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**NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC
OF CHINA**

中华人民共和国国家标准

GB/T 18990-2008

Replaces GB/T 18990.1-18990.3-2003

**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)**

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Quarantine of the People's Republic of China and Standardization
Administration Committee of PRC**

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Foreword

This Standard replaces GB/T 18990.1-18990.3-2003 of *Luteinizing Hormone (LH) Test Strip*. This Standard, in comparison with GB/T 18990.1-18990.3-2003, has the major changes as follows:

- Integrate and revise the Part 1 - Part 3 of former standards as a 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 is 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., Beijing Institute of Medical Device Testing.

Main drafters of this Standard: Ma Lan, Zhang Xinmei, Zhou Jianlei, Deng Shuangsheng, Zhao Lisheng.

The issuances of previous versions of standard 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

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 colloidal gold immunochromatographic assay principle, to predict the time of ovulation, for guiding women of childbearing age to choose the best time to conceive or guiding the rhythm in safe period.

2 Normative references

The articles contained in the following documents have become 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 the colloidal gold immunochromatographic assay.

3.2

Cut-off

It refers to the limit value for determination of negative and positive detection results.



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