GB

ICS 11.100
C 44

National Standard

of the People's Republic of China

GB/T 19634-2005

In vitro diagnostic test systems - General technical requirements for blood-glucose monitoring systems for self-testing

体外诊断检验系统 自测用血糖监测系统通用技术条件

(ISO 15197:2003, NEQ)

Issued on: January 24, 2005 **Implemented on: May 1, 2005**

Issued by: General Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China;

Standardization Administration Committee.

Table of Contents

Foreword

GB/T 19634 “In vitro diagnostic test systems - General technical requirements for blood-glucose monitoring systems for self-testing” is not equivalent to ISO 15197.

This Standard was proposed by China Food and Drug Administration.

This Standard shall be under the jurisdiction of the National Clinical Trial Laboratory and in-Vitro Diagnostic System Standardization Technical Committee.

Drafting organizations of this Standard: Beijing Institute of Medical Device Testing, and American Johnson & Johnson Ltd.

Main drafters of this Standard: Hu Dongmei, Xu Yong, and John Mahoney.

Introduction

Blood-glucose monitoring systems for self-testing are in vitro diagnostic medical devices used mainly by lay persons. When used properly, they can help diabetics to monitor and take action to control the glucose concentration in the blood.

The primary objectives of this Standard are to establish requirements for the design of blood-glucose monitoring systems that can result in acceptable results when used by lay persons on the premises that users have accepted certain training, devices have been properly maintained and operated according to the calibration and quality control procedures in instructions for use of manufacturers, and to specify procedures for verifying the conformance of blood-glucose monitoring systems' indicators to this Standard.

This Standard illustrates general technical requirements for blood-glucose monitoring systems for self-testing, including the information provided by the manufacturer and labels and instructions of blood-glucose monitoring systems for self-testing. Since the self-testing systems are used by lay persons, the information provided by the manufacturer shall be explicit and easily to be understood, for the convenience of users to have self-testing according to the operation procedures correctly. At the same time, it shall provide certain warnings or prompts, to guide the appropriate measures under abnormal results. This Standard specifies the information provided by the manufacturer in detail.

In vitro diagnostic test systems - General technical requirements for blood-glucose monitoring systems for self-testing

1 Scope

This Standard specifies the terms and definitions, requirements, test methods, labels and instructions for use, packaging, transportation, and storage for blood-glucose monitoring systems for self-testing.

This Standard is applicable to the blood-glucose monitoring systems for self-testing intended for in vitro monitoring the glucose concentration in capillary whole blood and/or venous whole blood (normally including portable glucose meters, disposable test strips, and control materials).

2 Normative references

The provisions in following documents become the provisions of this Standard through reference in this Standard. For dated references, the subsequent amendments (excluding corrigendum) or revisions do not apply to this Standard, however, parties who reach an agreement based on this Standard are encouraged to study if the latest versions of these documents are applicable. For undated references, the latest edition of the referenced document applies.

GB 4793.1-1995 Safety requirements for electrical equipment for measurement, control and laboratory use – Part 1: General requirements (idt IEC1010-1:1990)

GB 9706.1-1995 Medical electrical equipment – Part 1: General requirements for safety (idt IEC 601-1:1988)

GB/T 14710-1993 Environmental requirements and testing methods for medical electrical equipment

YY 0466-2003 Medical electrical equipment – Symbols for electrical equipment for label, mark and providing information (ISO 15223:2000, IDT)

3 Terms and definitions

The following terms and definitions apply to this Standard.

[ISO 3534-1:1993, Definition 3.14]

Note 1: The precision degree is expressed in numerical form of the measurement imprecision obtained by statistical measures, such as standard deviation (SD) and coefficient of variation (CV), that shows a negative correlation with precision. Quantitative measures of precision depend on the specified conditions.

Note 2: Precision of a given measurement procedure can be classified according to the clear precision conditions. Precision under specific conditions are termed as “repeatability” and “reproducibility”.

