



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

GB/T 42216.4-2024

**Molecular in vitro diagnostic examinations - Specifications for
pre-examination processes for formalin-fixed and paraffin-embedded
(FFPE) tissue - Part 4: In situ detection technique**

分子体外诊断检验 福尔马林固定及石蜡包埋组织检验前过程的规范 第4部分：原
位检测技术

(English Translation)

Issued on: August 23, 2024

Implemented on: August 23, 2024

**Issued by: State Administration for Market Regulation, China National
Standardization Administration**

Table of Contents

Preface	
Introduction	
1 Scope	
2 Normative references	
3 Terms and Definitions	
4 General Provisions	
5 Outside the laboratory	
5.1 Specimen Collection	
5.1.1 Overview	
5.1.2 Specimen Donor/Patient Information	
5.1.3 Specimen Information	
5.1.4 Specimen processing	
5.2 Shipping Requirements	
6 Inside the laboratory	
6.1 Specimen Receipt	
6.2 Formalin-fixed specimens/samples	
6.3 Pathological evaluation of specimens and sample selection	
6.3.1 Overview	
6.3.2 General Assessment	
6.3.3 Sample selection	
6.4 Post-fixation of intraoperative frozen specimens	
6.5 Sample decalcification/softening	
6.6 Tissue processing and paraffin embedding	
6.6.1 General requirements	
6.6.2 Dehydration and transparency	
6.6.3 Wax immersion and paraffin embedding	
6.7 FFPE tissue block storage	
6.8 Sectioning of FFPE tissue blocks and storage of slides	
6.9 Dewaxing and Rehydrating Slides	
6.10 Pretreatment of slides for in situ detection techniques	
6.10.1 Overview	

6.10.2 Pretreatment of in situ detection techniques based on antibodies or other affinity binders

6.10.3 Pretreatment of hybridization-based in situ detection techniques

6.10.4 Preprocessing of other in-situ detection technologies

6.11 Quality Assessment in the Pre-analytical Phase of In-situ Testing

Appendix A (Informative) Recommendations for verification and validation of laboratory-developed in-situ detection tests

Appendix B (Informative) Example of Operational Guidelines for Organization Processing
References

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 is required.

This document is a supplement to GB/T 42216 "Specification for pre-testing procedures of formalin-fixed and paraffin-embedded tissues for molecular in vitro diagnostic testing" Part 4: GB/T 42216 has published the following parts.

--Part 1: Isolation of RNA;

--Part 2: Isolation of proteins;

--Part 3: Isolation of DNA;

--Part 4: In situ detection techniques.

This document is equivalent to ISO.20166-4.2021 "Preparation of formalin-fixed and paraffin-embedded tissues for molecular in vitro diagnostic testing" Specification for the process - Part 4: In-situ detection techniques.

Introduction

The emergence of molecular in vitro diagnostics (including molecular pathology) has brought about significant progress in medicine.

Accuracy is affected by many factors, including irregularities in the pre-test process. For example, irregularities in specimen collection, transportation, storage, and processing Improper operation may cause significant changes in the content and/or integrity of these molecules, and subsequent analysis will be affected by the pre-test process.

The influence of human factors cannot fully reflect the patient's true condition, which affects the results of diagnosis or research.

The entire pre-inspection process from collection to testing is standardized.

GB/T 42216 "Specification for pre-testing procedures of formalin-fixed and paraffin-embedded tissues for molecular in vitro diagnostic testing" stipulates the the standardization requirements for pre-test procedures for molecular in vitro diagnostic tests on malin-fixed and paraffin-embedded tissues are proposed to consist of four parts.

--Part 1: Isolation of RNA. The purpose is to standardize the RNA analysis of formalin-fixed and paraffin-embedded tissues.

Pre-test operation steps can reduce changes and modifications in RNA spectra and ensure the validity and reliability of subsequent test results.

--Part 2: Isolation of proteins. The purpose is to standardize protein analysis of formalin-fixed and paraffin-embedded tissues.

Pre-test steps to reduce the impact of protein spectrum changes and modifications on subsequent tests.

--Part 3: Isolation of DNA. The purpose is to standardize the DNA testing of formalin-fixed and paraffin-embedded tissues.

Pre-test operation steps can reduce the impact of changes and modifications in DNA spectra on subsequent tests.

-- Part 4: In situ testing techniques. The purpose is to standardize the in situ testing of formalin-fixed and paraffin-embedded tissues.

Pre-test operation steps can reduce the impact of related test factors on in-situ test results.

Molecular in vitro diagnostic tests Formalin fixation and Specification of the process before paraffin-embedded tissue examination Part 4: In situ detection techniques

1 Scope

This document provides information on formalin fixation and paraffin embedding for in situ testing in the pre-analysis phase prior to molecular analysis.

Guidelines for the processing, recording, storage, and collection of FFPE tissue specimens.

This document applies to molecular in vitro diagnostic tests, including laboratory-developed tests performed by medical laboratories and molecular pathology laboratories.

This document is also intended for laboratory customers, in vitro diagnostic developers and manufacturers, biobanks, institutions engaged in biomedical research, and business organizations and regulatory bodies.

This document does not apply to the pre-analytical phase of RNA, protein, and DNA isolation from FFPE tissues.

NOTE: International, national and regional regulatory requirements also apply to the specific areas covered in this document.

2 Normative references

The contents of the following documents constitute the 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.

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

3 Terms and definitions

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

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

Affinity binder

Includes affibodies, peptides, antibody (3.3) fragments or other biomolecules (3.6) that can interact with cellular structural molecules and thus be used for Bit detection (3.27) technology.

Ambient temperature

The temperature of the unconditioned ambient air.

[Source. GB/T 42216.1-2022, 3.2]