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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 1249-2014

**Free prostate specific antigen quantitative
labelling immunoassay kit**
游离前列腺特异性抗原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: Huang Ying, Zhang Chuntao, Shen Shu, Yu Ting and Gao Shangxian.

Free prostate specific antigen quantitative labelling immunoassay kit

1 Scope

This standard stipulates the classification, requirements, test method, marks, labels, instructions, packaging, transportation and storage of the free prostate specific antigen quantitative labelling immunoassay kit. This standard is applied to the kit which quantitatively determine free prostate specific antigen (fPSA) by the principle of double antibody sandwich method (hereinafter referred to as: fPSA kit). It includes the immunoassay kit for quantitative determination of fPSA by using enzyme labelling, (electrical) chemiluminescent labelling, (time resolution) fluorescence labelling and other labelling methods as capture antibody, and taking microplates, pipes, magnetic particles, microbeads and plastic beads and others carriers as the coated antibody.

The standard does not apply to:

- a) Reagent which is used to qualitatively or semi-quantitatively determine fPSA by colloidal gold or other methods (such as: test strip method, etc.);
- b) Various types of fPSA radio-immunity or IRMA 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.

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

3 Classification

Depending on the marking method, fPSA kit can be divided into enzyme marking fPSA kit, (electric) chemiluminescence marking fPSA kit, (time-resolved fluorescence marking fPSA kit, etc.; Depending on the different solid phase carrier, it can be divided into micropore plate form, tube form, magnetic particle form, microsphere form and plastic bead form and



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