



NSAI
Standards

Irish Standard

I.S. EN ISO 20186-2:2019&LC:2019

Molecular in vitro diagnostic examinations
- Specifications for pre-examination
processes for venous whole blood - Part
2: Isolated genomic DNA (ISO 20186-
2:2019)

I.S. EN ISO 20186-2:2019&LC:2019

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National Foreword

I.S. EN ISO 20186-2:2019&LC:2019 is the adopted Irish version of the European Document EN ISO 20186-2:2019, Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 2: Isolated genomic DNA (ISO 20186-2:2019)

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In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

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Correction Notice

Reference: EN ISO 20186-2:2019

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Please include the following minor editorial correction(s) in the document related to:

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- ☒ English
- ☒ French
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- ☐ PQ/UQ
- ☐ Enquiry
- ☐ 2nd Enquiry
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- ☐ UAP
- ☐ TC Approval
- ☐ 2nd TC Approval
- ☐ Publication
- ☒ Parallel Publication

It has been brought to our attention that this document, issued on 2019-03-27, requires modification.
Correction of title.

Please find enclosed the updated English version.

We apologise for any inconvenience this may cause.

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EUROPEAN STANDARD
NORME EUROPÉENNE
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EN ISO 20186-2

March 2019

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Supersedes CEN/TS 16835-2:2015

English Version

**Molecular in vitro diagnostic examinations - Specifications
for pre-examination processes for venous whole blood -
Part 2: Isolated genomic DNA (ISO 20186-2:2019)**

Analyses de diagnostic moléculaire in vitro -
Spécifications relatives aux processus préanalytiques
pour le sang total veineux - Partie 2: ADN génomique
extrait (ISO 20186-2:2019)

Molekularanalytische in-vitro-diagnostische Verfahren
- Spezifikationen für präanalytische Prozesse für
venöse Vollblutproben - Teil 2: Isolierte genomische
DNA (ISO 20186-2:2019)

This European Standard was approved by CEN on 2 February 2019.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

EN ISO 20186-2:2019 (E)

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European foreword

This document (EN ISO 20186-2:2019) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 "In vitro diagnostic medical devices" the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by March 2022.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

This document supersedes CEN/TS 16835-2:2015.

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Endorsement notice

The text of ISO 20186-2:2019 has been approved by CEN as EN ISO 20186-2:2019 without any modification.

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INTERNATIONAL STANDARD

**ISO
20186-2**

First edition
2019-02

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

Part 2: Isolated genomic DNA

*Analyses de diagnostic moléculaire in vitro — Spécifications relatives
aux processus préanalytiques pour le sang total veineux —*

Partie 2: ADN génomique extrait



Reference number
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ISO 20186-2:2019(E)

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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

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.

A list of all parts in the ISO 20186 series can be found on the ISO website.

Introduction

Molecular in vitro diagnostics has enabled 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 the pre-examination process, including the specimen collection, transport, storage and processing. Consequently, this makes the outcome from diagnostics or research unreliable or even impossible, because the subsequent examination might not determine the real 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 (HMW 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 document 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.

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 venous whole blood —

Part 2: Isolated genomic DNA

1 Scope

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

This document 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, biobanks, institutions and commercial organizations performing biomedical research, and regulatory authorities.

Different dedicated measures are taken for stabilizing blood cell free circulating DNA, which are not described in this document.

NOTE Circulating cell free DNA in blood is covered in ISO 20186-3.

Different dedicated measures are 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 document.

This document 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 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 15189:2012, *Medical laboratories — Requirements for quality and competence*

3 Terms and definitions

For the purposes of this document, the following terms and definitions 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>
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