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# NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

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# Guidance for supervisors and operators of point-of-care testing (POCT) devices

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## Foreword

This document complies with the provisions of GB/T 1:1-2020 "Standardization Work Guidelines Part 1: Structure and Drafting Rules of Standardization Documents"

Drafting:

This document is equivalent to ISO /T S22583:2019 "Guidelines for Point-of-Care Testing (POCT) Equipment Supervisors and Operators": The document type is:

ISO 's technical specifications were adjusted into my country's national standardization guiding technical documents:

Please note that some content in this document may be subject to patents: The publisher of this document assumes no responsibility for identifying patents:



## Introduction

Due to the ease of use and immediacy of point-of-care testing (POCT), POCT equipment is widely used in patient health as a decision-making tool

related areas such as management or care needs: Simple and easy-to-use POCT equipment promotes the continuous development of POCT: Traditionally, the patient's physical

Fluid, excreta, and tissue examinations are performed in the controlled and supervised environment of medical laboratories, and POCT is increasingly performed globally

Conducted outside the traditional laboratory environment, such as pharmacies, clinics, nursing homes, emergency rescue sites, communities, shopping malls, etc:, and by people without

Medical laboratory support operators:

POCT results can be used for patient admission, transfer, and guidance of patient health management, and may also have significant civil and/or legal impacts:

effects, such as suspension or termination of employment, Family Court decisions, or revocation of bail or parole, so the equipment operates properly and produces the correct results, and

It is essential that operators are trained and competent, which requires supervisors to provide a quality inspection system and provide operators with

writer:

This document provides guidance for supervisors and operators performing POCT services to evaluate the POCT services, inspections and

Suitability of equipment selection, as well as technical performance and results interpretation requirements to ensure reliability of results, quality of results, and interpretation of results

Suitable for intended use:

Point-of-care Testing (POCT) Equipment Supervisor and

Operator's Guide

## 1 Scope

This document provides guidance for supervisors and operators performing point-of-care testing without medical laboratory training, supervision, or support:

Guidance on (POCT) services, including key points to consider in providing safe and reliable POCT results:

This document does not cover self-test products:

## 2 Normative reference documents

This document has no normative references:

## 3 Terms and definitions

The following terms and definitions apply to this document:

Terminology databases for standardization maintained by ISO and IEC at the following address:

---ISO online browsing platform: http://www:iso:org/obp;

3:1

analyteanalyte

An item that is measured, tested, or calculated:

Examples: glucose, troponin, cocaine, HIV antibodies:

3:2

reference rangereferencerange

normal rangenormalrange

normal valuenormalvalue

A defined interval of a distribution of values taken from a biological biological reference population:

Note 1: The reference interval consists of the values or ranges expected for the analyte (3:1) in "healthy persons": They are sometimes called "normal" values: Although the "normal" range can be said to

It indicates the health status of the patient (3:10), but it needs to be considered that the result is within the "normal" range and does not necessarily mean that the patient (3:10) is healthy:

Results in the "normal" range do not necessarily mean that the patient (3:10) is unhealthy: Also note that the "normal range" may vary from device to device (3:6) and

There are differences among different groups of people:

Note 2: In some cases, such as the normal value of drug testing is negative or not detected:

[Source: GB/T 22576:1-2018, 3:4, with modifications]

3:3

clinicalhandover clinicalhandover

patient handover patienthandover

Handover

The temporary or permanent transfer of some or all of the professional care duties and responsibilities for a patient (3:10) to another person or professional body:

Note 1: The handover of all or part of the treatment of a patient (3:10) between medical staff or between different locations is a high-risk situation, and errors in clinical handover can lead to

The main source of harm to patients (3:10), such mistakes can be avoided: