SLOVENSKI STANDARD
oSIST prEN ISO 6710:2016

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Kontejnerji (epruvete s podtlakom) za zbiranje venske krvi ob enkratni uporabi (ISO/DIS 6710:2016)

Single-use containers for venous blood specimen collection (ISO/DIS 6710:2016)

Gefäße zur einmaligen Verwendung für die venöse Blutentnahme (ISO/DIS 6710:2016)

Récipients non réutilisables pour prélèvements de sang veineux (ISO/DIS 6710:2016)

Ta slovenski standard je istoveten z: **prEN ISO 6710**

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Single-use containers for venous blood specimen collection

Récipients non réutilisables pour prélèvements de sang veineux

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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.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

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. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the WTO principles in the Technical Barriers to Trade (TBT) see the following URL: Foreword - Supplementary information

The committee responsible for this document is ISO/76, Transfusion, infusion and injection, and blood processing equipment for medical and pharmaceutical use.

This second edition cancels and replaces the first edition (ISO 6710:1995), of which the following has been changed:

— Clause 'Terms and definitions" has been updated and extended;

— Clause "Capacity" has been shortened and renamed to "Draw volume";

— Clause "Design" has been updated;

— Clause "Sterility" has been technically revised and renamed to "Sterility and special microbiological states";

— Clause "Additives" has been extended;

— Clause "Marking and labelling" has been slightly updated to meet current general requirements (except local requirements);

— Table "Letter codes and recommended colour codes for identifying additives" in Clause "Container identification" has been extended by additional entries for additives. The Table has been reduced to the specified letter codes, while the information on recommended colour codes for identifying additives has been moved to a new informative Annex F (for clarification see Introduction);

— Tests in Normative Annexes A to D have been updated in alignment with the requirements in the body part of the standard;

— Annex E has been completely revised;

— Normative references and Bibliography have been updated.

Introduction

ISO 6710 was first published in 1995. With the first revision starting in 2000 the Vienna Agreement was applied to develop an updated edition of the standard in parallel between ISO and CEN.

However, in 2002 the parallel ballot on ISO/DIS 6710-2 respectively prEN ISO 6710 failed on ISO level. The ongoing development was continued only on European level and led finally to the publication of EN 14820:2004. Though, during the development no consensus could be reached between the CEN member states to add a specification for a common colour code for identifying containers with different additives.

The EU commission considered the absence of colour code specifications as potential security risk and submitted in 2006 the standardization mandate M/384 to CEN with the request to solve the issue. But even with this confirmed need it was not possible to find a consensus between the CEN members.

Based on a Swedish standardization proposal in 2014 this subject was raised again and led finally to the initiation of the revision of ISO 6710:1995. The Vienna Agreement was applied in order to revise as well EN 14820 with the final goal again to development an International Standard in parallel with a harmonized European Standard.

During the development it was recognized that recommendations for appropriate colour code specifications should be amended. In order to avoid further disputes on this subject it was decided to add these recommendations in an informative Annex F. This provides the potential users the possibility of a smooth implementation of the colour code identification without being under pressure to comply with the standard in this subject. This way of introducing a common colour code allows manufacturers and/or users in healthcare to grant an evaluation phase. If there will be a higher acceptance in the years after the publication of this International Standard, with the next revision there is the intention to possibly move the content of the informative Annex F 'Recommended colour codes for identifying additives' to the normative part of the standard.

Single-use containers for venous blood specimen collection

1 Scope

This International Standard specifies requirements and test methods for evacuated and non-evacuated single-use venous blood specimen containers.

It does not specify requirements for blood collection needles, needle holders, blood culture receptacles or "arterial" blood gas collection devices that may be used for venous blood.

In some countries, the national pharmacopoeia or other national regulations are legally binding and take precedence over this standard.

