INTERNATIONAL STANDARD

ISO 18113-4

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In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 4: *In vitro* diagnostic reagents for self-testing

Dispositifs médicaux de diagnostic in vitro — Informations fournies par le fabricant (étiquetage) —

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

Reference number
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Foreword

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

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

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

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

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

ISO 18113 consists of the following parts, under the general title In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling)*:

— *Part 1: Terms, definitions and general requirements*

— *Part 2:* In vitro *diagnostic reagents for professional use*

— *Part 3*: In vitro *diagnostic instruments for professional use*

— *Part 4:* In vitro *diagnostic reagents for self-testing*

— *Part 5:* In vitro *diagnostic instruments for self-testing*

Introduction

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

The Global Harmonization Task Force (GHTF) encourages convergence of the evolution of regulatory systems for medical devices at the global level. Eliminating differences among regulatory jurisdictions could allow patients earlier access to new technologies and treatments. See Reference [9]. This part of ISO 18113 provides a basis for harmonization of labelling requirements for IVD reagents for self-testing.

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

This part of ISO 18113 is based on EN 376:2002[5]. The text has been modified to conform to Part 2 of the ISO/IEC Directives[4], but the requirements, including those in ISO 18113-1, are substantially equivalent to the original European harmonized standard. This part of ISO 18113 is intended to support the essential labelling requirements of all the GHTF partners, as well as other countries that have enacted or plan to enact labelling regulations for IVD medical devices.

For IVD reagents, calibrators and/or control materials that are intended to be used as a system with an instrument provided by the same manufacturer, this part of ISO 18113 is also intended to be used together with ISO 18113-1 and ISO 18113-5[3].

In vitro diagnostic medical devices — Information supplied by the manufacturer (labelling) —

Part 4: *In vitro* diagnostic reagents for self-testing

1 Scope

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

This part of ISO 18113 also applies to information supplied by the manufacturer with calibrators and control materials intended for use with IVD medical devices for self-testing.

This part of ISO 18113 can also be applied to accessories.

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

This part of ISO 18113 does not apply to:

a) IVD instruments or equipment,

b) IVD reagents for professional use.

2 Normative references

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

ISO 14971, *Medical devices — Application of risk management to medical devices*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO 18113-1, In vitro *diagnostic medical devices — Information supplied by the manufacturer (labelling) — Part 1: Terms, definitions and general requirements*

EN 980, *Symbols for use in the labelling of medical devices*

3 Terms and definitions

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

4 General

4.1 Essential requirements

The requirements of ISO 18113-1 apply. For the use of symbols, the requirements of ISO 15223-1 and EN 980 apply.

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

EXAMPLES ISO 15197[1]; ISO 17593[2].

4.2 Identification of kit components

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

4.3 Presentation of the instructions for use

4.3.1 The instructions for use shall be written to be easily understood and applied by a lay person, and where appropriate, supplemented with drawings and diagrams.

Some devices may require separate information for the healthcare professional.

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

NOTE Recommendations for developing user instruction manuals for IVD medical devices used in home health care are found in Reference [10].

5 Content of the outer container label

5.1 Manufacturer

The name and address of the manufacturer shall be given.

NOTE In the European Union, the name and address of the manufacturer's “EC Authorized Representative” is required on the outer container label or in the instructions for use, if the legal manufacturer is not located within the EU. See Reference [8].

5.2 Identification of the IVD reagent

5.2.1 IVD reagent name

The name of the IVD reagent shall be given.

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

EXAMPLES Catalogue number, commodity number.

5.2.2 Batch code

A batch code shall be given.

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

5.3 Contents

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

5.4 Intended use

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

EXAMPLE Pregnancy test.

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

5.5 *In vitro* diagnostic use

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

EXAMPLE Only for use outside the body.

5.6 Storage and handling conditions

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

EXAMPLE 1 2 °C to 8 °C or 2…8 °C or graphical symbol.

−18 °C or below or graphical symbol.

Other conditions that affect stability shall be indicated.

EXAMPLE 2 Light, humidity.

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

EXAMPLE 3 Fragile.

5.7 Expiry date

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

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

EXAMPLES 2007-05-01, 2007-May-01, May 01, 2007.

If only the year and month are given, the expiry date shall be the last day of the month indicated.

The label on the outer container shall indicate the expiry date of the component having the earliest expiry date or an earlier date.

Local, national or regional regulations may apply.

5.8 Warnings and precautions

If an IVD reagent is considered hazardous, the outer container label shall include the appropriate danger wording or symbol(s).

EXAMPLES Chemical and biological hazards.

Statements or warning symbols for specific hazards may be required by local, national or regional regulations.

6 Content of the immediate container label

6.1 General provisions

6.1.1 Single container

If the immediate container is the outer container, the requirements specified in Clause 5 apply.

6.1.2 Small label

If the available space on the immediate container label is too small to include all of the information listed below, the information about contents (6.4), *in vitro* diagnostic use (6.5) and storage and handling conditions (6.6) may be abbreviated or eliminated.

Local, national or regional regulations may apply.

6.2 Manufacturer

The manufacturer shall be identified. The name of the manufacturer or an unequivocal trade name or logo is sufficient.

6.3 Identification of the IVD reagent

6.3.1 IVD reagent or component name

The name shall ensure proper identification to the user of the IVD reagent or component.

6.3.2 Batch code

A batch code shall be given.

6.4 Contents

If not indicated by other means, the contents shall be specified.

EXAMPLES Mass, volume and/or the number of examinations.

6.5 *In vitro* diagnostic use

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

EXAMPLE Only for use outside the body.

6.6 Storage and handling conditions

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

Any other conditions that affect the handling or storage of the reagents, calibrators and control materials shall be given, if different from those given on the outer container.

