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PHARMACEUTICAL INDUSTRY STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

YY/T 0638-2008

In vitro diagnostic medical devices - Measurement of quantities in biological samples - Metrological traceability of values for catalytic concentration of enzymes assigned to calibrators and control materials

体外诊断医疗器械 生物样品中量的测量 校准品和控制物质中酶催化浓度赋值的计量学溯源性

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Foreword

This standard is identical with ISO 18153.2003 "in vitro diagnostic medical devices - Measurement of quantities in biological samples calibration and control materials Enzymatic concentration assignment metrological traceability. " For ease of use, this standard made the following editorial changes.

--- "This International Standard" be replaced by "this standard"; "."

--- With a decimal point instead of a comma as the decimal point, "";

--- Delete international standards foreword. The Standard Appendix A, Appendix B is an informative annex. This standard by the national medical clinical laboratory testing and in vitro diagnostic systems for Standardization Technical Committee (SAC/TC136) proposed. This standard by the national medical clinical laboratory testing and in vitro diagnostic systems for Standardization Technical Committee (SAC/TC136) centralized. This standard was drafted. Beijing Medical Device Testing, Roche Diagnostics (Shanghai) Co., Ltd. The main drafters of this standard. Hu Dongmei, Pingren Feng, Huang Boxing, Zhang Xinmei, Wangrui Xia, He Xueying. YY/T 0638-2008/ISO 18153.2003

Vitro Diagnostic Medical Devices Directive 98/79/EC requirements, assignment calibrators and control materials, need to be obtained through a higher level of participation Measurement test substance and reference measurement procedures to ensure that its metrological traceability. According to this concept of "traceability" standard GB/T 21415 The measurement procedures and calibration traceable grade material has been described in detail. General The standard also applies to the amount of catalytic activity. Should do May be on the measurement traceable to SI units, namely, the most advanced level of alignment. This standard catalytic activity of the enzyme concentration (hereinafter referred to as "catalyst concentration") level measurement of calibrators and measurement procedures are described. Enzyme Science measurement, always export the SI unit is defined as "Moore cubic meters per second [mol/(s · m3)]", General Conference on Weights and Measures will be named "Keita Seoul per cubic meter (katal/m3) ", is the most senior levels of traceability, followed by a reference measurement procedure, other lower-level measurement procedures, calibration Controlled substances and products should be traceable as possible to the program. Catalytic concentration measurements in blood or

other biological fluids enzymes contribute to the diagnosis of the disease. Enzymatic analysis principle to measure substrate conversion catalyst Of the rate, high speed, low detection limits, analysis of high specificity and low cost. Only catalytic measured under the same conditions of concentration Value was comparable. Therefore, the enzyme is measured will be described, not only the amount of type (such as catalytic concentration), and enzyme systems Name, and the need to include specific measurement procedures, especially in the measurement of the reaction indicating element. In the calibration level vertex, measurement procedures It should be internationally recognized, such as "creatine kinase (CK) of the IFCC reference measurement procedure to measure NADH conversion rate CK". Thus, the primary reference measurement procedure is defined measured integral part, must strictly follow all the details, for example, include the following content.

--- Species of the substrate (specific decision by the enzyme, may be different) and their concentrations;

--- Activator and concentration;

--- Catalytic reaction direction;

--- Indicating element;

--- Buffer system and pH;

--- Pre-heating time;

--- Responsive promoter substance;

---Reaction time. Definition of enzyme to be measured and the measurement results of the resulting reliance on the program, this defect is known. In the EQA (EQA) and the method may occur metastatic evaluation problem; there was diversity of biological reference intervals, thereby causing enzyme results of clinical error With risk. Conventional enzyme standardized measure of laboratory medicine is very important, by eliminating differences existing biological reference intervals, clinical improvement Applications and comparability of results. It can be considered in two ways.

a) General recommendation applies only to each enzyme or standardized measurement procedures; Interchangeable enzyme calibration material

1 Scope

YY/T 0638 governs how a value gets onto an enzyme calibrator and what that value means. It sets out the metrological traceability required for catalytic concentration values assigned to calibrators and control materials in in vitro diagnostics: the chain that links a number printed on a vial back through reference measurement procedures to a stated reference. Enzyme measurements are method-dependent in a way that concentration measurements are not, because the result depends on the assay conditions themselves,

which makes an explicit traceability chain the only way results from different laboratories can be compared. For an IVD manufacturer producing enzyme assays or calibrators for the Chinese market, this is the standard the value assignment documentation follows.

This standard specifies ensure calibrators and measurement of controlled substances assigned enzymatic concentration methodological traceability. These calibrators and controls Substance is expected to be used to establish or verify the accuracy of measuring the concentration of enzyme catalysis, provided by the manufacturer, as part of in vitro diagnostic medical device or In combination therewith. This standard does not apply to.

a) the reference measurement procedures designed or selected requirements;

b) the amount of enzyme or enzyme immunoassay of quality involved;

c) no assignment is only used to evaluate the precision of the measurement program, namely the repeatability or reproducibility of controlled substances (precision control materials);

d) controlled substances intended for internal quality control, the results of such substances acceptable range of values has recommended this interval by different Laboratory measurement procedures for the agreement to establish a provision, which limits non-metrological traceability;

e) the results of the conventional measurement products calibrator traceability of its relationship with the medical judgment of the limit;

f) nominal and ordinal scale related features.

2 Normative references

The following documents contain provisions which, through reference in this standard, constitute provisions of the standard. For dated references, subsequently Some amendments or revisions do not apply to this standard, however, whether these files can be used to encourage the parties in accordance with this standard agreement The latest version. For undated reference documents, the latest versions apply to this standard (including amendments).

GB/T 21415-2008 vitro diagnostic medical devices - Measurement of quantities in biological samples calibration and control materials assigned metrology Traceability (

ISO 17511.2003, IDT) International Fundamentals and vocabulary generic term measurement (VIM), 2nd edition, Geneva. ISO , 19931) Guide to the Expression of Uncertainty in Measurement, first edition, Geneva. ISO , 19932) 3) 1) In this standard abbreviations VIM.1993. 2) This publication is a joint working group of experts established by the agency assigned the following. BIMP International Bureau of Weights and Measures, IEC International Electrotechnical Commission, IFCC International Federation of Clinical

Chemistry and Laboratory Medicine, ISO International Standards Organization, IUPAC International Union Pure and Applied Chemistry, IUPAP International Li Theory and Applications of Physics, OIML International Organization of Legal Metrology. 3) the use of abbreviations in this standard GUM.1993.

3 Terms and Definitions

The following terms and definitions apply to this standard.

3.1 Name measure illustrated components. [ISO 17511.2003,3.2] Example. In the "plasma concentration of lactate dehydrogenase isozymes catalyze 1", the "lactate dehydrogenase isoenzyme 1" is the analyte. "Plasma lactate dehydrogenase isoenzyme

1 The catalytic concentration "represents the measurement, see 3.5. YY/T 0638-2008/ISO 18153.2003