SLOVENSKI STANDARD
SIST EN ISO 20184-3:2021

01-julij-2021

Nadomešča:

SIST-TS CEN/TS 16826-3:2018

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za zamrznjena tkiva - 3. del: Izolirana DNK (ISO 20184-3:2021)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 3: Isolated DNA (ISO 20184-3:2021)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für gefrorene Gewebeproben - Teil 3: Isolierte DNA (ISO 20184-3:2021)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus congelés - Partie 3: ADN extrait (ISO 20184-3:2021)

Ta slovenski standard je istoveten z: EN ISO 20184-3:2021

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 20184-3:2021 **en,fr,de**

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 20184-3

May 2021

ICS 11.100.10

Supersedes CEN/TS 16826-3:2018

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 3: Isolated DNA (ISO 20184-3:2021)

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Ref. No. EN ISO 20184-3:2021 E

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European foreword

This document (EN ISO 20184-3:2021) 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of an identical text or by endorsement, at the latest by November 2021, and conflicting national standards shall be withdrawn at the latest by May 2024.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 20184-3:2021 has been approved by CEN as EN ISO 20184-3:2021 without any modification.

INTERNATIONAL STANDARD

ISO 20184-3

First edition
2021-05

Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue —

Part 3: Isolated DNA

Analyses de diagnostic moléculaire in vitro — Spécifications relatives aux processus préanalytiques pour les tissus congelés —

Partie 3: ADN extrait

Reference number
ISO 20184-3:2021(E)

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Published in Switzerland

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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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

A list of all parts in the ISO 20184 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, integrity and profile of these molecules can change during specimen collection, transport, storage, and processing. As a consequence the outcome from diagnostics or research can become unreliable or even impossible because the subsequent examination assay might not determine the real situation in the patient but instead, an artificial profile which is generated during the pre-examination process.

DNA integrity in tissues can change during processing and storage. Modifications of the DNA molecules can impact the validity and reliability of the examination test results. It is essential to take special measures to minimize the described DNA changes and modifications for subsequent examination.

Therefore, a standardization of the entire process from specimen collection to DNA 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 frozen tissue with regard to DNA 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.