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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 1200-2013

Glucose assay kit (Enzymic method)

葡萄糖测定试剂盒（酶法）

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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: Wang Yumei, Liu Yan and Gao Shangxian.

Glucose assay kit (Enzymic method)

1 Scope

This Standard specifies the determination principle, requirements, test method, signs, label, instructions, packaging, transport and storage, etc. of glucose assay kit (enzymic method).

This Standard uses glucose hexokinase and oxidase method to measure kit which is used for the quantitative analysis of glucose concentration for serum, plasma, urine, cerebrospinal fluid and other body fluids in clinical examination.

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 Determination Principle

3.1 Hexokinase method

Glucose +ATP hexokinase→glucose-6-phosphoric acid+ADP

Glucose-6-phosphoric acid+NAD⁺ G₆PDH→6-p-glucuronic acid +NADPH+H⁺

Assay method: endpoint method

Detection wavelength: the wavelength given by the manufacturer.

3.2 Glucose oxidase method

Glucose +O₂+H₂OGOD→gluconic acid+H₂O₂

2H₂O₂+4-amino antipyrine + phenol POD→quinone-imine+4H₂O

Assay method: endpoint method

Detection wavelength: the wavelength given by the manufacturer.

Detect the color of quinone imine generated at certain wavelength, and calculate the content of glucose compared with the standard.

4 Requirement

4.1 Appearance

Comply with the normal appearance required by the manufacturer.

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