

DIN EN ISO 18113-4:2010-05 (E)

In vitro diagnostic medical devices - Information supplied by the manufacturer (labeling) - Part 4: In vitro diagnostic reagents for self-testing (ISO 18113-4:2009)

Contents		Page
Foreword		3
Introduction		4
1	Scope	5
2	Normative references	5
3	Terms and definitions	5
4	General	6
4.1	Essential requirements	6
4.2	Identification of kit components	6
4.3	Presentation of the instructions for use	6
5	Content of the outer container label	6
5.1	Manufacturer	6
5.2	Identification of the IVD reagent	6
5.3	Contents	7
5.4	Intended use	7
5.5	In vitro diagnostic use	7
5.6	Storage and handling conditions	7
5.7	Expiry date	7
5.8	Warnings and precautions	8
6	Content of the immediate container label	8
6.1	General provisions	8
6.2	Manufacturer	8
6.3	Identification of the IVD reagent	8
6.4	Contents	8
6.5	In vitro diagnostic use	8
6.6	Storage and handling conditions	9
6.7	Expiry date	9
6.8	Warnings and precautions	9
7	Content of the instructions for use	9
7.1	Manufacturer	9
7.2	Identification of the IVD reagent	9
7.3	Intended use	9
7.4	Principles of the examination method	10
7.5	Components	10
7.6	Additional required equipment	10
7.7	Reagent preparation	10
7.8	Storage and shelf life after first opening	10
7.9	Warnings and precautions	10
7.10	Primary sample collection, handling and storage	11
7.11	Examination procedure	11
7.12	Control procedure	11
7.13	Reading of examination results	11
7.14	Interpretation of results	11
7.15	Performance characteristics	11

7.16	Biological reference intervals	12
7.17	Limitations of examination procedure	12
7.18	Literature references	12
	Bibliography	13
	Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of the EU Directive 98/79/EC on "in vitro Diagnostic Medical Devices"	15