ICS 11.100
CCS C44

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 18990-2008

Replacing GB/T 18990.2-2003

Luteinizing hormone (LH) test strip (Colloidal gold immunochromatographic assay)

促黄体生成素检测试纸（胶体金免疫层析法）

Issued on: November 3, 2008 **Implemented on: October 1, 2009**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China;
Standardization Administration of China

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Foreword

This Standard replaces GB/T 18990.1 ~ 18990.3-2003 Luteinizing Hormone (LH) Test Strip. Compared with GB/T 18990.1 ~ 18990.3-2003, the main changes of this Standard are as follows: - Integrate and revise the Part 1 - Part 3 of former standards as a single-standard; - Modify the product name in accordance with relevant requirements in the Measures for the Administration of Registration of In-Vitro Diagnostic Reagents (Trial); - Modify the terms and definitions; - Add the technical requirements and test methods of "physical characteristics"; - Modify the technical requirements and test methods of "cut-off"; - Delete the "cross reaction with HCG" in the requirements of "specificity"; - Modify the technical requirements and test methods of "repeatability"; - Modify the technical requirements and test methods of "stability"; - Add the technical requirements and test methods of "difference between batches"; 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. Participating drafting organizations of this Standard. Kunming Yunda Bio-technology Co., Ltd., and Beijing Institute of Medical Device Testing. Main drafters of this Standard. Ma Lan, Zhang Xinmei, Zhou Jianlei, Deng Shuangsheng, and Zhao Lisheng. The previous versions replaced by this standard are as follows: - GB/T 18990.1-2003, GB/T 18990.2-2003, GB/T 18990.3-2003. Luteinizing hormone (LH) test strip (Colloidal gold immunochromatographic assay)

1 Scope

GB/T 18990-2008 is the Chinese national standard on luteinizing hormone (lh) test strip (colloidal gold immunochromatographic assay), in the field of health care technology. The /T

suffix marks it as a recommended standard: it is not compulsory by itself, but it becomes binding as soon as a contract, a tender or a customer specification calls it up - which in practice is how most foreign buyers meet it. It was issued on 3 November 2008 by the General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China; Standardization Administration of China, and has been in force since 1 October 2009. Classification: ICS 11.100, CCS C44. This page is published from the official record of the standard held by the Chinese standards administration: the identification, the dates, the classification and the issuing body are taken from there. The clause text, the tables and the numeric limits are in the document itself, which is delivered complete in English translation.

This Standard specifies the terms and definitions, technical requirements, test methods, inspection and judgment, packaging, marks and operation instructions, transportation, and storage of luteinizing hormone test strip. This Standard applies to luteinizing hormone test strip (Hereinafter referred to as strip) for the determination of LH levels in urine of women by using the principle of colloidal gold immunochromatographic assay, so as to predict the time of ovulation. It guides women of childbearing age to choose the best time to conceive or guides the rhythm in safe period.

2 Normative references The articles contained in the following documents have become part of this Standard when they are quoted herein. For the dated documents so quoted, all the modifications (excluding corrections) or revisions made thereafter shall not be applicable to this Standard. For the undated documents so quoted, the latest editions shall be applicable to this Standard. GB/T 191 Packaging - Pictorial marking for handling of goods (GB/T 191-2008, ISO 780. 1997, MOD)

3 Terms and definitions For the purpose of this Standard, the following terms and definitions apply.

3.1 Luteinizing hormone (LH) test strip It refers to the test strip for detection of luteinizing hormone in the women's urine by using the principle of colloidal gold immunochromatographic assay.

3.2 Cut-off It refers to the limit value for determination of negative and positive detection results.

5.5.1 The cross reaction with FSH TAKE the same batch of 3 test strips to determine the sample solution that contains 200 mIU/mL FSH standard substance. OPERATE in accordance with the manufacturer's instructions. Based on the determination results of 5.1, the 3 test strips shall comply with the requirements of 4.3.1.

5.5.2 The cross reaction with TSH TAKE the same batch of 3 test strips to determine the sample solution that contains 250 μIU/mL TSH standard substance. OPERATE in accordance with the manufacturer's instructions. Based on the determination results of 5.1, the 3 test strips shall comply with the requirements of 4.3.2.

5.6 Repeatability USE LH sample solution with concentrations of 10 mIU / mL, 25 mIU/mL and 50 mIU/mL to respectively measure the same batch of test strips. MEASURE 10 pcs for each concentration. OPERATE in accordance to the manufacturer's instructions. The results shall comply with the requirements of 4.4.

5.7 Stability TAKE the same batch of test strips. Place under the condition of 37°C for 20 days. DETECT the requirements in accordance with the methods shown in 5.3-5.6. The results shall comply with the requirements of 4.5.

5.8 Difference between batches TAKE test strips from 3 batches, 10 pcs for each batch, total 30 pcs. OPERATE in accordance with the instructions' steps. 10 test strips of each batch are duplicate detected by LH sample solution with the concentration of 25 mIU/mL. The test results of 3 batches shall comply with the requirements of 4.6.

6 Inspection and determination

6.1 Batch Products of the same-property, same-quality, continuously manufactured under the same-process condition, are deemed as a batch.

6.2 Amount of sampling Randomly sample from the same batch. The minimum amount of sampling shall not be less than 3 times of the detection amount.

6.3 Inspection and determination rules

7.2 The transport package (outer package) shall be marked with.

a) Product name and product specifications;

b) Manufacturer's name and address;

c) Production batch number or production date;

d) Product registration number;

e) Volume (Lengthxwidthxheight);

f) "Moisture proof", "heat proof" and other words or signs shall comply with the relevant provisions of GB/T 191.

7.3 The operating instructions shall include the following contents.

a) Product name;

b) Packaging specifications;

c) Intended purpose and principles;

d) Operation steps (it shall indicates the valid duration within which the result must be read. If they are test strips, it shall indicate the duration to immerse in urine before taking out);

e) Result determination.

g) Storage conditions;