SLOVENSKI STANDARD

SIST EN 13641:2002

01-november-2002

Izloļitev ali zmanjļanje tveganja okuļbe v povezavi z diagnostiļnimi reagenti in vitro

Elimination or reduction of risk of infection related to in vitro diagnostic reagents

Eliminierung oder Herabsetzung des von Reagenzien für in-vitro-diagnostische Untersuchungen ausgehenden Infektionsrisikos

Elimination ou réduction du risque d'infection relatif aux réactifs de diagnostic in vitro

Ta slovenski standard je istoveten z: **EN 13641:2002**

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11.100.10	Diagnostiļni preskusni sistemi in vitro	In vitro diagnostic test systems

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EUROPEAN STANDARD

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English version

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This European Standard was approved by CEN on 5 January 2002.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
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Foreword

This document EN 13641:2002 has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by November 2002, and conflicting national standards shall be withdrawn at the latest by November 2002.

This document 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 document.

This standard includes a Bibliography.

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, Malta, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland and the United Kingdom.

Introduction

Although medical laboratory staff routinely handle specimens that are potentially infectious and appropriate protective measures and safety procedures have to be followed, according to the provisions of the Directive 98/79/EC on in vitro diagnostic medical devices (IVD MDs) (see Bibliography, [1]) the additional risk of accidental infection caused by IVD MDs containing infectious or potentially infectious material is to be reduced to a minimum. This requirement of the EU Directive is an essential requirement relating to the design and manufacture of IVD MDs. Manufacturers are obliged to ensure by appropriate design features and manufacturing procedures that the risk of infection presented by the product itself is minimal. The EU Directive does not specifically address the following aspects which are covered by specific international, European and/or national legislation:

– general aspects of workers' protection and the measures that have to be implemented when infectious or potentially infectious materials are handled in laboratories or manufacturing sites,

– transportation of infectious goods,

– disposal routes and processes.

1 Scope

This European Standard specifies requirements related to design and manufacture in order to effectively control the risk of infection caused by in vitro diagnostic reagents including reagent products, calibrators, control materials and kits, hereinafter called IVD reagents. The standard is applicable to in vitro diagnostic reagents containing material of human origin. The standard is also applicable to in vitro diagnostic reagents containing materials obtained by biotechnology processes or materials of animal origin, in particular in view of relevant zoonoses, when the results of a risk analysis reveal that there is a risk of human infection.

The standard does not apply to the following:

– instruments and specimen receptacles;

NOTE 1 The prevention of infection due to handling of biological materials throughout such equipment is addressed in other relevant International and/or European Standards.

– general aspects of workers' protection;

– transportation of infectious goods;

– disposal measures.

NOTE 2 Some of the most relevant documents relating to aspects not covered by this standard are listed in Bibliography for information.

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).

EN 375, *Information supplied by the manufacturer with in vitro diagnostic reagents for professional use.*

EN 376, *Information supplied by the manufacturer with in vitro diagnostic reagents for self-testing.*

3 Terms and definitions

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

3.1
potentially infectious biological material
material which might contain infectious viable transmissible agents albeit with a low probability

NOTE Potentially infectious biological material includes all human and all animal sourced materials, including the specimens for routine diagnostic examination and biological materials of unknown origin.

3.2
infectious biological material
material which is known or highly likely to contain viable microorganisms or other transmissible agents which are known or suspected to cause disease in humans

NOTE Other transmissible agents are e.g. prions.

3.3
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 [1].

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

[EN 375:2001]

4 Requirements related to design and manufacture

4.1 General

In order to eliminate or reduce to a minimum the risk of infection related to IVD reagents the following aspects shall be considered:

– rationale for using infectious or potentially infectious biological material;

– sourcing and testing requirements (stipulated in material specifications);

– inactivation or other appropriate measures to reduce the risk of infection;

– warnings to be given in the information supplied by the manufacturer.

4.2 Use of infectious biological materials or potentially infectious biological materials

The use of infectious biological materials in IVD reagents shall be avoided as far as possible. If IVD reagents contain such material as an ingredient or component, its use shall be based on a sound scientific or technical rationale. Infectious material may be used only if it is indispensable for the diagnostic purpose of the product (e. g. positive controls, materials needed to utilise relevant antigens or antibodies in the final kit configuration.)

