SLOVENSKI STANDARD
SIST EN 376:2000

01-januar-2000

Diagnostiļ ni sistemi in vitro - Zahteve za oznaļ evanje diagnostiļ nih reagentov in vitro za samopreskuġanje

In vitro diagnostic systems - Requirements for labelling in vitro diagnostic reagents for self-testing

In-vitro-Diagnostik/Diagnostika - Kennzeichnung und Produktinformationen von In-vitro-Diagnostika für den Gebrauch durch Laien

Systemes d'analyses médicales in vitro - Etiquetage des réactifs pour le diagnostic pour l'utilisation comme auto-test

Ta slovenski standard je istoveten z: **EN 376:1992**

ICS:

11.100.10	Diagnostiļ ni preskusni sistemi in vitro	In vitro diagnostic test systems

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English version

In vitro diagnostic systems - Requirements for labelling of in vitro diagnostic reagents for self-testing

Systèmes d'analyses médicales in vitro - Etiquetage des réactifs pour le diagnostic pour l'utilisation comme auto-test

In-vitro-Diagnostik/Diagnostica - Kennzeichnung und Produktinformationen von In-vitro-Diagnostica für den Gebrauch durch Laien

This European Standard was approved by CEN on 1992-05-27. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

The European Standards exist in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart,36 B-1050 Brussels

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Foreword

This European Standard was prepared by the Technical Committee CEN/TC 140 "In vitro diagnostic systems".

The text is based on a proposal produced by the European Diagnostic Manufacturers Association (EDMA) and accepted as a working document in CEN/TC 140.

A bibliography is given in an informative annex.

National Standards identical to this European Standard shall be published at the latest by 92-11-30 and conflicting national standards shall be withdrawn at the latest by 92-11-30.

In accordance with the CEN/CENELEC Common Rules, the following countries are bound to implement this European Standard:
Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

1 Scope

This standard specifies requirements for the labelling of in vitro diagnostic reagents which are intended for use in self-testing, i.e. for lay use. The term "self-testing" includes both patient self-testing (i.e. home-testing carried out by patients under the supervision of their physician) and consumer self-testing (i.e. testing carried out by the lay public on their own initiative).

2 Definitions

For the purposes of this standard, the following definitions apply:

2.1 Calibration[1]): The set of operations which establish, under specified conditions, the relationship between values indicated by a measuring instrument or measuring system, or values represented by a material measure or a reference material, and the corresponding values of a measureable quantity realized by a measurement standard.

2.2 Calibrator[1]): Reference material used for calibration.

2.3 Expiry date[1]): The date beyond which product performance cannot be assured stated on the container in uncoded form and based on the stability of the in-vitro diagnostic reagent.

2.4 Immediate container[1]): A medium that protects the content(s) from contamination and/or physical damage.

NOTE: Examples are a sealed vial, ampoule or bottle, a foiled pouch, or a sealed plastics bag containing eg culture media, microtitration plates or coated tubes.

2.5 In vitro diagnostic reagent[1]): A reagent which, used alone or in combination with other in vitro diagnostic medical devices, is intended by the manufacturer wholly or mainly to be used in vitro for the examination of substances derived from the human body for the purpose of providing information relevant to the detection, diagnosis, monitoring or treatment of physiological states, states of health or disease, or congenital abnormality.

NOTE: A given in-vitro diagnostic reagent, as defined for use in human medicine, in some cases may serve also in veterinary medicine.

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[1]) Provisional statement, subject to revision depending upon future EC Directives and/or European Standards

2.6 In vitro diagnostic system[1]): A measuring system which is intended by the manufacturer wholly or mainly to be used in vitro for the examination of substances derived from the human body for the purpose of providing information relevant to the detection, diagnosis, monitoring or treatment of physiological states, states of health or disease, or congenital abnormality.

NOTE: A given in vitro diagnostic system, as defined for use in human medicine, in some cases may serve also in veterinary medicine.

2.7 Kit: A set of components and instructions for use packaged together.

2.8 Kit component: An in vitro diagnostic reagent or another material intended to be part of a kit.

2.9 Label[1]): Any printed, written or graphic information placed on a container.

2.10 Labelling[1]): All printed, written, graphic or other information affixed to, or accompanying an in vitro diagnostic reagent including labels on any of its containers or wrappers and package inserts.

2.11 Lot[1]): A defined quantity of material, either bulk, intermediate or finished product which is uniform in character and quality as evidenced by compliance with production and quality assurance test requirements and which has been produced during a defined validated process of manufacture.

2.12 Lot number: A distinctive combination of numbers and/or letters which specifically identify a lot and permit its manufacturing history to be traced.

2.13 Manufacturing[1]): The complete process of production from the acquisition of all materials through all processing stages and including final packaging.

2.14 Outer container: Material used in the packaging of the immediate container(s) of a product whereby the product consists of a single entity or an assembly of different or identical components.

