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

GB/T 44586.1-2024

**In vitro diagnostic medical devices - Multiplex molecular testing
for nucleic acids - Part 1: Terminology and general
requirements for nucleic acid quality evaluation**

体外诊断医疗器械 多重核酸分子检测 第1部分：核酸质量评价术语和通用要求
(English Translation)

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Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part 1: Structure and drafting rules for standardization documents" Drafting.

This document is part 1 of GB/T 44586 "Multiple Nucleic Acid Molecular Detection for In

Vitro Diagnostic Medical Devices". GB/T 44586 has been the following parts were published.

--- Part 1: Terminology and general requirements for nucleic acid quality assessment.

This document is equivalent to ISO 21474-1:2020 "In vitro diagnostic medical devices for multiplex nucleic acid molecule detection Part 1: Nucleic acid quality "Terms and general requirements for quality evaluation".

Introduction

GB/T 44586 specifies the requirements for multiple nucleic acid molecule detection of in vitro diagnostic medical devices and is intended to consist of three parts.

--- Part 1: Nucleic acid quality evaluation terms and general requirements. By specifying quality evaluation terms and general requirements, guide clinical specimen Quality control of nucleic acids from human or microbial pathogens.

--- Part 2: Confirmation and validation. By specifying the general requirements for confirmation and validation, guide the identification of human or microbial pathogens in clinical specimens Multiple nucleic acid molecule detection process of the body.

--- Part 3: Interpretation and reporting. This section specifies the interpretation and reporting of in vitro diagnostic medical devices and laboratory self-constructed tests.

Guide the process of multiple nucleic acid molecular detection of human or microbial pathogens in clinical specimens.

In vitro diagnostic medical device multiplex nucleic acid molecule detection Part 1: Terminology and general requirements for nucleic acid quality assessment

1 Scope

This document provides terminology and general requirements for the quality assessment of nucleic acids used as analytes in multiplex molecular assays.

This document applies to all multiplex molecular detection methods used for in vitro diagnosis.

The system can be used for the inspection of IVD medical devices and laboratory developed tests (LDTs), and provide information on the qualitative and quantitative detection of nucleic acid target sequences.

The purpose of this document is to provide guidance for the use of multiplex molecular assays to detect and/or characterize human nucleic acids or nucleic acids of microbial pathogens in human clinical specimens.

This document is applicable to various molecular in vitro diagnostic tests in medical

laboratories. It is also provided to laboratory customers, it is intended for use by in vitro diagnostic developers, manufacturers, biobanks, institutions and commercial organizations conducting biomedical research, and regulatory agencies.

Not suitable for metagenomics.

Note: The test method used within the laboratory is called "laboratory-developed method", "LDT", or "in-house test".

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document.

For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to this document.

GB/T 22576.1-2018 Requirements for 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.

ISO and IEC maintain terminology databases for standardization at the following addresses.

---IEC Electronic Encyclopedia <http://electropedia.org>.

Accuracy

The degree of agreement between a measurement result and the true value.

NOTE The term "accuracy", when applied to a set of test or measurement results, consists of a random error component and a systematic error component, i.e., a bias component (ISO 3534-2:2006,3.3.1).

[Source. ISO/IEC Guide 99:2007, 2.13, modified] 3.2 algorithm A set of rules or algorithms used to generate test data that allows for reasonable interpretation or reporting of results.

Allele

The different forms of a gene that control genetic variation.