

ICS 100.10.10
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**NATIONAL STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

GB/T 44672-2024

**In vitro diagnostic medical devices - Requirements for international
harmonisation protocols establishing metrological traceability of
values assigned to calibrators and human samples**

体外诊断医疗器械 建立校准品和人体样品赋值计量溯源性的国际一致化方案的要求

(English Translation)

Issued on: September 29, 2024

Implemented on: April 1, 2025

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

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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 is equivalent to ISO 21151:2020 "Establishing metrological traceability of calibrators and human specimens for in vitro diagnostic medical devices" Requirements for internationally harmonized schemes.

Introduction

A measurand of a human sample should have equivalent numerical results within a clinically meaningful range.

IVDMD results are equivalent, and practice guidelines for the use of uniform decision limits for the interpretation of laboratory results for clinical diagnosis and treatment decisions are possible.

Laboratory medicine has adopted the principle of metrological traceability of IVDMD calibration to high-level reference standards as a means to achieve the same measured the basis for the equivalence of results from different IVDMDs, different measurement times or different measurement locations.

ISO 17511:2020 describes six calibration hierarchies for reference measurement systems (see 5.2 to 5.7 of ISO 17511:2020).

They meet the requirements for metrological traceability of calibrations to higher-level reference standards. For cases 5.2, 5.3 and 5.4 of ISO 17511:2020 the metrological traceability of the values assigned to the calibrators for a specific IVDMD is based on an established reference measurement procedure.

Measurands for which there are certified reference materials or internationally agreed calibrators assigned values according to a consensus scheme, but for which there is no reference measurement procedure. Situations 5.6 and 5.7 this includes measurands for which there are neither reference measurement procedures nor certified reference materials or internationally agreed calibrators.

The consistency scheme is standardized and this document describes the requirements of such a consistency scheme. The situation in 5.7 includes the aforementioned traceability mode categories.

For the measured quantities not covered, metrological traceability is to the calibrator selected by the IVDMD manufacturer, not to the common reference in the case of 5.7, the results of different IVDMDs may differ from each other and from the decision limits in the medical decision guidelines.

The two may not be comparable.

For the measurands in the case of 5.6, it is technically difficult to develop high-level reference standards, so a standardization based on an agreed scheme is needed.

Pathways to achieve equivalence of two or more IVDMD results. Studies developed for the harmonization of measurands as appropriate for 5.6 constitute this the basis for the requirements in this document[5][11]. Standardization of results based on a harmonized protocol provides traceability of specific IVDMD calibrators to that protocol.

Metrological traceability. Harmonization schemes are established and implemented by international groups to achieve equivalence of results between different IVDMDs and meet the needs of medical decision-making.

Requirements for use of results.

Appendix A provides a worked example to illustrate the principles of the consensus scheme and one possible way to implement it.

Other approaches are possible and may be tailored for specific measurands and IVDMDs.

Establishment of calibrators and International harmonization of metrological traceability of human sample assignments Program Requirements

1 Scope

This document specifies the requirements for a harmonized scheme to be implemented by an international group for the measurement of in the case of reference materials or internationally agreed calibrators, the aim is to achieve equivalence of two or more IVDMD results for the same measurand.

In this case, the conformity scheme defines the highest level of metrological traceability for a specified measurand.

This document is applicable where certified reference materials or internationally agreed calibrators exist but are not applicable due to non-commutability with human samples, for example.

situation.

NOTE This document describes the context of traceability of assigned and measured values as described in 5.6 of ISO 17511:2020.

2 Normative references

The contents of the following documents constitute 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.

ISO 17511:2020 - Establishing metrological traceability of calibrators, trueness control materials and human specimens for in vitro diagnostic medical devices Note. GB/T 21415-2008 Metrological traceability of values assigned to calibrators and control substances for the measurement of quantities in biological samples for in vitro diagnostic medical devices (ISO 17511:2003, IDT) ISO 18113-2 Information provided by the manufacturer of in vitro diagnostic medical devices (labeling) Part 2: In vitro diagnostic reagents for professional use Note. GB/T 29791.2-2013 Information provided by the manufacturer of in vitro diagnostic medical devices (labeling) Part 2: Professional in vitro diagnostic reagents (ISO 18113-2:2009, IDT)

3 Terms and definitions

The following terms and definitions apply to this document.

ISO and IEC maintain terminology databases for standardization at the following addresses.

Aliquot

The portion of a bulk homogeneous substance when sampling errors are assumed to be negligible.

[Source. ISO 11074:2015, 4.3.1]