NATIONAL STANDARD OF THE

PEOPLE'S REPUBLIC OF CHINA

GB/T 19702-2021

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures

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Foreword

This Standard is drafted in accordance with the rules given in GB/T 1.1-2009.

This Standard replaces GB/T 19702-2005 "In vitro diagnostic medical devices

- Measurement of quantities in samples of biological origin - Description of

reference materials". Compared with GB/T 19702-2005, the main technical changes of this Standard are as follows:

- In the scope, add "This Standard specifies requirements for the content of a reference measurement procedure for in vitro diagnostic medical devices and medical laboratories." and "This Standard applies to reference measurement procedures providing values of differential or rational quantities. Annex A provides information on nominal properties and ordinal quantities." (see Clause 1);
- ADD the terms and definitions of "analytical sensitivity", "detection limit" and "calibrator" (see Clause 3);
- CHANGE the "quality assurance" element from an optional element to a mandatory element; CHANGE the "foreword", "normative references" and "special cases" elements from mandatory elements to optional elements (see Table 1);
- Delete the content of 4.2.2 in "Warning and safety precautions" (see 4.2.2 of the 2005 edition);
- Modify the subclause name: Modify "4.5 Terms" to "4.5 Terms, definitions, symbols and abbreviated terms" (see 4.5; 4.5 of the 2005 edition);
- Modify the subclause name: Modify "4.8 Reagents" to "4.8 Reagents and materials" (see 4.8; 4.8 of the 2005 edition);
- Modify the subclause name: Modify "4.16 Verification by inter-laboratory research" to "4.16 Validation of a reference measurement procedure" (see 4.16; 4.16 of the 2005 edition);
- In "4.10.2 Samples", add "Requirements for the primary sample shall be specified in terms of required sample container and/or sample handling procedure, as required to minimize changes of the measurand (e.g. loss and/or contamination)" (see 4.10.2);
- ADD the content of "4.14.13 Intermediate precision standard deviation"

(see 4.14.13);

- Modify the title of Annex A: Modify "Reference procedures for parameters other than quantities" to "Reference procedures for properties other than differential and rational quantities" (see Annex A; Annex A of the 2005 edition).

This Standard, using translation method, is identical to ISO 15193:2009 "In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of reference measurement procedures".

China's document which has a consistent correspondence with the international document normatively referenced in this Standard is as follows:

- GB/T 27418-2017 Guide to the evaluation and expression of uncertainty in measurement (ISO/IEC Guide 98-3:2008, MOD).

This Standard was proposed by National Medical Products Administration.

This Standard shall be under the jurisdiction of National Technical Committee

136 on System of Medical Clinical Test Lab and in Vitro Diagnostic System of

Standardization Administration of China (SAC/TC 136).

Drafting organization of this Standard: Beijing Institute of Medical Device Testing.

Main drafters of this Standard: Yang Zongbing, Kang Juan, He Xueying, Wang Huiru.

The previous editions of the standard replaced by this Standard were released as follows:

- GB/T 19702-2005.

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for content and presentation of

reference measurement procedures

1 Scope

This Standard specifies requirements for the content of a reference measurement procedure for in vitro diagnostic medical devices and medical laboratories.

Note 1: It is intended that an experienced laboratory worker who follows a measurement procedure written in accordance with this Standard can be expected to produce measurement results with a measurement uncertainty not exceeding the stipulated interval.

This Standard applies to reference measurement procedures providing values of differential or rational quantities. Annex A provides information on nominal properties and ordinal quantities.

This Standard is valid for any person, body or institution involved in one of the various branches of laboratory medicine whose intention is to write a document to serve as a reference measurement procedure.

Full descriptions of measurement methods are usually published in scientific literature, in which methods are described in sufficient detail that they can be used as the basis of a documented measurement procedure.

Note 2: In this Standard, "international measurement standard" designates a material standard. The term "international standard" is used by WHO for reference materials.

2 Normative references

The following documents are indispensable for the application of this document. For the dated references, only the editions with the dates indicated are applicable to this document. For the undated references, the latest edition (including all the amendments) are applicable to this document.

ISO 15194 In vitro diagnostic medical devices - Measurement of quantities

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