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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1230-2014

Cystatin C test reagent kit

胱抑素C测定试剂（盒）

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Foreword

This standard was drafted in accordance with GB/T 1.1-2009 given rules. Please note that some of the content of this document may involve patents. Distribution of this document Institutions do not assume the responsibility to identify these patents. This standard was proposed by the China Food and Drug Administration. This standard by the national medical clinical laboratory testing and in vitro diagnostic systems for Standardization Technical Committee (SAC/TC136) centralized. This standard was drafted. Beijing Medical Device Testing, Beijing Tongren Hospital, Capital Medical University, Beijing nine strong biological technology Ltd., Roche Diagnostics (Shanghai) Co., Ltd. Guilin gifted Litvin Electronics Group Co., Ltd., Beijing Leadman Biochemistry Co., BIOSINO Biotechnology Co., Ltd.. The main drafters of this standard. Kang Juan, Liu Xiang Yi, Chen Yang, Tian Wei, Cai Hao Bin, Wang Lanzhen, Daylight Saving North Korea, Duhai Ou. Cystatin C assay reagent (kit)

1 Scope

YY/T 1230 is the product standard for the cystatin C assay kit. Cystatin C is used to estimate glomerular filtration rate as an alternative or a complement to creatinine, and it is preferred precisely where creatinine misleads: in patients whose muscle mass is atypical, in the elderly, and in the early stages of kidney impairment where creatinine has not yet moved. That makes the assay's precision at low concentrations the property clinicians rely on. The standard covers the requirements and test methods together with the labelling and instructions for use, as the Chinese IVD kit standards do. For a manufacturer or a distributor registering a cystatin C kit in China, this is the standard the specification and registration testing follow.

This standard specifies the Cystatin C assay reagent (kit) requirements, test methods, labels, brochures, packaging, transportation and storage. This standard applies to the use of particle-enhanced immune transmission turbidity in human serum or plasma cystatin C quantitative detection test Agent (box), including manual reagents and on the semi-automatic biochemical analyzer used.

2 Normative references

The following documents for the application of this document is essential. For dated references, only the dated version suitable for use herein Member. For undated references, the latest edition (including any amendments) applies to this document.

GB 3100 International System of Units and Its Application

YY/T 0316 Medical Devices Risk Management for Medical Device Applications Symbols - Part 1

YY/T 0466.1 medical equipment used with medical device labels, labeling and information. General requirements

3 Requirements

3.1 Appearance In line with the provisions of the company's normal appearance requirements.

3.2 PACKING Not less than the indicated value.

3.3 reagent blank absorbance Producers meet the requirements specified.

3.4 Sensitivity Analysis Producers meet the requirements specified.

3.5 Linear Interval Reagent (box) linear in [0.40,7.50] mg/L range.

a) The linear correlation coefficient r not less than 0.990;

b) within [0.40,2.00] mg/L range, linearity deviation should not exceed ± 0.2mg/L; Within [2.01,7.50] mg/L range, linearity deviation should not exceed ± 10%.

3.6 Precision

3.6.1 Repeatability Repeat the test (1.00 ± 0.10) mg/L in the sample, the results of the coefficient of variation (CV) should not exceed 5%.