SLOVENSKI STANDARD
oSIST prEN ISO 4307:2021

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Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za slino - Izolirana človeška DNK (ISO/DIS 4307:2021)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for saliva - Isolated human DNA (ISO/DIS 4307:2021)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für Speichel - Isolierte DNA (ISO/DIS 4307:2021)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour la salive - ADN isolé (ISO/DIS 4307:2021)

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Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for saliva — Isolated human DNA

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Email: copyright@iso.org
Website: www.iso.org

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Contents

Page

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*.

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 analyzing profiles of nucleic acids, proteins, and metabolites in human tissues and body fluids. However, the profiles 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 analytical assay will not determine the situation in the patient but an artificial profile generated during the pre-examination process.

Genetic examination of DNA is commonly used in clinical practice. This includes e.g., predisposition testing, pharmacogenomics, analysis of genetic disorders with the perspective used in precision medicine. This is a fast-growing field in molecular diagnostics.

Saliva is increasingly used as a non-invasive alternative specimen to blood for the examination of human DNA. Saliva naturally contains microorganisms and extraneous substances (e.g., food debris), which make the composition of saliva more complex and unique among patients/donors. Dedicated measures are therefore needed for informing and preparing patients/donors for the collection and to check compliance with the instructions, in order to reduce the specimen variability. In contrast to invasive specimen collection, saliva collection does not require trained and educated professionals or dedicated facilities. By good instruction and verified collection device safety claims, saliva specimens can be self-collected at home; however, home collection also contributes to high variability in specimen quality. Similarly, medical laboratories/ *in vitro* manufacturers need to be aware of specimen variability when performing design verification and validation.

DNA in saliva can fragment or degrade after collection. In addition, bacteria present in the saliva specimen can continue to grow, thus diluting the human DNA. DNases secreted by these bacteria can also accelerate the DNA degradation. This can impact the sensitivity and reliability of DNA examination.

Standardization of the entire process from specimen collection to the DNA examination is needed to minimize DNA degradation and fragmentation after saliva collection. This document describes special measures which need to be taken to obtain good quality saliva specimen/samples and isolated DNA therefrom for human DNA 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.

Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for saliva — Isolated human DNA

1 Scope

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

This document is applicable to molecular in vitro diagnostic examination including laboratory developed tests performed by medical laboratories. 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.

Dedicated measures that need to be taken for saliva collected on absorbing material or by mouth washes are not described in this document. Neither are measures for preserving and handling of native saliva cell-free DNA, pathogens, and other bacterial or whole microbiome DNA in saliva described.

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*

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
ambient temperature
unregulated temperature of the surrounding air

[SOURCE: ISO 20184-1:2018, 3.2]

3.2
analyte
component represented in the name of a measurable quantity

[SOURCE: ISO 17511:2003, 3.2 modified — The examples were not taken over.]

3.3
examination performance
analytical test performance
analytical performance
accuracy, precision, and sensitivity of a test to measure the *analyte* (3.2) of interest

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

[SOURCE: ISO 20184-1:2018, 3.4]

3.4
DNA stabilizers
compounds, solutions or mixtures that are designed to minimize degradation and fragmentation of *DNA* (3.6)

[SOURCE: ISO 20186-2:2019, 3.5, modified — "genomic DNA in blood´ has been replaced with "DNA".]

3.5
closed system
non-modifiable system provided by the vendor including all necessary components for the analysis (i.e., hardware, software, procedures and reagents)

[SOURCE: ISO 20186-2:2019, 3.6]

3.6
DNA
deoxyribonucleic acid
polymer of deoxyribonucleotides occurring in a double-stranded (dsDNA) or single-stranded (ssDNA) form

[SOURCE: ISO 22174:2005, 3.1.2]

3.7
examination
analytical test
set of operations having the object of determining the value or characteristics of a property

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

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

3.8
examination provider
analytical test provider
group or company that provides the specific analytical test

3.9
interfering substances
endogenous or exogenous substances (e.g. stabilization solution) that can be present in specimens and that can alter an examination result

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

3.10
microorganism
entity of microscopic size, encompassing bacteria, fungi and protozoa

[SOURCE: ISO 11139:2018, 3.176]