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

WS/T 617-2018

**Reference procedure for the measurement of catalytic activity
concentration of aspartate aminotransferase
(English Translation)**

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Foreword

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

This standard was drafted. Peking Union Medical College Hospital of China Academy of Medical Sciences, Nantong University Affiliated Hospital, Beijing Hospital.

1 Scope

This standard specifies a reference measurement procedure for measuring the catalytically active concentration of aspartate aminotransferase in clinical medical applications.

This standard is mainly applicable to reference laboratories, as a trace source of the catalytic activity concentration measurement of aspartate aminotransferase, and can also be used as the traceability of the instrument and reagent manufacturing enterprises related to the enzyme catalytic activity concentration test can be used by the relevant accreditation supervision and management unit and the quality management department.

use. This reference measurement procedure can be used to trace the measurement results of clinical routine methods in China.

2 Normative references

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

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

ISO 15193 in vitro diagnostic apparatus - measurement of the amount of biological source samples - representation of reference measurement procedures

3 Terms and definitions

The following terms and definitions apply to this document.

Laboratory sample

A sample of the original sample or the original sample for measurement to be sent to the laboratory or laboratory for preparation.

Analytical sample

A sample prepared from a laboratory sample from which an analysis portion can be taken.

Note: The analysis sample can be subjected to various treatments before the analysis section is taken out.

Analytical part

The portion of the material taken from the analytical sample for actual measurement and observation.

Note: If no pretreatment is required, the analytical portion is taken directly from the original sample or laboratory sample. In some cases, the analysis part needs to be dissolved into an analysis.

The solution was measured on the machine.

Analytical solution

A solution prepared by dissolving a portion in a gas, a liquid or a solid may have a reaction occurring or no reaction occurring during the dissolution.

Matrix (of a material system) all components of a material system other than the analyte.

Reference measurement procedure Reference procedure the measurement procedure used to provide measurement results when calibrating or reference material settings, it is used to evaluate other measurements by similar quantities the measured accuracy of the measured magnitude obtained.

Sensitivity of a measuring system Sensitivity the change in the indication of the measurement system divided by the quotient of the corresponding measured value change.

Note 1: The sensitivity of the measurement system may be related to the measured value.

Note 2: The measured value of the measured value must be greater than the resolution of the measuring system.

Analytical specificity the ability of the measurement program to measure only measurable quantities.

Analytical interference A system measurement error caused by an amount of influence that does not generate a signal in the measurement system itself, but it causes an increase in the indication value.

High or low.

3.10

Influence quantity

An amount other than the one that can be measured that affects the measurement result.

3.11

Detection limit; limit of detection the measured value obtained by a given measurement procedure, the probability of misjudgment of the claimed substance composition is , claiming the existence of the material component the probability of judgment is .

Note 1: The International Union of Theoretical and Applied Chemistry (IUPAC) recommends a default value of 0.05 for and .

Note 2: The abbreviation LOD is sometimes used.

Note 3: Do not use the term "sensitivity" to mean "detection limit".

3.12

Calibrator

Measurement standard for calibration.

4 Abbreviations

The following abbreviations apply to this document.

AST. Aspartate Aminotransferase GUM. Guide to the expression of Uncertainty in Measurement IFCC. International Federation of Clinical Chemistry and Inspection Medicine (International Federation of Clinical Chemistry and Laboratory Medicine) LD. Lactate Dehydrogenase MD. Malate Dehydrogenase NAD. oxidized beta-nicotiamide-Adenine-Dinucleotide (oxidized form) NADH. Reduced beta-Nicotinamide-Adenine-Dinucleotide, reduced form P-5-P. 5'-Pyridoxal-5-Phosphoric acid QUAM. Quantifying Uncertainty In Analytical Measurement SOP. Standard Operation Procedure

5 Measurement principle and method

This reference measurement procedure uses a coupling reaction with the following reaction.

L-aspartate alpha-ketoglutarate oxaloacetate L-glutamic acid Oxaloacetate NADH H MD L-malic acid NAD at 339 nm, the oxidation rate of NADH was monitored, and the rate of decrease in absorbance was directly proportional to the concentration of AST catalytic activity.

6.1 Reagent List

The reagents used are listed in Table 1.

Table 1 Reagent List

Classification system name common name, abbreviations Reagent Tris L-aspartic acid no Alpha-ketoglutaric acid, disodium salt, dihydrate without

--nicotinamide adenine dinucleotide, reduced form, disodium salt reduced coenzyme I, NADH Lactate dehydrogenase LD Malate dehydrogenase MD Sodium azide Hydrochloric acid Sodium hydroxide Sodium chloride Bovine serum albumin, Fraction V 5'-pyridoxal phosphate, monohydrate P-5-P Pyruvate monosodium salt Oxaloacetate Solvent High-purity water of similar quality to double distilled water (conductivity < 2 $\mu\text{S}\cdot\text{cm}^{-1}$, pH 6~7, silicate < 0.1 $\text{mg}\cdot\text{L}^{-1}$) Reference material JCTLM and/or nationally approved reference material Quality control substances, conventional system calibrators no indicator