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| STN P | Molekulárno-diagnostické vyšetrenia <i>in vitro</i> Špecifikácie postupov pred vyšetrením aspiračnej biopsie tenkou ihlou (FNAs) Časť 3: Izolovaná genómová DNA | STN P CEN/TS 17688-3 85 6577 |
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Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for Fine Needle Aspirates (FNAs) - Part 3: Isolated genomic DNA

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 02/22

Táto predbežná STN je určená na overenie. Pripomienky zasielajte ÚNMS SR najneskôr do 15. 11. 2023.

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English Version

**Molecular in vitro diagnostic examinations - Specifications
for pre-examination processes for Fine Needle Aspirates
(FNAs) - Part 3: Isolated genomic DNA**

Analyses moléculaires de diagnostic in vitro -
Spécifications pour les processus préanalytiques pour
les ponctions à l'aiguille fine - Partie 3: ADN génomique
isolé

Molekularanalytische in-vitro-diagnostische Verfahren
- Spezifikationen für präanalytische Prozesse für
Feinnadelaspirate - Teil 3: Isolierte genomische DNA

This Technical Specification (CEN/TS) was approved by CEN on 15 November 2021 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.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
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European foreword

This document (CEN/TS 17688-3:2021) 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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Any feedback and questions on this document should be directed to the users’ national standards body. A complete listing of these bodies can be found on the CEN website.

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Introduction

Molecular *in vitro* diagnostics has enabled significant progress in medicine. Further progress is expected by new technologies analysing profiles of nucleic acids, proteins, and metabolites in human tissues and body fluids. However, the profiles of these molecules can change drastically during the pre-examination process, including the specimen collection, transport, storage and processing.

Examination of genomic DNA (gDNA) is commonly used in clinical practice. This includes e.g. prognostic and predictive biomarker examinations. This is a fast growing field in molecular diagnostics.

Fine needle aspiration is a non-surgical procedure that uses a thin, hollow-bore needle and syringe to collect a specimen from patients for cytopathological and molecular investigation. As a minimally-invasive technique, fine needle aspirates (FNAs) are commonly used to diagnose and monitor for example a range of cancer types e.g. breast, lung and thyroid cancer, and other diseases, such as inflammatory diseases. FNAs also provide the opportunity to sample metastatic sites (e.g. lymph nodes) and otherwise non-resectable tissues.

Besides cytological assessment, molecular biological analysis of FNAs is expected to become increasingly used for cancer and other disease diagnostics, including companion diagnostics.

One of the challenges facing molecular analysis of FNA samples is their small size and diversity in composition (cells, blood, body fluid). The low cellular content of FNAs means that the yield of isolated gDNA is typically towards the lower end of detection for molecular examination. Therefore, the gDNA isolation procedure should provide a sufficient amount of gDNA as required by the specific examination.

After specimen collection, gDNA can fragment and degrade by e.g. fixation, processing and storage. Additionally, chemical modifications introduced into gDNA during FNA fixation might lead to sequence alterations or changes in the methylation status. The described changes of the gDNA molecules can impact the validity, reliability and sensitivity of the examination results.

Therefore, standardization of the entire process from specimen collection to gDNA examination is needed to minimize gDNA changes introduced by e.g. degradation, fragmentation and modification after FNA collection. This document describes special measures which need to be taken to obtain good quality FNA specimens/samples and isolated gDNA therefrom for molecular 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.

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1 Scope

This document gives guidelines on the handling, documentation, storage and processing of fine needle aspirates (FNAs) intended for gDNA examination during the pre-examination phase before a molecular examination is performed.

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

Different dedicated measures are taken for collecting, stabilizing, transporting and storing of core needle biopsies (FNA Biopsy or FNA B) and are not covered in this document, but EN ISO 20184-3, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for frozen tissue — Part 3: Isolated DNA* and EN ISO 20166-3, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue — Part 3: Isolated DNA*.

This document is not applicable for pathogen DNA examination and gDNA examination by *in situ* detection.

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.

EN ISO 15189, *Medical laboratories — Requirements for quality and competence (ISO 15189)*

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