SLOVENSKI STANDARD
SIST EN ISO 20184-1:2019

01-marec-2019

Nadomešča:
SIST-TS CEN/TS 16826-1:2015

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za zamrznjena tkiva - 1. del: Izolirani RNK (ISO 20184-1:2018)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 1: Isolated RNA (ISO 20184-1:2018)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 1: Isolierte RNS (ISO 20184-1:2018)

Examens de diagnostic moléculaire in vitro - Spécifications pour les processus d'examens préliminaires des tissus congelés - Partie 1: ARN isolé (ISO 20184-1:2018)

Ta slovenski standard je istoveten z: **EN ISO 20184-1:2018**

ICS:

11.100.10	Diagnostični preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN ISO 20184-1:2019 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 20184-1

December 2018

ICS 11.100.10

Supersedes CEN/TS 16826-1:2015

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue - Part 1: Isolated RNA (ISO 20184-1:2018)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus congelés - Partie 1: ARN extrait (ISO 20184-1:2018)

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 1: Isolierte RNS (ISO 20184-1:2018)

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European foreword

This document (EN ISO 20184-1:2018) 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.

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The text of ISO 20184-1:2018 has been approved by CEN as EN ISO 20184-1:2018 without any modification.

INTERNATIONAL STANDARD

ISO 20184-1

First edition
2018-11

Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue —

Part 1: Isolated RNA

Analyses de diagnostic moléculaire in vitro — Spécifications relatives aux processus préanalytiques pour les tissus congelés —

Partie 1: ARN extrait

Reference number
ISO 20184-1:2018(E)

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Published in Switzerland

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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*.

A list of all parts in the ISO 20184 can be found on the ISO website.

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Introduction

Molecular in vitro diagnostics, including molecular pathology, has enabled a significant progress in medicine. Further progress is expected with new technologies analysing nucleic acids, proteins, and metabolites in human tissues and body fluids. However, the profiles and/or integrity 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 process.

Therefore, a standardization of the entire process from specimen collection to the 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 frozen tissue with regard to RNA examination in what is referred to as the pre-examination phase.

RNA profiles in tissues can change drastically before, during and after collection (due to e.g. gene induction or gene down regulation). RNA species can change differently in different donor's patients' tissues.

Therefore, it is essential to take special measures to minimize the described RNA profile changes and modifications within the tissue for subsequent examination.

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.