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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1969-2025

Microalbumin testing kit (immunoturbidimetry)

微量白蛋白测定试剂盒（免疫比浊法）

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Foreword

This document complies with the provisions of GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting. Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents. This document was proposed by the National Medical Products Administration. This document is under the jurisdiction of the National Technical Committee on Standardization of Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: Zhongyuan Huiji Biotechnology Co., Ltd., Chongqing Medical Device Quality Inspection Center, and Shanghai Clinical Laboratory Center. Center, Beijing Institute for Medical Device Testing (Beijing Medical Biological Protective Equipment Testing and Research Center), Shenzhen Mindray Bio-Medical Electronics Co., Ltd. Beijing Leadman Biochemical Co., Ltd., Beijing Jiuqiang Biotechnology Co., Ltd., Civil Aviation General Hospital, Beckman Coulter Specialized Trading (China) Co., Ltd., and Siemens Medical Diagnostics Products (Shanghai) Co., Ltd. The main drafters of this document are. Zhang Lihua, Ren Jiangtao, Ou Yuanzhu, Zhu Jinsheng, Wan Xianzi, Li Ran, Chen Yang, Wang Xuejing, Min Guihua, and Lai Liulian. Microalbumin Assay Kit (Immunoturbidimetric Method)

1 Scope

YY/T 1969 is the product standard for the microalbumin assay kit by immunoturbidimetry, the routine test for early kidney damage in diabetes and hypertension and one of the highest-volume assays in Chinese clinical laboratories. It specifies the requirements, the marking, the labelling, the instructions for use, the packaging, transport and storage of the kit, and describes the corresponding test methods. It applies to kits for the quantitative determination of microalbumin. As with the other Chinese IVD kit standards, the document regulates the product and its accompanying information together rather than the analytical method alone. For a manufacturer or a distributor registering a microalbumin kit in China, this is the standard the specification and the registration test report follow.

This document specifies the requirements, labeling, instructions for use, packaging, and transportation of microalbumin assay kits (immunoturbidimetric assay). Storage, and the corresponding experimental methods are described. This document pertains to kits for the quantitative detection of albumin in human urine samples using immunoturbidimetry.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included. For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies. This document.

GB/T 191 Pictorial Symbols for Packaging and Storage

GB/T 21415 Metrological Traceability of Calibrators and Control Substances for the Measurement of Quantities in Biological Samples of In Vitro Diagnostic Medical Devices Source

GB/T 29791.1 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and Definitions

The terms and definitions defined in GB/T 29791.1 apply to this document.

4 Requirements

4.1 Appearance Manufacturers should specify appropriate appearance requirements based on the product's packaging characteristics. Generally, this should include the composition and properties of each component of the reagent kit, as well as the inner and outer packaging. Requirements include being intact and having clear labels.

4.2 Net content The net content of liquid reagents should not be less than the labeled value.

4.3 Reagent blank absorbance The absorbance of the reagent blank should meet the requirements claimed by the manufacturer.

Note. This applies only to immunoturbidimetry.

4.4 Analytical Sensitivity When measuring a 30 mg/L sample, the absorbance difference should not be less than 0.02.

Note. This applies only to immunoturbidimetry.