INTERNATIONAL STANDARD

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Single-use containers for venous blood specimen collection

Récipients non réutilisables pour prélèvements de sang veineux

Reference number
ISO 6710:1995(E)

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.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 6710 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection equipment for medical use*.

Annexes A, B, C, D and E form an integral part of this International Standard. Annex F is for information only.

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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 or needle holders.

NOTE 1 This International Standard replaces the requirements for non-evacuated containers previously specified in ISO 4822, *Single use blood specimen containers up to 25 ml capacity*, which has been withdrawn.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

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

ISO 3696:1987, *Water for analytical laboratory use — Specification and test methods.*

ISO 7000:1989, *Graphical symbols for use on equipment — Index and synopsis.*

3 Definitions

For the purposes of this International Standard, the following definitions apply.

3.1 container: Vessel to contain a blood specimen, with closure in place.

3.2 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 blood is taken.

3.3 tube: That part of the container, without the closure, that contains the specimen.

3.4 closure: Component by which the container is closed.

3.5 primary pack: Smallest package of containers.

3.6 container interior: Inside surface of the container.

3.7 additive: Any substance (other than inside surface treatments designed to be irremovable) that is placed in the container in order to allow the intended analysis to be performed.

3.8 nominal capacity: Volume of whole blood with which the container is intended to be filled.

3.9 free space: Extra capacity, or head space, which is provided to allow adequate mixing of the contents of a container, as determined by the minimum free space tests laid down in annexes A and B.

3.10 fill line: Line marked on a tube or its label to indicate the nominal capacity of a container.

3.11 draw volume: Nominal capacity of an evacuated container.

3.12 expiry date: Date after which the manufacturer does not claim that a container complies with the requirements of this International Standard.

3.13 closing torque: Twisting force, specified by the manufacturer, that is required to tighten a closure sufficiently by means of a torque wrench to effect the sealing of a container.

3.14 visual inspection: Inspection by an observer with normal or corrected-to-normal vision without magnification under a uniform illuminance between 300 lx and 750 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.

It is recommended that the inner surfaces of glass tubes intended to receive specimens for blood coagulation studies should not allow contact activation (see [1]).

4.2 If a container is intended specifically for the determination of a certain substance, the maximum level of container interior 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 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.

NOTE 2 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 user is recommended to consult the manufacturer.

4.3 Containers with microbe-supporting additives such as trisodium citrate or citrate phosphate dextrose adenine solution shall have been subjected to a validated process to eliminate microbial contamination from the additive and the container interior.

NOTE 3 Validation of the process is the responsibility of the manufacturer. This International Standard does not specify a validation procedure but International Standards on this subject are being prepared.

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

5 Capacity

5.1 When tested in accordance with the methods specified in annexes A and B, the volume of water added from or drawn from the burette shall be within ± 10 % of the nominal capacity.

5.2 For containers with an additive, there shall be sufficient free space, when tested in accordance with the methods specified in annexes A and B, to allow adequate mixing by mechanical or manual means. The minimum free space shall be as specified in table 1. Allowance shall be made for the fact that the available free space for mixing the contents of a container is bounded by the underside of the closure and the liquid meniscus.

Table 1 — Minimum free space to enable adequate mixing

Nominal capacity of container	Minimum free space requirement
⩾ 0,5 ml and < 5 ml	+ 25 % of nominal capacity
⩾ 5 ml	+ 15 % of nominal capacity

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.

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.

NOTE 4 Some instrumentation, e.g. blood cell counters, is designed to enable aspiration of the contents of a blood specimen container without the need to remove the closure.

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

7 Construction

7.1 The container holding the specimen, when centrifuged, shall withstand an acceleration of 3 000*g* in a longitudinal axis when tested in accordance with the method specified in annex D.

NOTE 5 $g_n = 9{,}806\ 65\ m/s^2$

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

8.1 If a manufacturer claims that a product is sterile, the container interior and any contents shall have been subjected to a validated process designed to ensure that the unopened and unused container interior and any contents of the container are sterile.

