

This Standard applies to automatic luminescence immunoassay analyzer (hereinafter referred to as “the Analyzer”); the Analyzer uses luminescent system and immunological analyzing method to set and qualitative detect human blood serum, plasma or other body fluids in a variety of analytes, including luminescent immunoassay analyzer based on principle of chemiluminescence, electrochemical luminescence, fluorescence, etc.

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 191 Packaging - Pictorial marking for handling of goods

GB/T 14710 Environmental requirement and test methods for medical electrical equipment

GB 4793.1-2007 Safety requirements for electrical equipment for measurement, control, and laboratory use-Part 1: General requirements (IEC 61010-1: 2001, IDT)

YY 0466-2003 Medical devices -- Symbols to be used with medical device labels labelling and information to be supplied (ISO 15223: 2000, IDT)

3 Terms and definitions

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

3.1

Luminescence immunoassay

It refers to the method to detect antigen or antibody by combining luminescent system with immune response.

3.2

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