SLOVENSKI STANDARD
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Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za zamrznjena tkiva - 3. del: Izolirana DNK (ISO/DIS 20184-3:2020)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 3: Isolated DNA (ISO/DIS 20184-3:2020)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für gefrorene Gewebeproben - Teil 3: Isolierte DNA (ISO/DIS 20184-3:2020)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus congelés - Partie 3: ADN isolé (ISO/DIS 20184-3:2020)

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

Part 3: Isolated DNA

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

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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).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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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 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 significant progress in medicine. Further progress is expected with new technologies analysing nucleic acids, proteins, and metabolites in human tissues and body fluids. However, integrity of these molecules can change during specimen collection, transport, storage, and processing.

Consequently making the outcome from diagnostics or research unreliable or even impossible because the subsequent examination assay might not determine the real 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 DNA 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 DNA examination in what is referred to as the pre-examination phase.

DNA integrity in tissues can change during processing and storage. Modifications of the DNA molecules can impact the validity and reliability of the examination test results. Therefore, it is essential to take special measures to minimize the described DNA changes and modifications for subsequent examination.

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.

Further details can be found in the ISO/IEC Directives, Part 2.

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

Part 3: Isolated DNA

1 Scope

This document gives requirements and recommendations for the handling, storage, processing, and documentation of frozen tissue specimens intended for DNA examination during the pre-examination phase before a molecular examination is performed.

This document is applicable to molecular in vitro diagnostic examinations including laboratory developed tests performed by medical laboratories and molecular pathology laboratories that evaluate DNA isolated from frozen tissue. It is also intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions and commercial organizations performing biomedical research, and regulatory authorities.

Tissues that have undergone chemical stabilization pre-treatment before freezing are not covered in this document.

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

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO 15190, *Medical laboratories — Requirements for safety*

ISO/IEC 17020, *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 and the following apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

3.1
aliquot
portion of a larger amount of homogenous material, assumed to be taken with negligible sampling error

Note 1 to entry: The term is usually applied to fluids. Solid tissues are heterogeneous and therefore cannot be aliquoted.

[SOURCE: Compendium of Chemical Terminology Gold Book. International Union of Pure and Applied Chemistry. Version 2.3.3., 2014; the PAC, 1990,62,1193 (Nomenclature for sampling in analytical chemistry (Recommendations 1990)) p. 1206; and the PAC 1990, 62, 2167 (Glossary of atmospheric chemistry terms (Recommendations 1990)) p. 2173.]

3.2
ambient temperature
unregulated temperature of the surrounding air

3.3
analyte
component represented in the name of a measurable quantity

[SOURCE: ISO 17511:2003, 3.2, modified — The example was not taken over. [16]]

3.4
analytical test performance
accuracy, precision, and sensitivity of a test to measure the *analyte* (3.3) of interest

Note 1 to entry: Other test performance characteristics such as robustness, repeatability can apply as well.

3.5
cold ischemia
condition after removal of the tissue from the body until its stabilization or fixation

[SOURCE: ISO 20184-2:2018, 3.5 [19]]

3.6
diagnosis
can involve *examinations* (3.9) 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

[SOURCE: ISO 20184-2:2018, 3.6[19]]

3.7
DNA
deoxyribonucleic acid
polymer of deoxyribonucleotides occurring in a double-stranded (dsDNA) or single-stranded (ssDNA) form

[SOURCE: ISO 22174:2005, 3.1.2 [21]]

3.8
DNase
deoxyribonuclease
enzyme that catalyzes the degradation of *DNA* (3.7) into smaller components

[SOURCE: ISO 20184-1:2018, 3.8 [18]]

3.9
examination
analytical test
set of operations with the object of determining the value or characteristics of a property

Note 1 to entry: Processes that start with the isolated *analyte* (3.3) and include all kinds of parameter testing or chemical manipulation for quantitative or qualitative examination.

[SOURCE: ISO 15189:2012, 3.7, modified — Notes to entry 1 to 3 have been removed. Note 1 to entry has been added and "analytical test" has been added as a preferred term.]

3.10
grossing
gross examination
inspection of pathology specimens with the bare eye to obtain diagnostic information, while being processed for further microscopic *examination* (3.9)

[SOURCE: ISO 20184-1:2018, 3.10 [18]]

3.11
homogeneous
uniform in structure and composition

[SOURCE: ISO 20184-1:2018, 3.11 [18]]

3.12
interfering substance
endogenous substance of a *specimen* (3.14)/*sample* (3.17) or exogenous substance (e.g. stabilization solution) that can alter an *examination* (3.9) result

[SOURCE: ISO 20184-1:2018, 3.12 [18]]

3.13
pre-examination process
preanalytical phase
preanalytical workflow
process that starts in chronological order, from the clinician's request and include the *examination* (3.9) request, preparation and identification of the patient, collection of the *primary sample(s)* (3.14), transportation to and within the medical or pathology laboratory, isolation of *analytes* (3.3), and ends when the analytical *examination* (3.9) begins

Note 1 to entry: The pre-examination phase includes preparative processes that influence the outcome of the intended *examination* (3.9).

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

3.14
primary sample
specimen
discrete portion of a body fluid, breath, hair or tissue taken for *examination* (3.9), study or analysis of one or more quantities or properties assumed to apply for the whole

[SOURCE: ISO 20184-1:2018, 3.14 [18]]

3.15
proficiency test
evaluation of participant performance against pre-established criteria by means of inter-laboratory comparisons

[SOURCE: ISO/IEC 17043:2010, 3.7, modified — The term and definition are used here without the original notes. [23]]