SLOVENSKI STANDARD

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Kontejnerji (epruvete s podtlakom) za zbiranje venske krvi ob enkratni uporabi

Single-use containers for human venous blood specimen collection

Gefäße zur einmaligen Verwendung für die venöse Blutentnahme beim Menschen

Récipients a usage unique pour prélevements de sang veineux humain

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

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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of an identical text or by endorsement, at the latest by March 2005, and conflicting national standards shall be withdrawn at the latest by March 2005.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

3.7
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

3.8
expiry date
date after which the receptacle shall not be used

3.9
filling capacity
volume of a liquid specimen needed to achieve the required additive to blood ratio

3.10
free space
extra capacity, or headspace, which is provided to allow adequate mixing of the contents of a receptacle

3.11
graduation mark
mark on a container, or its label, to enable an estimation to be made of the volume of the specimen

3.12
gravimetric analysis
method of determining the volume of a liquid by weighing and correcting for the mass density of the liquid

NOTE For the purposes of this document 1,000 ml of water is considered to have a mass equal to 1,000 g.

3.13
maximum fill line
mark on a container or its label, to indicate the maximum volume of specimen permitted to ensure that the in vitro diagnostic test for which the specimen is intended, will give accurate results

3.14
minimum fill line
mark on a container, or its label, to indicate the minimum volume of specimen required to ensure that the in vitro diagnostic test, for which the specimen is intended, will give accurate results

3.15
needle and holder assembly
device that is intended to be attached to an evacuated receptacle to enable venous puncture and subsequent blood collection to be performed

3.16
nominal liquid capacity
volume of specimen with which the receptacle is intended to be filled plus the volume of any additive

NOTE This volume is stated on the label and/or instructions for use.

3.17
nominal fill line
mark on a container, or its label, to indicate the nominal liquid capacity of a receptacle

3.18
primary pack
smallest pack of receptacles

3.19
receptacle
vessel, whether evacuated or not, intended to contain a specimen, together with any receptacle accessory and additive, with closure in place

3.20
receptacle accessory
component inside the receptacle which is intended by the manufacturer to assist in the collection, or mixing, or separation, of the specimen

NOTE Examples of receptacle accessories are small plastic inert balls or a separate gel found in a serum or plasma receptacle, designed to separate the serum or plasma from the cells after centrifugation.

3.21
receptacle interior
inside surface of the receptacle or closure and the surface of any receptacle accessory exposed to the specimen

3.22
specimen
biological material (e.g. venous blood) which is obtained in order to detect properties or to measure one or more properties

3.23
visual inspection
inspection by an observer with normal, or corrected-to-normal, vision without magnification, under a uniform illumination in the range from 300 lx to 750 lx

4 Materials

4.1 If a receptacle is intended to contain a specimen for a specific examination, where the material of the closure, or container, or the interior coating, or the additive, or accessory, if present, may affect the final results of the examination, then the maximum level of the contamination with that substance, and the analytical method employed, shall be stated by the manufacturer in accompanying literature, or on the label, or packaging (see also 11.3). Validation of the suitability of material with regard to a receptacle's specifically intended use is the responsibility of the manufacturer.

NOTE 1 This document does not specify a validation procedure for material suitability.

NOTE 2 For certain infrequently performed examinations, limits of interference may not have been determined and the user is recommended to consult the manufacturer.

NOTE 3 A container should be manufactured from a material which allows a clear view of its contents when subjected to visual inspection (see 3.22) unless exposure to ultra-violet light, or visible light would degrade the contents.

NOTE 4 If the container is not made of material that allows a clear view of the contents, the closure may be removed, to facilitate the examination of the contents.

4.2 When subjected to visual inspection the material of the receptacle shall be free from foreign matter.

4.3 Receptacles containing a microbe-supporting additive shall have been subjected to a validated process to eliminate microbial contamination from the additive and the receptacle interior. Validation of the process is the responsibility of the manufacturer.

NOTE For the validation and routine control of sterilization procedures see EN 550, EN 552 and EN 554.

5 Nominal liquid capacity

5.1 When tested in accordance with the methods specified in either Annex A or B, the volume of water added from, or drawn from, the burette, plus the volume of any additive present, shall be between 90% and 110 % of the nominal capacity.

5.2 For receptacles with an additive, provision shall be made for mixing by using the free space bubble to facilitate agitation, or by some other physical means.

