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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 1213-2013

# Follicle stimulating hormone quantitative labelling immunoassay kit

# 促卵泡生成素定量标记免疫分析试剂盒

**Issued on December 21, 2013** **Implemented on October 1, 2014**

**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 China Clinical Laboratory Testing and In vitro Diagnostic Test System of Standardization Administration of China (SAC/TC 136).

This Standard is drafted by: National Institutes for Food and Drug Control.

The main drafters of this Standard: Huang Ying, Shen Shu, Yu Ting, Zhang Chuntao and Gao Shangxian.

# Follicle stimulating hormone quantitative labelling immunoassay kit

## 1 Scope

This Standard stipulates the classification, requirements, test method, marks, labels, instructions, packaging, transportation and storage etc. of the follicle stimulating hormone quantitative labelling immunoassay reagent (kit).

This Standard is applicable to the quantitative detection of follicle stimulating hormone (FSH) reagent (kit) [herein after referred to as “FSH reagent (kit)”] based on the principle of double antibody sandwich method. It includes the immunoassay kit for quantitative determination of FSH by using enzyme labelling, (electrical) chemiluminescent labelling, (time resolution) fluorescence labelling and other labelling methods as capture antibody, and taking microplates, pipes, magnetic particles, microbeads and plastic beads and others as the carrier coated antibody.

This Standard does not apply to:

a) Colloidal gold labeled FSH test strip;

b) Various types of FSH radio-immunity or IRMA reagent kit labeled with $^{125}$I and other radioactive isotopes.

## 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.

YY/T 0466.1 Devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements

## 3 Classification

The FSH reagent kits can be classified into enzyme labelling FSH reagent kit, (electrical) chemiluminescent labelling FSH reagent kit, (time resolution) fluorescence labelling FSH reagent kit etc. according to the various labelling methods; It can also be divided into

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