Väljaspool organismi (katseklaasis) toimuva protsessi diagnostiline meditsiiniaparatuur. Koguste mõõtmine bioloogilise algmaterjali proovides. Etalonainete kirjeldus

Measurement of quantities in sampels of biological origin - Description of reference materials

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 12287:2000 sisaldab Euroopa standardi EN 12287:1999 ingliskeelset teksti. Käesolev dokument on jõustatud 11.01.2000 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12287:2000 consists of the English text of the European standard EN 12287:1999. This document is endorsed on 11.01.2000 with the notification being published in the official publication of the Estonian national standardisation organisation. The standard is available from Estonian standardisation organisation.

Käsitlusala: This European Standard specifies requirements and formats for the description of reference materials. It is applicable to reference materials of higher metrological order, classifiable as primary measurement standards and secondary measurement standards that function either as calibrators or control materials for reference measurement procedures. This Standard does not apply to reference materials that are parts of an in vitro diagnostic measuring system.	**Scope:** This European Standard specifies requirements and formats for the description of reference materials. It is applicable to reference materials of higher metrological order, classifiable as primary measurement standards and secondary measurement standards that function either as calibrators or control materials for reference measurement procedures. This Standard does not apply to reference materials that are parts of an in vitro diagnostic measuring system.

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Võtmesõnad:

EUROPEAN STANDARD
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In vitro diagnostic medical devices

Measurement of quantities in samples of biological origin

Description of reference materials

Dispositifs médicaux de diagnostic in vitro – Measure des grandeurs dans les échantillons d'origine biologique – Description des matériaux de référence

In-vitro-Diagnostika – Messung von Größen in Proben biologischen Ursprungs – Beschreibung von Referenzmaterialien

This European Standard was approved by CEN on 1999-04-01.

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, the Czech Republic, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, the Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, and the 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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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. International Federation of Clinical Chemistry (IFCC) and the European Confederation of Laboratory Medicine (ECLM) have 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 December 1999, and conflicting national standards shall be withdrawn at the latest by December 1999.

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.

This European Standard is based on ISO Guide 31 "Contents of certificates of reference materials". The future European Standard "Measurement of quantities in samples of biological origin – Presentation of reference measurement procedures" presents requirements to ensure that values assigned to reference materials by such procedures are reliable and stated in a useful way.

Annexes A, B and ZA are for information only.

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.

Introduction

To produce useful and reliable results of measurement, whether in science, technology, or routine service, it is necessary that they are supported by a reference measurement system so as to be comparable and ultimately traceable to measurement standards of the highest metrological level.

The substances which are used to obtain this traceability, both through time, distances, and different measurement procedures, are the reference materials. A given reference material is supported by documentation containing descriptions, measurement results, instructions for use, stability data, and storage conditions. The present European Standard specifies the content and format of such supporting documentation.

Reference materials are used for one of three main purposes:

a) calibration of values indicated by a measuring system or of another reference material;

b) validation or control of trueness of measured values in a given laboratory, or in a group of laboratories;

c) evaluation of the performance of a new measurement procedure.

The maximum acceptable uncertainty of measurement of the assigned value of the reference material depends on the requirements of the results of the measurement procedure.

As the proper use of a reference material depends on its description, it is important to apply rules for the documentation of reference materials.

The advantages of having (written) standards available are listed in ISO/IEC Guide 15.

1 Scope

This European Standard specifies requirements and formats for the description of reference materials. It is applicable to reference materials of higher metrological order, classifiable as primary measurement standards and secondary measurement standards that function either as calibrators or control materials for reference measurement procedures. This standard does not apply to reference materials that are parts of an in vitro diagnostic measuring system.

This European Standard also provides instructions on how to collect basic data for value determination and how to present the assigned value. The standard also specifies the format for a certificate.

This European Standard is not applicable to the production of the reference materials.

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 publications referred to applies.

EN 375 : 1992, *In vitro diagnostic systems – Requirements for labelling of in vitro diagnostic reagents for professional use.*

ISO 31 : 1992, *Quantities and units.*

3 Terms and definitions

For the purposes of this Standard, the terms and definitions given in International Vocabulary of Basic and General Terms in Metrology apply (3.1 and 3.2 are quotes from VIM) together with the following:

3.1
primary measurement standard
standard that is designated or widely acknowledged as having the highest metrological qualities and whose value is accepted without reference to other standards of the same quantity [6.4 of VIM]

NOTE 1: The concept of primary standard is equally valid for base quantities and derived quantities.

NOTE 2: The word "measurement" has been included in the term here for consistency.

NOTE 3: Measurement standards include reference materials.

3.2
secondary measurement standard
standard whose value is assigned by comparison with a primary standard of the same quantity [6.5 of VIM]

NOTE 1: The word "measurement" has been included in the term here for consistency.

NOTE 2: Measurement standards include reference materials.

3.3
matrix (of a material system)
all components of a material system except the analyte

3.4
matrix effect
influence of a property of the sample, independent of the presence of the analyte, on the measurement and thereby on the value of the measurable quantity

NOTE 1: A specified cause of a matrix effect is an influence quantity.

NOTE 2: A matrix effect depends on the detailed steps of the measurement as described in the measurement procedure.

EXAMPLE:
The measurement of the amount-of-substance concentration of sodium ion in plasma by flame emission spectrometry may be influenced by the viscosity of the sample.