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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 1192-2011

Human chorionic gonadotropin (HCG) quantitative detection reagent (kit) (chemiluminescent immunoassay)

人绒毛膜促性腺激素(HCG)定量测定试剂盒（化学发光免疫分析法）

Issued on December 31, 2011 **Implemented on June 1, 2013**

Issued by China Food and Drug Administration

Contents

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 Food and Drug Administration.

This Standard is centralized by 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 Yuande Medical Engineering Co., Ltd., Beijing Chemclin Biotech Co., Ltd., Roche Diagnostic Products (Shanghai) Co., Ltd., Zhengzhou Autobio Lvke Bioengineering Co., Ltd.

The main drafters of this Standard: Wang Ruixia, Tang Lei, Cheng Yinghao, Cai Xiaorong and Li Xiaoxia.

Human chorionic gonadotropin (HCG) quantitative detection reagent (kit) (chemiluminescent immunoassay)

1 Scope

This Standard stipulates the classification, requirements, test method, marks, labels, instructions, packaging, transportation and storage etc. of the human chorionic gonadotropin quantitative detection reagent (kit) (chemiluminescent immunoassay).

This Standard is applicable to the quantitative detection of human chorionic gonadotropin (HCG) reagent (kit) [herein after referred to as “HCG reagent (kit)”] of the human blood matrix or other body fluid components based on the principle of chemiluminescent immunoassay, 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 human chorionic gonadotropin 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 Classification

HCG reagent (kit) can be divided into enzymatic and non-enzymatic chemiluminescent immunoassay reagents (kits) according to different chemiluminescence principles; According to different solid phase carriers, it can be divided into microplates, pipes,

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