Nederlandse voornorm

NVN-CEN/TS 16826-2

(en)

Moleculair in vitro diagnostisch onderzoek - Specificatie voor de pre-onderzoeksprocessen voor snel ingevroren weefsel - Deel 2: Geïsoleerde proteïnen

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for snap frozen tissue - Part 2: Isolated proteins

ICS 11.100.10
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Postbus 5059, 2600 GB Delft
Telefoon (015) 2 690 390, Fax (015) 2 690 190

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

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CEN/TS 16826-2

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Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for snap frozen tissue - Part 2: Isolated proteins

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus à congélation rapide - Partie 2: Protéines extraites

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für schockgefrorene Gewebeproben - Teil 2: Isolierte Proteine

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Contents

Page

European foreword

This document (CEN/TS 16826-2:2015) has been prepared by Technical Committee CEN/TC 140 "*In vitro* diagnostic medical devices", the secretariat of which is held by DIN.

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Introduction

Molecular *in vitro* diagnostics has enabled a significant progress in medicine. Further progress is expected by new technologies analysing signatures of nucleic acids, proteins, and metabolites in human tissues and body fluids. However, the profiles and/or integrity of these molecules can change drastically during primary sample collection, transport, storage, and processing thus making the outcome from diagnostics or research unreliable or even impossible because the subsequent analytical assay will not determine the situation in the patient but an artificial molecular pattern generated during the pre-examination process. Therefore, a standardization of the entire process from primary sample collection to protein analysis is needed. Studies have been undertaken to determine the important influencing factors. This Technical Specification draws upon such work to codify and standardize the steps for frozen tissue with regard to protein analysis in what is referred to as the preanalytical phase.

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