
Single-use containers for human venous blood specimen collection

Récipients non réutilisables pour prélèvements de sang veineux humain

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Contents

Page

Foreword	iv
Introduction	vi
1 Scope	1
2 Normative references	1
3 Terms and definitions	1
4 Materials	2
5 Draw volume	3
6 Design	3
7 Construction	3
8 Sterility and special microbiological states	3
9 Additives	4
10 Marking and labelling	4
11 Container identification	5
Annex A (normative) Draw volume test for non-evacuated containers	6
Annex B (normative) Draw volume test for evacuated containers	7
Annex C (normative) Test for leakage of container	9
Annex D (normative) Test for robustness of the container	11
Annex E (normative) Concentrations of additives and volume of liquid additives	12
Annex F (informative) Recommended colour codes for identifying additives and accessories	14
Bibliography	15

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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 voluntary nature of standards, the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 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), which has been technically revised.

The main changes compared to the previous edition are as follows:

- the Scope has been updated and phrased clearer. Blood culture bottles have been excluded from this document, as it does not address the special needs for this kind of testing;
- [Clause 3](#) has been updated and extended;
- [Clause 4](#) has been updated;
- [Clause 5](#) has been shortened and renamed to “Draw volume”;
- [Clause 6](#) has been updated;
- [Clause 8](#) has been technically revised and renamed to “Sterility and special microbiological states”;
- [Clause 9](#) has been extended;
- [Clause 10](#) has been slightly updated to meet current general requirements (except local requirements);
- [Table 1](#) has been extended by additional entries for additives. It has been reduced to the specified letter codes, while the information on recommended colour codes for identifying additives has been moved to a new [Annex F](#) (for clarification, see Introduction);
- tests in [Annexes A](#) to [D](#) have been updated in alignment with the requirements in the body of this document;
- [Annex E](#) has been completely revised;

— references in [Clause 2](#) and Bibliography have been updated.

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Introduction

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

However, in 2002 the parallel ballot on ISO 6710, 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. Although, 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 safety 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 14820:2004 with the final goal again to develop an International Standard in parallel with a harmonized European Standard.

During the development, it was recognized that at least 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 [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 this document 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 after the publication of this document, with the next revision there is the intention to possibly move the content of [Annex F](#) to the normative part of this document.

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

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Single-use containers for human venous blood specimen collection

1 Scope

This document 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 can be used for venous blood.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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.

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

3 Terms and definitions

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

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at <http://www.electropedia.org/>

— ISO Online browsing platform: available at <http://www.iso.org/obp>

3.1

accessory

component inside the *container* (3.4) which is intended by the manufacturer to assist in the collection, or mixing, or separation of the *specimen* (3.15)

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

substance (other than inside surface treatments designed to be irremovable) that is placed in the *container* (3.4) in order to facilitate the creation of the desired sample

3.3

closure

component by which the *container* (3.4) is sealed, which may consist of several parts

3.4

container

vessel, whether evacuated or not, intended to contain a *specimen* (3.15), together with any container *accessory* (3.1) and *additive* (3.2), with *closure* (3.3) in place

3.5

container interior

inner surface of the *container* (3.4) exposed to the *specimen* (3.15)

3.6

draw volume

volume of whole blood that will be collected in the *container* (3.4)

3.7

evacuated container

container (3.4) 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 indicator

line marked on a *tube* (3.16) or its label to indicate the correct filling

3.10

free space

space above the drawn sample

3.11

nominal liquid capacity

draw volume (3.6) plus volume of *additive* (3.2) not including any accessories

3.12

primary colour

dominant colour of *closure* (3.3) component most representative of the *additive* (3.2) in the *container* (3.4)

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* (3.4)

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relative centrifugal force

RCF

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* (3.4)

3.16

tube

part of the *container* (3.4), without the *closure* (3.3), that contains the *specimen* (3.15)

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 1 000 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 ultraviolet 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 supporting 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 $\pm 10\%$ of the draw volume. If $\pm 10\%$ of draw volume is not met throughout the shelf life, the manufacturer shall ensure 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, it shall be designed so that it can be removed by gripping with the fingers and/or by mechanical means, so that the part of the closure that could be in contact with the specimen is not touched.

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 shall not break, crack or leak, when centrifuged at an RCF 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 $g = 9,806\ 65\ \text{m/s}^2$.

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 For evacuated containers, the interior shall be sterile if unused. The container interior and any accessory or additive shall be subjected to a validated process designed to achieve sterility.

8.2 For non-evacuated containers, 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 be subjected to a validated process designed to achieve that claim.

8.3 For non-evacuated containers with microbe-supporting additives, such as trisodium citrate or citrate phosphate dextrose adenine, solution shall be subjected to a validated process to remove or to render non-viable microbes in the additive and the container interior.

9 Additives

9.1 The stated nominal amount of additive shall be within the range specified in [Annex E](#).

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

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

9.3 The free space in containers for coagulation testing should not impact the analytical results. The manufacturer should assess the risk associated with the free space in the correctly filled containers.

10 Marking and labelling

10.1 Non-transparent labels shall not completely encircle the tubes.

10.2 The marking and labelling on the container shall remain adherent over its shelf life, under storing conditions as specified by the manufacturer.

10.3 Each primary pack shall be marked on the outside at least with the following information:

- a) the manufacturer's or supplier's name or trademark;
- b) the batch number;
- c) the expiry date which should be expressed in the format YYYY-MM or YYYY-MM-DD;
- d) a description of the contents, which shall include the following:
 - the nominal liquid capacity or draw volume;
 - the letter code (see [Clause 11](#)) and/or product name and/or a description of the contents;
 - the word "STERILE" or the appropriate graphical symbol according to ISO 15223-1 if the manufacturer claims that the unopened container interior and any contents of the container are sterile;
 - the words "Single-use only" or the appropriate graphical symbol according to ISO 15223-1;
 - storage requirements;
 - labelling requirements from the local legislation.

10.4 If a container is provided specifically for the determination of a certain substance, the maximum level of contamination with that substance shall be stated on the label, the primary pack or in the supporting information.

10.5 If a container has a liquid additive, its volume shall be stated on the label, the primary pack or in the supporting information.

10.6 Containers shall have the following information marked directly onto the tube or on the label:

- a) the manufacturer's or supplier's name or trademark;