

ISO 18113-2:2009-12 (E)

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

Contents		Page
Foreword		iv
Introduction		v
1	Scope	1
2	Normative references	1
3	Terms and definitions	1
4	General	2
4.1	Essential requirements	2
4.2	Identification of kit components	2
5	Content of the outer container label	2
5.1	Manufacturer	2
5.2	Identification of the IVD reagent	2
5.3	Contents	2
5.4	Intended use	2
5.5	In vitro diagnostic use	3
5.6	Storage and handling conditions	3
5.7	Expiry date	3
5.8	Warnings and precautions	3
6	Content of the immediate container label	3
6.1	General provisions	3
6.2	Manufacturer	4
6.3	Identification of the IVD reagent	4
6.4	Contents	4
6.5	In vitro diagnostic use	4
6.6	Storage and handling conditions	4
6.7	Expiry date	4
6.8	Warnings and precautions	4
7	Content of the instructions for use	5
7.1	Manufacturer	5
7.2	Identification of the IVD reagent	5
7.3	Intended use	5
7.4	Principles of the examination method	5
7.5	Traceability of values assigned to calibrators and trueness-control materials	5
7.6	Components	6
7.7	Additional required equipment	6
7.8	Reagent preparation	6
7.9	Storage and shelf life after first opening	6
7.10	Warnings and precautions	6
7.11	Primary sample collection, handling and storage	7
7.12	Examination procedure	7
7.13	Control procedure	7
7.14	Calculation of examination results	7
7.15	Interpretation of results	7
7.16	Performance characteristics	7

7.17	Biological reference intervals	8
7.18	Limitations of the examination procedure	8
7.19	Literature references	8
	Bibliography	9