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S.R. CEN/TS 16835-1:2015

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for venous whole blood - Part 1: Isolated cellular RNA

S.R. CEN/TS 16835-1:2015

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English Version

**Molecular in vitro diagnostic examinations - Specifications for
pre-examination processes for venous whole blood - Part 1:
Isolated cellular RNA**

Tests de diagnostic moléculaire in vitro - Spécifications
relatives aux processus préanalytiques pour le sang
veineux total - Partie 1 : ARN cellulaire isolé

Molekularanalytische in-vitro-diagnostische Verfahren -
Spezifikationen für präanalytische Prozesse für venöse
Vollblutproben - Teil 1: Isolierte zelluläre RNS

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CEN/TS 16835-1:2015 (E)

Contents

Page

Foreword	3
Introduction	4
1 Scope	5
2 Normative references	5
3 Terms and definitions	5
4 General considerations	6
5 Outside the laboratory	7
5.1 Primary venous whole blood collection manual	7
5.1.1 Information about the primary sample donor	7
5.1.2 Selection of the venous blood collection tube by the laboratory	7
5.1.3 Primary venous whole blood collection from the patient and stabilization procedures	7
5.1.4 Information on the primary blood sample and storage requirements at the blood collection facility	8
5.2 Transport requirements	9
6 Inside the laboratory	9
6.1 Sample reception	9
6.2 Storage requirements	9
6.3 Isolation of the cellular RNA	10
6.4 Quality assessment of isolated cellular RNA	11
6.5 Storage of isolated cellular RNA	11
Annex A (informative) Impact of preanalytical workflow steps on venous whole blood cellular RNA profiles	12
A.1 General information on operated experiments in Annex A and Annex B	12
A.2 Influence of blood collection tube type (with or without blood cellular RNA profile stabilizer) on the analysis of specific blood cellular RNA profiles	12
A.2.1 Unstable blood cellular RNA profiles	12
A.2.2 Stable blood cellular RNA profiles	14
Annex B (informative) Influence of blood storage temperature on blood cellular RNA profiles	16
Bibliography	19

Foreword

This document (CEN/TS 16835-1:2015) 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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CEN/TS 16835-1:2015 (E)**Introduction**

Molecular *in vitro* diagnostics has enabled a significant progress in medicine. Further progress is expected by new technologies analyzing 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 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 venous whole blood cellular RNA analysis in what is referred to as the preanalytical phase.

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