

**SLOVENSKI STANDARD
SIST EN ISO 20186-1:2019****01-julij-2019****Nadomešča:****SIST-TS CEN/TS 16835-1:2015**

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za vensko polno kri - 1. del: Izolirana celična RNA (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)

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11.100.30	Analiza krvi in urina	Analysis of blood and urine

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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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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of an identical text or by endorsement, at the latest by September 2019, and conflicting national standards shall be withdrawn at the latest by March 2022.

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Isolated cellular RNA**

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

Partie 1: ARN cellulaire extrait

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Foreword

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

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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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