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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1890-2023

Hepatitis B virus surface antigen detection kit (immunochromatography)

乙型肝炎病毒表面抗原检测试剂盒（免疫层析法）

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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 be subject to patents. The publisher of this document assumes no responsibility for identifying patents. This document is proposed by the National Medical Products 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: China Institute of Food and Drug Control, Beijing Institute of Medical Device Inspection (Beijing Medical Biological Protective Equipment Medical Equipment Inspection Research Center), Guangdong Medical Device Quality Supervision and Inspection Institute, Beijing Wantai Biopharmaceutical Co., Ltd., Zhuhai Livzon Reagent Co., Ltd. Co., Ltd., Yingke Xinchuang (Xiamen) Technology Co., Ltd. The main drafters of this document. Liu Yan, Li Kejian, Zhou Cheng, Liu Yanchun, Pan Xiaofang, Xianyang Ling, Zhou Xin, Qin Rong. Hepatitis B virus surface antigen detection kit

1 Scope

YY/T 1890 is the Chinese standard for hepatitis B surface antigen rapid tests using immunochromatography. China has one of the world's largest populations of chronic hepatitis B carriers, and HBsAg is the first-line screening marker, used in blood donation, antenatal care, pre-employment screening and community programmes. A lateral flow format puts that test outside the laboratory, which is what makes the sensitivity near the cut-off and the stability in field conditions matter so much. The document sets out how such a kit is classified, the technical requirements it has to meet, the test methods that demonstrate them, and the labelling and storage rules. For a diagnostics manufacturer, this is the document a Chinese registration is assessed against and a public health tender refers to.

This document specifies the requirements, test methods, identification, labeling and use of hepatitis B virus surface antigen detection kit (immunochromatographic method) Instructions for use, packaging, transportation and storage, etc. This document is applicable to the detection of hepatitis B virus surface in human serum, plasma or whole blood using immunochromatographic methods such as colloidal gold method and latex method. Hepatitis B virus surface antigen detection kit for qualitative detection of antigen (hereinafter referred to as HBsAg). This document does not apply to hepatitis B virus expression using enzyme-linked immunoassay, chemiluminescence immunoassay, time-resolved immunofluorescence, etc. Facial antigen detection kit.

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 191 Packaging, storage and transportation pictorial mark

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.

4.1 Physical inspection

4.1.1 Appearance The appearance of the kit should be neat, the text and labels should be clear, and the liquid components should be clear.

4.1.2 Membrane strip width The width of the membrane strip should be no less than 2.5mm.

4.1.3 Liquid migration speed The liquid migration speed should not be less than 10mm/min.

4.2 Compliance rate of negative reference products Twenty copies of HBsAg national negative reference materials were used for testing, and the results were all negative, and the compliance rate of the negative reference materials was 100%. or use sutra mark