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GB/T 42080.2-2022

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 2: Isolated proteins

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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 2 of GB/T 42080 "Specification for the Pre-examination Process of Frozen Tissue for Molecular In Vitro Diagnostic Testing".

GB/T 42080 has issued the following parts.

--- Part 1.Isolation of RNA;

--- Part 2.Separation of proteins.

This document is equivalent to ISO.20184-2.2018 "Specification for the pre-examination process of frozen tissue for molecular in vitro diagnostic testing Part 2.

Protein Isolation".

Please note that some contents of this document may refer to patents. The issuing agency of this document assumes no responsibility for identifying patents.

Introduction

Molecular in vitro diagnostics, including molecular pathology, have enabled major advances in medicine. With the analysis of nucleic acids in human tissues and body fluids,

New technologies for proteins and metabolites are emerging and further developments are expected. However, the molecular profiles and/or completeness of these

Significant changes may occur during collection, transportation, storage and handling,

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making diagnosis or research results unreliable or even impossible. because

Therefore, the whole process from specimen collection to protein detection needs to be standardized. Studies have been carried out to identify important influencing factors

white. This document draws on these efforts to codify and standardize the steps for protein inspection of frozen tissues during the pre-examination process.

Protein profiles and protein profiles in tissues before, during (e.g., due to warm ischemia), and after (e.g., due to cold ischemia) tissue collection

Mass-protein interactions can change drastically. These changes are caused by gene induction, gene downregulation, protein degradation, etc. different

The amount of protein species may vary in donor/patient tissue. Gene expression can be affected by specific treatments or interventions (surgery, live

test) or drugs used for anesthesia or even to treat concomitant diseases, and the influence of different environmental conditions after the tissue is removed from the body.

Therefore, it is necessary to take special measures to minimize changes and modifications of protein profiles within said tissues for subsequent examination.

GB/T 42080 "Molecular In Vitro Diagnostic Tests Specifications for Pre-examination Procedures for Frozen Tissues" specifies the molecular in vitro diagnostic tests for frozen tissues

The standardization requirements of pre-inspection operation steps are proposed to be composed of three parts.

--- Part 1.Isolation of RNA. The purpose is to standardize the standardized pre-test operation steps for RNA detection of frozen tissues, reduce

Changes in the RNA profile ensure the validity and reliability of follow-up inspection results.

--- Part 2.Separation of proteins. The purpose is to standardize the pre-test operation steps of protein detection in frozen tissues, reduce

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.

Molecular In Vitro Diagnostic Tests

Specification for pre-examination procedures for frozen tissue

Part 2.Isolating Proteins

1 Scope

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This document provides guidelines for the handling, documentation, storage of frozen tissue specimens for protein testing in the pre-test phase prior to molecular analysis.

A guide to archiving and retrieving materials.

This document is applicable to any molecular in vitro diagnostics performed by medical laboratories and molecular pathology laboratories on proteins extracted from frozen tissues

test. This document is also applicable to laboratory customers, developers and manufacturers of in vitro diagnostics, biobanks, institutions conducting biomedical research

and business organizations and regulators.

Note. International, national or regional regulations or requirements can also apply to specific content covered by this document.

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2 Normative references

The contents of the following documents constitute the essential provisions of this document through normative references in the text. Among them, dated references

For documents, only the version corresponding to the date is applicable to this document; for undated reference documents, the latest version (including all amendments) is applicable to

this document.

GB/T 22576.1-2018 Requirements for the quality and competence of medical laboratories Part 1.General requirements (ISO 15189.2012,

IDT)

3 Terms and Definitions

The following terms and definitions defined in GB/T 22576.1-2018 apply to this document.

The ISO and IEC terminology databases for standardization are maintained at the following addresses.

3.1

aliquot of sample

Assuming that sampling errors are negligible, a portion of a mass of homogeneous substance.

Note 1.This term is usually applied to liquids. Tissues are heterogeneous and so cannot be equally divided.

Note 2.This term is derived from references [17], [18], [19].

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3.2

Ambient temperature ambient temperature

The temperature of the unconditioned ambient air.

3.3

Analyte

The component represented by the name of the measurand.

[Source. GB/T 21415-2008, 3.2]

3.4

Measures the accuracy, precision, and sensitivity of an assay for the analyte being measured.

Note. It can also be applied to other detection performance characteristics, such as robustness, repeatability, etc.

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