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GB/T 42216.3-2022

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 3: Isolated DNA

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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 of GB/T 42216 "Specification for the pre-examination process of formalin-fixed and paraffin-embedded tissue for molecular in vitro diagnostic testing"

Part 3.GB/T 42216 has issued the following parts.

--- Part 1.Isolation of RNA;

--- Part 2.Separation of proteins;

--- Part 3.Isolation of DNA.

This document is equivalent to the ISO.20166-3.2018 "Molecular in vitro diagnostic test formalin-fixed and paraffin-embedded tissue before inspection

Specification of the procedure Part 3.Isolation of DNA.

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

The advent of molecular in vitro diagnostic (including molecular pathology) techniques has enabled major advances in medicine. However, molecular in vitro diagnostic results

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Accuracy is affected by many factors, including irregularities in the pre-test process. Such as in the process of specimen collection, transportation, storage and processing

Irregular operations may cause significant changes in the content and/or integrity of these molecules, and subsequent inspection and analysis will be subject to pre-inspection process personnel.

Because of the influence of factors, it cannot fully reflect the real state of the patient, which will affect the results of diagnosis or research. Therefore, it is necessary to examine the specimens from

Standardize the entire pre-test process from acquisition to detection.

GB/T 42216 specifies the standardized pre-test procedures for molecular in vitro diagnostic tests of formalin-fixed and paraffin-embedded tissues

The requirements are to be composed of 4 parts.

--- Part 1.Isolation of RNA. Aims to standardize RNA testing of formalin-fixed and paraffin-embedded tissues

The pre-test operation steps reduce the changes and modifications of RNA profiles, and ensure the validity and reliability of subsequent test results.

--- Part 2.Separation of proteins. Aims to standardize the standardization of protein assays in formalin-fixed and paraffin-embedded tissues

The operation steps before chemical testing can reduce the impact of protein profile changes and modifications on subsequent testing.

--- Part 3.Isolation of DNA. Aims to standardize DNA testing of formalin-fixed and paraffin-embedded tissues

Pre-test operation steps to reduce the impact of DNA profile changes and modifications on subsequent tests.

--- Part 4.In situ detection technology. Aims to standardize in situ testing of formalin-fixed and paraffin-embedded tissues

Pre-test operation steps to reduce the influence of relevant test factors on in-situ test results.

Molecular in vitro diagnostic tests for formalin fixation and

Specification for pre-examination procedures for paraffin-embedded tissue

Part 3.Isolating DNA

1 Scope

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This document presents formalin-fixed and paraffin-embedded panels for DNA testing at the pretest stage prior to molecular analysis.

Guidelines for the handling, recording, storage and collection of tissue (FFPE) specimens.

This document is applicable to molecular in vitro diagnostic tests, including laboratory self-created test items carried out by medical laboratories and molecular pathology laboratories

Also applicable to laboratory customers, in vitro diagnostic developers and manufacturers, biobanks, institutions and commercial organizations engaged in biomedical research

and regulators.

Note. International, national and regional regulatory requirements also apply to specific content covered in 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)

GB/T 27020-2016 Operational requirements for various inspection agencies for conformity assessment (ISO /IEC 17020.2012, IDT)

and competence)

Note. GB 19781-2005 Medical Laboratory Safety Requirements (ISO 15190.2003, IDT)

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

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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 definition comes from references [26], [27], [28].

3.2

Ambient temperature ambient temperature

The temperature of the unconditioned ambient air.

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