2 Normative references

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

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

ISO/IEC/DIS 80369-7:2013, *Small bore connectors for liquids and gases in healthcare applications — Part 7: Connectors with 6% (Luer) taper for intravascular or hypodermic applications*

3 Terms and definitions

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

3.1
accessory
component inside the container which is intended by the manufacturer to assist in the collection, or mixing, or separation of the specimen

Note 1 to entry: Examples of accessories are small plastic inert balls or a separate gel found in a serum or plasma container designed to separate the serum or plasma from the cells after centrifugation

3.2
additive
any substance (other than inside surface treatments designed to be irremovable) that is placed in the container in order to facilitate the creation of the desired sample

3.3
closure
component by which the container is sealed, which may consist of several parts

3.4
container
vessel, whether evacuated or not, intended to contain a specimen, together with any container accessory and additive, with closure in place

3.5
container interior
inside surface of the container or closure and the surface of any accessory exposed to the specimen

3.6
draw volume
volume of whole blood that will be collected in the container

3.7
evacuated container
container intended for blood collection by means of evacuation either already induced by the manufacturer (i.e. pre-evacuated containers) or induced by the user before or during blood collection

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

3.9
fill indication
line marked on a tube or its label to indicate the correct filling

3.10
free space
space above the drawn sample

3.11
nominal liquid capacity
draw volume plus volume of additive not including any accessories

3.12
primary colour
dominant colour of closure component most representative of the additive in the container

Note 1 to entry: Dominant is the colour of the closure that covers the majority of the surface.

3.13
primary pack
smallest package of containers

3.14
RCF
relative centrifugal force, the force that is generated during the sample centrifugation process, which is specified by the manufacturer for adequate separation

3.15
specimen
venous blood collected in a container

3.16
tube
part of the container, without the closure, that contains the specimen

3.17
visual inspection
inspection by an observer with normal or corrected-to-normal vision without magnification under a uniform illuminance between 500 lx and 1000 lx

4 Materials

4.1 The tube shall be made of material which allows a clear view of the contents when subjected to visual inspection, unless exposure to ultra violet light or visible light would degrade the contents.

4.2 If a container is intended specifically for the determination of a certain element/substance, the maximum level of the element/substance in the container interior and the analytical method employed shall be stated by the manufacturer in accompanying literature or on the label or packaging (see also 10.4).

For the determination of specified metals and other specified substances, the formulation of the closure material should be such as not to interfere with the determination thereby affecting the results.

For highly sensitive determinations (for example those using fluorimetry) or little-used tests, limits of interference may not have been agreed on. In such cases the laboratory should establish a blank value and consult the manufacturer.

4.3 The container shall be free from foreign matter when subjected to visual inspection.

5 Draw volume

When tested in accordance with the methods specified in Annexes A and B, the volume of water should be within ± 10 % of the draw volume. If the ± 10 % of draw volume is not met throughout the shelf life, the manufacturer has to assure that correct results shall be obtained.

6 Design

6.1 The closure shall not become loose during mixing when tested for leakage in accordance with the methods specified in Annex C or other equivalent method and no fluorescence shall be detectable in the water in which the container has been immersed.

6.2 Where a closure is intended to be removed to gain access to the contents of the container, it shall be designed so that it can be removed by gripping with the fingers and/or by mechanical means without that part of the closure which may be contaminated by contact with the specimen being touched by the fingers.

6.3 Consideration in the design shall be given to ensure compatibility with transportation systems, processes, pre-analytical and analytical automation.

7 Construction

7.1 The container holding the specimen, when centrifuged, shall withstand an acceleration at a RCF minimum of 3 000 g , or the value specified by the manufacturer for the intended use, when tested in accordance with the method specified in Annex D.

NOTE $g_n = 9{,}806\ 65\ m/s^2$

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

8 Sterility and special microbiological states

8.1 The interior of the evacuated container shall be sterile if unused.

8.2 If a manufacturer claims that the interior of the unopened and unused container, or the whole container, 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.