In vitro meditsiinilised diagnostikaseadmed. Bioloogilise päritoluga proovide koguste mõõtmine. Nõuded sertifitseeritud lähtematerjalidele ja saatedokumentide sisule

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN ISO 15194:2009 sisaldab Euroopa standardi EN ISO 15194:2009 ingliskeelset teksti.	This Estonian standard EVS-EN ISO 15194:2009 consists of the English text of the European standard EN ISO 15194:2009.
Standard on kinnitatud Eesti Standardikeskuse 30.10.2009 käskkirjaga ja jõustub sellekohase teate avaldamisel EVS Teatajas.	This standard is ratified with the order of Estonian Centre for Standardisation dated 30.10.2009 and is endorsed with the notification published in the official bulletin of the Estonian national standardisation organisation.
Euroopa standardimisorganisatsioonide poolt rahvuslikele liikmetele Euroopa standardi teksti kättesaadavaks tegemise kuupäev on 01.05.2009.	Date of Availability of the European standard text 01.05.2009.
Standard on kättesaadav Eesti standardiorganisatsioonist.	The standard is available from Estonian standardisation organisation.

ICS 11.100.10

EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English Version

In vitro diagnostic medical devices - Measurement of quantities in samples of biological origin - Requirements for certified reference materials and the content of supporting documentation (ISO 15194:2009)

Dispositifs médicaux de diagnostic in vitro - Mesurage des grandeurs dans les échantillons d'origine biologique - Exigences relatives aux matériaux de référence certifiés et au contenu de la documentation associée (ISO 15194:2009)

In-Vitro-Diagnostika - Messung von Größen in Proben biologischen Ursprungs - Anforderungen an zertifizierte Referenzmaterialien und an den Inhalt der Begleitdokumentation (ISO 15194:2009)

This European Standard was approved by CEN on 16 April 2009.

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 CEN 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 CEN Management Centre has the same status as the official versions.

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

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Ref. No. EN ISO 15194:2009: E

Foreword

This document (EN ISO 15194:2009) has been prepared by Technical Committee CEN/TC 140 "In vitro diagnostic medical devices", the secretariat of which is held by DIN, in collaboration with Technical Committee ISO/TC 212 "Clinical laboratory testing and in vitro diagnostic test systems".

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 2009, and conflicting national standards shall be withdrawn at the latest by November 2009.

This document supersedes EN 12287:1999.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN [and/or CENELEC] shall not be held responsible for identifying any or all such patent rights.

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.

For relationship with EU Directive, see informative Annex ZA, which is an integral part of this document.

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

Annex ZA
(informative)

Relationship between this European Standard and the Essential Requirements of EU Directive 98/79

This European Standard has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association to provide one means of conforming to Essential Requirements of the New Approach Directive 98/79.

Once this standard is cited in the Official Journal of the European Union under that Directive and has been implemented as a national standard in at least one Member State, compliance with the normative clauses of this standard confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding Essential Requirements of that Directive and associated EFTA regulations.

WARNING: Other requirements and other EU Directives may be applicable to the products falling within the scope of this standard.

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Introduction

Reference measurement systems are needed to produce useful and reliable measurement results, whether in science, technology or routine service, so as to be comparable and ultimately metrologically traceable to measurement standards and/or measurement procedures of the highest metrological level.

Substances or devices that are used to obtain this metrological traceability, through time, distances and different measurement procedures, are reference materials. Certified reference materials are needed at the higher metrological levels of a calibration hierarchy.

A given certified reference material is supported by documentation containing sources of material, descriptions, measurement results, metrological traceability, instructions for use, stability data and storage conditions, as well as health and safety warnings. This International Standard specifies the quality requirements for such materials and the content of their supporting documentation.

Reference materials are used for one of three main purposes:

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

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

NOTE In ISO terminology “trueness” is related to “bias”, “systematic effect” and “systematic error”, whereas “accuracy” is related both to “trueness” (with its relations) and “precision”, where the latter is related to “standard deviation”, “coefficient of variation ”, “random effect” and “random error”.

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

The maximum acceptable measurement uncertainty of the assigned value of a reference material depends on the requirements of the measured quantity values obtained by a measurement procedure involving the reference material.

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 standards available are listed in ISO/IEC Guide 15.

In Clause 3 of this International Standard, concepts are indicated by *italicized text*.

In vitro diagnostic medical devices — Measurement of quantities in samples of biological origin — Requirements for certified reference materials and the content of supporting documentation

1 Scope

This International Standard specifies requirements for certified reference materials and the content of their supporting documentation, in order for them to be considered of higher metrological order in accordance with ISO 17511. It is applicable to certified reference materials classifiable as primary measurement standards, secondary measurement standards and international conventional calibrators that function either as calibrators or trueness control materials. This International Standard also provides requirements on how to collect data for value determination and how to present the assigned value and its measurement uncertainty.

This International Standard applies to certified reference materials with assigned values of differential or rational quantities. Annex A provides information on nominal properties and ordinal quantities.

This International Standard does not apply to reference materials that are parts of an *in vitro* diagnostic measuring system, although it is possible that many elements are helpful.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 31 (all parts)[1)], *Quantities and units*

ISO 5725-2*, Accuracy (trueness and precision) of measurement methods and results — Part 2: Basic method for the determination of repeatability and reproducibility of a standard measurement method*

ISO 17511:2003, In vitro *diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values assigned to calibrators and control materials*

ISO 18153, In vitro *diagnostic medical devices — Measurement of quantities in biological samples — Metrological traceability of values for catalytic concentration of enzymes assigned calibrators and control materials*

ISO Guide 31, *Reference materials — Contents of certificates and labels*

ISO Guide 34, *General requirements for the competence of reference material producers*

ISO Guide 35, *Reference materials — General and statistical principles for certification*

ISO/IEC Guide 98-3:2008, *Guide to the expression of uncertainty in measurement (GUM:1995)*

ISO/IEC Guide 99:2007, *International vocabulary of metrology — Basic and general concepts and associated terms (VIM)*

1) The ISO 31 series is currently being replaced progressively by the ISO 80000 series and the IEC 80000 series.