

ISO 18113-2:2022-10 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labelling) - Part 2: In vitro diagnostic reagents for professional use

Contents		Page
Foreword		v
Introduction		vi
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General	1
4.1	Essential requirements	1
4.2	Identification of kit components	2
5	Content of the outer container label	2
5.1	Manufacturer	2
5.2	Identification of the in vitro diagnostic (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)	2
5.3	3
5.4	Intended use/intended purpose	3
5.5	In vitro diagnostic use	3
5.6	Storage, transport, and handling conditions	3
5.7	Expiry date	3
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	4
6.2	Manufacturer	4
6.3	Identification of the IVD reagent	4
6.3.1	IVD reagent or component name	4
6.3.2	Batch code/lot number	4
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	5
7	Content of the instructions for use	5
7.1	Manufacturer	5
7.2	Identification of the IVD reagent	6
7.3	Intended use/intended purpose	6
7.4	Principles of the examination 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	Reagent preparation	7

7.9	Storage and shelf life after first opening	8
7.10	Warnings and precautions and/or measures to be taken and limitations of use regarding the device	8
7.11	Primary sample collection, handling, and storage	8
7.12	Examination procedure	9
7.13	Control procedure	9
7.14	Calculation of examination results	9
7.15	Interpretation of results	9
7.16	Performance characteristics	9
7.16.1	Analytical performance characteristics	9
7.16.2	Clinical performance characteristics	10
7.16.3	Measuring interval	10
7.17	Biological reference intervals	10
7.18	Limitations of the examination procedure	10
7.19	Literature references	10
7.20	Document control	10
Bibliography		11