Ühekordsed katsutid inimese veenivere proovide kogumiseks

Single-use containers for human venous blood specimen collection

EESTI STANDARDI EESSÕNA **NATIONAL FOREWORD**

Käesolev Eesti standard EVS-EN 14820:2004 sisaldab Euroopa standardi EN 14820:2004 ingliskeelset teksti. Käesolev dokument on jõustatud 23.11.2004 ja selle kohta on avaldatud teade Eesti standardiorganisatsiooni ametlikus väljaandes. Standard on kättesaadav Eesti standardiorganisatsioonist.	This Estonian standard EVS-EN 14820:2004 consists of the English text of the European standard EN 14820:2004. This document is endorsed on 23.11.2004 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 single-use receptacles, intended by their manufacturer, for the collection of venous blood specimens derived from the human body, for the purposes of in vitro diagnostic examination. This standard also applies to receptacles containing media for blood culture.	**Scope:** This standard specifies requirements and test methods for single-use receptacles, intended by their manufacturer, for the collection of venous blood specimens derived from the human body, for the purposes of in vitro diagnostic examination. This standard also applies to receptacles containing media for blood culture.

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Võtmesõnad:

EUROPEAN STANDARD

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English version

Single-use containers for human venous blood specimen collection

Récipients à usage unique pour prélèvements de sang veineux humain

Gefäße zur einmaligen Verwendung für die venöse Blutentnahme beim Menschen

This European Standard was approved by CEN on 27 May 2004.

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.

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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Foreword

This document (EN 14820:2004) 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 March 2005, and conflicting national standards shall be withdrawn at the latest by March 2005.

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.

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.

Introduction

This document provides requirements relevant to specimen receptacles for venous blood. Revision of ISO 6710:1995 was proposed by a number of countries, mainly in Europe, due to technical changes made in the manufacture of these receptacles. A number of countries strongly require colour coding of receptacles for their perceived safety of patients. Two well-established colour codes are in common use. Furthermore, it is suggested that bespoke colour coding of these products is an increasing trend. Any changes by manufacturers increase the cost of production and as a consequence the price of receptacles to users. It has not therefore been possible to make any agreed international recommendations on colour codes of receptacles and so this document has been prepared without a recommended colour codes as the only possible means of obtaining consensus by Standards bodies.

1 Scope

This document specifies requirements and test methods for single-use receptacles, intended by their manufacturer, for the collection of venous blood specimens derived from the human body, for the purposes of in vitro diagnostic examination. This document also applies to receptacles containing media for blood culture.

This document does not specify requirements for capillary blood specimen receptacles or arterial blood specimen receptacles. This document does not specify requirements and test methods for single-use receptacles intended for the collection of specimens, other than blood.

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.

EN 20594-1, *Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment - Part 1: General requirements (ISO 594-1:1986)*

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

3 Terms and definitions

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

3.1
additive
substance, other than surface treatments designed to be irremovable, that is placed inside the receptacle to facilitate the preservation of the specimen, or is intended to react with the specimen, in order to allow the intended analysis to be performed

3.2
blood collection system
all the components required for the collection of a specimen of blood

3.3
closing torque
twisting force, specified by the manufacturer, that is required to tighten a screw threaded closure sufficiently, by means of a torque wrench, to effect the sealing of a receptacle

3.4
closure
component by which the container is closed

3.5
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 blood specimen may also be known as a "tube", "bottle", "vial" or similar name.

3.6
draw volume
quantity of liquid specimen drawn into an evacuated receptacle