

ISO 17593:2022-03 (E)

Clinical laboratory testing and in vitro medical devices - Requirements for in vitro monitoring systems for self-testing of oral anticoagulant therapy

Contents		Page
Foreword		v
Introduction		vi
1 Scope		1
2 Normative references		1
3 Terms and definitions		2
4 Design and development		8
4.1 General requirements.....		8
4.2 Measuring interval.....		8
4.3 Safety.....		8
4.4 Risk management.....		8
4.4.1 Identification of hazards.....		8
4.4.2 Risk management.....		9
4.5 Ergonomic and human factor aspects.....		9
4.6 Quality assurance and risk controls.....		10
4.6.1 General.....		10
4.6.2 Measurement verification.....		10
4.6.3 Control of system performance.....		10
4.6.4 Verification of self-testing performance.....		10
4.7 Metrological traceability.....		10
5 Information supplied by the manufacturer		11
5.1 General requirements.....		11
5.2 Instructions for use of the oral-anticoagulation monitoring system.....		12
5.3 Labels for the reagents and control(s).....		13
5.4 Instructions for use of reagents and control materials.....		14
6 Safety and reliability testing		14
6.1 General requirements.....		14
6.1.1 Protocol.....		14
6.1.2 Instruments and reagents.....		15
6.1.3 Acceptance criteria.....		15
6.2 Protection against electric shock.....		15
6.3 Protection against mechanical hazards.....		15
6.4 Electromagnetic compatibility.....		15
6.5 Resistance to heat.....		15
6.6 Resistance to moisture and liquids.....		15
6.7 Protection against liberated gases, explosion, and implosion.....		15
6.8 Instrument components.....		15
6.9 Performance test.....		15
6.10 Mechanical resistance to shock, vibration, and impact.....		16
6.10.1 Vibration test protocol.....		16
6.10.2 Drop test protocol.....		16
6.11 Temperature exposure limits.....		16
6.11.1 High-temperature test protocol.....		16
6.11.2 Low-temperature protocol.....		17
6.12 Humidity-exposure test protocol.....		17
6.13 Reagent and storage and use testing.....		17
7 Training and education programs		18

7.1	Training of healthcare providers.....	18
7.2	Education of lay persons.....	18
7.3	Evaluation of user conformance in following the manufacturer’s and the physician’s instructions.....	19
8	System performance validation.....	19
8.1	General.....	19
8.2	Contributors to measurement uncertainty.....	19
8.3	System performance validation study.....	19
8.4	Validation of measurement precision.....	20
8.4.1	General.....	20
8.4.2	Validation of measurement repeatability.....	21
8.4.3	Validation of intermediate precision.....	21
8.4.4	Data analysis.....	23
8.5	Validation of system accuracy.....	26
8.5.1	General requirements.....	26
8.5.2	Study population.....	26
8.5.3	Samples/Specimen.....	27
8.5.4	Instruments and reagents.....	28
8.5.5	Comparator measurement procedure.....	28
8.5.6	Study design.....	28
8.5.7	Procedure.....	29
8.5.8	Data analysis.....	30
8.6	Minimum acceptable system accuracy.....	33
8.6.1	System accuracy requirement.....	33
8.6.2	System accuracy assessment.....	34
8.6.3	Data presentation.....	34
9	Lay person performance evaluation.....	35
9.1	General.....	35
9.2	Study overview.....	35
9.3	Study sites.....	37
9.4	Subjects.....	37
9.5	Instruments and materials.....	37
9.6	Evaluation of lay person proficiency.....	37
9.6.1	Initial evaluation.....	37
9.6.2	Home use.....	38
9.6.3	Mid and final evaluation.....	38
9.7	Evaluation of instructions for use.....	38
9.8	Acceptance criteria and data assessment.....	39
	Annex A (normative) Additional requirements for electromagnetic compatibility.....	40
	Annex B (informative) Traceability chain examples.....	42
	Annex C (informative) Examples of an uncertainty calculation for a prothrombin INR determination using an oral anticoagulation monitoring system.....	46
	Annex D (informative) Elements of quality assurance of oral-anticoagulation monitoring systems.....	50
	Bibliography.....	51