



Clinical laboratory testing and in vitro diagnostic medical systems — Information supplied by the manufacturer (labelling) —

Part 4:

In vitro diagnostic reagents for self-testing

Essais cliniques de laboratoire et systèmes médicaux de diagnostic in vitro — Informations fournies par le fabricant (marquage) —

Partie 4: Réactifs de diagnostic in vitro pour auto-essais

ICS 11.100.10

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50 **Foreword**

51 ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies
52 (ISO member bodies). The work of preparing International Standards is normally carried out through ISO
53 technical committees. Each member body interested in a subject for which a technical committee has been
54 established has the right to be represented on that committee. International organizations, governmental and
55 non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the
56 International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

57 International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

58 The main task of technical committees is to prepare International Standards. Draft International Standards
59 adopted by the technical committees are circulated to the member bodies for voting. Publication as an
60 International Standard requires approval by at least 75 % of the member bodies casting a vote.

61 Attention is drawn to the possibility that some of the elements of this document may be the subject of patent
62 rights. ISO shall not be held responsible for identifying any or all such patent rights.

63 ISO 18113-4 was prepared by Technical Committee ISO/TC 212, *Clinical laboratory testing and in vitro*
64 *diagnostic test systems*.

65 ISO 18113 consists of the following parts, under the general title *Clinical laboratory testing and in vitro*
66 *diagnostic test systems — In vitro diagnostic medical devices — Information supplied by the manufacturer*
67 *(labelling)*:

- 68 — *Part 1: Vocabulary and general requirements;*
- 69 — *Part 2: In vitro diagnostic reagents for professional use;*
- 70 — *Part 3: In vitro diagnostic instruments for professional use;*
- 71 — *Part 4: In vitro diagnostic reagents for self-testing;*
- 72 — *Part 5: In vitro diagnostic instruments for self-testing.*

73 This is the first edition.

74 Introduction

75 Manufacturers of *in vitro* diagnostic (IVD) reagents for self-testing supply users with information to enable their
76 safe use and expected performance. The type and level of detail varies according to the intended uses and
77 country-specific regulations.

78 The Global Harmonization Task Force (GHTF) is encouraging the elimination of unnecessary differences
79 among regulatory jurisdictions in order to reduce the time required for regulatory compliance and allows
80 patients earlier access to new technologies and treatments. [9] This International Standard provides a basis
81 for harmonization of labelling requirements for IVD reagents for self-testing.

82 This part of ISO 18113 is concerned solely with information supplied with IVD reagents, calibrators and control
83 materials intended for self-testing. It is intended to be used in conjunction with 18113-1, which contains the
84 general requirements for information supplied by the manufacturer and definitions of general labelling
85 concepts.

86 This part of ISO 18113 is based on EN 376:2002, *Information supplied by the manufacturer with in vitro*
87 *diagnostic reagents for self-testing*. [5] The text has been modified to conform to Part 2 of the ISO/IEC
88 Directives [4], but the requirements including those in ISO 18113-1 are substantially equivalent to the original
89 European harmonized standard. This International Standard is intended to support the essential labelling
90 requirements of all the GHTF partners, as well as other countries that have enacted or plan to enact labelling
91 regulations for IVD medical devices.

92 For IVD reagents, calibrators and/or control materials that are intended to be used as a system with an
93 instrument provided by the same manufacturer, this part of ISO 18113 is also intended to be used together
94 with ISO 18113-5 [2].

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Clinical laboratory testing and in vitro diagnostic medical systems — Information supplied by the manufacturer (labelling) —

Part 4:

In vitro diagnostic reagents for self-testing

95 1 Scope

96 This part of ISO 18113 specifies requirements for information supplied by the manufacturer of IVD reagents
97 for self-testing.

98 Furthermore, this part of ISO 18113 applies to information supplied by the manufacturer with calibrators and
99 control materials intended for use with IVD medical devices for self-testing.

100 This part of ISO 18113 can also be applied to accessories, where appropriate.

101 This part of ISO 18113 applies to labels for the outer and immediate container and to the instructions for use.

102 This part of ISO does not apply to

- 103 a) material safety data sheets,
- 104 b) information supplied with reagents for performance evaluation (e.g., for investigational use only),
- 105 c) IVD instruments or equipment, or
- 106 d) IVD reagents for professional use.

