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**

*Incorporating amendments/corrigenda/National Annexes issued since publication:*

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NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie
W NSAI.ie

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

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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:**

the following language version(s) :
- ☒ English
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- ☐ PQ/UQ
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- ☐ 2nd Parallel Formal Vote
- ☐ UAP
- ☐ TC Approval
- ☐ 2nd TC Approval
- ☐ Publication
- ☒ Parallel Publication

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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.



Rue de la Science, 23 • 1040 Bruxelles
Tel : +32 2 550 08 11 • Fax : +32 2 550 08 19

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

# EN ISO 20186-2

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

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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*

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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# Foreword

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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).

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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.

INTERNATIONAL STANDARD ISO 20186-2:2019(E)

# 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

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