SLOVENSKI STANDARD
SIST-TS CEN ISO/TS 7552-1:2025

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Nadomešča:
SIST-TS CEN/TS 17390-1:2020

Molekularne diagnostične preiskave in vitro - Specifikacije za predpreiskovalne procese za cirkulirajoče tumorske celice (CTC) v venski polni krvi - 1. del: Izolirana RNK (ISO/TS 7552-1:2024)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumour cells (CTCs) in venous whole blood - Part 1: Isolated RNA (ISO/TS 7552-1:2024)

Spezifikationen für präanalytische Prozesse für zirkulierende Tumorzellen (CTC) in venösen Vollblutproben - Teil 1: Isolierte RNA (ISO/TS 7552-1:2024)

Analyses de diagnostic moléculaire in vitro - Spécifications relatives aux processus préanalytiques pour les cellules tumorales circulantes (CTC) dans le sang total veineux - Partie 1: ARN isolé (ISO/TS 7552-1:2024)

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European foreword

This document (CEN ISO/TS 7552-1:2024) has been prepared by Technical Committee ISO/TC 212 "Medical laboratories and in vitro diagnostic systems" in collaboration with Technical Committee CEN/TC 140 “In vitro diagnostic medical devices” the secretariat of which is held by DIN.

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Endorsement notice

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Molecular in vitro diagnostic examinations — Specifications for pre-examination processes for circulating tumour cells (CTCs) in venous whole blood —

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Foreword

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This document was prepared by Technical Committee ISO/TC 212, *Medical laboratories and in vitro diagnostic systems*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

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Introduction

Solid tumours release cells and bioanalytes into blood and other body fluids. This has opened the option of utilizing such body fluids (liquid biopsies) for a minimally-invasive procedure for tumour detection, diagnosis and characterization. Liquid biopsies can enable earlier detection and diagnosis of cancers and advance personalized patient treatment.[20,21]

These applications have become one of the fastest growing segments of the entire diagnostic market.

Circulating tumour cells (CTCs) in venous whole blood can reflect the disease complexity that evolves during tumour progression, with distinct genetic, epigenetic and gene expression biomarkers.[41]

Besides the prognostic role of CTC identification and enumeration in cancer progression, CTC molecular characterization can improve disease outcome prediction, therapeutic guidance and post-treatment monitoring of the patient.[39]

CTCs are now considered as a surrogate of tumour tissue in cancer early development, progression and metastatic phase[23].

Molecular characterization of CTCs can provide a strategy for monitoring cancer genotypes during systemic therapies,[24] identifying mechanisms of disease progression, identifying novel targets for biological treatment[25] and selecting targeted therapies[39].

Moreover, CTC single-cell sequencing is emerging as an important tool for tumour genomic heterogeneity analysis.[26-28] CTCs are fragile and tend to degrade within a few hours when collected in conventional blood collection tubes, e.g. EDTA containing tubes, without dedicated CTC stabilizers. CTCs are extremely rare, especially in early disease, e.g. less than 10 cells per 10 ml of blood, representing a ratio of approximately $1:10^7$ CTCs to white blood cells (WBCs). This low ratio represents a significant challenge to CTC enrichment required for examination.

RNA profiles of CTCs resemble gene expression profiles of tumours. For RNA profile analysis, measures to remove the WBCs are necessary in order to obtain sufficiently enriched CTC-specific RNA.

RNA profiles can change significantly after blood collection, during CTC enrichment and isolation. Therefore, special measures are necessary to obtain CTC samples of adequate quality and isolated RNA of appropriate quality for ensuring the specified RNA examination performance.[29]

Standardization includes all steps of the pre-examination process, including blood collection and stabilization, transport, storage, CTC enrichment, CTC isolation (if included), and RNA isolation. This pre-examination standardization is crucial to ensure reliable examination results in current clinical use and is also critical to develop new CTC based diagnostic examinations and to establish these in clinical healthcare.[30]

An illustration of critical steps of the CTC pre-analytical workflow is provided in Annex A.

This document describes special measures to obtain appropriate quality and quantity of RNA from CTC-containing blood specimens for subsequent examination.