ICS 11.100.10
CCS C44

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1917-2023

Anti-Xa testing kit (chromogenic assay)

抗Xa测定试剂盒（发色底物法）

Issued on: September 5, 2023 **Implemented on: September 15, 2024**

Issued by: National Medical Products Administration

Table of Contents

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. Release of this document The Agency 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: Beijing Jishuitan Hospital, Shanghai Zhenyuan Diagnostic Supplies Technology Co., Ltd., Beijing Institute of Medical Device Inspection (Beijing Medical Biological Protective Equipment Inspection and Research Center), Beijing Stagau Diagnostic Products Trading Co., Ltd., Roche Diagnostic Products (Shanghai) Co., Ltd., Beijing Jiuqiang Biotechnology Co., Ltd., Sysmex Medical Electronics (Shanghai) Co., Ltd., Beijing Secoxide Technology Co., Ltd., Shanghai Sun Biotechnology Co., Ltd. The main drafters of this document. Wu Jun, Wang Ping, Song Wei, Guo Xin, Yao Xuehua, He Lina, Su Jing, Ding Chonghui, Zhang Wenjie, and Xie Yonghua. Anti-Xa assay kit (chromogenic substrate method)

1 Scope

YY/T 1917 covers anti-Xa assay kits using a chromogenic substrate. The anti-Xa assay measures the anticoagulant effect of heparins and of direct factor Xa inhibitors, and it is the test used where the standard clotting times do not work: low molecular weight heparin, obesity, pregnancy, renal impairment and patients on the newer oral anticoagulants who arrive bleeding or needing urgent surgery. The document sets out how such a kit is classified, the technical requirements it has to satisfy, the test methods that demonstrate them, and the labelling and storage rules. The clinical decisions that follow are immediate: whether to reverse anticoagulation, whether to operate. For a diagnostics manufacturer, this is the text a Chinese registration is judged against.

This document specifies the requirements, marking, labeling and instructions for use, packaging, transportation and storage of anti-Xa assay kits (chromogenic substrate method), Corresponding test methods are described. This document is applicable to the chromogenic substrate method anti-Xa assay kit (hereinafter referred to as the "kit"), which is used to perform common assays in human plasma samples. Quantitative detection of heparin (UFH) and low molecular weight heparin (LMWH).

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 29791.2 Information provided by manufacturers of in vitro diagnostic medical devices (labeling) Part

3 Terms and definitions

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

4 Requirements

4.1 Appearance The appearance should meet the following requirements.

a) All components of the kit should be complete and without leakage, and the labels should be clear and easy to identify;

b) Liquid reagents should be clear and transparent;

c) The freeze-dried product should be clear and transparent after reconstitution.

4.2 Blank limit Should not be higher than 0.08IU/mL.

4.3 Detection limit Should not be higher than 0.1IU/mL.

4.4 Linear

4.4.1 Unfractionated heparin (UFH) linearity The linearity of the kit for unfractionated heparin (UFH) covers at least [0.1, 1.2]IU/mL. Within the linear interval, the slope of the linear regression equation is Within the range of 1±0.05, the correlation coefficient r>=0.980.