

SLOVENSKI STANDARD

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Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za zamrznjena tkiva - 2. del: Izolirani proteini (ISO 20184-2:2018)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 2: Isolated proteins (ISO 20184-2:2018)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 2: Isolierte Proteine (ISO 20184-2:2018)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus congelés - Partie 2: Protéines extraites (ISO 20184-2:2018)

Ta slovenski standard je istoveten z: EN ISO 20184-2:2018

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
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en

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EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN ISO 20184-2

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Supersedes CEN/TS 16826-2:2015

English Version

**Molecular in vitro diagnostic examinations - Specifications
for pre-examination processes for frozen tissue - Part 2:
Isolated proteins (ISO 20184-2:2018)**

Analyses de diagnostic moléculaire in vitro -
Spécifications relatives aux processus préanalytiques
pour les tissus congelés - Partie 2: Protéines extraites
(ISO 20184-2:2018)

Molekularanalytische in-vitro-diagnostische Verfahren
- Spezifikationen für präanalytische Prozesse für
schockgefrorene Gewebeprobe - Teil 2: Isolierte
Proteine (ISO 20184-2:2018)

This European Standard was approved by CEN on 30 September 2018.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 30 January 2019.

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European foreword

This document (EN ISO 20184-2:2018) 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of an identical text or by endorsement, at the latest by June 2019, and conflicting national standards shall be withdrawn at the latest by December 2021.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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INTERNATIONAL STANDARD

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

Part 2: Isolated proteins

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

Partie 2: Protéines extraites

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

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*.

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 a 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. Therefore, 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 frozen tissue with regard to protein examination in what is referred to as the pre-examination phase.

Protein profiles and protein-protein interactions in tissues can change drastically before, during (e.g. due to warm ischemia) and after tissue collection (e.g. due to cold ischemia). The changes are caused by 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.

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

Tissues that have undergone chemical stabilization pre-treatment before freezing are not covered in this document. In addition this document is not applicable to protein examination by immunohistochemistry.

In this document, the following verbal forms are used:

- "shall" indicates a requirement; [SIST EN ISO 20184-2:2019](https://standards.iteh.ai/catalog/standards/sist/fl265b1d-e848-444c-b7b5-1067d4b176c0/sist-en-iso-20184-2-2019)
- "should" indicates a recommendation; <https://standards.iteh.ai/catalog/standards/sist/fl265b1d-e848-444c-b7b5-1067d4b176c0/sist-en-iso-20184-2-2019>
- "may" indicates a permission;
- "can" indicates a possibility or a capability.