SLOVENSKI STANDARD
SIST EN ISO 20166-2:2019

01-maj-2019

Nadomešča:
SIST-TS CEN/TS 16827-2:2015

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za tkiva, ki so fiksirana v formalinu ter položena v parafin - 2. del: Izolirani proteini (ISO 20166-2:2018)

Molecular in vitro diagnostic examinations - Specifications for pre-examinations processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 2: Isolated proteins (ISO 20166-2:2018)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für formalinfixierte und paraffineingebettete (FFPE)-Gewebeproben - Teil 2: Isolierte Proteine (ISO 20166-2:2018)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus fixés au formol et inclus en paraffine (FFPE) - Partie 2: Protéines extraites (ISO 20166-2:2018)

Ta slovenski standard je istoveten z: **EN ISO 20166-2:2018**

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11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

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European foreword

This document (EN ISO 20166-2:2018) 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of an identical text or by endorsement, at the latest by June 2019, and conflicting national standards shall be withdrawn at the latest by December 2021.

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 20166-2:2018 has been approved by CEN as EN ISO 20166-2:2018 without any modification.

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

Part 2: Isolated proteins

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

Partie 2: Protéines extraites

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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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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

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

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.

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

Introduction

Molecular in vitro diagnostics, including molecular pathology, has enabled a significant progress in medicine. Further progress is expected with new technologies analyzing nucleic acids, proteins, and metabolites in human tissues and body fluids. However, the profiles and/or integrity of these molecules can change drastically during specimen collection, transport, storage, and processing, thus making the outcome from diagnostics or research unreliable or even impossible because the subsequent examination assay will not determine the situation in the patient but an artificial molecular pattern generated during the pre-examination process.

Although originally thought as being impossible due to the crosslinking activities of formaldehyde, protein isolation techniques from formalin-fixed and paraffin-embedded (FFPE) tissues have been much improved in recent years. Heat-induced reversal of formaldehyde-induced crosslinks has been demonstrated as an essential step in the protein isolation procedures[5][6]. Currently, most investigators accept that proteins isolated from FFPE tissue are suitable for downstream proteomic examination[7].

Protein profiles, protein integrities, and protein–protein interactions in tissues can change drastically before, during and after collection (due to, e.g. gene induction, gene down regulation, protein degradation). Protein species amounts can change differently in different donors'/patients' tissues. The expression of genes can be influenced by the given treatment or intervention (surgery, biopsy), or drugs administered for anaesthesia or even treatment of concomitant disease as well as by the different environmental conditions after the tissue removal from the body.

Furthermore, the formalin-fixation and paraffin-embedding processes lead to modifications of the protein molecules, which can impact the validity and reliability of the examination test results.

Therefore, it is essential to take special measures to minimize the described protein profile changes and modifications within tissues for subsequent examination.

A standardization of the entire process from specimen collection to the protein examination is needed. Studies have been undertaken to determine the important influencing factors. This document draws upon such work to codify and standardize the steps for FFPE tissue with regard to protein examination in what is referred to as the pre-examination phase.

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.