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# INDUSTRY STANDARD

# OF THE PEOPLE'S REPUBLIC OF CHINA

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）



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# Foreword

This standard was 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 issuing organization of this file does not bear the responsibility to identify these patents.

This standard was proposed by the China Food and Drug Administration.

This standard shall be under the jurisdiction of the China Clinical Laboratory Testing and In vitro Diagnostic Test System of Standardization Administration of China (SAC/TC 136).

Drafting organizations of this standard: 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 immunoassay kit (chemiluminescent immunoassay)

## 1 Scope

This standard specifies the product classification, requirements, test method, marks, labels, instructions, packaging, transportation and storage etc. of the follicle stimulating hormone (FSH) quantitative immunoassay kit (chemiluminescent immunoassay).

This standard is applicable to follicle stimulating hormone (FSH) kit [hereinafter referred as “FSH kit”] of quantitative detection in human blood matrix or other body fluid components, based on the principle of chemiluminescent immunoassay. It includes the enzymatic and non-enzymatic chemiluminescent immunoassay detection kit in the carriers of micro-plates, pipes, magnetic particles, micro-beads and plastic beads.

This standard does not apply to:

a) The calibrator and quality control product of follicle stimulating hormone intended for separate sale;

b) Biochip that uses the principle of chemiluminescent immunoassay.

## 2 Normative references

The articles contained in the following documents have become part of 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 kit can be divided into enzymatic and non-enzymatic chemiluminescent immunoassay kits according to different chemiluminescent principles. It can be divided into different kinds of chemiluminescent immunoassay kits taking micro-plates, tubes, magnetic particles, micro-beads and plastic beads as carrier according to the various solid phase carriers. According to different operation processes, it can be divided into manual operation method and instrument-automatic operation method.

coefficient *r* of the kit, within the linear range specified by the manufacturing enterprise, shall not be less than 0.990.

### 4.7 Repeatability

Use the samples with at least 2 concentration levels. Respectively repeat the detection for 10 times. The coefficient of variation (*CV*) shall not be more than 8.0% (instrument-automatic operation method) or not more than 12.0% (manual operation method).

### 4.8 Within-batch difference

Use 3 batches of kits to detect the same sample. The coefficient of variation (*CV*) among the 3 kits shall not be more than 15.0%.

### 4.9 Stability

The following methods can be used for verification:

a) Stability within the validity: The manufacturing enterprise shall specify the validity of the kit. Take the kit that has been expired to detect the accuracy, minimum detection limit, linearity and repeatability. It shall meet the requirements of 4.3, 4.4, 4.6 and 4.7;

b) Thermal stability test: The kit within the period of validity is placed at 37°C for 3d. Test the accuracy, minimum detection limit, linearity and repeatability. It shall meet the requirements of 4.3, 4.4, 4.6 and 4.7.

Note 1: Thermal stability test cannot be used to derive the validity of products, unless it uses the derivation formula that is established and based on a large number of stability study data;

Note 2: Any arbitrary combination of a) and b) can be selected according to the product characteristics, but the selected method shall be capable of verifying the stability of the product, so as to ensure that the performance of the product can comply with the standard requirements within valid period.

## 5 Test methods

### 5.1 Appearance

Use the corrected-visual-acuity to visually inspect, under the natural light. It shall meet the requirements of 4.1.

### 5.2 Traceability

Traceability information provided by the manufacturing enterprise shall meet the requirements of 4.2.

e) Product batch number;

f) Expiration date;

g) Storage conditions.

### 6.2 Marks and labels of each component package of kit

It shall contain at least the following contents:

a) Product names and packaging specifications;

b) Name or trademarks of manufacturers;

c) Product batch number;

d) Expiration date;

e) Storage conditions.

### 6.3 Instructions of kit

It shall include at least the following contents:

a) Product name;

b) Packaging specifications;

c) Intended use;

d) Detection principle;

e) Main compositions;

f) Storage conditions and expiration date;

g) Applicable instrument;

h) Sample requirement;

i) Detection method;

j) Reference value (Reference range);

k) Explanation of the detection result;

l) The limitations of detection methods;

m) Product performance index;

# Bibliography

1. YY/T 0316-2008 Medical devices — Application of risk management to medical devices (ISO 14971: 2007, IDT)

2. YY/T 0466.1-2009 Devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1:General requirements (ISO 15223.1-2009, IDT)

3. GB/T 191-2008 Packaging - Pictorial marking for handling of goods

4. GB/T 9969-2008 General principles for preparation of instructions for use of industrial products

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