

# ISO 18113-4:2009-12 (E)

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

---

<b>Contents</b>		<b>Page</b>
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
4.3	Presentation of the instructions for use .....	2
5	Content of the outer container label .....	2
5.1	Manufacturer .....	2
5.2	Identification of the IVD reagent .....	2
5.3	Contents .....	3
5.4	Intended use .....	3
5.5	In vitro diagnostic use .....	3
5.6	Storage 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
6.2	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 .....	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 .....	5
7.3	Intended use .....	5
7.4	Principles of the examination method .....	6
7.5	Components .....	6
7.6	Additional required equipment .....	6
7.7	Reagent preparation .....	6
7.8	Storage and shelf life after first opening .....	6
7.9	Warnings and precautions .....	6
7.10	Primary sample collection, handling and storage .....	7
7.11	Examination procedure .....	7
7.12	Control procedure .....	7
7.13	Reading of examination results .....	7
7.14	Interpretation of results .....	7
7.15	Performance characteristics .....	7

7.16	Biological reference intervals .....	8
7.17	Limitations of examination procedure .....	8
7.18	Literature references .....	8
	Bibliography .....	9