

ICS 11.020
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**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

WS/T 644-2018

**External Quality Assessment/Proficiency Testing in Clinical
Laboratory
(English Translation)**

Issued on: December 12, 2018

Implemented on: June 1, 2019

Issued by: National Health Commission

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Foreword

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

This standard is revised on the basis of GB/T 20470-2006 "Clinical Laboratory Inter-room Quality Evaluation Requirements".

Compared with GB/T 20470-2006, this standard is mainly revised as follows.

- modified terminology and definitions;
- increased the requirements for inter-room quality evaluation providers;
- Increased inter-room quality evaluation participants' requirements;
- Increased use of inter-room quality evaluation results;
- Deleted informative Appendix A.

This standard was drafted. Beijing Hospital, Hubei Provincial Clinical Testing Center, Chongqing Clinical Testing Center, Huazhong University of Science and Technology Tongji

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1 Scope

This standard specifies the requirements for the quality evaluation provider of clinical laboratory, the requirements of participants, the utilization of evaluation results of inter-room quality and the flow of evaluation Cheng.

This standard is applicable to inter-room quality evaluation providers for clinical testing services and medical laboratory and blood transfusion departments of medical and health institutions.

Medical laboratory of blood supply institutions, medical laboratory, etc.

2 Terms and definitions

The following terms and definitions apply to this document.

A set of inherent characteristics that meet the requirements.

Note 1: The term "quality" can be modified using adjectives such as poor, good or excellent.

Note 2: "Inherent" (the antonym of which is "given") refers to the existence of something or something that exists in itself, especially the permanent character.

[ISO/T 19000 -2016, 3.1.1] 2.2 Quality control, QC Part of quality management is committed to meeting quality requirements.

[GB/T 19000-2016, 3.2.10] 2.3 Quality assurance, QA Part of quality management is committed to providing the trust that quality requirements will be met.

[GB/T 19000-2016, 3.2.11] 2.4 Quality indicator A measure of the extent to which a set of intrinsic features meets the requirements.

Note 1: The measurement of quality can be expressed as, for example, the percentage of output (percentage within the specified requirements) and the percentage of defects (a hundred outside the specified requirements) Score), Million Opportunity Defect (DPMO) or Six Sigma level.

Note 2: Quality indicators measure the extent to which an organization meets user needs and the quality of all operational processes.

If all the urine samples received by the participants are "contaminated", then the contaminated urine samples are received and all urine samples are received.

The percentage of the inherent characteristics of the process is a measure of the quality of this process.

Metrological traceability Link measurement results to reference standards through a documented calibration chain with defined measurement uncertainty and uninterrupted Characteristics.

Note 1: For this definition, the reference standard can be a definition of a certain unit of measurement that is actually reproduced, or a measurement range that includes a unit of non-sequence measurement.

Order, or a measurement standard;

Note 2: The metrological traceability requires the establishment of a calibration level map;

Note 3: The technical requirements of the reference standard must include the time to establish a calibration level map using the reference standard, and other measurement information about the reference standard, for example, the time at which the calibration was first performed in the calibration level map;

Note 4: For measurements with more than one input in the measurement model, each input value should be traceable in terms of measurement, and the relevant calibration level map can be shaped.

Into a structure or network. The workload of each input value in establishing the traceability of the meter shall correspond to the contribution of the magnitude to the measurement result;

Note 5: The metrological traceability of measurement results does not guarantee that the uncertainty of measurement is suitable for a specific purpose, or that there is no error;

Note 6: If the comparison is used for verification, the comparison between the two measurement standards can be considered as calibration, and if necessary, the magnitude and measurement of one of the measurement standards the uncertainty is corrected;

Note 7: ILAC believes that the elements that confirm the traceability of the measurement include. an uninterrupted metrological traceability chain linked to international measurement standards or national measurement standards;

Documented measurement uncertainty; documented measurement procedures; recognized technical capabilities; metered traceability to SI; and calibration intervals (see ILAC P-10..2002);

Note 8: The term "traceability" refers to "metameter traceability" and sometimes other concepts such as "sample traceability" and "document".

Traceability, material traceability, these represent the history of an item (trace source). Therefore, if there is a risk of confusion, it is best the full term "metering traceability" is used.

[ISO/IEC Guide 99.2007, definition 2.4.1] 2.6 Robust statistical method A statistical method that is insensitive to a small deviation of a given probability model assumption.

Bias bias

Estimation of system measurement error.

Accuracy

The degree of agreement between the measured result and the measured true value.

Correctness trueness Infinitely repeated measures the degree of agreement between the average of the magnitudes obtained and a reference magnitude.

Note 1: The measurement accuracy is related to the system measurement error and is independent of the random measurement error.

Note 2: "Measurement accuracy" cannot be expressed by "measurement accuracy" and vice versa.

Note 3: Correctness is usually expressed in terms of bias.

2.10

Measurement uncertainty/ of measurement A non-negative parameter that imparts dispersibility to the measured magnitude is characterized based on the information used.

Note 1: Measurement uncertainty includes uncertainty components derived from system effects, such as uncertainty components associated with correction values and measurement criteria.

And the uncertainty of the definition. Sometimes, the estimated system impact is not corrected and the system impact is combined with the accompanying measurement uncertainty.

Together

Note 2: The parameter may be a standard deviation (or a specific multiple thereof) called a standard measurement uncertainty, or a half-width interval with a specified inclusion factor probability;

Note 3: Measurement uncertainty usually consists of multiple components, some of which can be assessed by class A uncertainty based on the statistical distribution of the magnitudes measured in the series.

Evaluation was performed and characterized by standard deviation. Other components are assessed using a Class B uncertainty, a probability density function based on experience or other information.

The number is evaluated and can also be characterized by standard deviation;

Note 4: Generally, for a given set of information, the measurement uncertainty should be accompanied by the magnitude of the measured value, and the change in the value will also cause the accompanying the degree of certainty changes.

[ISO/IEC Guide 99:2007, definition 2.26] 2.11 Standard deviation for proficiency assessment A measure of the dispersibility used to evaluate the inter-room quality