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NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 29790-2020

Replacing GB/T 29790-2013

Instant inspection quality and ability requirements

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Foreword

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

This standard replaces GB/T 29790-2013 "Requirements for Instant Testing Quality and Capability". Compared with GB/T 29790-2013, the main

The main technical changes are as follows.

---Modify the "Immediate Inspection" in the standard to "Immediate Inspection";

---Modified some terms in the standard, changed "laboratory leader" to "laboratory director", "detection limit" to "detection limit", "medical care

"Provider" is replaced by "medical personnel", etc.;

--- Deleted the "GB/T 22576-2008 5.1.3 and the following content applies" requirements (see 5.1.2, the.2013 edition of 5.1.2);

--- Deleted 5.1.3, 5.6.4, 5.6.7 (see 5.1.3, 5.6.4, 5.6.7 of the.2013 version);

--- Modified b) and d) in 5.1.4, and added "certification" related content (see 5.1.4, 5.1.5 of the.2013 edition);

---Modified 5.4 "pre-inspection procedure", changed to "pre-inspection process" (see 5.4,.2013 edition of 5.4);

---Modified 5.5 "inspection procedure", changed to "inspection process" (see 5.5, the.2013 edition of 5.5);

---Modified 5.6 "Quality Assurance of Inspection Procedures" and changed to "Quality Assurance of Inspection Processes" (see 5.6,.2013 edition of 5.6);

--- Modified 5.7 "procedure after inspection", changed to "process after inspection" (see 5.7, 5.7 in the.2013 edition).

The use of the translation method in this standard is equivalent to the adoption of ISO 22870.2016 "Requirements for immediate inspection quality and ability."

Please note that certain contents of this document may involve patents. The issuing agency of this document is not responsible for identifying these patents.

This standard was proposed by the State Drug Administration.

This standard is under the jurisdiction of the National Medical Clinical Laboratory and In Vitro Diagnostic System Standardization Technical Committee (SAC/TC136).

Drafting organizations of this standard. Beijing Institute of Medical Device Inspection, China National Accreditation Center for Conformity Assessment, No.

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Introduction

Traditional testing of patient fluids, excreta and tissue samples is usually in a regulated and controlled environment of a recognized medical laboratory

In progress. There is growing interest in these laboratories to introduce quality management systems and gain accreditation.

Technological advancements have led to the emergence of various in vitro diagnostic (IVD) medical devices that are compact in design and convenient to use.

It is possible to conduct inspections at or near the location. Immediate/proximity testing is beneficial to patients and medical institutions.

The risks that immediate inspection brings to patients and institutions can be controlled by a well-designed and fully implemented quality management system, which can

promote.

--- Evaluation of new or alternative POCT equipment and systems;

---Evaluation and approval of end user proposals and plans;

--- Equipment purchase, installation and maintenance;

---Maintenance of consumables and reagents;

---POCT system operator training, certification and renewal;

---Quality control and quality assurance.

Organizations that recognize the capabilities of POCT laboratories can use this standard as the basis for their activities. Seeking for some or all of its activities

An accredited medical institution should choose an accredited institution that operates in accordance with the specific requirements of POCT.

Instant inspection of quality and capability requirements

1 Scope

This standard specifies special requirements applicable to point-of-care inspection (POCT) and is used in conjunction with GB/T 22576.1-2018.This standard

The requirements apply to real-time inspections in hospitals, clinics or medical institutions that provide mobile medical services. This standard can be applied to

Skin measurement, breath analysis and in vivo monitoring of physiological parameters.

This standard does not include patient self-tests at home or in the community, but the elements of this standard are applicable.

Note. Local, regional and national regulations need to be considered.

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.

GB/T 22576.1-2018 Requirements for the quality and competence of medical laboratories Part 1.General requirements (ISO 15189.2012,

IDT)

3 Terms and definitions

The following terms and definitions apply to this document.

3.1

Point-of-care testing; POCT

Near-patient testing

Tests performed near or at the patient's location, the results of which may lead to changes in the patient's treatment.

4.1.1 GB/T 22576.1-2018 4.1.1.2, 4.1.1.3 and the following clauses apply.

The management of laboratory services should plan and formulate the processes required for POCT.

When applicable, the following should be considered.

a) POCT's quality objectives and requirements;

b) Need to establish POCT-specific processes and documents, and provide resources;

c) Specific verification, confirmation and supervision activities required by POCT;

d) Provide records proving that the POCT process and procedures meet the requirements.

The manager of the organization is ultimately responsible for ensuring that appropriate measures are in place to monitor the accuracy and quality of the POCT running in the medical institution.

4.1.2 The clauses 4.1.2.2 and below in GB/T 22576.1-2018 apply.

4.1.2.1 A medical professional body (such as a medical advisory committee) should be