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Single-use containers for human venous blood specimen collection

Récipients non réutilisables pour prélèvements de sang veineux humain

Reference number
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Foreword

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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).

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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.

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.

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)

3.14
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 ±10 % of the draw volume. If ±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 $g = 9{,}806\ 65\ m/s^2$.

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;

b) the batch number;

c) the letter code (see Clause 11) and/or product name and/or a description of the contents;

d) the expiry date which should be expressed in the format YYYY-MM or YYYY-MM-DD;

e) the nominal liquid capacity or draw volume, specified where appropriate on the container;

f) the words “Single-use only” or the appropriate graphical symbol according to ISO 15223-1;

g) a fill indicator; if that is not possible, information on how to fill the container correctly shall be provided on the primary pack or in the supporting literature;

h) the word “STERILE” or the appropriate graphical symbol according to ISO 15223-1 if the manufacturer claims that the unopened and unused container interior and any contents of the container are sterile.

10.7 If the container is intended to be stored, or used, under specific conditions, this shall be clearly stated on the container or on the label and/or on the supporting literature in the primary pack.

11 Container identification

Containers shall be identified by means of the letter code and/or a description of the contents for the additives and accessories given in Table 1 and/or product name. Where there are additives and accessories other than those in Table 1, containers shall be identified by means of the description of the additive and/or product name.

Recommended colour codes for identifying additives and accessories are provided in Annex F (for more details, see also Introduction).

Table 1 — Letter codes for identifying additives and accessories

Additive/Accessory	Letter code
EDTA[a] dipotassium salt tripotassium salt	K2E K3E
Trisodium citrate 9:1[b]	9NC
Trisodium citrate 4:1[b]	4NC
Fluoride oxalate Fluoride EDTA Fluoride heparin Fluoride, citric acid	FX FE FH FC
Lithium heparin Lithium heparin and gel Sodium heparin	LH LH NH
Citrate phosphate dextrose adenine Acid citrate dextrose	CPDA ACD
Clot activator Clot activator with gel	CAT CAT
None	Z

[a] EDTA is the abbreviation for ethylenediaminetetraacetic acid which by established custom is used in preference to the correct systematic name, i.e. (ethylenedinitrilo)tetraacetic acid.

[b] Denotes the ratio between the intended volumes of blood and liquid anticoagulant (e.g. 9 volumes of blood to 1 volume of citrate solution).

Annex A
(normative)

Draw volume test for non-evacuated containers

A.1 Reagents and apparatus

A.1.1 **Deionized water**.

A.1.2 **Calibrated electronic balance**, accurate to a minimum of three decimal places, 0,001 g.

A.1.3 **Device**, to hold the test container vertically in the correct orientation on the balance.

A.1.4 **Vessel**, to enable dispensing of water into the test container, e.g. syringe, pipette.

A.2 Test conditions

A.2.1 The tests shall be carried out in ambient conditions of 101 kPa and 20 °C; make corrections if other conditions are used.

A.2.2 The containers to be tested shall be unused.

A.3 Test procedure

A.3.1 Fill the vessel with the deionized water.

A.3.2 Place the container onto the balance and tare (zero).

A.3.3 Position the test container with closure removed and fill with water until the meniscus is level with the fill indicator.

A.3.4 Place the test container on the previously tared balance and read the weight in grams.

A.3.5 Calculate the fill volume 1 000 g = 1 000 mL.

A.4 Test criteria

The container shall pass the draw volume test as specified in Clause 5.

Annex B
(normative)

Draw volume test for evacuated containers

B.1 Reagents and apparatus

B.1.1 **Deionized water**.

B.1.2 **Calibrated electronic balance**, accurate to a minimum of three decimal places, 0,001 g.

B.1.3 **Device**, to hold the test container vertically in the correct orientation on the balance.

B.1.4 **Reservoir**, with spout at its base to enable connection to the tubing.

B.1.5 **Tubing**, that can be pierced with a blood collection needle, fitted with a spring clip at one end and attached to the reservoir at the other end (see Figure B.1).

B.1.6 **Blood collection needles**, as recommended by the manufacturer of the test container.

B.1.7 **Holder**, as recommended by the manufacturer of the test container.

B.2 Test conditions

B.2.1 The tests shall be carried out in ambient conditions of 101 kPa and 20 °C; make corrections if other conditions are used.

B.2.2 The container to be tested shall be unused.

B.3 Test procedure

B.3.1 Assemble the reservoir to the tubing, tighten the spring clip on end of the tubing.

B.3.2 Fill the reservoir with the water.

B.3.3 Bleed the water through the spring clip to fill the tubing.

B.3.4 If not supplied ready-assembled, fit the blood collection needle into the holder in accordance with the manufacturer's instructions.

B.3.5 Place the test container on to the balance and tare (zero).

B.3.6 Insert the intravenous needle of the blood collection needle/holder assembly through the wall of the tubing until the needle is well inside the lumen of the tubing.

B.3.7 Connect the test container to the needle/holder assembly in accordance with the manufacturer's instructions.

