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Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za zamrznjena tkiva - 1. del: Izolirani RNK (ISO/DIS 20184-1:2016)

Molecular in-vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 1: Isolated RNA (ISO/DIS 20184-1:2016)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 1: Isolierte RNS (ISO/DIS 20184-1:2016)

Examens de diagnostic moléculaire in vitro - Spécifications pour les processus d'examens préliminaires des tissus congelés - Partie 1: ARN isolé (ISO/DIS 20184-1:2016)

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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 1:
Isolated RNA

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 20184-1 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 profile generated during the pre-examination process. Therefore, a standardization of the entire process from specimen collection to the RNA 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 RNA 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 1: Isolated RNA

1 Scope

This International Standard recommends the handling, documentation, storage and processing of frozen tissue specimens intended for RNA examination 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 RNA extracted 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.

RNA profiles in tissues can change drastically before and after collection (due to e.g., gene induction or gene down regulation). RNA species can change differently in different donor's patients' tissues.

Therefore, it is essential to take special measures to minimize the described RNA 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.

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*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 15189:2012 and the following terms and definitions 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
DNase
deoxyribonuclease catalyzes the degradation of DNA into smaller components

3.7
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.]

3.8
grossing
gross examination

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

3.9
homogeneous
uniform in structure and composition

3.10
interfering substances
a component of the sample, other than the analyte, that causes a bias in the measured concentration

3.11
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, aliquoting, 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.]

3.12
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.]

3.13
proficiency test
determines the performance of individual laboratories for specific tests or measurements

3.14
quantitative RNA profile
RNA profile
amounts of the individual RNA molecules that are present in a sample and that can be measured in the absence of any losses, inhibition and interference

3.15
RNA
ribonucleic acid
polymer of ribonucleotides occurring in a double-stranded or single-stranded form

[SOURCE: ISO 22174:2005, 3.1.3]

3.16
RNase
ribonuclease catalyzes the degradation of RNA into smaller components

3.17
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.

3.18
sample
one or more parts taken from a primary sample

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

3.19
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

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

[SOURCE: ISO Guide 30:1992, 2.7]

3.20
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.

Note 2 to entry: Adapted from ISO 9000:2005, definition 3.8.5.

[SOURCE: ISO 15189:2012, 3.26]