5.3 Where free space is intended to facilitate mixing there shall be sufficient free space to allow mixing by mechanical or manual means.

5.4 The manufacturer shall validate that adequate mixing of the blood specimen, with any additive present, can be achieved.

NOTE This document does not specify a validation procedure for adequate mixing of the blood specimen.

6 Graduation and fill lines

Evacuated receptacles that have a fill line on the container, or container label, shall fill such that the meniscus of the liquid does not exceed or fall below the position of the line by more than 10% when tested in accordance with the method specified in Annex B.

When non-evacuated receptacles that have graduation marks are tested in accordance with methods specified in Annex A, the volume of the water shall be between 90% and 110% of the indicated volume.

NOTE see Annex A, A.3.6

7 Design

7.1 The closure shall not become loose when tested for leakage in accordance with the method specified in Annex C. The receptacle shall pass the test for leakage if no fluorescence is observed.

7.2 Where a closure is intended to be removed, to gain access to the contents of the receptacle, it shall be designed, as far as is reasonable and practical to do, so that it can be removed by gripping with the fingers, and/or by mechanical means, without that part of the closure which may become contaminated by contact with the specimen, being touched by the fingers, or the mechanical removal device.

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

7.3 When the receptacle is tested for leakage in accordance with the method specified in Annex C, no fluorescence shall be detectable in the water in which the receptacle has been immersed.

8 Construction

8.1 Receptacles shall withstand 4 cycles of removal and replacement of the closure in accordance with the manufacturers instructions, without breaks, collapse, cracks, or other visible damage, and when tested according to the Annexes A, B, C and D. Where the initial opening of the receptacle destroys the closure, these requirements shall apply to the subsequent closure.

NOTE 1 This requirement does not apply to tamper-evident seals.

NOTE 2 It has proved difficult to specify a single test procedure for robustness. The requirements specified above are intended to simulate the mechanical stress that occurs during the normal filling of the receptacle, storage, transportation and removal of the sample. Requirements for the transport of the specimen, in the receptacle, are given in UN 650 [6].

8.2 Receptacles intended for centrifugation shall withstand a minimum acceleration of $3000g_n$ (or the acceleration specified by the manufacturer), in their longitudinal axis without breaks, collapse, cracks, or other visible damage, and when tested according to Annex D.

8.3 When subjected to visual inspection the receptacle shall not have a sharp edge, projection or surface roughness capable of accidentally cutting, puncturing or abrading the skin, or gloves, of the user.

9 Sterility and special microbiological states

9.1 If a manufacturer claims that the interior of the unopened and unused receptacle, or the whole receptacle, is sterile, or has a special microbiological state, the container interior and any accessory or additive shall have been subjected to a validated process designed to achieve that claim.

NOTE For the validation and routine control of sterilization procedures see EN 550, EN 552 and EN 554.

9.2 Sterility is mandatory when, during blood collection, there is any possibility of direct contact between the receptacle interior and the patient's blood flow.

9.3 Sterility or an aseptic process or a validated special microbiological state (e. g. a diphasic culture media) is mandatory when the blood collection receptacle is intended for the culture of micro-organisms in blood and/or when the receptacle contains culture media.

10 Additives

10.1 The actual amount of additive, in each receptacle, shall be within the range specified by the manufacturer.

10.2 The maximum permitted tolerance interval of the specified volume of a liquid additive shall be from 90 % to 110 %. Validation of the choice of additive (including culture medium), its efficacy and its specified concentration range shall be the responsibility of the manufacturer

NOTE 1 The quantity of an additive in a receptacle should be determined, if appropriate, with a correction being made for the mass density of any liquid, by gravimetric analysis using a balance with an accuracy of 0,001 g.

NOTE 2 This document does not specify any test method for validation of the choice of additives.

NOTE 3 This document does not provide a list of culture media suitable for blood culture purposes.

NOTE 4 The Bibliography gives references that contain recommendations for additives [5, 7].

10.3 The manufacturer shall ensure that the physical form for the specified additive is suitable for its purpose.

10.4 The manufacturer shall ensure that the intended blood/additive ratio is obtainable throughout the shelf-life of the product.

11 Information supplied by the manufacturer

11.1 Each receptacle shall be accompanied by the information needed to use it properly, taking account of the training and knowledge of the potential user, and to identify the manufacturer. This information shall be set out on the receptacle itself, where space permits, and on any accompanying literature and/or on the primary pack.