3.5

Repeatability

Consistency between test results obtained with continuous multiple measurements under the same measurement conditions.

[JJF 1001-1998, Definition 5.6]

3.6

Repeatability conditions

Conditions where independent test results are obtained with the same test method, on same test object, in the same laboratory, by the same operator, using the same equipment, and within short intervals of time.

[ISO 3534-1:1993, Definition 3.16]

Note: Essentially constant conditions, intended to represent conditions resulting in test results of minimum variability.

3.7

Blood-glucose meter

Component of a blood-glucose monitoring system, it can convert the result of a chemical reaction into the glucose concentration in the sample.

3.8

Label

Printed, written or graphic information placed on a device or container.

3.9

Instructions for use

(> 75 mg/dL)	

4.4 Batch-batch difference of blood-glucose test strips

Batch-batch difference between different batches of blood-glucose test strips shall not be greater than 15%.

4.5 Control material

95% of test result obtained with control material shall be within the quality control range of blood-glucose test strips.

4.6 Environmental test for blood-glucose meter

It shall meet the requirements of applicable articles in GB/T 14710-1993.

4.7 Safety requirements for blood-glucose meter

It shall meet the requirements of applicable articles in GB 9706.1-1995 and/or GB 4793.1-1995.

5 Test method

5.1 Test materials

a) Blood-glucose meter (at least 2 blood-glucose meters of the same specification are recommended);

b) Blood-glucose test strips;

c) Reference analysis meter in accordance with manufacturer's suggestions;

d) Blood-glucose reference materials with traceability (such as the reference material SRM 965 of National Institute of Standards and Technology (NIST));

e) Venous blood-sample or capillary blood-sample;

f) Blood collection tube added with proper anticoagulant;

g) Low speed centrifuge;

h) Straw;

i) Colorimetric tube or small test tube used for reference analysis meter;

j) Instructions for use of calibration and control procedures provided by the manufacturer;

Note 1: In some cases, to promise the completion of measurement, a second skin puncture may be necessary.

Note 2: It can adjust glucose concentrations in capillary blood-samples according to the method in 5.5.1a), to obtain samples in the lowest and highest concentration ranges.

5.4.2.2 Test procedure

DIVIDE capillary blood-sample into two aliquots firstly. PERFORM glucose concentration test on one portion by reference analysis meter according to the standard measurement procedure of manufacturer. TEST another portion by two glucose meters according to the method in the instructions for use of manufacturer.

If reference analysis meter is only designed for testing plasma samples, then add an anticoagulant recommended by the manufacturer into one portion, and collect plasma by centrifugation at 1000g for 10 min. PERFORM the glucose measurement according to the standard measurement procedure of manufacturer.

The differences between results of blood/plasma from each blood-glucose meter and the results of blood/plasma from reference analysis meters are deemed as the deviation.

5.5 Batch-batch difference of blood-glucose test strips

~~USE blood-glucose test strips of 2 different batches to repeatedly measure the fresh anticoagulant venous blood or control material of normal fasting people for 10 times respectively on a same blood-glucose meter. CALCULATE mean value of test results of 2 batches respectively, and calculate the total mean value of test results of 3 batches. CALCULATE batch-batch difference according to formula (2).~~

USE blood-glucose test strips of 3 different batches to repeatedly measure the fresh anticoagulant venous blood or control material of normal fasting people for 10 times respectively on a same blood-glucose meter. CALCULATE mean value of test results of 3 batches respectively, and calculate the total mean value of test results of 3 batches. CALCULATE batch-batch difference according to formula (2). [Translator Note: Amendment No. 1, National Standard Committee Announcement [2005] 69, February 6, 2005]

$$\text{Batch-batch differences} = \frac{\text{Max. mean - Min. mean}}{\text{Total mean}} \times 100\% \qquad \cdots\cdots (2)$$

5.6 Control material

MEASURE concentration of control material repeatedly for 20 times by same blood-glucose meter and same batch of blood-glucose test strips.