EXAMPLE Fragile.

6.7 Expiry date

An expiry date based upon the stated storage instructions shall be expressed as specified in 5.7.

6.8 Warnings and precautions

If an IVD reagent is considered hazardous, the immediate container label shall include the appropriate danger wording or symbol(s).

EXAMPLES Chemical and biological hazards.

Statements or warning symbols for specific hazards may be required by local, national or regional regulations.

7 Content of the instructions for use

7.1 Manufacturer

The name and address of the manufacturer shall be given.

NOTE In the European Union, the name and address of the manufacturer's "EC Authorized Representative" is required on the outer container label or in the instructions for use, if the legal manufacturer is not located within the EU. See Reference [8].

7.2 Identification of the IVD reagent

The name of the IVD reagent shall be indicated.

If the name does not uniquely identify the IVD reagent, an additional means of identification shall also be provided.

EXAMPLES Catalogue number, commodity number.

7.3 Intended use

The intended use shall be described in appropriate detail, including, where appropriate, the measurand, primary sample type and patient population, in terminology suitable for a lay person.

Benefits and limitations of the IVD medical device with respect to the intended use shall be described, where appropriate.

Medical use shall be described, where appropriate.

EXAMPLES Self-testing of cholesterol, suitable for the demonstration of an elevated cholesterol but not for its monitoring.

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

7.4 Principles of the examination method

The principle of the examination method shall be briefly described, in terminology suitable for a lay person, to provide the user with the necessary basic information.

7.5 Components

The nature, number, amount, concentration or content of the reactive ingredients shall be given.

EXAMPLE Antibody.

Information concerning other ingredients that may influence the examination procedure shall be given.

EXAMPLE Buffer.

7.6 Additional required equipment

Any special equipment required for proper performance and safe use but not provided by the manufacturer shall be listed.

Information necessary to enable special equipment to be identified and connected for proper use shall be given.

EXAMPLES Timing device, absorbent material, sterile or clean tissue required to cover the puncture site.

7.7 Reagent preparation

All steps required for preparation of the reagent(s) shall be described.

EXAMPLES Mixing, bringing to room temperature, whether tap (chlorinated) water is satisfactory or not.

7.8 Storage and shelf life after first opening

The storage conditions and shelf life following the first opening of the immediate container shall be given if different from the storage conditions and shelf life given on the container label.

The storage conditions and stability of working reagents, calibrators and control materials shall be given.

7.9 Warnings and precautions

If an IVD reagent is considered hazardous, the instructions for use shall include with the appropriate danger wording or symbol(s).

If a hazard is associated with storage, use or disposal of the IVD reagent, including reasonably foreseeable misuse, information that enables the user to reduce the risk shall be given.

EXAMPLES Chemical or biological hazard.

Local, national or regional regulations may apply.

The requirements of ISO 14971 pertaining to information for safety apply.

NOTE Information that enables users to reduce a risk is called “information for safety”. See ISO 14971.

If an IVD reagent includes substances of human or animal origin that present a risk of infection, a warning shall be given.

Information on the safe handling and disposal of hazardous materials shall be given.

If the IVD reagent is intended for single use, an appropriate warning shall be included.

7.10 Primary sample collection, handling and storage

The primary sample to be used and any special conditions of collection pre-treatment and/or storage conditions shall be specified.

Any special instructions for the preparation of the person to be tested prior to primary sample collection shall be given.

7.11 Examination procedure

A complete, detailed description of the examination procedure to be followed shall be provided.

The procedure shall include all the steps necessary to prepare the sample, carry out the examination and obtain a result.

Where appropriate, the procedure should be illustrated with a diagram, drawings and/or pictures.

7.12 Control procedure

Adequate information about a means to verify that the IVD reagent is performing within specifications shall be provided.

7.13 Reading of examination results

Instructions on how to read the result of the examination shall be provided.

Results shall be expressed and presented in a way that can be readily understood by a lay person.

A positive or negative result shall be clearly defined.

If the measurement procedure requires the interpretation of "visual" results, a clear description shall be included, which may be a representation or reproduction of expected results.

EXAMPLE A colour chart for colorimetric reactions.

7.14 Interpretation of results

The significance of the examination results obtained shall be explained.

Advice shall be given on actions to be taken, based on the IVD examination results taking into account the possibility of incorrect results. The information shall include a statement directing the user not to make any decision of medical relevance without first consulting his or her healthcare provider.

EXAMPLE Information regarding the degree to which a negative result excludes or does not exclude the possibility of exposure to, or infection with, a particular organism.

7.15 Performance characteristics

7.15.1 General

The performance characteristics relevant to the intended uses shall be described for the lay person.

7.15.2 Measuring interval

For quantitative measurement procedures, the concentration interval over which the performance characteristics of the IVD reagent have been validated shall be given.

EXAMPLE 5 mmol/l to 500 mmol/l.

7.16 Biological reference intervals

Where appropriate, biological reference intervals shall be provided in a way that can be readily understood by a layperson.

Reference interval units shall be consistent with the units used for reporting examination results.

NOTE For information regarding the description of biological reference intervals, see References [6], [7] and [11] to [18].

Relevant medical decision values may also be given.

7.17 Limitations of examination procedure

Any limitations of the examination procedure shall be described, including information regarding

a) known, clinically relevant interfering substances,

b) the examination of inappropriate primary samples and potential consequences, if known,

c) factors and circumstances that can affect the result, together with precautions to avoid incorrect results.

EXAMPLES Fasting, medication.

The requirements of ISO 14971 pertaining to information for safety apply.

NOTE Information that enables users to reduce a risk is called “information for safety”. See ISO 14971.

7.18 Literature references

Pertinent literature references shall be given.

EXAMPLE Biological reference intervals.

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