The use of potentially infectious biological materials shall be critically questioned in any case (weighing risks against benefit).

If either type of material is used, additional measures as specified in 4.3, 4.4 and clause 5 shall be considered to reduce the risk of infection to a minimum. The justification for use of such materials shall be documented.

4.3 Raw material specifications

4.3.1 General

For all infectious and potentially infectious biological materials used in the manufacture of reagents, appropriate specifications shall be defined (including sourcing and testing requirements) in order to control adequately the risk of infection.

4.3.2 Sourcing requirements

Appropriate procedures for sourcing infectious or potentially infectious biological materials shall be established and documented by the IVD reagents manufacturer.

Information shall be available on

– supplier of the raw material;

– type of material (e. g. blood, plasma, serum, tissue, urine, cells);

– nature of the source (e. g. human, animal, microbial);

– origin (e. g. geographical site, human donors group);

– purification procedures and chemical treatments, if performed.

4.3.3 Testing requirements

Testing of markers for the most relevant infections, such as HIV 1 and HIV 2 antibodies, HCV antibodies and HB_sAg shall be performed.

As a rule, tests based on CE-Marked IVD reagents shall be used, where available. Other techniques may be used only if their relevant performance characteristics are at least equivalent and documented.

In the case of human blood, including plasma and serum, each individual donation shall be tested. If in justified cases testing is performed on pooled material, an appropriately sensitive testing technology shall be used (e. g. PCR or other amplification techniques).

Traceability of test results shall be ensured. A certificate of analysis for the source material may be considered.

Only materials found to be non-reactive in the above-mentioned tests shall be used, except when reactive material is indispensable for the diagnostic purpose. Any exception shall be justified and documented.

4.4 Manufacturing process

If infectious biological materials are used, inactivation or other appropriate measures to reduce to a minimum the risk of infection shall be performed unless the performance of the IVD reagent is adversely affected. Adequate evidence on effectiveness and limitations of such measures shall be available (e. g. use of literature evidence, "state-of-the-art" procedures, validation data).

During the production process appropriate organisational and hygienic measures shall be taken to prevent secondary contamination (in particular cross contamination). Infectious materials and IVD reagents containing infectious materials shall be stored and filled in appropriate containers that effectively avoid dissemination of infectious agents.

5 Information supplied by the manufacturer

In addition to the requirements specified in EN 375 and EN 376 appropriate statements about the relevant infection markers tested and the outcome obtained shall be included in the instructions for use.

Any warning given shall be appropriate to the particular risk of infection (potential or known) presented by the reagent. Different wording shall be considered for different levels of risk.

For example, in case all the performed tests show no reactivity for the relevant infection markers or an effective treatment has been performed, a very general warning about the residual risk may be sufficient. By contrast, an explicit and very clear warning shall be made if infectious material is present for justified reasons and additional measures shall be suggested to the user to reduce the risk of infection.

Annex ZA
(informative)

Clauses of this European Standard addressing essential requirements or other provisions of EU Directives

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 the EU Directive 98/79/EC.

WARNING Other requirements and other EU Directives may be applicable to the product(s) falling within the scope of this standard.

The following clauses of this standard, as detailed in Table ZA.1, are likely to support requirements of the EU Directive 98/79/EC.

Compliance with these clauses of this standard provides one means of conforming to the specific essential requirements of the Directive concerned and associated EFTA regulations.

Table ZA.1 - Correspondence between this European Standard and Directive 98/79/EC

Clauses/subclauses of this European Standard	Corresponding essential requirements of Directive 98/79/EC	Qualifying remarks/Notes
4.1	A.1, A.2, B.2.1	
4.2	B.2.1, B.2.2	
4.3.1	B.2.2	
4.3.2	B.2.2, B.2.5	
4.3.3	B.2.1, B.2.2	
4.4	B.2.1, B.2.2	
5	B.8.4 (j), B.8.7 (q), B.8.7 (s)	