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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 1216-2013

**Alpha-fetoprotein quantitative labeling
immunoassay kit**

甲胎蛋白定量标记免疫分析试剂盒

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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: Liu Yan, Huang Ying and Gao Shangxian.

Alpha-fetoprotein quantitative labeling immunoassay kit

1 Scope

This Standard stipulates the classification, requirements, test method, marks, labels, operating instructions, packaging, transportation and storage of the alpha-fetoprotein quantitative labeling immunoassay kit.

This Standard is applicable to the quantitative detection of alpha-fetoprotein labeling immunoassay kit (hereinafter referred to as AFP kit).including AFP 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.

This Standard does not apply to:

- a) Colloidal gold labeled AFP test strip;
- b) Various types of 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 AFP kits can be classified into ELISA reagent kit, chemiluminescent reagent kit, (time resolution) fluorescence reagent kit etc. according to the various labeling methods. It can also be divided into different kinds of AFP kits taking microplates, pipes, magnetic particles, microbeads and plastic beads as carrier according to the various solid phase carriers. The AFP kits can be divided into manual operation method and automatic operation method of instrument according to the different process of operation.

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