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STN	**Molekulárne in vitro diagnostické vyšetrenia. Špecifikácie na procesy pred vyšetrením FFPE tkanív. Časť 2: Izolované proteíny.**	**STN** **P CEN/TS 16827-2** 85 6574

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

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 12/15

Táto predbežná STN je určená na overenie. Pripomienky zasielajte ÚNMS SR najneskôr do augusta 2017.

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English Version

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

Tests de diagnostic moléculaire in vitro - Spécifications pour les processus préanalytiques pour tissu FFPE - Partie 2: Protéines extraites

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

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Ref. No. CEN/TS 16827-2:2015 E

Contents

Page

European foreword

This document (CEN/TS 16827-2:2015) 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.

Although originally thought as being impossible due to the crosslinking activities of formaldehyde, protein extraction techniques from formalin formalin fixed and paraffin embedded (FFPE) tissues have been much improved in recent years. Heat-induced reversal of formaldehyde-induced crosslinks has been demonstrated as an essential step in the protein extraction procedures [1], [2]. Currently, most investigators accept that proteins extracted from FFPE tissue are suitable for downstream proteomic analysis [3].

However, 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 standardise the steps for FFPE tissue with regard to protein analysis in what is referred to as the preanalytical phase.

1 Scope

This Technical Specification gives recommendations for the handling, documentation and processing of FFPE tissue specimens intended for the analysis of extracted proteins during the preanalytical phase before a molecular assay is performed. This Technical Specification is applicable to molecular *in vitro* diagnostic examinations (e.g., *in vitro* diagnostic laboratories, laboratory customers, developers and manufacturers of *in vitro* diagnostics, institutions and commercial organizations performing biomedical research, biobanks, and regulatory authorities).

Protein profiles and protein-protein interactions in tissues can change drastically before and after collection (due to e.g., gene induction, gene down regulation, protein degradation). Protein species amounts can change differently in tissues from different donors / patients. The expression of genes can be influenced by the given treatment or intervention (surgery, biopsy), or drugs administered for anaesthesia or even treatment of concomitant disease as well as by the different environment conditions after the tissue removal from the body.

Furthermore, the formalin fixation and paraffin embedding process leads to modifications of the protein molecules, which can impact the validity and reliability of the analytical test results.

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

This document is not applicable for protein analysis by immunohistochemistry.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN ISO 15189:2012, *Medical laboratories — Requirements for quality and competence (ISO 15189:2012, Corrected version 2014-08-15)*

ISO 15190, *Medical laboratories — Requirements for safety*