5.7 Environmental test for blood-glucose meter

PERFORM the test in accordance with the method specified in GB/T 14710-1993.

5.8 Safety test for blood-glucose meter

PERFORM the test in accordance with the methods specified in GB 9706.1-1995 and/or GB 4793.1-1995.

6 Labels and instructions for use

6.1 Labels for the blood-glucose meter

6.1.1 Labels for blood-glucose meter shall provide at least the following information:

a) Name and address of the manufacturer;

b) Product name or symbol (it shall be indicated directly on a label attached to the device);

c) Intended purpose (include a statement that the device is an in vitro diagnostic medical device for self-testing, and reagent information to be used with the device);

d) Lot or serial number indicated directly on a label attached to the device;

e) Storage and transportation conditions;

f) Operation method shall reference or illustration of users manual.

6.1.2 If applicable, the above information shall be expressed in form of symbols. Symbols used shall comply with specifications in YY 0466. If there is no existing standard for the symbols used, all symbols shall be described in the relevant information of blood-glucose meter.

6.2 Instructions for use for the blood-glucose meter

6.2.1 The instructions for use shall be clear, concise, and use plain words that are readily understood by a lay person. The content of manual shall be well organized and easy to read by persons without a scientific or technical background. The typographic fonts of easy operation manual shall be large and clear, and easy for reading. Symbols and illustrations shall be used as much as possible.

The instructions for use shall clearly state what actions to take if the verification indicates an invalid result.

It shall use Chinese; other languages are optional.

fails;

l) Type of samples to be used, any special conditions of collection and pretreatment;

m) Measures to be taken to prevent infection before the use of the instrument;

n) If applicable, measures to be taken to prevent electrostatic discharge, magnetic fields, and other electrical conditions, as well as temperature, humidity, and other environmental conditions;

o) Description and explanation of all symbols used on labels and in the instructions for use;

p) Advice on action to be taken by the user according to measurement result, including:

— REFERENCE the instructions given by a physician and/or other diabetes specialists;

— a warning to users, without consulting the physician and other diabetes specialists, do not to deviate from their instructions on the basis of the result;

— countermeasures when measurement result appears to be questionable to the user;

— methods for the monitoring system alerting the user when the result is outside the analysis range (e.g. error messages, error notifications, etc.);

— PERFORM regular check on laboratory. And compare the measurement result from blood-glucose meter to that from laboratory.

q) If applicable, information on the safe disposal of the system and its components;

r) The year and month of issue or the revision number of the instructions for use.

6.3 Labels for the blood-glucose test strips and control material

6.3.1 The blood-glucose test strips and control material shall be identified by a label or labels. The following information shall be included on the label(s):

a) Name and address of the manufacturer;

b) Names, models, or brand names of blood-glucose test strips and control material;

c) Intended purpose and applicable blood-glucose meter;

d) Explanation of “only for in vitro monitoring”;

e) Storage conditions;

f) Volumes;

g) Batch number;

h) Validity period;

i) Validity and expiration date after the first opening;

j) Description of the necessity of reference to the instructions for use.

Note: Warning statements about how to use and treat random reagent of blood-glucose system shall be included on the label, to ensure reliability of measurement results and safety of disposal measures.

6.3.2 It shall use Chinese. Other languages are optional.

6.4 Instructions for use for blood-glucose test strips and control material

6.4.1 Instructions for use for blood-glucose test strips and control material shall include the following elements:

a) Name, address, and customer service phone number of manufacturer and/or distributor;

b) Blood-glucose meter matched with the blood-glucose test strips and control material;

c) The storage conditions (e.g. temperature, humidity, light, and other environmental factors) (include a warning statement about the need to tightly seal the cap of the container for users, to avoid exposure of blood-glucose test strips or sensors to the air);

d) The measurement interval, including the upper and lower concentration limits within which the glucose results are accurate and reportable; explanation of “only for in vitro monitoring”;

e) The performance characteristics (e.g. system accuracy) stated in language that is understandable by the intended user. The manufacturer can report system accuracy characteristics according to the following means:

