SLOVENSKI STANDARD
SIST EN ISO 20186-2:2019

01-julij-2019

Nadomešča:

SIST-TS CEN/TS 16835-2:2015

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za vensko polno kri - 2. del: Iz genoma izolirana DNK (ISO 20186-2:2019)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA (ISO 20186-2:2019)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 2: Isolierte genomische DNA (ISO 20186-2:2019)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour le sang total veineux - Partie 2: ARN cellulaire extrait (ISO 20186-2:2019)

Ta slovenski standard je istoveten z: **EN ISO 20186-2:2019**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
11.100.30	Analiza krvi in urina	Analysis of blood and urine

SIST EN ISO 20186-2:2019 **en**

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Supersedes CEN/TS 16835-2:2015

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA (ISO 20186-2:2019)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour le sang total veineux - Partie 2: ADN génomique extrait (ISO 20186-2:2019)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 2: Isolierte genomische DNA (ISO 20186-2:2019)

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European foreword

This document (EN ISO 20186-2:2019) 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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by March 2022.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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The text of ISO 20186-2:2019 has been approved by CEN as EN ISO 20186-2:2019 without any modification.

INTERNATIONAL STANDARD

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Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood —

Part 2: Isolated genomic DNA

Analyses de diagnostic moléculaire in vitro — Spécifications relatives aux processus préanalytiques pour le sang total veineux —

Partie 2: ADN génomique 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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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 20186 series can be found on the ISO website.

Introduction

Molecular in vitro diagnostics has enabled significant progress in medicine. Further progress is expected by new technologies analysing profiles of nucleic acids, proteins, and metabolites in human tissues and body fluids. However, the profiles of these molecules can change drastically during the pre-examination process, including the specimen collection, transport, storage and processing. Consequently, this makes the outcome from diagnostics or research unreliable or even impossible, because the subsequent examination might not determine the real situation in the patient but an artificial profile generated during the pre-examination processes.

Genomic DNA can fragment or degrade after blood collection. Therefore, special measures need to be taken to secure good quality specimens for genomic DNA examination. This is particularly relevant for examination test procedures requiring high molecular weight DNA (HMW DNA).

Standardization of the entire workflow from specimen collection to the genomic DNA examination is needed due to genomic DNA degradation and fragmentation after blood collection. Studies have been undertaken to determine the important influencing factors. This document draws upon such work to codify and standardize the steps for venous whole blood genomic 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.