ICS 11.100.10
CCS C44

YY

PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1585-2024

Replacing YY/T 1585-2017

25-hydroxy vitamin D testing kit

25-羟基维生素D测定试剂盒

Issued on: September 29, 2024 **Implemented on: October 15, 2025**

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" Drafting is required. This document replaces YY/T 1585-2017 "Total 25-hydroxyvitamin D Assay Kit (Labeled Immunoassay)" and is compatible with YY/T 1585- Compared with.2017, in addition to structural adjustments and editorial changes, the main technical changes are as follows: -- The scope adds the methodologies applicable to this document and deletes the inapplicable contents of this document (see Chapter 1,.2017 edition). Chapter 1); -- The classification method has been deleted (see Chapter 4 of the.2017 edition); --The main changes in technical indicators are as follows: l Changed the appearance requirements (see

4.1.1 and 4.2.1,

4.1 of the.2017 edition), l Changed the linearity requirements (see

4.1.3 and 4.2.3,

4.5 of the.2017 edition), l Changed the repeatability requirements (see

4.1.4 and 4.2.4,

4.6 of the.2017 edition), l Changed the accuracy requirements (see

4.1.6 and 4.2.6,

4.3 of the.2017 edition), l Changed the detection limit requirements (see

4.1.7 and 4.2.7,

4.4 of the.2017 edition), l Added the limit of quantification requirements (see

4.1.8 and 4.2.8), l Added analytical specificity requirements (see

4.1.9 and 4.2.9); --The test method has been changed to be compatible with the requirements of Chapter 4 (see Chapter 5, Chapter 5 of the.2017 edition); --Changes have been made to packaging, transportation and storage (see Chapter 7, Chapter 7 of the.2017 edition). 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/TC 136). This document was drafted by: Beijing Institute of Medical Device Inspection (Beijing Medical Bioprotection Equipment Inspection and Research Center), National Health Commission of China National Health Commission Clinical Laboratory Center, Zhejiang Medical Device Evaluation Center, Zhengzhou Antu Bioengineering Co., Ltd., Beijing Shuimu Jihengsheng Biotechnology Co., Ltd., Beijing Hospital, Comed Diagnostics Technology Co., Ltd., and Abbott Trading (Shanghai) Co., Ltd. The main drafters of this document are. Sun Xueqing, Zhou Weiyan, Ye Chaofu, Zhang Lihong, Yang Zongbing, Qiang Zhonghua, Wu Xiaojun, Wu Kechun, and Zhang Chuanbao. The previous versions of this document and the documents it replaces are as follows: --First published in.2017 as YY/T 1585-2017; --This is the first revision. 25-Hydroxyvitamin D Assay Kit

1 Scope

YY/T 1585 is the product standard for the 25-hydroxyvitamin D assay kit, the test used to assess vitamin D status and one of the most frequently ordered and most method-dependent assays in clinical chemistry. It specifies the requirements, the identification, the labelling, the instructions for use, the packaging, transport and storage of the kit, and describes the corresponding test methods. 25-OH vitamin D exists as two forms that different platforms recover differently, which is why results have historically varied between laboratories enough to move a patient across a treatment threshold. A kit-level standard is the mechanism for closing that gap. For a manufacturer or a distributor registering a vitamin D kit in China, this is the standard the specification and the registration testing follow.

This document specifies the requirements, identification, labeling and instructions for use, packaging, transportation and storage of 25-hydroxyvitamin D assay kits. The corresponding test methods are described. This document is applicable to the quantitative detection of total 25-hydroxyvitamin D, 25-hydroxyvitamin D2, 25-hydroxyvitamin D3 kits include labeled immunoassays (such as enzyme labeling, luminescent labeling, etc.), immunochromatography, immunoturbidimetry, and liquid chromatography-tandem Mass spectrometry, etc.

2 Normative references

The contents of the following documents constitute the 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 Metrological traceability of values assigned to calibrators and control materials for the measurement of quantities in biological samples of in vitro diagnostic medical devices Origin

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 Liquid chromatography-tandem mass spectrometry kit

4.1.1 Appearance Manufacturers should specify appropriate appearance requirements based on the packaging characteristics of their products. Generally, the components and properties of the kit should be Requirements for outer packaging, labeling, etc.

4.1.2 Traceability If calibrators are included, the manufacturer shall provide the source, value assignment process and Measurement uncertainty etc.

4.1.3 Linearity The linear range of 25-hydroxyvitamin D2 should cover [4.0, 100.0] ng/mL. Within the linear range specified by the manufacturer, the correlation coefficient (r) should not be less than 0.990

0.In the interval [4.0, 15.0] ng/mL, the absolute deviation should not exceed ±

2.25 ng/mL, (15.0, 100.0] ng/mL Within the range, the relative deviation should not exceed ±15.0%.