SLOVENSKI STANDARD
SIST EN ISO 20166-4:2021

01-oktober-2021

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za tkiva, ki so fiksirana v formalinu ter položena v parafin - 4. del: Tehnike detekcije in situ (ISO 20166-4:2021)

Molecular in vitro diagnostic examinations - Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 4: In situ detection techniques (ISO 20166-4:2021)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für formalinfixierte und paraffineingebettete (FFPE-) Gewebeproben - Teil 4: In-situ-Detektionstechniken (ISO 20166-4:2021)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus fixés au formol et inclus en paraffine (FFPE) - Partie 4: Techniques de détection in situ (ISO 20166-4:2021)

Ta slovenski standard je istoveten z: **EN ISO 20166-4:2021**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 20166-4:2021 **en,fr,de**

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NORME EUROPÉENNE
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EN ISO 20166-4

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English Version

Molecular in vitro diagnostic examinations - Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 4: In situ detection techniques (ISO 20166-4:2021)

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (EN ISO 20166-4:2021) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by January 2022, and conflicting national standards shall be withdrawn at the latest by July 2024.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

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The text of ISO 20166-4:2021 has been approved by CEN as EN ISO 20166-4:2021 without any modification.

INTERNATIONAL STANDARD

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Molecular in vitro diagnostic examinations — Specifications for preexamination processes for formalin-fixed and paraffin-embedded (FFPE) tissue —

Part 4: In situ detection techniques

Analyses de diagnostic moléculaire in vitro — Spécifications relatives aux processus préanalytiques pour les tissus fixés au formol et inclus en paraffine (FFPE) —

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Foreword

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The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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This document was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

A list of all parts in the ISO 20166 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Molecular in vitro diagnostics, including molecular pathology, has enabled significant progress in medicine. Further progress is expected by new technologies analyzing tissue morphology and biomolecules, such as (e.g. proteins, DNA, RNA and/or metabolites (e.g. glucose) in human tissues and body fluids.

In pathology, the majority of diagnoses are based on in situ staining of formalin-fixed and paraffin-embedded (FFPE) tissue sections. In the context of personalized medicine, classical histological staining (e.g. hematoxylin and eosin) for morphological evaluation is increasingly complemented by additional in situ detection techniques, such as immunohistochemistry or in situ hybridization, as well as molecular analysis of isolated biomolecules. For example, many regulatory bodies approved companion diagnostics in oncology are based on in situ detection techniques applied on FFPE tissue sections. Developments in personalized medicine and new technologies, such as multi-label immunostaining and computer-based analysis of digital images (e.g. generated by using a slide scanner) pose new requirements on standardization of pre-analytical procedures to obtain reproducible qualitative and quantitative results.

Profiles and/or integrity of biomolecules and their in situ localization, amount and accessibility for in situ detection in tissues can change drastically during the pre-examination process comprising specimen collection, tissue processing, embedding, transport, storage, sectioning and pretreatment for in situ detection. This makes the outcome from in situ detection in diagnostics or research unreliable or even impossible because the subsequent examination will not represent the in vivo state of molecules, but instead, an artificial profile or morphology generated during the pre-examination process.

Therefore, a standardization of the entire pre-examination process of FFPE tissue specimens intended for in situ examinations of morphology and biomolecules on FFPE tissue sections by using different in situ detection techniques, is needed.

There is multiple scientific evidence that several factors of the pre-examination phase influence the outcome (e.g. quality or quantity in terms of specificity or sensitivity) of in situ detection and, thus, can have major impact on the diagnostic results.

This document draws upon such work to organize and standardize the steps for formalin-fixed and paraffin-embedded (FFPE) tissue with regard to various in situ detection techniques in what is referred to as the pre-examination phase. This document is for the pre-examination phase of in situ detection techniques and is applicable to the whole spectrum of in situ detection techniques.

These include but are not limited to:

— Classical histological staining, e.g. Hematoxylin & Eosin staining (H&E);

— Histochemical techniques, e.g. Lipid staining, Periodic Acid Schiff (PAS) reaction, Perls' Prussian Blue reaction, Feulgen's reaction, enzyme histochemistry;

— Immunohistochemical staining (IHC) or immunofluorescence staining using antibodies (polyclonal, monoclonal or recombinant antibodies) or other affinity binders;

— Hybridization-based techniques such as RNA or DNA in situ hybridization (ISH) techniques, e.g. fluorescence in situ hybridization (FISH), chromogenic in situ hybridization (CISH), or silver enhanced in situ hybridization (SISH);

— Molecular analysis of isolated biomolecules that can be mapped to a defined region of an FFPE section (by e.g. in situ sequencing, imaging mass spectrometry).

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.