SLOVENSKI STANDARD
oSIST prEN ISO 20184-2:2016

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Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za zamrznjena tkiva - 2. del: Izolirani proteini (ISO/DIS 20184-2:2016)

Molecular in-vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 2: Isolated proteins (ISO/DIS 20184-2:2016)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 2: Isolierte Proteine (ISO/DIS 20184-2:2016)

Examens de diagnostic moléculaire in vitro - Spécifications pour les processus d'examens préliminaires des tissus congelés - Partie 2: Protéines isolées (ISO/DIS 20184-2:2016)

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ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

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

Part 2:
Isolated proteins

Titre manque

ICS: 11.100.10

ISO/CEN PARALLEL PROCESSING

This draft has been developed within the International Organization for Standardization (ISO), and processed under the **ISO lead** mode of collaboration as defined in the Vienna Agreement.

This draft is hereby submitted to the ISO member bodies and to the CEN member bodies for a parallel five month enquiry.

To expedite distribution, this document is circulated as received from the committee secretariat. ISO Central Secretariat work of editing and text composition will be undertaken at publication stage.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 20184-2 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

ISO 20184 consists of the following parts, under the general title *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue*:

— *Part 1: Isolated RNA*

— *Part 2: Isolated proteins*

Introduction

Molecular *in vitro* diagnostics, including molecular pathology, has enabled a significant progress in medicine. Further progress is expected by new technologies analyzing 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 International Standard 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.

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

Part 2: Isolated proteins

1 Scope

This International Standard recommends the handling, documentation, storage and processing of frozen tissue specimens intended for the examination of isolated proteins during the pre-examination phase before a molecular assay is performed. This International Standard is applicable to any molecular *in vitro* diagnostic examination performed by medical laboratories and molecular pathology laboratories that evaluate proteins isolated from frozen tissue. It is also intended to be used by laboratory customers, *in vitro* diagnostics developers and manufacturers, as well as institutions and commercial organisations performing biomedical research, biobanks, and regulatory authorities.

Protein profiles and protein-protein interactions in tissues can change drastically before tissue collection (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.

NOTE International, national or regional regulations or requirements may also apply to specific topics covered in this International Standard.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189:2012, *Medical laboratories — Requirements for quality and competence*

ISO 15190, *Medical laboratories — Requirements for safety*

ISO/IEC 17020:2012, *Conformity assessment – Requirements for the operation of various types of bodies performing inspection*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15189:2012 and the following apply.

3.1
ambient temperature
unregulated temperature of the surrounding air

3.2
analyte
component represented in the name of a measurable quantity (ISO 17511)

3.3
analytical test performance
the accuracy, precision, and sensitivity of a test to measure the analyte of interest

3.4
cold ischemia
condition after removal of the tissue from the body until its stabilization or fixation

3.5
diagnosis
identification of a disease from its signs and symptoms, where the diagnostic process can involve examinations and tests for classification of an individual's condition into separate and distinct categories or subclasses that allow medical decisions about treatment and prognosis to be made

3.6
examination
analytical phase

set of operations having the object of determining the value or characteristics of a property

Note 1 to entry: Processes that start with the isolated analyte and include all kinds of parameter testing or chemical manipulation for quantitative or qualitative examination.

[SOURCE: ISO 15189:2012, 3.7, modified — The term and definition is used here without the original notes.]

3.7
grossing
gross examination

inspection of pathology specimens with the bare eye to obtain diagnostic information, while being processed for further microscopic examination

3.8
homogeneous
uniform in structure and composition

3.9
pre-examination processes
preanalytical phase
preanalytical workflow
processes that start, in chronological order, from the clinician's request and include the examination request, preparation and identification of the patient, surgical procedure, collection of the primary sample(s), temporary storage, transportation to and within the analytical laboratory, aliquotting, retrieval, isolation of analytes, and end when the analytical examination begins

Note 1 to entry: The pre-examination phase includes preparative processes that influence the outcome of the intended examination.

[SOURCE: ISO 15189:2012, 3.15, modified — An additional term was added and more details were included.]

3.10
primary sample
specimen
discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole

[SOURCE: ISO 15189:2012, 3.16, modified — The term and definition is used here without the original notes.]

3.11
protein
type of biological macromolecules composed of one or more chains with a defined sequence of amino acids connected through peptide bonds

3.12
protein profile
amounts of the individual protein molecules that are present in a sample and that can be measured in the absence of any losses, inhibition and interference

3.13
protein species
amounts of a chemically clearly-defined protein corresponding to one spot on a high-performance two-dimensional gel electrophoresis pattern

[SOURCE: Jungblut *et. al.*1996][4]

3.14
PTM
post translational modifications
chemical alterations to a primary protein structure, often crucial for conferring biological activity on a protein

[SOURCE: Encyclopedia of Psychopharmacology, 2010][5]

3.15
sample
one or more parts taken from a primary sample

[SOURCE: ISO 15189:2012, 3.24, modified — The example was not taken over.]

3.16
room temperature
temperature which is defined as 18 °C to 25 °C for the purposes of this document

Note 1 to entry: Local or national regulations can have different definitions.

3.17
stability
ability of a sample material, when stored under specified conditions, to maintain a stated property value within specified limits for a specified period of time

[SOURCE: ISO Guide 30:1992, 2.7]

Note 1 to entry: The analyte for the purpose of this document is extracted protein.

3.18
validation
confirmation, throughout the provision of objective evidence, that the requirements for a specific intended use or application have been fulfilled

Note 1 to entry: The term “validated” is used to designate the corresponding status.