SLOVENSKI STANDARD
oSIST prEN ISO 20186-2:2017

01-februar-2017

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za vensko polno kri - 2. del: DNA, izoliran iz genoma (ISO/DIS 20186-2:2016)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA correct (ISO/DIS 20186-2:2016)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 2: Isolierte genomische DNA (ISO/DIS 20186-2:2016)

Ta slovenski standard je istoveten z: **prEN ISO 20186-2**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

oSIST prEN ISO 20186-2:2017 **en**

DRAFT INTERNATIONAL STANDARD

ISO/DIS 20186-2

ISO/TC **212**

Secretariat: **ANSI**

Voting begins on:
2016-12-23

Voting terminates on:
2017-03-16

Molecular *in vitro* diagnostic examinations — Specifications for pre-examination processes for venous whole blood —

Part 2:
Isolated genomic DNA correct

Titre manque

ICS: 11.100.10

This document is circulated as received from the committee secretariat.

ISO/CEN PARALLEL PROCESSING

Reference number
ISO/DIS 20186-2:2016(E)

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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 20186-2 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

ISO 20186 consists of the following parts, under the general title *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood*:

— *Part 1: Isolated cellular RNA*

— *Part 2: Isolated genomic DNA*

— *Part 3: Isolated circulating cell free DNA from plasma*

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 examination assay will not determine the situation in the patient but an artificial profile generated during the pre-examination processes.

Genomic DNA can fragment or degrade after blood collection. Therefore, special measures need to be taken to secure good quality specimens for genomic DNA examination. This is particularly relevant for examination test procedures requiring high molecular weight DNA.

Standardization of the entire workflow from specimen collection to the genomic DNA examination is needed due to genomic DNA degradation and fragmentation after blood collection. Studies have been undertaken to determine the important influencing factors. This International Standard draws upon such work to codify and standardize the steps for venous whole blood genomic DNA examination in what is referred to as the pre-examination phase.

Molecular *in vitro* diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 2: Isolated genomic DNA

1 Scope

This International Standard recommends the handling, documentation, storage and processing of venous whole blood specimens intended for genomic DNA examination during the pre-examination phase before a molecular examination is performed. This International Standard covers specimens collected in venous whole blood collection tubes.

This International Standard is applicable to any molecular *in vitro* diagnostic examination performed by medical laboratories. It is also intended to be used by laboratory customers, *in vitro* diagnostics developers and manufacturers, as well as institutions and commercial organizations performing biomedical research, biobanks, and regulatory authorities.

Different dedicated measures have to be taken for stabilizing blood cell free circulating DNA, which are not described in this International Standard. Circulating cell free DNA in blood is covered in ISO 20186-3, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 3: Isolated circulating cell free DNA from plasma*.

Different dedicated measures need to be taken for collecting, stabilizing, transporting and storing capillary blood as well as for collecting and storing blood by paper based technologies or other technologies generating dried blood. These are not described in this International Standard.

This International Standard does not cover the isolation of specific blood cells and subsequent isolation of genomic DNA therefrom.

DNA in pathogens present in blood is not covered by this International Standard.

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 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 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

[SOURCE: ISO 17511:2013, 3.2]

3.3
backflow
flow of a liquid opposite to the usual or desired direction

3.4
blood collection set
intravenous device specialized for venipuncture consisting of a stainless steel beveled needle and tube (tubing) with attached plastic wings and fitting connector; the connector attaches to an additional blood collection device, e.g., a blood collection tube.

3.5
blood collection tube
tube used for blood collection, usually in a vacuum which forces blood from the vein through the needle and into the tube

3.6
blood genomic DNA stabilizers
compounds, solutions or mixtures that are designed to minimize degradation and fragmentation of genomic DNA in blood

3.7
closed system
non-modifiable system provided by the vendor including all necessary components for the analysis (i.e., hardware, software, procedures and reagents)

3.8
DNA
deoxyribonucleic acid
polymer of deoxyribonucleotides occurring in a double-stranded (dsDNA) or single-stranded (ssDNA) form

[SOURCE: ISO 22174:2005, 3.1.2]

3.9
DNA proficiency testing program
proficiency testing for genomic DNA based examinations

Note 1 to entry: Commonly, a program periodically sends multiple specimens to members of a group of laboratories for analysis and/or identification; the program then compares each laboratory's results with those of other laboratories in the group and/or with an assigned value, and reports the results to the participating laboratory and others;

Note 2 to entry: Other forms of PT/EQA include: data transformation exercises, single-item testing (where one item is sent to a number of laboratories sequentially and returned to the program at intervals), and one-off exercises (where laboratories are provided with a test item on a single occasion).

3.10
DNase
deoxyribonuclease
enzyme that catalyzes the degradation of DNA into smaller components