SLOVENSKI STANDARD
SIST EN 375:2000

01-januar-2000

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

In vitro diagnostic systems - Requirements for labelling in vitro diagnostic reagents for professional use

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

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

Ta slovenski standard je istoveten z: **EN 375:1992**

ICS:

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

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EUROPEAN STANDARD

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English version

In vitro diagnostic systems - Requirements for labelling of in vitro diagnostic reagents for professional use

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

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

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.

CEN members are the national standards bodies of Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

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 for professional use.

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 Control material[1]**:** Material used for internal quality control or external quality assessment purposes.

2.4 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.

2.5 External quality assessment[1]**:** Checking results of measurement produced at a certain site by comparing with the results obtained by other sites on the same material distributed by an external agency that also analyses the data statistically.

2.6 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.

2.7 Internal quality control[1]**:** Operational techniques and activities within a production site that are used to fulfil requirements for quality of services.

NOTE: Internal quality control comprises all steps of activity for production of results from assessing clinical needs, via collection of sample, and measurement of a measurable quantity to reporting of result of measurement.

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

2.8 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.

2.9 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.

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

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

NOTE: Primary components of a typical kit can be an enzyme, substrate, chromogen, or binding reagent, tracer and calibrator; secondary components include the separation materials, special devices, buffers and quality control materials if included.

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

2.13 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.

2.14 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.

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

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

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[1]) See page 3

2.17 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.

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

2.19 Professional use: Use by personnel who have received special education and training with regard to laboratory procedures utilizing in vitro diagnostic systems.

2.20 Shelf life: Period until expiry date.

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

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

2.23 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 and 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.

As a minimum requirement, this information on the immediate container shall be given in English; the following abbreviations may be used: "Exp." for expiry date and "Lot" for lot number. Individual immediate containers either as a separate accessory to a kit or not part of a kit shall be labelled according to 3.2.

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.

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[1]) See page 3

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 content in terms of eg mass, volume and/or the number of measurements shall be given.

3.1.6 Intended use

A general statement such as "for in vitro diagnostic use (only)" or "in vitro diagnostic(um)" or "in vitro test" shall be used.

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 °C 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.

As a minimum requirement this information shall be given in English. However, packaging requirements concerning the language(s) of the countries in which the product is distributed shall be observed. Ideally multilingual outer container labels should be considered.

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 in the 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 may be used.

3.2.5 Contents

The content in terms of eg mass, volume and/or the number of measurements shall be given.

The components of a kit (see 3.1.1) shall be listed and briefly characterized (eg "buffer"). This can be completed in a package insert.

3.2.6 Intended use

The intended use may be given by means of the product name or the analytical method, eg "Glucose, Hexokinase Method" or "ASAT, for in vitro diagnostic use (only)" or only by "in vitro diagnostic(um)" or "in vitro test".

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