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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1915-2023

General requirements for laboratory testing of immunochromatographic kits

免疫层析试剂盒实验室检测通则

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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 be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Standardization Technical Committee for Medical Clinical Laboratory and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: Beijing Institute of Medical Device Inspection (Beijing Medical Biological Protective Equipment Inspection and Research Center), China Qualified Assessment National Accreditation Center, Beijing Medical Device Review and Inspection Center, China Institute of Food and Drug Control, Chongqing Medical Device Quality Inspection Center, Guangdong Provincial Institute of Medical Device Quality Supervision and Inspection, Guangzhou Wanfu Biotechnology Co., Ltd., Shanghai Aopu Biopharmaceutical Co., Ltd. Company, Beijing Cool Technology Co., Ltd. The main drafters of this document. Sun Li, Wang Huiru, Lin Hongsai, Jiang Yan, Gao Fei, He Lechun, Pan Xiaofang, Sun Yaling, Gong Jie, Chen Lizhu. General rules for laboratory testing of immunochromatographic kits

1 Scope

YY/T 1915 sets the general requirements for laboratory testing of immunochromatographic kits, the lateral flow strips and cassettes behind rapid tests for infection, pregnancy, cardiac markers and drugs of abuse. The format is simple to use and difficult to evaluate: the result is read by eye or by a small reader, the response is not linear, and performance depends on the sample matrix and on the operator as much as on the chemistry. This document fixes how such kits are tested in the laboratory so that manufacturers' claims are generated consistently and can be compared. Lateral flow moved from niche to universal during the pandemic years and stayed there. For a manufacturer, this is the framework a Chinese registration dossier for a rapid test is built on.

This document stipulates the testing quality requirements for laboratories during the performance verification process of immunochromatography kits, including personnel, environment, Instruments, testing process control and testing result analysis requirements. This document is applicable to testing laboratories that verify the performance of immunochromatographic kits for in vitro diagnostics, including manufacturing enterprise laboratories.

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text. Among them, the dated quotations For undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments) applies to this document.

GB/T 27025 General requirements for testing and calibration laboratory capabilities

3 Terms and definitions

There are no terms or definitions to be defined in this document.

4 Pre-test requirements

4.1 Overview The immunochromatography kit (hereinafter referred to as the "kit") is a solid-phase immunochromatography kit that combines antigen/antibody labeling with colloidal gold, latex, fluorescence and other identifiable labels. On the carrier, capillary action is used to detect the analyte through the specific binding between antigens and antibodies. When the laboratory performs performance verification testing on the kit, it should comply with the requirements of GB/T 27025.Laboratory for different testing principles (such as fluorescence immunochromatography kit, colloidal gold immunochromatography kit, quantum dot immunochromatography kit, etc.) and different measurement types (such as quantitative kits, qualitative kits, etc.) for performance verification management. Quantitative products generally require matching instruments; if qualitative products are used with matching instruments, the results should be reported directly, for example, negative/positive, Yes/no, yes/no, etc. The detection indicators of qualitative immunochromatography kits generally include appearance, net content (when applicable), membrane strip width, liquid migration speed, positive character coincidence rate, negative coincidence rate, detection limit, analytical specificity (when applicable), precision, stability, etc. The detection indicators of quantitative immunochromatography kits generally include appearance, net content (when applicable), membrane strip width, liquid migration speed, accuracy Degree, detection limit, linearity, analytical specificity (when applicable), precision, traceability, stability, etc.

4.2 Personnel The laboratory should establish requirements for the health and technical ability assessment of testing personnel, including assessment content, methods and frequency, to ensure the health and technical ability of testing personnel. Technical work ability; it is required that personnel engaged in kit testing should be evaluated and qualified and obtain authorization. The health assessment of inspectors should at least include vision requirements. Kit testers who interpret the results through manual visual inspection need to distinguish Only small color changes can correctly interpret the results, and should not be used by people with color weakness or color blindness. The assessment of technical capabilities of testing personnel should at least include familiarity with the principles of kit testing methods, proficiency in testing operation skills, and independent execution.