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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 1193-2011

Follicle stimulating hormone (FSH) quantitative immunoassay kit (chemiluminescent immunoassay)

促卵泡生成激素（FSH）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 under the jurisdiction of 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., IVD Reagents and Culture Medium Laboratory of National Institute for the Control of Pharmaceutical and Biological Products, Beijing Bio-Ekon Biotechnology Co., Ltd and Johnson & Johnson Medical (Shanghai) Ltd.

The main drafters of this Standard: Wang Ruixia, Tang Lei, Huang Ying, Wang Jianming and Nie Jing.

Follicle stimulating hormone (FSH) 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 follicle stimulating hormone (FSH) quantitative detection reagent (kit) (chemiluminescent immunoassay).

This Standard is applicable to the quantitative detection of follicle stimulating hormone (FSH) reagent (kit) [herein after referred to as “FSH 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 follicle stimulating hormone 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

FSH reagent (kit) can be divided into enzymatic and non-enzymatic chemiluminescent immunoassay reagents (kits) according to different chemiluminescence principles; It can also be divided into different kinds of chemiluminescent immunoassay kits taking microplates, pipes, magnetic particles, microbeads and plastic beads as carrier according

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