In vitro meditsiinilised diagnostikaseadmed. Ühekordselt kasutatavad anumad verest erinevate proovide võtmiseks inimestelt

In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

Käesolev Eesti standard EVS-EN 14254:2004 sisaldab Euroopa standardi EN 14254:2004 ingliskeelset teksti. Käesolev dokument on jõustatud 23.09.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 14254:2004 consists of the English text of the European standard EN 14254:2004. This document is endorsed on 23.09.2004 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 standard specifies requirements and test methods for evacuated and non-evacuated single-use specimen receptacles intended by their manufactures for the primary containment and preservation of spectimens, other than blood specimens, derived from the human body, for the purposes of in vitro diagnostic examination.	**Scope:** This standard specifies requirements and test methods for evacuated and non-evacuated single-use specimen receptacles intended by their manufactures for the primary containment and preservation of spectimens, other than blood specimens, derived from the human body, for the purposes of in vitro diagnostic examination.

ICS 11.100

Võtmesõnad: in-vitro diag, laboratories, laboratory medicine, markings, materials, medical equipment, medical sciences, medicine, personnel, receptacles, reference materials, reference methods, samples, specification (approval), specifications, specimens, sterility, utilization

EUROPEAN STANDARD

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EUROPÄISCHE NORM

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English version

In vitro diagnostic medical devices - Single-use receptacles for the collection of specimens, other than blood, from humans

Dispositifs médicaux de diagnostic in vitro - Récipients à usage unique pour prélèvement humains non sanguins

In-vitro-Diagnostika - Einmalgefäße für Untersuchungsgut vom Menschen mit Ausnahme von Blutproben

This European Standard was approved by CEN on 23 April 2004.

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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 Central Secretariat has the same status as the official versions.

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

Management Centre: rue de Stassart, 36 B-1050 Brussels

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Contents

Foreword

This document (EN 14254:2004) 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 December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

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.

Annexes A, B, C, D and E are normative.

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

1 Scope

This standard specifies requirements and test methods for single-use evacuated and non-evacuated receptacles, intended by their manufacturers, for the primary containment and preservation of specimens, other than blood specimens, derived from the human body, for the purposes of in vitro diagnostic examination.

NOTE 1 Requirements and test methods for evacuated and non-evacuated single-use venous blood specimen containers are specified in EN 14820.

NOTE 2 While it is desirable that specimen receptacles should be designed to avoid spontaneous discharge of the contents, when being opened, this standard does not specify a test procedure for this because it has not been possible to devise an objective and reproducible test.

This standard does not specify requirements for collection needles or needle holders or other accessories used in conjunction with specimen receptacles.

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 ISO 3696, *Water for analytical laboratory use — Specification and test methods (ISO 3696:1987)*

ISO 4788, *Laboratory glassware — Graduated measuring cylinders*

3 Terms and definitions

For the purposes of this European Standard, the following terms and definitions apply.

3.1
receptacle
vessel, whether evacuated or not, intended to contain a specimen, together with any receptacle accessory and additive, with closure in place

3.2
evacuated receptacle
receptacle intended for specimen collection by means of evacuation, either already induced by the manufacturer (i. e. pre-evacuated receptacle), or induced by the user immediately before a liquid specimen is taken

3.3
container
part of the receptacle without the closure, and without any accessory, that contains the specimen

NOTE Depending on the intended application, the part of the receptacle, without the closure, that contains a specimen, may also be known as a “tube”, “bottle”, “vial”, or similar name.

3.4
closure
component by which the container is closed

3.5
receptacle accessory
component inside the receptacle which is intended by the manufacturer to assist in the collection or mixing, or separation, of the specimen

EXAMPLE Sampling spoons intended for the collection of solid specimens.