

**SLOVENSKI STANDARD
SIST EN ISO 20186-3:2020****01-januar-2020****Nadomešča:****SIST-TS CEN/TS 16835-3:2015**

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za vensko polno kri - 3. del: Iz plazme izolirana cirkulirajoča brezcelična DNK (ISO 20186-3:2019)

Molecular in-vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 3: Isolated circulating cell free DNA from plasma (ISO 20186-3:2019)

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Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 3: Aus Plasma isolierte zirkulierende zellfreie DNS (ISO 20186-3:2019)

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Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus pré-analytiques pour le sang - ARN cellulaire - Partie 3: ADN libre circulant extrait du plasma (ISO 20186-3:2019)

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11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
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SIST EN ISO 20186-3:2020**en**

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EUROPEAN STANDARD

EN ISO 20186-3

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Molecular in-vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 3: Isolated circulating cell free DNA from plasma (ISO 20186-3:2019)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour le sang total veineux - Partie 3: ADN libre circulant extrait du plasma (ISO 20186-3:2019)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 3: Aus Plasma isolierte zirkulierende zellfreie DNA (ISO 20186-3:2019)

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European foreword

This document (EN ISO 20186-3:2019) 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 April 2020, and conflicting national standards shall be withdrawn at the latest by October 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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INTERNATIONAL
STANDARD

ISO
20186-3

First edition
2019-09

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

Part 3:

**Isolated circulating cell free DNA
from plasma**

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

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Partie 3: ADN libre circulant extrait du plasma



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Foreword

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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*.

A list of all parts in the ISO 20186 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 has enabled a 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.

Circulating cell free DNA (ccfDNA) profiles can change significantly after blood collection (e.g. release of genomic DNA from cells in blood, ccfDNA degradation and fragmentation and ccfDNA quantity change). Therefore, special measures need to be taken to secure good quality specimens for ccfDNA examination. Studies have been undertaken to determine the important influencing factors^[23].

Standardization of the entire workflow from specimen collection to the ccfDNA examination is needed.

This document standardizes the steps of the pre-examination phase of circulating cell free DNA prepared from plasma of venous whole blood.

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.

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