

ISO 21474-1:2020 (E)

In vitro diagnostic medical devices — Multiplex molecular testing for nucleic acids — Part 1: Terminology and general requirements for nucleic acid quality evaluation

Contents

	Foreword
	Introduction
1	Scope
2	Normative references
3	Terms and definitions
4	General considerations
4.1	General
4.1.1	Pre-analytical phase considerations
4.1.2	Specimen quality considerations
4.1.3	Nucleic acid quality considerations
4.2	Multiplex molecular test quality nucleic acid and evaluation
4.2.1	Evaluation of nucleic acid quality for multiplex molecular tests
4.2.2	Evaluation of nucleic acid quantity
5	Procedure for preparation of nucleic acid
5.1	General
5.2	Preparation of samples
5.2.1	General
5.2.2	Consideration on tissue preparation
5.2.3	Nucleic acid extraction and purification
5.2.4	Quality evaluation method
Annex A	(informative) Evaluation of RNA Integrity
Annex B	(informative) Evaluation of DNA Integrity
Annex C	(informative) Use of PCR to assess amplifiable DNA from FFPE samples
Annex D	(informative) microRNA Sample

Page count: 22