

# 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)

---

<b>Contents</b>		<b>Page</b>
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

<b>7.16</b>	<b>Biological reference intervals .....</b>	<b>12</b>
<b>7.17</b>	<b>Limitations of examination procedure .....</b>	<b>12</b>
<b>7.18</b>	<b>Literature references .....</b>	<b>12</b>
	<b>Bibliography .....</b>	<b>13</b>
	<b>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" .....</b>	<b>15</b>