SLOVENSKI STANDARD
SIST EN ISO 20166-3:2019

01-maj-2019

Nadomešča:
SIST-TS CEN/TS 16827-3:2015

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za tkiva, ki so fiksirana v formalinu ter položena v parafin - 3. del: Izolirani DNK (ISO 20166-3:2018)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 3: Isolated DNA (ISO 20166-3:2018)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für formalinfixierte und paraffineingebettete (FFPE)-Gewebeproben - Teil 3: Isolierte DNS (ISO 20166-3:2018)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus fixés au formol et inclus en paraffine (FFPE) - Partie 3: ADN extrait (ISO 20166-3:2018)

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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 20166-3:2019) 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of an identical text or by endorsement, at the latest by July 2019, and conflicting national standards shall be withdrawn at the latest by January 2022.

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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Part 3: Isolated DNA

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

Partie 3: ADN extrait

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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 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 with new technologies analysing 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. Studies have been undertaken to determine the influencing factors for the DNA examination from formalin-fixed and paraffin-embedded (FFPE) tissue. These studies demonstrated that a standardization of the entire process from specimen collection to the DNA examination is needed. This document draws upon such work to codify and standardize the steps for FFPE tissue with regard to DNA examination in what is referred to as the pre-examination phase.

DNA integrity in tissues can change before, during and after formalin fixation, processing and storage. Chemical modifications introduced into DNA during tissue fixation might lead to fragmentation and sequence alterations, changes in the methylation status or even structural changes which can lead to, for instance, spurious copy number changes in array-CGH profiles. These modifications of the DNA molecules can impact the validity and reliability of the examination test results. Therefore, it is essential to take special measures to minimize the described DNA changes and modifications for subsequent examination.

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.