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

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

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English Version

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

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour la salive - ADN humain extrait

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für Speichel - Isolierte menschliche DNA

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CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

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European foreword

This document (CEN/TS 17305:2019) has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

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Introduction

Molecular *in vitro* diagnostics has enabled a significant progress in medicine. Further progress is expected by new technologies analysing 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 use 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 also 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.

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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 organisations 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 technical specification. 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.

EN ISO 15189:2012, *Medical laboratories - Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)*

ISO 15190, *Medical laboratories — Requirements for safety*

3 Terms and definitions

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

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

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp

3.1
ambient temperature
unregulated temperature of the surrounding air

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.]

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