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

GB/T 39367-2025

Replacing GB/T 39367.1-2020

**In vitro diagnostic test systems - Nucleic acid amplification-based
examination procedures for detection and identification of microbial
pathogens - Laboratory quality practice guide**

体外诊断检测系统 基于核酸扩增的病原微生物检测和鉴定程序 实验室质量实践
通则

(English Translation)

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Table of Contents

Preface
1 Scope
2 Normative References
3 Terms and Definitions
4 General Requirements for Microbial Pathogen Laboratories
4.1 General Requirements for Laboratory Risk Management and Biosafety
4.2 General Laboratory Setup for Pathogen Detection
4.3 Commercial equipment (including software)
4.4 Laboratory Staff
5 Design and establishment of a pathogen nucleic acid amplification detection kit
5.1 Quality control products
5.1.1 Selection of Quality Control Products
5.1.2 Determine the target sequence
5.2 Performance Verification and Validation
6 Verification or validation of the detection system
6.1 Performance verification or validation methods
7 Design and establishment of LDT
7.1 Overview
7.1.1 Determine the client/patient and stakeholder needs for the intended use of the analysis.13
7.1.2 General Standards for Performance Verification
7.1.3 Verification of the preset performance indicators of the test method
7.1.4 Confirmation of Intended Use
7.2 Workflow of Nucleic Acid Amplification Detection Procedure
7.2.1 Pre-analysis workflow requirements
7.2.2 Workflow Requirements in Analysis (15)
7.2.3 Post-analysis workflow requirements
7.3 Verification and Validation of Performance Characteristics
7.3.1 Detection range
7.3.2 Accuracy
7.4 Analytical sensitivity/limit of detection
7.4.1 Analysis confirms

8 Laboratory Implementation and Use

9 Reporting and interpretation of results

10 Quality Assurance Procedures

10.1 Performance Monitoring and Analysis Optimization

10.2 Interlaboratory comparison

Appendix A (Informative) Pre-analytical Factors in Sample Preparation

A.1 Serum and Plasma

A.1.1 Sample Collection

A.1.2 Sample Storage and Transportation

A.1.3 Control of Interfering Substances

A.2 Urine

A.2.1 Sample Collection

A.2.2 Sample Preservation and Transportation

A.2.3 Sample Preparation

A.3 Sputum

A.3.1 Sample Collection

A.3.2 Sample Preservation and Transportation

A.3.3 Sample Preparation

A.4 Whole blood and bone marrow

A.4.1 Sample Collection

A.4.2 Sample Preservation and Transportation

A.4.3 Sample Preparation

A.5 Pleural effusion, ascites, pericardial fluid, pancreatic juice, and bronchoalveolar lavage fluid

A.5.1 Sample Collection

A.5.2 Sample Preservation and Transportation

A.5.3 Sample Preparation

A.6 Lymph nodes and solid tissues (biopsy or surgery)

A.6.1 Sample Collection

A.6.2 Sample Preservation and Transportation

A.6.3 Sample Preparation

A.7 Fecal specimen

A.7.1 Sample Collection

A.7.2 Sample Preservation and Transportation

A.7.3 Sample Preparation

Appendix B (Informative) Verification and Validation of Experiments

References

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 replaces GB/T 39367.1-2020 "In vitro diagnostic testing systems for the detection and identification of pathogenic microorganisms - qualitative in vitro nucleic acid testing".

The "Test Procedures Part 1: General Requirements, Terms and Definitions" is the same as GB/T 39367.1-2020, except for structural adjustments and editorial changes.

In addition, the main technological changes are as follows.

---Added content on in vitro quantitative nucleic acid detection procedures (see Chapters 5, 7, and 9);

---Changes have been made to the general requirements for pathogen nucleic acid detection, including pathogen nucleic acid detection assays, performance validation and verification, quality assurance and risk management.

See the requested content (Chapters 4, 5, and 6; 4.1, 4.3, 4.4, Chapters 5, 6, and 9 of the 2020 edition);

---Added content related to the construction of microbial pathogen laboratories, medical laboratory quality practices, and the design and establishment of LDTs (see 4.2,...).

Chapters 7, 8, and 10.

This document is equivalent to ISO 17822:2020 "In vitro diagnostic testing systems - Detection and identification of pathogenic microorganisms based on nucleic acid amplification".

Preface to General Guidelines for Laboratory Quality Practices.

Please note that some content in this document may involve patents. The issuing organization of this document assumes no responsibility for identifying patents.

This document was proposed by the National Medical Products Administration.

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

1 Scope

This document describes methods for the detection, identification, and quantification of microbial pathogens based on nucleic acid amplification, and specifies the procedures for their use in clinical laboratories.

The relevant quality assurance requirements.

Laboratories that develop NAAT methods and/or conduct NAAT testing projects.

This document does not apply to the research and development of in vitro diagnostic (IVD) medical devices by manufacturers. However, this document contains practical...

The performance verification and validation of medical devices and/or corresponding processes during laboratory implementation and use.

2 Normative references

The contents of the following documents, through normative references within the text, constitute essential provisions of this document. Dated citations are not included.

For references to documents, only the version corresponding to that date applies to this document; for undated references, the latest version (including all amendments) applies.

This document.

and competition)

Note: GB/T 22576.1-2018 Requirements for the quality and competence of medical laboratories - Part 1: General requirements (ISO 15189:2012, IDT) Note. GB 19781-2005 Safety requirements for medical laboratories (ISO 15190:2003, IDT)

3 Terms and Definitions

The following terms and definitions apply to this document.

The URLs for the terminology databases maintained by ISO and IEC for standardization are as follows.

accuracy

The degree of consistency between the test results or measurement results and the true value.

Note 1: In practice, the true value is replaced by the accepted reference value.

Note 2: When the term "accuracy" is used for a set of test or measurement results, it consists of random error components and systematic error components, i.e., bias components.

Note 3: Accuracy is a combination of correctness and precision.