



BSI Standards Publication

Molecular in vitro diagnostic examinations – Specifications for pre-examination processes for snap frozen tissue

Part 3: Isolated DNA

National foreword

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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.

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English Version

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

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

Molekularanalytische in-vitro-diagnostische
Verfahren - Spezifikationen für
präanalytische Prozesse für schockgefrorene
Gewebeproben - Teil 3: Isolierte DNA

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European foreword

This document (CEN/TS 16826-3:2018) 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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CEN/TS 16826 consists of the following parts:

- *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for snap frozen tissue — Part 1: Isolated RNA;*
- *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for snap frozen tissue — Part 2: Isolated proteins;*
- *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for snap frozen tissue — Part 3: Isolated DNA.*

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Introduction

Molecular *in vitro* diagnostics, including molecular pathology, has enabled a significant progress in medicine. Further progress is expected with new technologies analysing nucleic acids, proteins, and metabolites in human tissues and body fluids. However, integrity of these molecules can change 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 pattern generated during the pre-examination process. Therefore, a standardization of the entire process from specimen collection to the DNA 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 frozen tissue with regard to DNA examination in what is referred to as the pre-examination phase.

DNA integrity in tissues can change during processing and storage. Modifications of the DNA molecules can impact the validity and reliability of the examination test results. Therefore, it is essential to take special measures to minimize the described DNA changes and modifications 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.