

ISO 15193:2026-06 (E)

In vitro diagnostic medical devices - Requirements for reference measurement procedures

Contents

Page

Foreword.....	v
Introduction.....	vi
1 Scope.....	1
2 Normative references.....	1
3 Terms and definitions.....	1
4 Requirements for a reference measurement procedure.....	10
4.1 General.....	10
4.2 Elements of a reference measurement procedure.....	11
4.3 Warning and safety precautions.....	11
4.4 Introduction.....	12
4.5 Scope.....	12
4.6 Terms, definitions, symbols, and abbreviated terms.....	12
4.6.1 Concepts.....	12
4.6.2 Nomenclature.....	12
4.6.3 Trivial names.....	13
4.7 Measurement principle and measurement method.....	13
4.8 Reagents and materials.....	13
4.8.1 General.....	13
4.8.2 Descriptive items.....	13
4.8.3 Expression of concentration.....	14
4.8.4 Expression of dilution.....	15
4.8.5 Reference to patented items.....	15
4.9 Apparatus and equipment.....	15
4.9.1 Description.....	15
4.9.2 Auxiliary equipment.....	15
4.10 Consumables.....	15
4.11 Sampling and sample.....	15
4.11.1 General.....	15
4.11.2 Samples.....	15
4.12 Preparation of measuring system and analytical portion.....	16
4.12.1 General.....	16
4.12.2 Preparation of apparatus.....	16
4.12.3 Calibration.....	16
4.12.4 Types of analytical sample.....	17
4.12.5 Design of analytical series.....	17
4.12.6 Analytical portion.....	17
4.12.7 Analytical solution.....	17
4.13 Operation of measuring system.....	17
4.13.1 Sequence of measurement steps.....	17
4.13.2 Blank.....	17
4.13.3 Validation of measurement conditions.....	18
4.14 Data processing.....	18
4.14.1 Calculation of measurement results.....	18
4.14.2 Conversion equations.....	18
4.15 Validation.....	19
4.15.1 Concepts, values, and their use.....	19
4.15.2 Analytical calibration function.....	19
4.15.3 Analytical measurement function.....	19

4.15.4	Analytical sensitivity	19
4.15.5	Analytical influence quantities	19
4.15.6	Blank measurement	20
4.15.7	Carry-over	20
4.15.8	Recovery studies	20
4.15.9	Measurement trueness	20
4.15.10	Measurement precision	20
4.15.11	Limit of detection	21
4.15.12	Measurement interval	21
4.15.13	Validation by using RM	21
4.15.14	Interlaboratory comparison	21
4.15.15	Measurement uncertainty	21
4.16	Special cases	22
4.17	Reporting of measurement results	22
4.18	Quality assurance	22
4.19	Bibliography	23
4.20	Dates of authorization and revision	23
Annex A (informative) Reference procedures for ordinal quantities and nominal properties		24
Bibliography		25