

ICS 11.100
CCS C 44



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

GB/T 19634-2005

**[Including 2006XG1] In vitro diagnostic test systems -- General
technical requirement for blood-glucose monitoring systems
for self-testing**

(English Translation)

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**

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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.