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

GB/T 43279.2-2023

**Molecular in vitro diagnostic examinations - Specifications for
pre-examination processes for venous whole blood - Part 2:
Isolated genomic DNA**

分子体外诊断检验 静脉全血检验前过程的规范 第2部分：分离基因组DNA
(English Translation)

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Table of Contents

Introduction

1 Scope

2 Normative references

3 Terms and Definitions

4 General considerations

5 Outside the laboratory

5.1 Specimen collection

5.2 Shipping requirements

6 Inside the laboratory

6.1 Specimen Receipt

6.2 Storage requirements

6.3 Isolation of genomic DNA

6.4 Isolated genomic DNA content and quality assessment

6.5 Storage of isolated genomic DNA

Appendix A (informative) Impact of pre-test process steps on the quality of venous whole blood genomic DNA¹⁰

A:1 General information on test operations

A:2 Effect of pre-test variables (blood storage time, temperature, DNA isolation method) on genomic DNA integrity

A:3 Impact of genomic DNA integrity on detection based on long PCR amplicons

A:4 Effect of blood storage time on genomic DNA integrity

A:5 Effect of blood storage conditions on short amplicon-based PCR detection performance

Reference

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 Part 2 of GB/T 43279 "Specification for pre-examination process of venous whole blood for molecular in vitro diagnostic testing":

GB/T 43279 has published the following parts:

---Part 1: Isolation of cellular RNA;

---Part 2: Isolation of genomic DNA;

---Part 3: Isolation of plasma circulating cell-free DNA:

This document is equivalent to ISO :20186-2:2019 "Specification for pre-examination of venous whole blood for molecular in vitro diagnostic testing Part 2:

Isolating Genomic DNA":

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

The emergence of molecular in vitro diagnostics has enabled significant advances in medicine: However, the accuracy of molecular in vitro diagnostic results is affected by many factors:

For example, irregular operations during specimen collection, transportation, storage, and processing before testing may cause the content of these molecules to and/or the integrity has changed significantly, and subsequent test analysis is affected by human factors in the pre-test process and cannot fully reflect the patient's true condition:

The actual state affects the results of diagnosis or research:

Genomic DNA will be broken or degraded after blood collection: Therefore, specific measures need to be taken to ensure high-quality genomic DNA testing:

test sample: This is particularly important for testing procedures requiring high molecular weight DNA (HMWDNA):

The entire process from specimen collection to genomic DNA testing needs to be standardized to prevent degradation and fragmentation of genomic DNA after blood collection:

Segmentation: Studies have identified important influencing factors: This paper leverages these existing efforts to compile and standardize venous whole blood genomes the steps of DNA testing, the so-called pre-test process:

GB/T 43279 specifies the requirements for standardized pre-test procedures for venous whole blood molecular in vitro diagnostic tests: GB/T 43279 it is planned to consist of three parts:

---Part 1: Isolating cellular RNA: The purpose is to standardize the standardized pre-test steps for RNA testing in venous whole blood testing:

Steps are taken to reduce changes and modifications in RNA profiles and ensure the validity and reliability of subsequent test results:

---Part 2: Isolating genomic DNA: The purpose is to standardize the standardized pre-test operations for DNA testing in venous whole blood testing steps to reduce the impact of DNA profile changes and modifications on subsequent testing:

---Part 3: Isolation of plasma circulating cell-free DNA: The purpose is to standardize the standards for circulating cell-free DNA testing in venous whole blood testing:

Standardize the pre-test steps to reduce the impact of changes and modifications in circulating free DNA on subsequent tests:

Molecular in vitro diagnostic test venous whole blood pre-test process Specification Part 2: Isolating Genomic DNA

1 Scope

This document provides operational guidelines for the pre-test phase of venous whole blood specimens used for genomic DNA testing, including specimen handling, storage, processing and recording: This document covers specimens collected with venous whole blood collection tubes:

This document is applicable to molecular in vitro diagnostic tests performed by medical laboratories and is also applicable to laboratory customers, in vitro diagnostic developers and manufacturers:

suppliers, biobanks, institutions and commercial organizations engaged in biomedical research, and regulatory agencies:

This document does not cover specific methods for stabilizing circulating cell-free DNA in blood:

Note: For relevant content on circulating free DNA in blood, see GB/T 43279.3-2023:

This document does not address the collection, stabilization, transportation and storage of capillary blood, or the use of paper technology or other methods that produce dried blood:

A specialized method of collecting and storing blood using technology:

This document does not address the isolation of specific blood cells and subsequent isolation of genomic DNA:

This document does not address the presence of pathogen DNA in blood:

2 Normative reference documents

The contents of the following documents constitute essential provisions of this document through normative references in the text: Among them, the dated quotations for undated referenced documents, only the version corresponding to that date applies to this document; for undated referenced documents, the latest version (including all amendments)

applies to this document:

GB/T 22576.1-2018 Medical laboratory quality and capability requirements Part 1: General requirements (ISO 15189:2012, IDT)

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>;

analyteanalyte

The component represented by the name of the measurand:

[Source: GB/T 21415-2008, 3:2, with modifications] 3.2 backflow the flow of liquid in the opposite direction to the usual or desired direction:

blood collection device bloodcollectionset A device specifically designed for venipuncture consisting of a stainless steel beveled needle and tubing (tubing) with plastic wings and connectors: