საქართველოს სტანდარტი

მოწყობილობები სამედიცინო "ინ ვიტრო" დიაგნისტიკისათვის-ბიოლოგიური წარმოშობის ნიმუშების სიდიდის განსაზღვრა-მოთხოვნები ატესტირებული სანიმუშო მასალებისა და დამხმარე დოკუმენტაციის შინაარსისათვის

საქართველოს სტანდარტების და მეტროლოგიის
ეროვნული სააგენტო
თბილისი

საინფორმაციო მონაცემები

1 შემუშავებულია საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს სტანდარტების დეპარტამენტის მიერ

2 დამტკიცებულია და შემოღებულია სამოქმედოდ საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს 2013 წლის 20 დეკემბრის № 92 განკარგულებით

3 მიღებულია გარეკანის თარგმნის მეთოდით სტანდარტიზაციის საერთაშორისო ორგანიზაციის სტანდარტი ისო 15194:2009 ,,მოწყობილობები სამედიცინო "ინ ვიტრო" დიაგნისტიკისათვის-ბიოლოგიური წარმოშობის ნიმუშების სიდიდის განსაზღვრა-მოთხოვნები ატესტირებული სანიმუშო მასალებისა და დამხმარე დოკუმენტაციის შინაარსისათვის“

4 პირველად

5 რეგისტრირებულია საქართველოს სტანდარტების და მეტროლოგიის ეროვნული სააგენტოს რეესტრში: 2013 წლის 20 დეკემბერი №268-1.3-5635

INTERNATIONAL STANDARD

ISO 15194

Second edition
2009-05-01

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

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

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

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

ISO 15194 was prepared by the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, In vitro *diagnostic medical devices*, in collaboration with Technical Committee ISO/TC 212, *Clinical laboratory testing and* in vitro *diagnostic test systems*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO 15194:2002), which has been technically revised.

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*.