

Irish Standard Recommendation S.R. CEN/TS 16827-1:2015

Molecular in vitro diagnostic examinations -Specifications for pre-examination processes for FFPE tissue - Part 1: Isolated RNA

© CEN 2015 No copying without NSAI permission except as permitted by copyright law.

S.R. CEN/TS 16827-1:2015

Incorporating amendments/corrigenda/National Annexes issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard — national specification based on the consensus of an expert panel and subject to public consultation.

S.R.~xxx: Standard~Recommendation-recommendation~based~on~the~consensus~of~an~expert~panel~and~subject~to~public~consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces/revises/consolidates the NSAI adoption of the document(s) indicated on the CEN/CENELEC cover/Foreword and the following National document(s):

NOTE: The date of any NSAI previous adoption may not match the date of its original CEN/CENELEC document.

This document is based on:

Published:

CEN/TS 16827-1:2015

2015-08-12

This document was published under the authority of the NSAI and comes into effect on:

ICS number: 11.100.10

2015-08-29

NOTE: If blank see CEN/CENELEC cover page

NSAI T +353 1 807 3800 Sales:

 1 Swift Square,
 F +353 1 807 3838
 T +353 1 857 6730

 Northwood, Santry
 E standards@nsai.ie
 F +353 1 857 6729

 Dublin 9
 W NSAI.ie
 W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

This is a free page sample. Access the full version online.

National Foreword

S.R. CEN/TS 16827-1:2015 is the adopted Irish version of the European Document CEN/TS 16827-1:2015, Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for FFPE tissue - Part 1: Isolated RNA

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

Compliance with this document does not of itself confer immunity from legal obligations.

In line with international standards practice the decimal point is shown as a comma (,) throughout this document.

This is a free page sample. Access the full version online.

This page is intentionally left blank

TECHNICAL SPECIFICATION

CEN/TS 16827-1

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

August 2015

ICS 11.100.10

English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for FFPE tissue - Part 1: Isolated RNA

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les tissus FFPE - Partie 1: ARN extrait

Molekularanalytische in-vitro-diagnostische Verfahren -Spezifikationen für präanalytische Prozesse für FFPE-Gewebeproben - Teil 1: Isolierte RNS

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

CEN/TS 16827-1:2015 (E)

Cont	Contents Pag				
Europe	ean foreword	3			
Introdu	uction	4			
1	Scope	5			
2	Normative references				
3	Terms and definitions				
4	General considerations				
5	Outside the laboratory				
5 5.1	Primary tissue collection manual				
5.1.1	Information about the primary sample donor				
5.1.2	Information on the primary tissue sample				
5.1.3	Information on the primary tissue sample processing				
5.2	Transport requirements	9			
6	Inside the laboratory	9			
6.1	Information on the primary tissue sample receipt				
6.2	Formalin fixation of the specimen				
6.3	Evaluation of the pathology of the specimen and selection of the sample				
6.4	Post-fixation of frozen samples				
6.5	Processing and paraffin embedding				
6.6	Storage requirements				
6.7 6.7.1	Isolation of the total RNAGeneral				
6.7.2	General information for RNA isolation procedures				
6.7.3	Using commercial kits				
6.7.4	Using the laboratories' own protocols				
6.8	Quantity and quality assessment of isolated RNA				
6.9	Storage of isolated RNA				
Annex	A (informative) Quality control of RNA extracted from formalin fixed and paraffin				
,	embedded tissue samples: implications for RT-qPCR based analyses	15			
A.1	Summary				
A.2	Results	15			
A.2.1	Time dependency of RNA integrity	15			
A.2.2	Impact of formalin-fixation on cDNA synthesis efficiency	16			
A.2.3	Fixation and storage introduces major gene-to-gene variations in RT-qPCR	17			
A.2.4	Impact of storage conditions of FFPE blocks on RNA Integrity	18			
A.3	Conclusions	18			
A.4	Further reading	19			
Bibliog	jraphy	20			



The is a new provider i arenade and chare publication at the limit below	This is a free preview.	Purchase the	entire publication	at the link below:
--	-------------------------	--------------	--------------------	--------------------

Product Page

- Dooking for additional Standards? Visit Intertek Inform Infostore
- Dearn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation