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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1786-2024

Hepatitis B e antigen (HBeAg) detection kit (chemiluminescent immunoassay)

乙型肝炎病毒e抗原检测试剂盒(化学发光免疫分析法)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1.Structure and drafting rules for standardization documents" Drafting. Please note that some of the contents of this document may involve patents. The issuing organization of this document does not assume the responsibility for identifying patents. This document is proposed by the State Food and Drug Administration. This document is under the jurisdiction of the National Technical Committee for Standardization of Medical Clinical Testing Laboratories and In Vitro Diagnostic Systems (SAC/TC136). This document was drafted by: China Food and Drug Inspection Institute, Abbott Trading (Shanghai) Co., Ltd., Zhengzhou Antu Bioengineering Co., Ltd. Co., Ltd., Guangzhou Darui Biotechnology Co., Ltd., Beijing Wantai Biopharmaceutical Co., Ltd., Kemei Diagnostics Technology Co., Ltd. company. The main drafters of this document are. Li Kejian, Zhou Cheng, Wang Xuefeng, Zhang Lihong, Wu Yingsong, Wang Honglan and Wang Jianmei. Hepatitis B virus e antigen detection kit (Chemiluminescent Immunoassay)

1 Scope

YY/T 1786 is the product standard for the hepatitis B e antigen assay by chemiluminescent immunoassay. HBeAg is the marker that indicates active viral replication and high infectivity in a chronic hepatitis B patient, and its loss is one of the endpoints by which treatment is judged, so the assay is used both to stage disease and to follow therapy. China carries one of the world's largest chronic hepatitis B populations, which makes this one of the higher-volume serology assays in its laboratories. As with the other Chinese IVD kit standards, the requirements cover the analytical performance together with the labelling and instructions for use. For a manufacturer or a distributor registering an HBeAg kit in China, this is the governing product standard.

This document specifies the technical requirements, identification, labeling, use, and The instructions, packaging, transportation and storage, etc. describe the corresponding test

methods. This document applies to the kit for determining hepatitis B virus e antigen in human serum and plasma using chemiluminescent immunoassay technology (with The kit includes chemiluminescence, microparticle chemiluminescence, electrochemiluminescence, photoluminescence and time-resolved fluorescence. method. This document does not apply to.

a) Hepatitis B virus e antigen calibrators and hepatitis B virus e antigen quality controls intended for separate sale;

b) Biochip based on chemiluminescent immunoassay principle.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB/T 191 Pictorial markings for packaging, storage and transportation

GB/T 21415-2008 Metrology for the measurement of quantities in biological samples for in vitro diagnostic medical devices - Calibrators and control materials Traceability

GB/T 29791.2 Information provided by the manufacturer of in vitro diagnostic medical devices (labeling) Part

3 Terms and definitions

There are no terms or definitions that require definition in this document.

4.1 Quantitative detection kit

4.1.1 Appearance The following requirements should be met.

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

b) The Chinese packaging label should be clear and undamaged.

4.1.2 Traceability Manufacturers should provide the source, value assignment method and uncertainty of the calibration materials used in accordance with GB/T 21415-2008 and relevant regulations. content.