2.15 Package insert[1]): Any printed or graphic material(s) accompanying an in vitro diagnostic reagent which is not attached and contains instructions for use.

2.16 Shelf life: Period until expiry date.

2.17 Specimen: Biological material which is obtained in order to detect or to measure one or more quantities.

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[1]) See page 3

2.18 Stability: Ability of a product to retain its fitness for the intended use during the shelf life.

2.19 Supplier: Party that is responsible for the product, process or service.

NOTE: The definition may apply to manufacturers, distributors, importers, assemblers, service organizations, etc.

3 Labels

3.1 Immediate container

The label for an immediate container shall provide the information given below (at least 3.1.1 to 3.1.4, 3.1.6 to 3.1.8) in legible characters. If the available space is too small for this purpose, or if such labelling would interfere with the reading of analytical results the information may be reduced to the product name, supplier, lot number, expiry date and appropriate cautionary symbols as a minimum requirement, with the remaining information (3.1.5, 3.1.6 and 3.1.8) being given on an outer container (carton or overwrap) or in the instructions for use if more appropriate.

The language(s) shall be that of the country(ies) in which the product is distributed; additional languages are optional. Abbreviations and/or symbols may be used.

If an outer container encloses components intended to perform a single measurement, the components of such a container shall be identified in the same manner as described in the instructions for use (see 4.4), eg name, letter, number, symbol, colour or graphics. If appropriate, immediate containers shall carry cautionary statements.

3.1.1 Product name

The name shall ensure proper identification to the user of the product. Additionally, in a kit each component shall be identified by name, letter, number, symbol, colour or graphics in the same manner as described in the instructions for use or on the outer container.

3.1.2 Supplier

The name of the supplier shall be given. Instead of the supplier's name an unequivocal logo is sufficient.

3.1.3 Lot number

A lot number shall be given.

3.1.4 Expiry date

An expiry date based upon the stated storage instructions shall be given. This may be day, month and year or month and year. In the latter case this means that the expiry date is the last day of the month indicated.

3.1.5 Contents

The number of measurements or tests that can be performed should be stated.

3.1.6 Intended use

A brief indication, eg "pregnancy test", plus a statement in lay terms clearly signifying in vitro use, eg "not to be taken", shall be given.

3.1.7 Cautionary statements

If an in vitro diagnostic reagent is considered hazardous the immediate container shall be labelled with the appropriate cautionary symbols and/or statements eg according to annex II of the EEC Directive 91/325/EEC.

3.1.8 Storage information

The storage conditions necessary to protect the stability of the product in the unopened state shall be indicated. Recommended storage temperature intervals shall be given.

Examples are

2 °C to 8 °C	or	2...8 °C	or	graphical symbol according to ISO 7000-0632
-18 ° or below	or	≤ -18 °C	or	graphical symbol according to ISO 7000-0533
protect from freezing	or	do not freeze	or	graphical symbol according to ISO 7000-0027 in combination with the prohibition sign according to ISO 3864

If storage conditions for the opened or reconstituted product are different from those in the unopened state they shall also be given.

3.2 Outer container

The label for an outer container shall give the information specified in 3.2.1 to 3.2.8.

A statement to read carefully the instructions for use shall be made on the outer container or, if space does not permit, in the package insert.

The language(s) shall be that of the country(ies) in which the product is distributed; additional languages are optional.

If an approval of the product is obligatory, the number or code of approval has to be given on the label of the outer container.

3.2.1 Product name

The product name (see 3.1.1) shall be given. Where appropriate, the catalogue reference (product code) should also be given.

3.2.2 Supplier

The name and address of the supplier shall be given.

As a minimum requirement for EEC member countries name and address of the manufacturer or distributor within EEC shall be given.[2])

3.2.3 Lot number

A lot number shall be given.

3.2.4 Expiry date

An expiry date based upon the stated storage instructions shall be given using the procedure of 3.1.4. The label of the outer container shall give the expiry date of the component having the earliest expiry date. Abbreviations and/or symbols may be used.

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The number of measurements or tests that can be performed shall be stated.

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A brief indication, eg "pregnancy test", plus a statement in lay terms clearly signifying in vitro use, eg "not to be taken", shall be given.

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If an in vitro diagnostic reagent is considered hazardous the outer container shall be labelled with the appropriate cautionary symbols and/or statements eg according to annex II of the EEC Directive 91/325/EEC.

3.2.8 Storage information

The storage conditions necessary to protect the stability of the product in the unopened state shall be indicated. Recommended storage temperature intervals shall be given.

Examples are

2 °C to 8 °C	or	2...8 °C	or	graphical symbol according to ISO 7000-0632
-18 °C or below	or	≤ -18 °C	or	graphical symbol according to ISO 7000-0533
protect from freezing	or	do not freeze		graphical symbol according to ISO 7000-0027 in combination with the prohibition sign according to ISO 3864

Other conditions that can affect stability (eg light or humidity) shall be mentioned.

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[2]) National/local requirements should be followed.