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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 19703-2020

Replacing GB/T 19703-2005

In Vitro Diagnostic Medical Devices Measurement of Biological Source Samples Requirements for certified reference materials and supporting document content

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Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard replaces GB/T 19703-2005 "In Vitro Diagnostic Medical Device Biological Source Samples Measurement Reference Substances"

Ming Dynasty, compared with GB/T 19703-2005, the main technical changes are as follows.

---Introduced ISO 5725-2, ISO 17511.2003, ISO 18153, ISO Guide31, ISO Guide34, ISO Guide35,

ISO /IEC Guide98-3.2008, ISO /IEC Guide99.2007 content;

---Added the terms and definitions of "internationally agreed calibrators", "reference

materials" and "certified reference materials" (see 3.3, 3.4, 3.5);

---Added the content of "5 Characteristics, production and value of certified reference materials" (see Chapter 5);

--- "5 Description of Reference Substances" is revised to "6.4 Fixed Value Report";

--- Deleted the content of the "rationality of choice" clause (see 5.6 of the.2005 edition);

--- "5.9 Verification" is changed to "6.4.8 Fixed value";

--- "5.12 Supplier" is amended to "6.4.11 Development Organization";

--- Deleted the content of the "Packaging Insert" clause (see Chapter 8 of the.2005 edition).

The translation method used in this standard is equivalent to ISO 15194.2009 "In vitro diagnostic medical device biological sample measurement

Requirements for the content of certified reference materials and supporting documents.

The Chinese documents that have a consistent correspondence with the international documents cited in this standard are as follows.

---GB/T 3102 (all parts) quantity and unit [(ISO 31 (all parts)];

---GB/T 6379.2-2004 Measurement method and accuracy of results (accuracy and precision) Part 2.Determine standard measurement

The basic method of measurement method repeatability and reproducibility (ISO 5725-2.1994, IDT);

---GB/T 15000.3-2008 Guidelines for the Work of Standard Samples (3) General principles and statistical methods for the determination of standard samples

(ISO Guide35.2006,IDT);

---GB/T 15000.4-2019 Standard Sample Work Guidelines Part 4.The content of certificates, labels and accompanying documents (ISO Guide

31.2015, IDT);

---GB/T 15000.7-2012 Guidelines for Standard Sample Work (7) General Requirements for the Ability of Standard Sample Producers (ISO Guide

34.2009, IDT);

---GB/T 27418-2017 Measurement Uncertainty Evaluation and Expression (ISO /IEC Guide98-3.2008, MOD);

---GB/T 27419-2018 Evaluation and Expression of Measurement Uncertainty Supplementary File 1.Distribution based on Monte Carlo method

(ISO /IEC Guide98-3/Suppl.1.2008,IDT);

---YY/T 0638-2008 In Vitro Diagnostic Medical Device Biological Samples Measurement of calibrators and enzyme catalysis in control substances

Metrological traceability of concentration assignment (ISO 18153.2003, IDT).

This standard was proposed by the State Drug Administration.

This standard is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136).

Drafting organizations of this standard. Beijing Institute of Medical Device Inspection, Chinese Academy of Metrology, Zhongsheng Beikong Biotechnology Co., Ltd.,

National Health Commission Clinical Laboratory Center, Beijing Leadman Biochemical Co., Ltd.

Introduction

In scientific, technical, and routine service work, a reference measurement system is required to obtain useful and reliable measurement results to make it comparable

And finally traceable in metrology to the measurement standards and/or measurement procedures with the highest metrological level.

Reference substances are substances or equipment used to obtain metrological traceability across time and space and between different measurement procedures.

A certified reference material is required for the calibration level sequence of the quantity level.

A designated certified reference material should have a supporting document, which includes the source, description, measurement results, metrology traceability of the material

Performance, instructions for use, stability data and storage conditions, and health and safety warnings. This standard specifies the content of such substances and supporting documents

Requirements.

Reference substances are used for one of the three main purposes.

a) Calibrate the indication value of a measurement system or be used for the assignment of other reference materials;

b) Verify or control the accuracy of the values measured by a designated laboratory or batch of laboratories;

Note. In ISO terminology, "correctness" is related to "bias", "system effect" and "system error", while "accuracy" is related to "correctness" and "precision".

"Precision" is related to "standard deviation", "coefficient of variation", "random effect" and "random error".

c) Evaluate the performance of a new measurement procedure.

The maximum acceptable measurement uncertainty of a reference substance assignment result depends on the measurement procedure including the reference substance.

Requirement of quantity.

Since the correct use of a reference material depends on its description, it is necessary to specify the documentation of the reference material.

The advantages of having standards available are listed in ISO /IEC Guide15.

In Vitro Diagnostic Medical Devices

Measurement of amount in biological samples

Requirements for certified reference materials and supporting document content

1 Scope

This standard specifies the requirements for the content of certified reference materials and supporting documents, so that they can be considered to be consistent with GB/T 21415-2008.

The result is a higher level of metrology. This standard applies to all types of certified reference materials, including primary measurement standards, secondary measurement standards and calibration

Or an internationally agreed calibrator for accuracy control. This standard also provides how to collect data for setting value, and how to express the result of setting value and

Its measurement uncertainty requirements.

This standard is applicable to certified reference materials whose assignment result is differential value or proportional value. Appendix A provides relevant nominal characteristics and order

Amount of information.

This standard does not apply to reference materials that are part of the in vitro diagnostic measurement system, but many elements may help it.

2 Normative references

The following documents are indispensable for the application of this document. For dated reference documents, only the dated version applies to this article