ICS 11.100.10

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1868-2023

Hepatitis B virus core antibody (HBcAb) detection kit (luminescence immunoassay)

乙型肝炎病毒核心抗体检测试剂盒（发光免疫分析法）

Issued on: January 13, 2023 **Implemented on: January 15, 2024**

Issued by: National Medical Products Administration

Table of Contents

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" to be drafted. Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents. This document is proposed by the State Drug Administration. This document is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136). This document was drafted by: China National Institutes for Food and Drug Control, Zhengzhou Antu Bioengineering Co., Ltd., Abbott Trading (Shanghai) Co., Ltd., Siemens Medical Diagnostic Products (Shanghai) Co., Ltd., Shanghai Clinical Laboratory Center, Mike Biological Co., Ltd. The main drafters of this document. Li Kejian, Zhang Lihong, Wu Xiaojun, Wang Ruirong, Zhu Yuqing, Long Tengxiang. Hepatitis B virus core antibody detection kit (luminescence immunoassay)

1 Scope

YY/T 1868 is the Chinese standard for hepatitis B core antibody test kits using luminescence immunoassay. Anti-HBc is the marker that reveals past exposure to hepatitis B even when surface antigen has cleared, which makes it central to two things China cares about a great deal: transfusion safety, where an occult infection can be transmitted by a donor who tests surface antigen negative, and the risk of reactivation when a patient is given immunosuppressive or chemotherapeutic treatment. 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 text an NMPA registration is assessed against and a blood service refers to when qualifying a supplier.

This document specifies the technical requirements, test methods, signs, Labels, instructions for use, packaging, transportation and storage, etc. This document is applicable

to the qualitative or quantitative detection of human serum, Kits for hepatitis B virus core antibody (hereinafter referred to as "HBcAb") in plasma, including chemiluminescence, microparticle chemiluminescence, electrochemical Luminescence, photoinduced chemiluminescence, and time-resolved fluorescence. This document does not apply to.

a) Hepatitis B virus core antibody calibrator and hepatitis B virus core antibody quality control to be sold separately;

b) Biochip based on the principle of luminescent immunoassay.

2 Normative references

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

GB/T 191 Packaging, storage and transportation icon marks

GB/T 21415-2008 In vitro diagnostic medical devices, measuring calibrators and control substances in biological samples, and assigning values Traceability

GB/T 29791.2 Information provided by manufacturers of in vitro diagnostic medical devices (labelling) Part

3 Terms and Definitions

This document does not have terms and definitions that need to be defined.

4.1 Quantitative detection kit

4.1.1 Appearance The following requirements should be met.

a) The components of the kit should be complete and complete without liquid leakage;

b) The package is not damaged, and the Chinese label should be clear.

4.1.2 Traceability According to GB/T 21415-2008 and relevant regulations, the manufacturer shall provide the source, assignment method and uncertainty of the calibration products used, etc. content.