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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

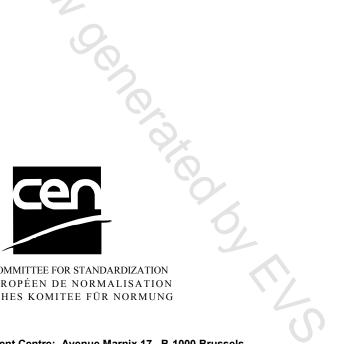
Molekularanalytische in-vitro-diagnostische Verfahren -Spezifikationen für präanalytische Prozesse für FFPE-Gewebeproben - Teil 1: Isolierte RNS

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Contents

European foreword			
Introduction			
1	Scope	5	
2	Normative references	5	
3	Terms and definitions	5	
4	General considerations	7	
5	Outside the laboratory		
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		
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	11	
6.6	Storage requirements	12	
6.7	Isolation of the total RNA	12	
6.7.1	General	12	
6.7.2	General information for RNA isolation procedures	12	
6.7.3	Using commercial kits	13	
6.7.4	Using the laboratories' own protocols	13	
6.8	Quantity and quality assessment of isolated RNA	14	
6.9	Storage of isolated RNA	14	
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	15	
A.2	Results		
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	Bibliography		
		S	

European foreword

This document (CEN/TS 16827-1:2015) 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 profile generated during the pre-examination process. Therefore, a standardization of amp encing : urmalin fixe earnalytical ph. the entire process from primary sample collection to RNA 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 formalin fixed and paraffin embedded (FFPE) tissue with regard to RNA 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 RNA analysis 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).

The formalin fixation and the paraffin embedding process lead to modifications of the RNA 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 RNA analysis.

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

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 15189:2012 and the following apply.

3.1

ambient temperature

unregulated temperature of the surrounding air

3.2

analytical phase

processes that start with the isolated analyte and include all kinds of parameter testing or chemical manipulation for quantitative or qualitative analysis

3.3

cold ischemia

condition after removal of the tissue from the body until its stabilization or fixation

3.4

FFPE

formalin fixation and paraffin embedding

3.5

FFPE tissues

formalin fixed and paraffin embedded tissues

3.6

formalin

saturated formaldehyde solution containing a mas fraction of 37 % (corresponding to a volume fraction of 40 %) formaldehyde, termed 100 % formalin

2