ICS 11.100.30 SLOVENSKÁ TECHNICKÁ NORMA Marec 2016

STN	**Molekulárne in vitro diagnostické vyšetrenia. Špecifikácie na procesy pred vyšetrením žilovej krvi. Časť 3: Izolovaná cirkulujúca bunková DNA z plazmy.**	**STN P CEN/TS 16835-3** 85 1023

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 3: Isolated circulating cell free DNA from plasma

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. 02/16

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Úrad pre normalizáciu, metrológiu a skúšobníctvo SR, 2016
Podľa zákona č. 264/1999 Z. z. v znení neskorších predpisov sa môžu slovenské technické normy rozmnožovať a rozširovať iba so súhlasom Úradu pre normalizáciu, metrológiu a skúšobníctvo SR.

TECHNICAL SPECIFICATION

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CEN/TS 16835-3

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English Version

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 3: Isolated circulating cell free DNA from plasma

Tests de diagnostic moléculaire in vitro - Spécifications relatives aux processus pré-analytiques pour le sang total veineux - Partie 3: ADN libre circulant extrait du plasma

Molekularanalytische in-vitro-diagnostische Verfahren - Spezifikationen für präanalytische Prozesse für venöse Vollblutproben - Teil 3: Aus Plasma isolierte zirkulierende zellfreie DNS

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European foreword

This document (CEN/TS 16835-3:2015) 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 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 the entire process from primary sample collection to circulating cell free DNA (ccfDNA) 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 circulating cell free DNA analysis from plasma prepared from human venous whole blood in what is referred to as the preanalytical phase.

1 Scope

This Technical Specification recommends the handling, documentation and processing of venous whole blood specimens intended for circulating cell free DNA (ccfDNA) analysis during the preanalytical phase before a molecular assay is performed. This Technical Specification covers specimens collected by venous whole blood collection tubes. This Technical Specification is applicable to molecular *in vitro* diagnostic examinations (e.g. *in vitro* diagnostic laboratories, laboratory customers, *in vitro* diagnostics developers and manufacturers, institutions and commercial organizations performing biomedical research, biobanks, and regulatory authorities).

Blood ccfDNA profiles can change significantly after blood collection from the donor (e.g. release of genomic DNA from white blood cells, ccfDNA fragmentation and ccfDNA quantity change). Special measures need to be taken to secure good quality blood samples for ccfDNA analysis and storage.

Different dedicated measures need to be taken for preserving blood genomic DNA. These are not described in this Technical Specification. Blood genomic DNA is covered in CEN/TS 16835-2, *Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for venous whole blood — Part 2: Isolated genomic DNA*

NOTE CcfDNA obtained from blood by the procedures suggested in this document can contain DNA present in exosomes [3] [4].

DNA from pathogens present in blood is not covered by this Technical Specification.

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*

koniec náhľadu – text ďalej pokračuje v platenej verzii STN