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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 1231-2014

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**Creatinine test reagent kit (Method of  
sarcosine oxidase)**  
**肌酐测定试剂(盒)(肌氨酸氧化酶法)**

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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 Beijing Institute of Medical Device Testing, Beijing Branch of Hitachi High-Tech (Shanghai) International Trade Co., Ltd, Shanghai Rongsheng Biology Pharmacy Co., Ltd, Merit Choice Bio-Engineering Co., Ltd and Abbott Trade (Shanghai) Co., Ltd.

The main drafters of the Standard: Wang Jun, Bi Chunlei, Zhang Yongmei, Zhang Zhengqiang, Xu Donghuan and Wang Xuefeng.

# Creatinine Test Reagent Kit (Method of sarcosine oxidase)

## 1 Scope

This standard specifies the technical requirements, test method, labeling, instructions for use, packaging, transport and storage of creatinine test reagent (kit) (method of sarcosine oxidase).

This standard applies to the creatinine test reagent (kit) used to carry out quantitative determination of the creatinine concentration in serum, plasma and urine with the method of sarcosine oxidase, including hand reagent and reagents used in semi-automatic and full-automatic biochemical analyzer.

This standard does not apply to the creatinine test reagent (kit) with picric acid method. This standard does not apply to the dry creatinine test reagent (kit).

## 2 Normative References

The following document is indispensable for the application of this document. For dated references, only dated edition applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

GB 3100 The international system of units and its application

GB/T 21415-2008 In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values assigned to calibrators and control materials

YY/T 0316 Medical devices—Application of risk management to medical devices

YY/T 0466.1 Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied—Part 1: General requirements

## 3 Requirement

### 3.1 Appearance

Comply with the normal appearance required by the manufacturer.

### 3.2 Load

The load of liquid reagent shall not be less than the labeled amount.

### 3.3 Absorbance of reagent blank

The absorbance of reagent blank shall be within the range given by the manufacturer.

### 3.4 Sensitivity analysis

The rate of change in absorbance shall be within the range given by the manufacturer when carrying out test of the 100  $\mu$  mol/L creatinine.

### 3.5 Linear interval

The linear interval of the reagent shall be within [30, 1500]  $\mu$ mol/L(37 °C) when testing

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