— when glucose concentration <4.2mmol/L (75mg/dL), the percentage of results of which the deviations with reference values are within the range of ±0.28mmol/L, ±0.56mmol/L, ±0.83mmol/L (±5mg/dL, ±10mg/dL, ±15mg/dL);

— when glucose concentration <4.2mmol/L (75mg/dL), the percentage of

References

[1] Evaluation protocol for self blood-glucose monitoring devices. Agence Francaise de Securite Sanitaire des Produits de Sante (previously Agence du Medicament), France, April 1998.

[2] Consensus statement on self-monitoring of blood-glucose, American Diabetes Association. *Diabetes Care*, 10(1), 1987, pp. 95-99

[3] Self-monitoring of blood-glucose. American diabetes Association. *Diabetes Care*, 17(1), 1994, pp. 81-86

[4] CSA Z316. 4-94, Performance Specifications for Portable Whole Blood Glucose Monitor Systems for Use in Diabetes Management. Canadian Standards Association. March 1994.

[5] Whole Blood Glucose Proficiency Survey Program, College of American Pathologists (USA). 1997.

[6] ISO 3534-1, Vocabulary and Symbols - Part 1: Probability and general Statistical Terms.

[7] ISO 5725-1, Accuracy (trueness and precision) of measurement methods and results - Part 1: General principle and definitions

[8] ISO 5725-2, Accuracy (trueness and precision) of measurement methods and results - Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement procedure

[9] ISO 5725-3, Accuracy (trueness and precision) of measurement methods and results - Part 3: Intermediate measure of the precision of a standard measurement method

[10] ISO/FDIS 17511, In vitro diagnostic medical device - Measurement of auantities in samples of biological origin - Metrological traceability of values assigned to calibrators and control materials.

[11] ISO 15197: 2003, In vitro diagnostic test systems - Requirements for blood-monitoring systems for self-testing in managing diabetes mellitus.

[12] ISO/DIS. 2 15197, In vitro diagnostic test systems - Requirements for blood-monitoring systems for self-testing in managing diabetes mellitus.

[13] International vocabulary of basic and general terms in metrology, 2nd edition, ISO, Geneva, 1993 (VIM 1993).

[14] NCCLS. Ancillary (Bedside) Blood Glucose Testing in Acute and Chronic Care Facilities; Approved Guideline. C30-A2. Villanova, PA: NCCLS, 2002.

[15] NCCLS. Evaluation of Precision Performance of Clinical Chemistry Devices; Approved Guideline. NCCLS document EP5-A (ISBN 1-56238-368-X). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, 1999.

[16] NCCLS. Interference Testing in Clinical Chemistry; Preliminary Guideline. NCCLS document EP7-P (ISBN 1-56238-TBD). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, 1986.

[17] NCCLS. Method Comparison and Bias Estimation Using Patient Samples; Approved Guideline. NCCLS document EP9-A (ISBN 1-56238-283-7). NCCLS, 940 West Valley Road, Suite 1400, Wayne, PA 19087-1898, 1995.

[18] prEN 592, In vitro diagnostic systems; Requirements for user manual for in vitro diagnostic systems for home use.

[19] prEN 13532, General requirements for in vitro diagnostic medical devices for self-testing.

[20] Council Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on In vitro Diagnostic Medical Devices, Official Journal of the European Union L331, December 7, 1998

[21] The Expert Committee, The Expert Committee on the diagnosis and classification of diabetes mellitus. Report of the Expert Committee on the diagnosis and classification of diabetes mellitus, Diabetes Care 2003; 26: S5-20.

This is an excerpt of the PDF (Some pages are marked off intentionally)

------ The End ------