PD CEN/TS 16827-3:2015

BSI Standards Publication

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

Part 3: Isolated DNA

bsi.

...making excellence a habit.™

Document Sharing Hub

Full document details: PD CEN/TS 16827-3:2015

National foreword

This Published Document is the UK implementation of CEN/TS 16827-3:2015.

The UK participation in its preparation was entrusted to Technical Committee CH/212, IVDs.

A list of organizations represented on this committee can be obtained on request to its secretary.

This publication does not purport to include all the necessary provisions of a contract. Users are responsible for its correct application.

© The British Standards Institution 2015. Published by BSI Standards Limited 2015

ISBN 978 0 580 85032 5

ICS 11.100.10

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 31 August 2015.

Amendments issued since publication

Date	Text affected

Documents
Document Sharing Hub

Full document details: PD CEN/TS 16827-3:2015

TECHNICAL SPECIFICATION

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

CEN/TS 16827-3

August 2015

ICS 11.100.10

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for FFPE tissue - Part 3: Isolated DNA

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus FFPE - Partie 3: ADN isolé

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für FFPE-Gewebeproben - Teil 3: Isolierte DNS

This Technical Specification (CEN/TS) was approved by CEN on 6 July 2015 for provisional application.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

CEN members are required to announce the existence of this CEN/TS in the same way as for an EN and to make the CEN/TS available promptly at national level in an appropriate form. It is permissible to keep conflicting national standards in force (in parallel to the CEN/TS) until the final decision about the possible conversion of the CEN/TS into an EN is reached.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

© 2015 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. CEN/TS 16827-3:2015 E

Documents
Document Sharing Hub

Full document details: PD CEN/TS 16827-3:2015

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 7
5.1 Primary tissue collection manual 7
5.1.1 Information about the primary sample donor 7
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 8

6 Inside the laboratory 9
6.1 Information on the primary tissue sample receipt 9
6.2 Formalin fixation of the specimen 9
6.3 Evaluation of the pathology of the specimen and selection of the sample 10
6.4 Post-fixation of frozen samples 11
6.5 Processing and paraffin embedding 11
6.6 Storage requirements 11
6.7 Isolation of DNA 12
6.7.1 General 12
6.7.2 General information for DNA isolation procedures 12
6.7.3 Using commercial kits 12
6.7.4 Using the laboratories' own protocols 13
6.8 Quantity and quality assessment of isolated RNA 13
6.9 Storage of isolated RNA 14

Annex A (informative) Impact of the storage temperature on DNA Integrity in FFPE blocks of tissue 15

A.1 Introduction 15

A.2 Results 15

A.3 Conclusions 15

Bibliography 16

Documents
Document Sharing Hub

Full document details: PD CEN/TS 16827-3:2015

European foreword

This document (CEN/TS 16827-3:2015) has been prepared by Technical Committee CEN/TC 140 "*In vitro* diagnostic medical devices", the secretariat of which is held by DIN.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, Former Yugoslav Republic of Macedonia, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and the United Kingdom.

Documents
Document Sharing Hub
Full document details: PD CEN/TS 16827-3:2015

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. Studies have been undertaken to determine the influencing factors for DNA analysis from formalin fixed and paraffin embedded (FFPE) tissue. These studies demonstrated that a standardization of the entire process from primary sample collection to DNA analysis is needed. This Technical Specification draws upon such work to codify and standardize the steps for FFPE tissue with regard to DNA analysis in what is referred to as the preanalytical phase.

Documents
Document Sharing Hub
Full document details: PD CEN/TS 16827-3:2015