ISO 15197:2013-05 (E)

In vitro diagnostic test systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

Contents

Page

Foreword iv

Introduction v

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 2

4 Design and development 8
4.1 General requirements 8
4.2 Metrological traceability 8
4.3 Safety and risk management 9
4.4 Ergonomics and human factors 10
4.5 User verification requirements 10

5 Safety and reliability testing 10
5.1 General requirements 10
5.2 Protection against electric shock 11
5.3 Protection against mechanical hazards 11
5.4 Electromagnetic compatibility 11
5.5 Resistance to heat 11
5.6 Resistance to moisture and liquids 11
5.7 Protection against liberated gases, explosion and implosion 12
5.8 Meter components 12
5.9 Performance test 12
5.10 Mechanical resistance to vibration and shock 12
5.11 Equipment temperature exposure limits for storage 13
5.12 Equipment humidity exposure limits for storage 13

6 Analytical performance evaluation 14
6.1 General requirements 14
6.2 Measurement precision 16
6.3 System accuracy 19
6.4 Influence quantities 25
6.5 Stability of reagents and materials 30

7 Information supplied by the manufacturer 30
7.1 General requirements 30
7.2 Performance characteristics 31
7.3 Options for supplying instructions for use 31

8 User performance evaluation 31
8.1 General requirements 31
8.2 Acceptance criteria and evaluation of results 32
8.3 Selection and preparation of subjects 32
8.4 Execution of study protocol 32
8.5 Glucose reference values 33
8.6 Human factors 33
8.7 Data analysis and presentation of results 33

8.8 Evaluation of instructions for use 34

Annex A (informative) Possible interfering substances 35

Annex B (informative) Traceability chain 36

Annex C (informative) Rationale for the analytical performance requirements 38

Bibliography 45