SLOVENSKI STANDARD
SIST EN 375:2001

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Nadomeģ a:
SIST EN 375:2000

Informacije proizvajalca o diagnostiļ nih reagentih in vitro za poklicno uporabo

Information supplied by the manufacturer with in vitro diagnostic reagents for professional use

Bereitstellung von Informationen durch den Hersteller von Reagenzien für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal

Informations fournies par le fabricant avec les réactifs de diagnostic in vitro pour usage professionnel

Ta slovenski standard je istoveten z: **EN 375:2001**

ICS:

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

SIST EN 375:2001 **en**

EUROPEAN STANDARD
NORME EUROPÉENNE
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EN 375

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ICS 01.040.11; 11.100

Supersedes EN 375:1992

English version

Information supplied by the manufacturer with in vitro diagnostic reagents for professional use

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Bereitstellung von Informationen durch den Hersteller von Reagenzien für in-vitro-diagnostische Untersuchungen zum Gebrauch durch Fachpersonal

This European Standard was approved by CEN on 6 December 2000.

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 Management Centre or to any CEN member.

This European Standard exists 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 Management Centre has the same status as the official versions.

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

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Contents

Foreword

This European Standard has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

The European Diagnostic Manufacturers Association (EDMA) has contributed to its preparation.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2001, and conflicting national standards shall be withdrawn at the latest by July 2001.

This European Standard supersedes EN 375:1992.

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative Annex ZA, which is an integral part of this standard.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

1 Scope

This standard specifies the requirements for the information supplied by the manufacturer of in vitro diagnostic reagents including reagent products, calibrators, control materials and kits for professional use, which hereafter are called IVD reagents.

NOTE This standard can also be applied to accessories.

2 Normative references

This European Standard incorporates by dated or undated reference, provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

ISO 1000, *SI units and recommendations for the use of their multiples and of certain other units.*

3 Terms and definitions

For the purposes of this standard, the following terms and definitions apply.

3.1
active ingredient
constituent that participates in the reaction used to measure or detect the analyte

3.2
batch
lot
defined amount of material, either starting material, intermediate or finished product which is uniform in its properties and has been produced in one process or series of processes

3.3
batch code
lot number
code that is a distinctive combination of numbers and/or letters which specifically identifies a batch and permits its manufacturing history to be traced

3.4
calibrator
substance, material or article intended by its manufacturer to be used to establish the measurement relationships of an in vitro diagnostic medical device

3.5
control material

substance, material or article intended by its manufacturer to be used to verify the performance characteristics of an in vitro diagnostic medical device

3.6

expiry date
date up to which product performance is assured by the manufacturer based on the stability of the IVD reagent

3.7
immediate container
primary container
packaging which protects the contents from contamination and/or other effects of the external environment

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

3.8
internal quality control
operational techniques and activities at the point of use that are used to fulfil requirements for quality of services

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

3.9
in vitro diagnostic reagent
IVD reagent
in vitro diagnostic medical device which is a reagent, reagent product, calibrator, control material or kit

NOTE 1 For the definition of an in vitro diagnostic medical device see [13].

NOTE 2 In some cases a particular IVD reagent, as defined for use in human medicine, may serve also in veterinary medicine.

3.10
kit
set of components (reagents and/or other materials) packaged together

3.11
kit component
in vitro diagnostic medical device intended to be part of a kit

NOTE Typical kit components are e. g. antibody solutions, buffer solutions, calibrators or control materials.

3.12
label
printed, written or graphic information placed on a container

3.13
outer container
sales packaging
material used in the packaging of the immediate container(s) of (an) IVD reagent(s) consisting of a single entity or an assembly of different or identical components

3.14
professional use
use by personnel who have received special education and training with regard to procedures utilizing in vitro diagnostic medical devices

3.15
reagent product
reagent carrier
product in which the reagents are fixed to or included in a carrier

EXAMPLES
Reagent strips, slides, discs and sticks.

3.16
shelf life
period until expiry date

3.17
specimen
biological material which is obtained in order to detect or to measure one or more quantities

3.18
stability
ability of an IVD reagent when kept under specified conditions, to retain throughout the shelf life its properties and/or performance within limits specified by the manufacturer

3.19
trueness
closeness of agreement between the average value obtained from a large series of test results and an accepted reference value [ISO 3534-1]

NOTE Directive 98/79/EC uses "accuracy" synonymously with "trueness", whereas the term "accuracy" includes both "trueness" and "precision", according to ISO 3534-1 and ISO 5725-1.

4 Requirements for labels

4.1 Outer container

4.1.1 General

The label for an outer container shall give the information specified in 4.1.2 to 4.1.10.

