

# SLOVENSKI STANDARD

## SIST EN ISO 20186-1:2019

01-julij-2019

Nadomešča:

SIST-TS CEN/TS 16835-1:2015

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### Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za vensko polno kri - 1. del: Izolirana celična RNK (ISO 20186-1:2019)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 1: Isolated cellular RNA (ISO 20186-1:2019)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 1: Isolierte zelluläre RNA (ISO 20186-1:2019)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour le sang total veineux - Partie 1: ARN cellulaire extrait (ISO 20186-1:2019)

**Ta slovenski standard je istoveten z: EN ISO 20186-1:2019**

#### **ICS:**

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems
11.100.30	Analiza krvi in urina	Analysis of blood and urine

**SIST EN ISO 20186-1:2019**

**en**

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EUROPEAN STANDARD  
 NORME EUROPÉENNE  
 EUROPÄISCHE NORM

**EN ISO 20186-1**

March 2019

ICS 11.100.10

Supersedes CEN/TS 16835-1:2015

English Version

**Molecular in vitro diagnostic examinations - Specifications  
 for pre-examination processes for venous whole blood -  
 Part 1: Isolated cellular RNA (ISO 20186-1:2019)**

Analyses de diagnostic moléculaire in vitro -  
 Spécifications relatives aux processus préanalytiques  
 pour le sang total veineux - Partie 1: ARN cellulaire  
 extrait (ISO 20186-1:2019)

Molekularanalytische in-vitro-diagnostische Verfahren  
 - Spezifikationen für präanalytische Prozesse für  
 venöse Vollblutproben - Teil 1: Isolierte zelluläre RNA  
 (ISO 20186-1:2019)

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 20186-1:2019) 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.

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

Part 1:  
**Isolated cellular RNA**

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

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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.

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](http://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](http://www.iso.org/patents)).

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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](http://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 process.

Blood cellular RNA profiles can change significantly after blood collection. Therefore, special measures need to be taken to secure good quality blood samples for cellular RNA examination and storage.

Standardization of the entire workflow from specimen collection to the cellular RNA examination is needed. 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 cellular RNA 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.

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