ISO 18113-4:2022-10 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 4: In vitro diagnostic reagents for self-testing

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Termsanddefinitions 1

4 General 1
4.1 Essential requirements 1
4.2 Identification of kit components 2
4.3 Presentation of the instructions for use 2

5 Content of the outer container 2
5.1 Manufacturer 2
5.2 Identification of the IVD reagent 2
5.2.1 IVD reagent name 2
5.2.2 Batch code / lot number 2
5.2.3 Unique device identifier (UDI) 3
5.3 3
5.4 Intended use/Intended purpose 3
5.5 In vitro diagnostic use 3
5.6 Storage and handling conditions 4
5.7 Expiry date 4
5.8 Warnings and precautions 4

6 Content of the immediate container label 4
6.1 General provisions 4
6.1.1 Single container 4
6.1.2 Small label 5
6.2 Manufacturer 5
6.3 Identification of the IVD reagent 5
6.3.1 IVD reagent or component name 5
6.3.2 Batch code/lot number 5
6.3.3 Unique device identifier (UDI) 5
6.4 5
6.5 In vitro diagnostic use 5
6.6 Storage and handling conditions 5
6.7 Expiry date 5
6.8 Warnings and precautions 6

7 Content of the instructions for use 6
7.1 Manufacturer 6
7.2 Identification of the IVD reagent 6
7.3 Intended purpose/Intended use 6
7.4 Principles of the method 6
7.5 Traceability of values assigned to calibrators and trueness-control materials 7
7.6 Components 7
7.7 Additional required equipment and / or materials 7

7.8 Storage and shelf life after first opening 8
7.9 Warnings and precautions 8
7.10 Primary sample collection, handling and storage 8
7.11 Procedure to obtain a result 8
7.12 Control procedure 9
7.13 Reading of test results 9
7.14 Interpretation of results 9
7.15 Performance characteristics 9
7.15.1 General 9
7.15.2 Measuring interval 9
7.16 Biological reference intervals 9
7.17 Limitations of the procedure 10
7.18 Literature references 10
7.19 Document control 10

Bibliography 11