ICS 11.100.10
CCS C30

NATIONAL STANDARD OF THE PEOPLE'S REPUBLIC OF CHINA

GB/T 42080.1-2022

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 1: Isolated RNA

分子体外诊断检验 冷冻组织检验前过程的规范 第1部分：分离RNA

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Standardization Administration of the PRC

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Foreword

This document was issued on 30 December 2022 by the State Administration for Market Regulation; Standardization Administration of the PRC and takes effect on 1 July 2023.

It is a GB/T standard: recommended rather than compulsory, but it is the text a Chinese reviewer applies when assessing a submission.

It is classified under ICS 11.100.10, Chinese classification C30.

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 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.20184-1.2018 "Specification for the pre-examination process of frozen tissue for molecular in vitro diagnostic testing Part 1

Subsection. Isolating RNA.

The following minimal editorial changes have been made to this document.

--- Changed the number of notes in 6.3.

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

This document is proposed by the State Drug Administration.

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

This document was drafted by. Guangdong Provincial People's Hospital, Beijing Institute of Medical Device Inspection (Beijing Medical Biological Protection Equipment Inspection Institute)

Research Center), China National Institutes for Food and Drug Control.

The main drafters of this document. Yan Lixu, Dai Leiying, Qu Shoufang.

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, making diagnosis or research results unreliable or even impossible. this

This is because the patient's condition will not be considered in the subsequent test analysis, but the artificial map generated before the test is referred to. Therefore, it is necessary to make the subscript

The entire process from collection to detection is standardized.

GB/T 42080 "Molecular in vitro diagnostic testing of frozen tissue pre-examination process specification" stipulates the molecular in vitro diagnostic of frozen tissue

The standardization requirements for the pre-inspection operation steps of the inspection 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 testing of frozen tissues, reducing the

Minimize the change of RNA profile to ensure the validity and reliability of follow-up inspection results.

--- Part 2.Separation of proteins. The purpose is to standardize the pre-test procedures for

protein testing of frozen tissues, reducing the

Minimal 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.

At present, studies have identified some important factors affecting the whole process from specimen collection to RNA detection. This document is based on this

work, has written a standardized pre-assay procedure for RNA testing of frozen tissues, and this phase of pre-assay is referred to as pre-assay

stage.

Due to the influence of various factors such as gene induction or gene downregulation, RNA profiles in frozen tissues can vary before, during, and after collection.

can undergo drastic changes. RNA species may also vary differently in different donor patient tissues. Therefore, it is necessary to take special

Measures to minimize changes in the described RNA and modifications within its tissue for subsequent examination.

Molecular In Vitro Diagnostic Tests

Specification for pre-examination procedures for frozen tissue

Part 1.Isolating RNA

1 Scope

GB/T 42080.1-2022 is the part of the GB/T 42080 series that governs everything done to a frozen tissue specimen before its RNA is examined - the work outside the laboratory, where the specimen is collected, and the work inside it, from receiving the specimen and recording the information that arrives with it, through pathological evaluation and the selection of the sample to be tested, the freezing of that specimen or sample, the conditions under which it is then stored, and finally the isolation of the RNA. General provisions and the terms used sit ahead of those steps, the definitions drawing on ISO 15189. The chain is written down because a molecular profile is not stable: the nucleic acids in tissue change during collection, transport, storage and handling, so a result can come out unreliable, or fail to come out at all, for reasons that have nothing to do with the assay or the instrument that ran it. Recording each handling step is what allows a later measurement to be traced back to a specimen whose history is known. Written for medical laboratories and molecular pathology laboratories examining RNA extracted from frozen tissue, and for the hospital and biobank staff who collect and freeze the tissue those laboratories receive.

This document provides information on the handling, recording,

Guidelines for storage and extraction.

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

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.

This document does not cover tissues that have been chemically stabilized before freezing.

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

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)

and competence)

3 Terms and Definitions

The terms and definitions defined in ISO 15189 and the following 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.