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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 1549-2024

Replacing YY/T 1549-2017

Calibrators for biochemical analyzers

生化分析仪用校准物

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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. This document replaces YY/T 1549-2017 "Calibrators for Biochemical Analysis". Compared with YY/T 1549-2017, except for the structural adjustment and editing In addition to the logical modifications, the main technical changes are as follows:

--- Added the definition of "total allowable error" (see 3.6);

--- Changed the uniformity requirements (see 4.7,

4.7 of the.2017 edition);

--- Changed the stability requirements (see 4.8,

4.8 of the.2017 edition);

--- The uniformity test method has been changed (see 5.8,

5.8 of the.2017 edition);

--- Changed the stability test method (see 5.9,

5.9 of the.2017 edition);

--- Changed the labeling and instructions for use requirements (see Chapter 6, Chapter 6 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/TC136). This document was drafted by: Beijing Medical Device Inspection Institute (Beijing Medical Biological Protection Equipment Inspection and Research Center), Beijing Shuimu Jiheng Biotechnology Co., Ltd., Beijing Jinyuan Medical Testing Laboratory Co.,

Ltd., the First Medical Center of the General Hospital of the Chinese People's Liberation Army, Beijing Jingantu Bioengineering Co., Ltd., Beijing Jiuqiang Biotechnology Co., Ltd., Shenzhen Mindray Bio-Medical Electronics Co., Ltd., Di Rui Medical Technology Co., Ltd., MyBiotech Co., Ltd., Sysmex Biotech (Wuxi) Co., Ltd., Sinopharm Biopharmaceuticals Technology Co., Ltd. The main drafters of this document are. Song Wei, Yang Zongbing, Chen Baorong, Yang Qiuliang, Liu Chunlong, Wang Xiaojian, Wan Xianzi, Chang Shuqin, Long Tengxiang, Hu Fangyu, Jin Ling. The previous versions of this document and the documents it replaces are as follows:

---First published in.2017 as YY/T 1549-2017;

---This is the first revision. Calibrators for biochemical analyzers

1 Scope

YY/T 1549 is the product standard for the calibrator used on a clinical chemistry analyser. A calibrator is the material that fixes the relationship between an instrument's signal and a reported concentration, so every patient result on that analyser inherits whatever error the calibrator carries: its assigned values, their uncertainty and their traceability to higher-order references are the properties that matter, along with the stability and commutability that let it behave like a patient sample. The standard specifies the requirements, labelling, instructions for use and packaging with the corresponding test methods. It works alongside YY/T 0638 on traceability for enzyme values. For a manufacturer or a distributor supplying calibrators to Chinese laboratories, this is the governing standard.

This document specifies the requirements, labeling and instructions for use, packaging, transportation and storage of calibrants for biochemical analyzers and describes the corresponding Test method. This document is applicable to calibrants used in fully automatic biochemical analyzers and semi-automatic biochemical analyzers for analysis of clinical test items.

Note. See Appendix A for examples of clinical test items. This document does not apply to calibrants for electrolyte modules of biochemical analyzers.

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 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

The following terms and definitions apply to this document.

3.1 The measured The quantity to be measured. [Source: GB/T 29791.1-2013, 3.39]

3.2 Analyte A component of a sample that has a measurable property. [Source: GB/T 29791.1-2013, 3.3]

3.3 Calibrator Measurement standards used for calibration of in vitro diagnostic instruments or systems.

Note. This includes the commonly used terms calibration fluid and calibrant. [Source: GB/T 29791.1-2013, 3.11]

3.4 measurement standard measurement standard A defined realization of a given quantity with a definite value and associated measurement uncertainty, used as a reference. [Source: GB/T 29791.1-2013, A.3.33]

3.5 A non-negative parameter that characterizes the dispersion of the values of the quantity being measured, based on the information used.