

ISO 20186-1:2019 (E)

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

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General considerations
5	Outside the laboratory
5.1	Specimen collection
5.1.1	Information about the specimen donor/patient
5.1.2	Selection of the venous whole blood collection tube by the laboratory
5.1.3	Venous whole blood specimen collection from the donor/patient and stabilization procedures
5.1.4	Information about the specimen and storage requirements at the blood collection facility
5.1.4.1	General
5.1.4.2	Using blood collection tubes with stabilizers
5.1.4.3	Using blood collection tubes without stabilizers
5.2	Transport requirements
6	Inside the laboratory
6.1	Specimen reception
6.2	Storage requirements
6.3	Isolation of the cellular RNA
6.3.1	General
6.3.2	Using blood collection tubes with RNA profile stabilizers
6.3.3	Using blood collection tubes without RNA profile stabilizers
6.4	Quantity and quality assessment of isolated cellular RNA
6.5	Storage of isolated cellular RNA
6.5.1	General
6.5.2	Cellular RNA isolated with commercially available kits
6.5.3	Cellular RNA isolated with the laboratory's own protocols
Annex A	(informative) Impact of pre-examination process steps on venous whole blood cellular RNA profiles
A.1	General information about operated experiments in Annex A and Annex B
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
A.2.1	Unstable blood cellular RNA profiles
A.2.2	Stable blood cellular RNA profiles
Annex B	(informative) Influence of blood storage temperature on blood cellular RNA profiles