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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 1218-2013

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**Thyroid-stimulating hormone quantitative  
labeling immunoassay kit  
促甲状腺素定量标记免疫分析试剂盒**

**Issued on October 21, 2013**

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**Issued by China Food and Drug Administration**

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## **Foreword**

This Standard is drafted according to the rules specified in GB/T 1.1-2009

Please note that some content of the Document may involve any patent. The issuing authority of the Document will not undertake the responsibility of identifying these patents.

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 National Institutes for Food and Drug Control.

The main drafters of the Standard: Huang Ying, Li Lili, Yu Ting and Gao Shangxian.

# Thyroid-stimulating hormone quantitative labeling immunoassay kit

## 1 Scope

This Standard stipulates the classification, requirements, test methods, marks, labels, instructions, packaging, transportation and storage of the thyroid-stimulating hormone quantitative labeling immunoassay kit.

This Standard is applicable to the quantitative determination of thyroid-stimulating hormone (TSH) kit (hereinafter referred to as "TSH kit") based on the principle of double antibody sandwich method. It includes the immunoassay kit for quantitative determination of TSH by using enzyme labeling, (electrical) chemiluminescent labeling, (time resolution) fluorescence labeling and other labeling 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 TSH test strip;
- b) Various types of radio-immunity or IRMA kit labeled with  $^{125}\text{I}$  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 0466.1-2009 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

## 3 Classifications

According to different labeling methods, TSH kit can be divided into the enzyme-labeled TSH kit, (electrical) chemiluminescent labeled TSH kit, (time resolution) fluorescence labeled TSH kit and the like; according to the solid carrier, it can be divided into microplates, pipes, magnetic particles, microbeads and plastic beads and others as the

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