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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 1240-2014

D-Dimer reagent (kit)

D-二聚体定量检测试剂（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 Peoples Liberation Army General Hospital, Beijing Institute of Medical Device Testing, Beijing Success Technology Development Co., Ltd, Werfen Medical Device International Trading (Shanghai) Co., Ltd.

The main drafters of the Standard: Li Jian, Bi Chunlei, Ding Chonghui and Yu Hui.

D-Dimer reagent (kit)

1 Scope

The standard specifies the term and definition, requirements, test methods, symbols, labels and instructions, packing, transportation as well as the storage of D-Dimer quantitative detection reagent (kit). The standard applies to the quantitative detection of the D-Dimer reagent (kit) (hereinafter referred to as D-D reagent) by immunoturbidimetry in the laboratory.

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

GB 3100 The international system of units and its application

GB 3101 General principles concerning quantities, units and symbols

GB 3102 (All parts) Quantities and Units

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 Terms and definitions

For the purpose of this document, the following terms and definitions apply.

3.1

immunoturbidimetric D-dimer assay

The specific binding of the homogeneous latex particles, coated by monoclonal antibody, and the degradation products of the soluble fibrin with D-D antigen determinants in plasma makes the latex particles coagulate, and the coagulation degree is proportional to the concentration of the D-Dimer in the specimen. In a certain wavelength, the value of the D-Dimer can be acquired by measuring the change of the transmission light or scattered light produced by the coagulation.

3.2



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