ISO 21151:2020-05 (E)

In vitro diagnostic medical devices - Requirements for international harmonisation protocols establishing metrological traceability of values assigned to calibrators and human samples

Contents

Page

Foreword ... **iv**

Introduction ... **v**

1 Scope ... **1**

2 Normative references ... **1**

3 Terms and definitions ... **1**

4 Abbreviated terms and symbols ... **3**

5 Requirements for a harmonisation protocol ... **3**

5.1 Description of the measurand ... 3
5.2 Specifications for agreement among results from different IVD MDs ... 3
5.3 Inclusion or exclusion of IVD MDs ... 4
5.4 Harmonisation reference materials required for a harmonisation protocol ... 4
5.5 Measuring the quantity values of harmonisation reference materials by participants in a harmonisation protocol ... 6
5.6 Assigning a single quantity value to each harmonisation reference material used in a harmonisation protocol ... 6
5.7 Modifying the calibration hierarchy for each IVD MD using the harmonisation reference materials to achieve harmonised results for human samples from different IVD MDs ... 6
5.8 Assigning quantity values to calibration verification controls ... 8
5.9 Effectiveness of the harmonisation protocol ... 8
5.10 Sustainability of the harmonisation protocol over time ... 9
5.11 Harmonisation of IVD MDs not included in the original group ... 9

6 Information on metrological traceability to be provided in instructions for use ... **10**

Annex A (informative) **Worked Example of a Harmonisation Protocol** ... **11**

Bibliography ... **20**