

ISO/TS 7552-3:2024-11 (E)

Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for circulating tumour cells (CTCs) in venous whole blood - Part 3: Preparations for analytical CTC staining

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General considerations	5
5	Activities outside the laboratory	6
5.1	Specimen collection	6
5.1.1	General	6
5.1.2	Information about the specimen donor/patient	6
5.1.3	Selection of the venous whole blood collection tube by the laboratory	6
5.1.4	Venous whole blood specimen collection from the patient/donor	7
5.2	Specimen storage and transport	7
5.2.1	General	7
5.2.2	Storage and transport using blood collection tubes with stabilizers	8
5.2.3	Storage and transport using blood collection tubes without stabilizers	8
6	Activities inside the laboratory	8
6.1	Specimen reception	8
6.2	Specimen storage after transport and reception	9
6.3	Enrichment of CTCs	9
6.3.1	General	9
6.3.2	Using a commercial CTC enrichment system intended for diagnostic use	9
6.3.3	Using the laboratory developed CTC enrichment procedure	10
6.4	Quality of enriched CTCs	10
6.5	Storage of enriched CTCs	10
6.6	Preparation for CTC staining	10
6.6.1	General	10
6.6.2	Pretreatment for different staining techniques (antibody, colour staining, in situ techniques)	11
Annex A (informative) Decision guideline for critical steps of the CTC pre-analytical workflow		12
Bibliography		14