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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1970-2025

Lipoprotein-associated phospholipase A2 testing kit (chemiluminescent immunoassay)

脂蛋白相关磷脂酶A2测定试剂盒（化学发光免疫分析法）

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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: Guangdong Provincial Institute of Medical Device Quality Supervision and Inspection, Beijing Institute for Medical Device Testing (Beijing Medical Biotechnology Institute). Protective Equipment Testing and Research Center), Shanghai Clinical Testing Center, Fuwai Hospital of Chinese Academy of Medical Sciences, Chongqing Medical Device Quality Inspection Center Heart, Shenzhen Pumen Technology Co., Ltd., Xiamen Wantai Kerry Biotechnology Co., Ltd. The main drafters of this document are. Pan Xiaofang, Dai Leiying, Ou Yuanzhu, Lin Yahui, Wu Jingbiao, He Lechun, Shi Dandan, and Song Liuwei. Lipoprotein-associated phospholipase A2 assay kit (Chemiluminescent immunoassay)

1 Scope

YY/T 1970 is the product standard for the Lp-PLA2 assay kit by chemiluminescent immunoassay, a cardiovascular risk marker used to assess vascular inflammation and plaque instability. 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. In China an IVD kit is standardised as a product, not only as a method, so the performance characteristics and the accompanying documentation are regulated together and the instructions for use are part of what is approved. For a manufacturer or a distributor of Lp-PLA2 kits seeking Chinese registration, this is the standard the specification and the registration testing are built on.

This document specifies the requirements, labeling, marking, and use of the

lipoprotein-associated phospholipase A2 assay kit (chemiluminescent immunoassay). Instructions, packaging, transportation, and storage are provided, along with descriptions of the corresponding test methods. This document applies to reagents for the quantitative determination of human serum and plasma lipoprotein-associated phospholipase A2 using chemiluminescence immunoassay. Kits (hereinafter referred to as kits) include chemiluminescence analysis kits using microplates, tubes, magnetic particles, microbeads and plastic beads as carriers.

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 The appearance should meet the following requirements.

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

b) Chinese packaging labels should be clear and undamaged.

4.2 Traceability Manufacturers should provide the source, assignment process, and other details of the lipoprotein-associated phospholipase A2 calibrators in accordance with GB/T 21415 and relevant regulations. Contents such as measurement uncertainty.

4.3 Limit of Detection The detection limit should not exceed 10 ng/mL.