107 2 Normative references

108 The following referenced documents are indispensable for the application of this document. For dated
109 references, only the edition cited applies. For undated references, the latest edition of the referenced
110 document (including any amendments) applies.

111

112 EN 980, *Graphical symbols for use in the labelling of medical devices*

113 ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and*
114 *times*

115 ISO 14971, *Application of risk management to medical devices*

116 ISO 15198, *Clinical laboratory medicine — In vitro diagnostic medical devices — Validation of user quality*
117 *control procedures by the manufacturer*

118 ISO 15223, *Medical devices — Symbols to be used with medical device labels, labelling and information to be*
119 *supplied*

120 ISO 18113-1, *Clinical laboratory testing and in vitro diagnostic test systems — In vitro diagnostic medical*
121 *devices — Information supplied by the manufacturer (labelling) — Part 1: General requirements and*
122 *definitions*

123 **3 Terms and definitions**

124 For the purposes of this document, the concepts and definitions given in ISO 18113-1 apply.

125 **4 General**

126 **4.1 Essential requirements**

127 The requirements of ISO 18113-1 apply.

128 ISO standards for specific IVD medical devices may also contain requirements for information supplied by the
129 manufacturer.

130 EXAMPLES ISO 15197, for *in vitro* monitoring systems intended for self-testing of blood-glucose in managing
131 diabetes mellitus; ISO 17593, for *in vitro* monitoring systems intended for self-testing of anticoagulant therapy

132 **4.2 Identification of kit components**

133 In the case of a kit, each component shall be identified by name, letter, number, symbol, colour or graphics in
134 the same manner on all labels and the instructions for use.

135 **4.3 Form and presentation of the instructions for use**

136 **4.3.1** The instructions for use shall be written to be easily understood and applied by a lay person.

137 **4.3.2** The information supplied shall be sufficient to enable a lay person to use the IVD reagent safely and
138 properly and to understand the IVD examination results.

139 NOTE Recommendations for developing user instruction manuals for medical devices used in home health care may
140 be found in reference [10].

141 **5 Content of the outer container label**

142 **5.1 Manufacturer**

143 The name and location of the manufacturer shall be given.

144 The location should include city, state, country, province and region, where appropriate.

145 NOTE In the European Union, the name of the manufacturer's authorized representative is required on the outer
146 container label or in the instructions for use if the legal manufacturer is not located within the EU. See reference [8].

147 **5.2 Identification of the IVD reagent**

148 **5.2.1 IVD reagent name**

149 The name of the IVD reagent shall be given.

150 When the name does not uniquely identify the IVD reagent, an additional means of identification shall also be
151 given.

152 EXAMPLE catalogue number, commodity number

153 5.2.2 Batch code

154 A batch code shall be given.

155 If a kit contains different components bearing different batch codes, the batch code indicated on the outer
156 container shall enable the individual batch code of each component to be traced from the manufacturer's
157 production record.

158 5.3 Contents

159 The mass, volume and/or the number of examinations shall be indicated, where appropriate.

160 5.4 Intended use

161 If the intended use is not indicated by the name of the IVD reagent, then an abbreviated intended use
162 statement shall be given in terminology suitable for a lay person.

163 EXAMPLE pregnancy test

164 The fact that the IVD reagent is intended for self-testing shall be clearly stated.

165 5.5 *In vitro* diagnostic use

166 The *in vitro* diagnostic use of the reagent shall be stated, in suitable terminology for a lay person.

167 EXAMPLE For use outside the body.

168 5.6 Storage and handling conditions

169 The storage conditions necessary to maintain the stability of the reagents, calibrators and control materials in
170 the unopened state shall be indicated.

171 EXAMPLES 2 to 8 °C or 2...8 °C or graphical symbol

172 -18 °C or below or graphical symbol

173 Other conditions that affect stability of the reagents, calibrators and control materials shall be indicated.

174 EXAMPLES light, humidity

175 Any other conditions that affect the handling or storage of the reagents, calibrators and control materials shall
176 be specified.

177 EXAMPLE fragile

178 5.7 Expiry date

179 An expiry date based upon the stated storage instructions shall be indicated.

180 Expiry dates shall be expressed in a format generally familiar to the lay users.

181 EXAMPLES 2006-Jan-01 or Jan 01, 2006