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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 1214-2013

Human chorionic gonadotrophin quantitative labeling immunoassay kit

人绒毛膜促性腺激素定量标记免疫分析试剂盒

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

Issued by China Food and Drug Administration

Contents

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 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, Shen Shu, Zhang Chuntao, Yu Ting and Gao Shangxian.

Human chorionic gonadotrophin quantitative labeling immunoassay kit

1 Scope

This Standard stipulates the classification, requirements, test method, marks, labels, operating instructions, packaging, transportation and storage of the human chorionic gonadotrophin quantitative labeling immunoassay kit.

This Standard is applicable to the quantitative detection of human chorionic gonadotrophin (HCG) quantitative labeling immunoassay kit [herein after referred to as “HCG reagent (kit)”] based on the principle of double antibody sandwich method. It includes the HCG immunoassay kit for quantitative detection 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.

The Standard does not apply to:

a) Colloidal gold labeled HCG test strip;

b) Various types of HCG 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 0466.1-2009 Medical devices -- Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements

3 Classifications

The HCG reagent kits can be classified into enzyme labeling HCG reagent kit, (electrical) chemiluminescent labeling HCG reagent kit, (time resolution) fluorescence labeling HCG reagent kit etc. according to the various labeling methods; It can also be divided into different kinds of HCG reagent kits taking microplates, pipes, magnetic particles,

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