

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
september 2015

Als Nederlandse voornorm is aanvaard:
 - CEN/TS 16826-2:2015, IDT

Normcommissie 301086 "In vitro Diagnostica"



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English Version

**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	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 General considerations	7
5 Outside the laboratory	8
5.1 Primary tissue collection manual	8
5.1.1 Information about the primary sample donor	8
5.1.2 Information on the primary tissue sample	8
5.1.3 Information on the primary tissue sample processing	8
5.2 Transport requirements	9
6 Inside the laboratory	9
6.1 Information on the primary tissue sample receipt	9
6.2 Evaluation of the pathology of the specimen and selection of the sample	9
6.3 Cryo-storage of the specimen	10
6.4 Storage requirements	11
6.5 Isolation of total protein	11
6.5.1 General	11
6.5.2 Using commercial kits	11
6.5.3 Using the laboratories' own protocols	11
6.6 Quality assessment of isolated proteins	12
6.7 Storage of isolated total protein	12
Annex A (informative) Quantitative protein analysis demonstrates changes of protein amounts during cold ischemia	13
A.1 Introduction	13
A.2 Example	13
A.2.1 General	13
A.2.2 Experimental procedures	13
A.2.2.1 General	13
A.2.2.2 Tissues	14
A.2.2.3 Protein analysis	14
A.2.3 Results	15
A.2.4 Further reading	16
Bibliography	17

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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