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

GB/T 42080.3-2024

**DNA Molecular in vitro diagnostic examinations - Specifications
for pre-examination processes for frozen tissue - Part 3:
Isolated DNA**

分子体外诊断检验 冷冻组织检验前过程的规范 第3部分：分离DNA
(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 3 of GB/T 42080 "Specifications for pre-testing procedures for frozen tissues for molecular in vitro diagnostic testing".

The following parts have been published.

- Part 1: Isolation of RNA;
- Part 2: Isolation of proteins;
- Part 3: Isolation of DNA.

This document is equivalent to ISO.20184-3.2021 "Specification for pre-testing processes

of frozen tissues for molecular in vitro diagnostic tests Part 3 Separation of DNA.

Introduction

Molecular in vitro diagnostics (including molecular pathology) have made great progress in medicine.

Further progress is expected with the advent of new technologies for the analysis of proteins, acids, and metabolites. However, the integrity and profile of these molecules are limited in specimens.

Changes may occur during collection, transportation, storage and processing, thus making the results of diagnosis or research unreliable or even impossible.

Because the actual situation of the patient will not be considered in the subsequent test analysis, but the artificial map generated before the test will be used.

The entire process from specimen collection to testing is standardized.

GB/T 42080 "Specification for pre-testing procedures for frozen tissues for molecular in vitro diagnostic testing" specifies the molecular in vitro diagnostic procedures for frozen tissues.

The standardized requirements for pre-inspection operation steps of the inspection are planned to consist of three parts.

--- Part 1: Isolation of RNA. The purpose is to standardize the pre-test procedures for RNA testing of frozen tissues and reduce Minimize changes in RNA spectrum and ensure the validity and reliability of subsequent test results.

--- Part 2: Protein separation. The purpose is to standardize the pre-test procedures for protein testing of frozen tissues and reduce Fewer protein profile changes and modifications.

--- Part 3: Isolation of DNA. The purpose is to standardize the pre-test procedures for DNA testing of frozen tissues.

The integrity of DNA in tissues may change during processing and storage. Modifications to DNA molecules can affect test results.

Special measures are necessary to minimize changes and modifications in the described DNA for subsequent testing.

Therefore, there is a need to standardize the entire process from specimen collection to DNA testing.

This document builds on this work by codifying and standardizing the steps involved in DNA testing of frozen tissues at the so-called pre-test stage.

Standardization.

Molecular in vitro diagnostic testing before frozen tissue testing Specification of the process Part 3: Isolation of DNA

1 Scope

This document specifies the procedures for handling, recording, and analyzing frozen tissue specimens for DNA testing during the pre-test phase prior to molecular analysis.

The requirements for storage and material collection are given and corresponding suggestions are provided.

This document applies to molecular in vitro diagnostic tests performed by medical laboratories and molecular pathology laboratories on DNA extracted from frozen tissues.

This document is also applicable to laboratory customers, in vitro diagnostic developers and manufacturers, biobanks, Institutional and commercial organizations involved in biomedical research and regulatory agencies.

This document does not apply to tissues that have been chemically stabilized prior to freezing.

NOTE: International, national or regional regulations or requirements may also apply to the specific areas covered by this document.

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.

competence

Note: GB/T 22576.1-2018 Requirements for 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

For the purpose of this document, the terms and definitions defined in ISO 15189 and the following apply.

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

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

Aliquot

The portion of a bulk homogeneous substance when sampling errors are assumed to be negligible.

NOTE: This term is usually applied to liquids. Tissues are heterogeneous and cannot be aliquoted.

[Source. GB/T 42080.1-2022, 3.1] 3.2 Ambient temperature the temperature of the unconditioned ambient air.