

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

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**Guide to the estimation of the measurement uncertainty of
reference methods in enzymology reference laboratories
(English Translation)**

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Table of Contents

Preface
1 Scope
2 Normative references
3 Terms and definitions
4 Abbreviations
5 Measurement uncertainty
5.1 Error and uncertainty
5.2 Sources of uncertainty
5.3 Classification of uncertainty
6 Evaluation of measurement uncertainty
6.1 General steps for evaluating measurement uncertainty
6.2 Process of evaluating measurement uncertainty
7 Specific steps to assess measurement uncertainty
7.1 Provision to be measured
7.2 Measurement procedures and measurement models for the IFCC reference method to measure the concentration of enzyme catalytic activity
7.3 Identify all possible sources of measurement uncertainty
7.4 Drawing the cause and effect (fishbone) diagram of the measurement process and the uncertainty calculation formula of the whole measurement process
7.5 List the value of each input
7.6 Calculate the standard uncertainty of each input and draw the estimated table
7.7 Calculate the concentration of enzyme catalytic activity ($\mu\text{kat/L}$)
7.8 Evaluation of the uncertainty of the synthetic standard in the whole process of measurement
7.9 Calculate the expanded uncertainty (U) and determine the synthesis factor (K) and unit
7.10 Contribution graph of input quantity to measurement uncertainty and main input quantity
8 Uncertainty report
8.1 General
8.2 Required information
8.3 Reporting standard uncertainty
8.4 Report expanded uncertainty
8.5 Compliance with limits

Appendix A (informative appendix) Finding the source of measurement uncertainty and drawing of causal (fishbone) diagram

Appendix B (informative appendix) Common sources and values of uncertainty

Appendix C (informative appendix) Data distribution function

Foreword

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

Drafting organizations of this standard. Beijing Hospital, Beijing Aerospace General Hospital, First Affiliated Hospital of Nantong Medical College of Jiangsu Province, Guangdong Provincial Hospital of Traditional Chinese Medicine, Shanghai Shanghai Municipal Clinical Laboratory Center, Peking Union Medical College Hospital of Chinese Academy of Medical Sciences, Beijing Shijitan Hospital.

1 Scope

This standard specifies the source of measurement uncertainty, the steps for evaluating measurement uncertainty, and the procedures for the evaluation of the Report method.

This standard applies to the measurement uncertainty of the enzymatic reference laboratory evaluation reference method for measuring the concentration of enzyme catalytic activity, and also applies to the the measurement uncertainty evaluation of other reference methods measured by the principle of spectrophotometry can also be used by accredited assessors in the assessment process use.

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 Pieces. For undated references, the latest version (including all amendments) applies to this document.

JJF1001-2011 General measurement terms and definitions JJF1059.1-2012 Evaluation and expression of measurement uncertainty CNAS-GL06..2006 Guidelines for the Evaluation of Uncertainty in Chemical Analysis

3 Terms and definitions

The following terms and definitions defined in JJF1001-2011 apply to this document.

System formation provides reference.

Example 1.A certain amount of serum derived from a larger amount of serum.

Example 2.An unbiased or randomly selected subgroup of a set of measurement results.

Verification by checking and providing objective evidence to show that it can meet the specific requirements of the intended application.

Example. The measurement program that is usually used to measure the nitrogen concentration in water is also confirmed to be able to measure the nitrogen concentration in human serum.

Note: The expected application or user needs are outside the measurement system and have nothing to do with it; but the performance is part of the measurement system or measurement program, that is, it Within the measurement system (verification).

Through inspection and provide objective evidence to show that a specified item can meet specific requirements.

Example. Demonstrate that the performance of the measurement system or regulatory requirements are met.

Note 1: The prescribed items can be processes, measurement procedures, substances, compounds or measurement systems.

Note 2: The specific requirements can be to meet the manufacturer's technical performance.

Note 3: In chemistry, the verification of the nature or activity of the entity involved requires the description of the structure or characteristics of the entity or activity.

4 Abbreviations

The following abbreviations apply to this document.

5.1 Error and uncertainty

5.1.1

The error is a single value. In principle, the value of the known error can be used to correct the result. The uncertainty is in the form of an interval it shows that when evaluating an analysis process and the specified sample type, it can be applied to all the measurement values described. For most medical experiments in terms of testing items in the laboratory, the measurement uncertainty is related to the measurement value. Generally, the uncertainty value cannot be used to correct the measurement result. this in addition, the difference between error and uncertainty is also reflected in. the revised analysis result may be very close to the measured value, so the error can be ignore. The uncertainty can be large because the analyst is not sure how close the measurement results are. The uncertainty of the measurement result is not it can be interpreted as representing the error itself or the residual error after correction.

Note: Error is an ideal concept, it is impossible to know exactly.

5.1.2

It is generally believed that the error contains two components, called random component and systematic component, including the following.

--- Random errors usually result from unpredictable changes in the amount of influence. These random effects make the measured repeated observations Make a change. Random errors in analysis results cannot be eliminated, but they can usually be reduced by increasing the number of observations;

Note: The arithmetic mean value or the experimental standard deviation of the mean value of a series of observations is a measure of the uncertainty of the mean value produced by some random effects.

Random error that is not the mean. The exact value of the random error of the average value produced by these random effects is unknown.

---Systematic error is defined as the error that remains constant or changes in a predictable way during a large number of analyses of the same measured Differential component. It is independent of the number of measurements, so it cannot be used by increasing the number of analyses under the same measurement conditions.

It reduces. include.

- Constant system error. For example, reagent blanks are not considered in quantitative analysis, or inaccuracy in calibration of multi-point equipment, it may be constant at a given measurement value level, but it may also change with the level of different measurement values;

- Unstable systematic error. In a series of analyses, the influencing factors have undergone systematic changes in quantity, such as Insufficient control of conditions will produce unconstrained systematic errors.

Example 1.During chemical analysis, the temperature of a group of samples is gradually increasing, which may cause gradual changes in the results.

Example 2.During the entire test, the sensors and probes may have aging effects, which may introduce inconstant system errors.

5.1.3

Another form of error is false error or excessive error. This type of error makes the measurement invalid, and it is usually caused by human error or instrumentation.

The generator fails. Digital carry when recording data, bubbles in the flow cell of the spectrometer, or accidental cross-contamination between samples, etc.

Common causes of errors. Include the following.

---False errors are not always obvious. When the number of repeated measurements is