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Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue - Part 1: Isolated RNA (ISO 20166-1:2018)

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This standard includes the English version of the European Standard.

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Contents

Page

European foreword..... 3

European foreword

This document (EN ISO 20166-1:2018) has been prepared by Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by June 2019, and conflicting national standards shall be withdrawn at the latest by December 2021.

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

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Endorsement notice

The text of ISO 20166-1:2018 has been approved by CEN as EN ISO 20166-1:2018 without any modification.

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Part 1: Isolated RNA

Analyses de diagnostic moléculaire in vitro — Spécifications relatives aux processus préanalytiques pour les tissus fixés au formol et inclus en paraffine (FFPE) —

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Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 General considerations ... **5**

5 Outside the laboratory ... **6**

5.1 Specimen collection ... 6

5.1.1 General ... 6

5.1.2 Information about the specimen donor/patient ... 6

5.1.3 Information about the specimen ... 6

5.1.4 Specimen processing ... 6

5.2 Transport requirements ... 7

6 Inside the laboratory ... **7**

6.1 Information about the reception of the specimen ... 7

6.2 Formalin fixation of the specimen or sample(s) ... 8

6.3 Evaluation of the pathology of the specimen and selection of the sample(s) ... 9

6.4 Post-fixation of frozen samples ... 10

6.5 Decalcification ... 10

6.6 Processing and paraffin embedding ... 10

6.7 Storage requirements ... 10

6.8 Isolation of RNA ... 11

6.8.1 General ... 11

6.8.2 General information for RNA isolation procedures ... 11

6.8.3 Using commercial kits ... 12

6.8.4 Using the laboratories' own protocols ... 12

6.9 Quantity and quality assessment of isolated RNA ... 13

6.10 Storage of isolated RNA ... 13

6.10.1 General ... 13

6.10.2 Using commercially available kits for RNA isolation ... 14

6.10.3 Using the laboratory's own protocols for RNA isolation ... 14

Annex A (informative) **Quality control of RNA extracted from formalin-fixed and paraffin-embedded tissue samples: implications for RT-qPCR based examinations** ... **15**

Bibliography ... **21**

Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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For an explanation of the voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see www.iso.org/iso/foreword.html.

The committee responsible for this document is ISO/TC 212, *Clinical laboratory testing and in vitro diagnostic test systems*.

A list of all parts in the ISO 20166 series can be found on the ISO website.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

Introduction

Molecular in vitro diagnostics, including molecular pathology, has enabled significant progress in medicine. Further progress is expected with new technologies analysing nucleic acids, proteins, and metabolites in human tissues and body fluids. However, the profiles and/or integrity of these molecules can change drastically during specimen collection, transport, storage and processing, thus making the outcome from diagnostics or research unreliable or even impossible because the subsequent examination assay will not determine the situation in the patient but an artificial profile generated during the pre-examination process.

Therefore, a standardization of the entire process from specimen collection to the RNA examination is needed. Studies have been undertaken to determine the important influencing factors. This document draws upon such work to codify and standardize the steps for formalin-fixed and paraffin-embedded (FFPE) tissue with regard to RNA examination in what is referred to as the pre-examination phase.

The formalin-fixation and the paraffin-embedding processes lead to modifications of the RNA molecules, which can impact the validity and reliability of the examination test results.

RNA profiles in tissues can change drastically before, during and after collection and change differently in different donors'/patients' tissues. Therefore, it is essential to take special measures to minimize the described RNA profile changes and modifications within the tissue for subsequent examination.

In this document, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

INTERNATIONAL STANDARD **ISO 20166-1:2018(E)**

Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue —

Part 1: Isolated RNA

1 Scope

This document gives guidelines on the handling, documentation, storage and processing of formalin-fixed and paraffin-embedded (FFPE) tissue specimens intended for RNA examination during the pre-examination phase before a molecular assay is performed.

This document is applicable to molecular in vitro diagnostic examinations including laboratory developed tests performed by medical laboratories and molecular pathology laboratories. It is also intended to be used by laboratory customers, in vitro diagnostics developers and manufacturers, biobanks, institutions and commercial organizations performing biomedical research, and regulatory authorities.

NOTE International, national or regional regulations or requirements can also apply to specific topics covered in this document.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 15189:2012, *Medical laboratories — Requirements for quality and competence*

ISO 15190, *Medical laboratories — Requirements for safety*

ISO/IEC 17020:2012, *Conformity assessment — Requirements for the operation of various types of bodies performing inspection*

