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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1962-2025

Aldosterone testing kit (chemiluminescent immunoassay)

醛固酮测定试剂盒（化学发光免疫分析法）

Issued on: June 18, 2025 **Implemented on: July 1, 2026**

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Foreword

This document is in accordance with GB/T 1.1-2020 "Standardization Work Guidelines Part

1.Structure and Drafting Rules of Standardization Documents". Drafting is scheduled. Please note that some content in this document may involve patents. This document is published. The organization is not responsible 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: Beijing Tongren Hospital, Capital Medical University; National Center for Clinical Laboratories, National Health Commission; and Civil Aviation General Hospital. Soling Diagnostics (Shanghai) Co., Ltd., Zhengzhou Antu Bioengineering Co., Ltd., and Shenzhen Mindray Bio-Medical Electronics Co., Ltd. The company, Shandong Boke Diagnostic Technology Co., Ltd., and Shenzhen Tailede Medical Co., Ltd. The main drafters of this document are. Liu Xiangyi, Zhou Weiyan, Wang Xuejing, Shi Mengmeng, Li Bin, Liu Junjun, Xie Qinghua, and Wang Yu. Aldosterone Assay Kit (Chemiluminescent Immunoassay)

1 Scope

YY/T 1962 is the product standard for the aldosterone assay kit by chemiluminescent immunoassay, the test behind the workup for primary aldosteronism and one of the more common causes of secondary hypertension. It specifies the technical requirements, the labelling, the instructions for use, the packaging, transport and storage of the kit, and describes the corresponding test methods. Aldosterone measurement is notoriously method-dependent, with results that vary between platforms enough to change a diagnosis, which is exactly the problem a national kit standard exists to contain. For a manufacturer or a distributor registering an aldosterone kit in China, this is the standard the specification and the registration testing follow.

This document specifies the technical requirements, labeling, instructions for use, and packaging for aldosterone assay kits (chemiluminescent immunoassay). Transportation and storage, with corresponding test methods described. This document applies to kits for the

quantitative determination of aldosterone in human serum or plasma based on the principle of chemiluminescent immunoassay.

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 29791.2 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and Definitions

This document does not contain any terms or definitions that need to be defined.

4 Requirements

4.1 Appearance The appearance should meet the following requirements.

a) All components of the kit should be complete and intact, with no leakage of liquid;

b) The liquid components should be homogeneous and free of foreign matter;

c) Packaging labels should be clear, undamaged, and easily identifiable.

4.2 Traceability Manufacturers shall provide information on the source, assignment process, and measurement uncertainty of the aldosterone calibrators used, in accordance with GB/T 21415 and relevant regulations. Content such as degree.

4.3 Accuracy Accuracy should meet one of the following requirements.

a) Relative bias. The sample is tested using a certified reference material or other recognized reference material that can be used to evaluate conventional methods. The relative deviation of the measurement results should not exceed ±15%.

b) Recovery test. The recovery rate should be within the range of [85%, 115%];

c) Comparison test. Compare with commercially available kits or reference methods, within the sample concentration coverage range claimed by the manufacturer.