Requirements concerning the language(s) of the country in which the IVD reagent is distributed shall be met. Information which is a proper name, address or symbol does not require to be expressed in multiple languages.

4.1.2 Manufacturer

The name and address of the manufacturer shall be given.

NOTE The manufacturer is the entity which has taken legal responsibility for the IVD reagent.

The name and address of the authorized representative shall also be given when this is a legal requirement.

4.1.3 Product name

The product name shall be given.

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

4.1.4 Microbiological state

If necessary for proper performance of the IVD reagent, the microbiological state or state of cleanliness, e. g. "microbiologically controlled" or "sterile", shall be given.

4.1.5 Batch code

A batch code shall be given.

If a kit contains different components bearing different batch codes, the batch code given on the outer container shall enable the individual product histories to be traced from the manufacturer's production file.

NOTE The graphical symbol as given in EN 980 should be used.

4.1.6 Expiry date

An expiry date based upon the stated storage instructions shall be given. This shall be expressed as the year, the month, and, where relevant, the day in that order. In the case of year and month this means that the expiry date is the last day of the month indicated. The label of the outer container shall give the expiry date of the component having the earliest expiry date or an earlier date if appropriate.

NOTE 1 The graphical symbol as given in EN 980 should be used.

NOTE 2 The format for the expiry date should be either "CCYY-MM-DD" or "CCYY-MM" .

4.1.7 Contents

The content in terms of e. g. mass, volume, volume after reconstitution and/or the number of measurements shall be given.

In the case of a kit the components shall be designated in the same way as on the immediate containers as specified in 4.2.3.

Information on additional materials, e. g. accessories, may be given on the label and/or in the instructions for use where practicable and appropriate.

4.1.8 Intended purpose

Where appropriate, the intended purpose shall be given.

EXAMPLES
– Measurement of glucose concentration in serum,
– measurement of thromboplastin time.

Additionally the in vitro use of the reagent shall be indicated.

NOTE A graphical symbol for in vitro diagnostic medical device should be used. [1])

4.1.9 Storage and handling information

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

EXAMPLES

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

Other conditions that affect stability, e. g. light or humidity, shall be mentioned.

Any other particular measures to be taken in the handling of the product shall be given (e. g. "treat as fragile").

4.1.10 Warnings and precautions

If an IVD reagent is considered dangerous (e. g. chemical, radioactive or biological risk), the outer container shall be labelled with the appropriate danger symbol(s). If in the case of chemical hazards the IVD reagent is not accompanied with instructions for use giving appropriate risk and safety phrases, these phrases shall be given on the label of the outer container.

NOTE For chemical hazards labelling see [11].

4.2 Immediate container

4.2.1 General

The label for an immediate container shall give the information specified in 4.2.2 to 4.2.10 in legible characters and/or symbols. If the available space is too small for this purpose, the information may be reduced to 4.2.2, 4.2.3, 4.2.5, 4.2.6 and 4.2.10.

Information consisting of proper names and symbols does not require expression in multiple languages.

If the immediate container is also the outer container, the requirements for the label as specified in 4.1 apply.

4.2.2 Manufacturer

The name of the manufacturer shall be given. Alternatively, an unequivocal trade name or logo is sufficient.

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[1]) Graphical symbol as given in ISO 15223/DAM 1 : 1999 and as proposed for a future revision of EN 980.

4.2.3 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.

4.2.4 Microbiological state

If necessary for proper performance of the IVD reagent, the microbiological state or state of cleanliness, e. g. "microbiologically controlled" or "sterile", shall be given.

4.2.5 Batch code

A batch code shall be given.

NOTE The graphical symbol as given in EN 980 should be used.

4.2.6 Expiry date

An expiry date based upon the stated storage instructions shall be given. This shall be expressed as the year, the month, and, where relevant, the day in that order. In the case of year and month this means that the expiry date is the last day of the month indicated.

NOTE 1 The graphical symbol as given in EN 980 should be used.

NOTE 2 The format for the expiry date should be either "CCYY-MM-DD" or "CCYY-MM".

4.2.7 Contents

The content in terms of e. g. mass, volume, volume after reconstitution and/or the number of measurements shall be given.

4.2.8 Intended purpose

The in vitro use of the reagent shall be indicated.

NOTE A graphical symbol for in vitro diagnostic medical device should be used[1]).

4.2.9 Storage and handling information

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

EXAMPLES

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

Any other particular measures to be taken in the handling of the product shall be given (e. g. "treat as fragile").

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NOTE For chemical hazards labelling see [11].

[1]) See page 6.