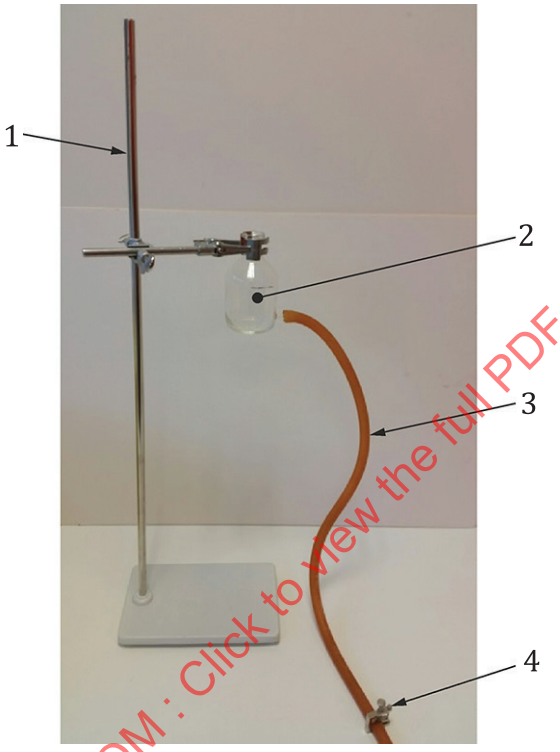
B.3.8 Allow the test container to fill for at least 1 min or fill as specified by the manufacturer.

B.3.9 Place the test container on the previously tared balance and read the weight in grams.

B.3.10 Calculate the fill volume 1 000 g = 1 000 mL.

B.4 Test criteria

The container shall pass the draw volume test as specified in Clause 5.



Key

1 clamps stand
2 water reservoir
3 tubing
4 spring clip

Figure B.1 — Water reservoir assembly for draw volume test for evacuated containers

Annex C
(normative)

Test for leakage of container

C.1 Reagents

C.1.1 Solution, prepared by dissolving 2,5 g of sodium fluorescein (uranine; CAS number 518-47-81)[1)] in 100 mL of 0,15 mol/l sodium chloride (NaCl; CAS number 7647-14-5) solution containing 60 g/l Dextran 70 (CAS number 9004-54-0) or equivalent.

C.1.2 Deionized water that shows no sign of fluorescence when viewed under ultraviolet light (C.2.2) in a darkened room by an observer with normal or corrected-to-normal vision without magnification.

C.2 Apparatus

C.2.1 Apparatus, to fill non-evacuated containers as described in A.1.4, **apparatus** to fill evacuated containers as described in B.1.3 to B.1.7.

C.2.2 Long-wave ultraviolet light (UV) source.

C.2.3 Roller-type mixer or other mixer recommended by the manufacturer of the container.

C.2.4 Torque wrench (where necessary).

C.3 Test procedure for non-evacuated container

C.3.1 Fill the vessel with the reagent (C.1.1).

C.3.2 Remove the closure from the container and fill it to its nominal liquid capacity from the vessel, taking care not to contaminate the outside of the tube or closure with the reagent. Fit the closure exactly as specified by the manufacturer.

C.3.3 With normal or corrected-to-normal vision without magnification, examine the container in a darkened room to ensure that there is no surface contamination with the reagent. If necessary, wash off contamination with water, examining under UV light as before.

C.3.4 Rotate the container on the roller-type mixer for 2 min or mix as recommended by the manufacturer of the container. Immerse the container upside down in a tank containing not more than 100 mL of the water to cover the closure completely. Leave at between 15 °C and 20 °C for 60 min. Remove the container from the water and examine the water under UV light as described in C.3.3.

C.4 Test procedure for evacuated container

C.4.1 Fill the reservoir with the reagent (C.1.1).

1) CAS number means Chemical Abstracts Service Registry Number.

C.4.2 Fill the container to its nominal liquid capacity from the reservoir fitted with the blood collection needle as described in B.3, taking care not to contaminate the outside of the container with the reagent. When the container has been filled, remove it from the needle and wash the outside of the container free of any contamination with the reagent, examining under UV light as described in C.3.3.

C.4.3 Follow the procedure described in C.3.4.

C.5 Test criteria

The container shall pass the test as specified in 6.1.

Annex D
(normative)

Test for robustness of the container

D.1 Reagents and apparatus

D.1.1 **A test liquid**, having the same specific gravity as normal human blood.

D.1.2 **Blood sample container.**

D.1.3 **Centrifuge**, capable of subjecting the base of the container to an RCF of 3 000 *g* for 10 min.

D.2 Test procedure

D.2.1 Fill the container with the test liquid using the method specified by the manufacturer, removing and replacing the closure where necessary (see Annex A and B for more details).

D.2.2 Take care to ensure that the container is correctly supported and adequately balanced in the centrifuge bucket.

D.2.3 Centrifuge the filled container, subjecting the base of it to an RCF of 3 000 *g* for 10 min, then carefully place in a rack and subject to visual inspection.

D.3 Test criteria

The material shall pass the test as specified in 7.1.