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PEOPLE'S REPUBLIC OF CHINA**

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**Autoverification of Clinical Laboratory Quantitative Test Results
(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 Chinese Academy of Medical Sciences, Zhongshan Hospital affiliated to Sun Yat-sen University, Guangdong Provincial People's Hospital, China Shengjing Hospital affiliated to Medical University, Civil Aviation General Hospital, Ruijin Hospital affiliated to Shanghai Jiaotong University School of Medicine, and 1982 Chinese People's Liberation Army Hospital, Beijing Sixth Hospital.

1 Scope

This standard specifies the general procedures and methods for the design, establishment and verification of automated laboratory auditing results.

Use management.

This standard is applicable to the guidance of medical laboratories, clinical laboratories, independent medical laboratories and related information management departments, laboratory information.

System (LIS) manufacturers develop and apply automatic audit procedures for inspection results. In vitro diagnostic equipment manufacturers can also refer to use.

2 Terms and definitions

The following terms and definitions apply to this document.

Automatic review of autoverification Subject to the operating procedures, the computer system follows the verified rules, standards, and logic set by the clinical laboratory.

The act of reviewing the test results and publishing the test report becomes a medical record. In the process, with the laboratory's preset acceptance criteria Consistent results are automatically entered into the patient report in the prescribed format without any additional intervention.

Laboratory information system;

The software used by clinical laboratories to collect, store, analyze, and apply data for the management of pre-, post-, and post-test data.

Middleware Middleware is a type of basic software that sits in the middle layer of operating system software (instrument control software) and user application software (LIS).

Difference check delta check Compare the current results of a test item with the previous results of the same patient, also known as historical results.

Verification A determination that the stated requirements have been met by providing objective evidence.

Issue release

When reviewing a report, sign and report on the report that meets the audit requirements. Automatic issuance refers to the execution of signature by the automatic auditing system.

And publish a report.

3 Implementation of automatic audit software selection

Clinical laboratories can perform automated audits using LIS or middleware. The laboratory can design its own automated review process or introduce it an information system with an automated review process implements an automated review.

4.1.1.1 Patient Information

The patient's descriptive information can be used as a judgment parameter in the operation of the program, including age, gender, inspection department, clinical diagnosis, Medication, unique patient identification code, etc.

4.1.1.2 Sample Information

Sample related information may include, but is not limited to.

- a) sample type;
- b) acquisition time;
- c) the collection site;
- d) receiving time;
- e) sample traits (eg hemolysis, lipemia, jaundice, presence or absence of clots, etc.);
- f) Others (such as remarks filled in at the time of application, such as before dialysis, after dialysis, etc.).

4.1.2 Inspection

The object of the program operation can also be derived from information related to the detection system status, including.

- a) calibration status;
- b) indoor quality control;
- c) instrument alarm information;
- d) reagent related information (such as reagent validity period, open bottle stability period);
- e) Methods Analyze performance related information and others (eg analytical measurement range, sample dilution factor, interference, etc.).

4.1.3 After inspection

The program can also use data from the following sources.

- a) the result warning symbol (for example, a warning symbol indicating that the biochemical

reaction substrate is exhausted);

b) the previous measurement result of the same test item of the same patient (for the difference check);

c) the results of other test items in the sample (for correlation or logical relationship analysis between different items, such as LDL cholesterol the sum of alcohol and high-density lipoprotein cholesterol should not be greater than the total cholesterol), or the test results of the same sample of the patient (eg the urinary albumin is abnormally abnormal, and its total urinary protein should not be normal);

d) Results of different patients on the same test instrument (eg for calculating the moving average of certain items).

4.1.4 Data selection

The laboratory can select the appropriate data for the analysis of the automated review process based on the workflow of the medical institution.

4.2.1 Analysis of patient information

The program combines the test results with patient information (age, gender, inspection department, diagnosis, etc.) for analysis.

4.2.2 Analysis of sample information

The program should be able to identify samples that are not in compliance with the requirements for collection and inspection. For fully automated inspection systems with automated sample preparation, the sequence should be able to identify abnormal sample traits that affect the test results (eg, by determining serum index or image judgment system to identify hemolysis, lipemia, yellow specimen).

4.2.3 Detection system status analysis

The program should be able to identify various types of warning symbols transmitted or generated by the inspection system, LIS, middleware, etc. that are relevant to the accuracy of the test results (eg the result is beyond the warning range of analysis and measurement range, interference, and quality control out of control).

4.2.4 Numerical comparison

Numerical comparisons should include, but are not limited to, the following.

a) The program compares the test results with the set range. Commonly used ranges include biological reference intervals, analytical measurement ranges, and reportable Scope, critical value, medical decision level, etc.