In vitro kasutatavad diagnostilised meditsiiniseadmed. Bioloogilise päritoluga proovide koguste mõõtmine. Etalon-mõõtmistoimingute esitamine

In vitro diagnostic medical devices - Measurements of quantities in samples of biological origin - Presentation of reference measurement procedures

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 12286:1999 sisaldab Euroopa standardi EN 12286:1998 ingliskeelset teksti. Käesolev dokument on jõustatud 23.11.1999 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 12286:1999 consists of the English text of the European standard EN 12286:1998. This document is endorsed on 23.11.1999 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 for the drafting of a reference measurement procedure.	**Scope:** This European Standard specifies requirements for the drafting of a reference measurement procedure.

ICS 11.100

Võtmesõnad: bioassay, in vitro diagnostics, measurements, medicine, procedure, sampling

EUROPEAN STANDARD
NORME EUROPÉENNE
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EN 12286

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Descriptors: *In vitro* diagnostic systems, sampling, measurements.

English version

In vitro diagnostic medical devices

Measurement of quantities in samples of biological origin

Presentation of reference measurement procedures

Dispositifs médicaux de diagnostic *in vitro* – Mesure des grandeurs dans des échantillons d'origine biologique – Présentation des modes opératoires de mesure de référence

In-vitro-Diagnostika – Messung von Größen in Proben biologischen Ursprungs – Darstellung von Referenzmeßverfahren

This European Standard was approved by CEN on 1998-10-14.

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

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 International Federation of Clinical Chemistry and Laboratory Medicine (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 May 1999, and conflicting national standards shall be withdrawn at the latest by May 1999.

This European Standard is based on ISO/DIS 78-2 with special consideration of the requirements for biological materials and for reference measurement procedures. prEN 12287 "In vitro diagnostic medical devices – Measurement of quantities in samples of biological origin – Description of reference materials" specifies requirements of importance to the calibration and quality assurance of reference measurement procedures.

Annexes A and B 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

Reference measurement systems are needed for producing useful and reliable results of measurement, whether in science, technology, or routine service so as to be comparable and ultimately traceable to measurement standards of the highest metrological level. Analytical reference measurement procedures play a crucial role in this metrological system because they can be used

– in assessing performance characteristics of measuring systems – comprising measuring instruments, auxiliary equipment as well as reagents,

– in demonstrating the functional interchangeability of different routine measurement procedures purporting to measure the same quantity,

– in assigning values to reference materials that are then used for purposes of calibration or control of routine measurement procedures and

– in detecting analytical influence quantities in patient samples.

For clinical laboratory measurements, in particular, it is vitally important to acute and continuous patient care that the results reported to the physicians and patients are adequately comparable, reproducible, and accurate.

In some cases, a reference measurement procedure should be given in the form of a (written) standard, namely when it is related to technical requirements

– specified in standards, technical specifications, or technical regulations, etc.;

– for which values are to be stated by the supplier;

– that have a direct relationship to the performance of a product or process.

The advantages of having such a standard are listed in the ISO/IEC Guide 15.

1 Scope

This European Standard specifies requirements for the drafting of a reference measurement procedure.

NOTE: It is intended that an experienced laboratory worker, following a measurement procedure written in accordance with this European Standard can be expected to produce results with an uncertainty of measurement not exceeding the stipulated range.

This European Standard is applicable to any person, body, or institution, involved in one of the various branches of laboratory medicine, intending to write a document to serve as a reference measurement procedure.

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.

EN ISO 3696 Water for analytical laboratory use – Specification and test methods (ISO 3696 : 1987)

ISO 6353-2 Reagents for chemical analysis – Part 2: Specifications – First series

ISO 6353-3 Reagents for chemical analysis – Part 3: Specifications – Second series

ISO/IEC Directives – Part 2 : 1992 Methodology for the development of International Standards

International Vocabulary of Basic and General Terms in Metrology (VIM), 2nd edition, Geneva: ISO, 1993 [1] [2]

Guide to the Expression of Uncertainty in Measurement, 1st edition, Geneva: ISO, 1993 [1]

3 Definitions

For the purposes of this European Standard, the definitions given in "International Vocabulary of Basic and General Terms in Metrology" and in "Guide to the Expression of Uncertainty in Measurement" apply together with the following:

3.1 primary sample: Collection of one or more parts initially taken from a system and intended to provide information about the system or to serve as a basis for a decision about the system.

NOTE: In some cases, the information provided also applies to a larger system or a set of systems of which the sampled system is an element.

3.2 laboratory sample: Primary sample or a subsample of it as prepared for sending to or as received by the laboratory and intended for measurement.

3.3 analytical sample: Sample prepared from the laboratory sample and from which analytical portions may be taken.

NOTE: The analytical sample can be subjected to various treatments before an analytical portion is taken.

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[1]) This document has been prepared by a joint working group consisting of experts appointed by:

BIPM	International Bureau of Weights and Measures
IEC	International Electrotechnical Commission
IFCC	International Federation of Clinical Chemistry and Laboratory Medicine
ISO	International Organization for Standardization
IUPAC	International Union of Pure and Applied Chemistry
IUPAP	International Union of Pure and Applied Physics
OIML	International Organization of Legal Metrology.

[2]) The abbreviation VIM is used in this standard.