

**In vitro diagnostiliste reaktiividega
seotud infektsiooniriski kõrvaldamine
või vähendamine**

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

<p>Käesolev Eesti standard EVS-EN 13641:2002 sisaldab Euroopa standardi EN 13641:2002 ingliskeelset teksti.</p> <p>Käesolev dokument on jõustatud 19.06.2002 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes.</p> <p>Standard on kättesaadav Eesti standardiorganisatsioonist.</p>	<p>This Estonian standard EVS-EN 13641:2002 consists of the English text of the European standard EN 13641:2002.</p> <p>This document is endorsed on 19.06.2002 with the notification being published in the official publication of the Estonian national standardisation organisation.</p> <p>The standard is available from Estonian standardisation organisation.</p>
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<p>Käsitlusala: 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.</p>	<p>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.</p>
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ICS 11.100

Võtmesõnad: consistency, diagnosis (medical), health protection, in vitro, infection, in-vitro diagnostic, medical products, medical sciences, medicine, production, protective measures, reagents, risk, safety, safety measures, specification (approval), specifications, testing

ICS 11.100

English version

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

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

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

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.