

ISO 15194:2026-06 (E)

In vitro diagnostic medical devices - Requirements for certified reference materials and the content of supporting documentation

Contents	Page
Foreword	iv
Introduction	v
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Intended use, production and characterization of a certified reference material (CRM)	9
4.1 Intended use	9
4.2 Production and certification	10
4.3 Commutability	10
5 Content of supporting documentation	10
5.1 Supporting documentation	10
5.2 Label	10
5.3 RM certificate	11
5.4 Certification report	12
5.4.1 General	12
5.4.2 Warning and safety precautions	12
5.4.3 Introduction to a certification report	13
5.4.4 Scope of application for the CRM	13
5.4.5 Terms and definitions used in the certification report	13
5.4.6 General properties	13
5.4.7 Specific properties	14
5.4.8 Assignment of certified values	15
5.4.9 Intended use	16
5.4.10 Instructions for use	17
5.4.11 Reference material producer	18
5.4.12 Bibliography	18
5.4.13 Annexes	18
5.4.14 Dates of authorization and revision	18
Annex A (informative) Certified reference materials (CRMs) with nominal properties or ordinal quantities	19
Bibliography	20