NOTE 6 Validation of the efficacy of the process is the responsibility of the manufacturer. This International Standard does not specify a validation procedure but International Standards on methods of controlling and validating sterilization processes are being prepared. In the absence of International Standards, it is recommended that reference should be made to any national requirements that exist. Where no national requirements exist, reference should be made to the current European Pharmacopoeia, the current United States Pharmacopoeia or the current British Pharmacopoeia.

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

9 Additives

9.1 The stated nominal amount of additive shall be within the range specified in annex E.

NOTE 7 With one exception (see 9.2), assay methods are not specified. Flame photometric assays are recommended where additives contain sodium, potassium or lithium. It is important that assays are carried out with an accuracy commensurate with the limit of error implied in annex E. If the assay method used is non-specific, e.g. flame photometry for sodium and potassium salts of EDTA, it is recommended that an identification test be carried out.

9.2 The volume of a liquid additive in a container shall be determined gravimetrically with a correction being made for the specific gravity of the liquid.

10 Marking and labelling

10.1 Labels shall not completely encircle the tubes.

10.2 The marking and labelling on the container shall remain adherent after exposure in air at (4 ± 1) °C for not less than 48 h.

NOTE 8 This subclause specifies the requirement for products under normal conditions. However, when products are stored or used under extreme conditions (e.g. extreme temperature or humidity, or abnormal transportation or storage for long periods) the requirement may be inadequate. A manufacturer is responsible for a claim that a product is suitable for storage or use under extreme or abnormal conditions.

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

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

b) the batch number;

c) the expiry date;

d) a description of the contents, which shall include

— the nominal capacity,

— all tube coatings (e.g. non-contact activation) or additives,

— the name of any additive or its formulation and/or the letter code as given in table 2,

— the word "sterile" if the manufacturer claims that the unopened container interior and any contents of the container are sterile,

— the words "single-use only" or the graphical symbol according to ISO 7000-1051,

— storage requirements.

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 or the primary pack.

10.5 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 a description of the contents;

d) the expiry date;

e) the nominal capacity;

f) a fill line where necessary, i.e., for non-evacuated containers;

g) the word "sterile" if the manufacturer claims that the unopened and unused container interior and any contents of the container are sterile.

If glycerol is used in the manufacture of a container, this should be stated on the label and on the packaging.

11 Container identification

Containers shall be identified by means of the letter code and/or a description for the additives given in table 2. Where there are additives other than those in table 2, containers shall be identified by means of the description of the additive.

NOTES

9 At present there is no international agreement on colour coding.

10 If colour coding is also used, the colours in table 2 are recommended.

11 If colour coding is also used, it is recommended that the colour of the closure is similar to that on the tube or label.

Table 2 — Letter codes and recommended colour codes for identifying additives

Additive		Letter code	Recommended colour code
EDTA[1]	dipotassium salt	K2E	Lavender
	tripotassium salt	K3E	Lavender
	disodium salt	N2E	Lavender
Trisodium citrate	9:1[2]	9NC	Light blue
Trisodium citrate	4:1[2]	4NC	Black
Fluoride/oxalate		FX	Grey
Fluoride/EDTA		FE	Grey
Fluoride/heparin		FH	Green
Lithium heparin		LH	Green
Sodium heparin		NH	Green
Citrate phosphate dextrose adenine		CPDA	Yellow
None[3]		Z	Red

1) 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.

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

3) It is recommended that containers with a blood-clotting accelerator may be coded with the letter code Z and have a red colour code, together with a description of the additive.

Annex A
(normative)

Nominal capacity and minimum free space tests for non-evacuated containers

A.1 Reagents and apparatus

A.1.1 Water, complying with ISO 3696, at 20 °C to 25 °C.

A.1.2 Burette, 50 ml capacity, graduated in 0,1 ml increments (accurate to ± 0,1 ml) with a tap at the bottom or side.

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 Close the tap of the burette and fill it with water.

A.3.2 Position containers with closures removed under the delivery jet of the burette and carefully run in the water until the meniscus is level with the fill line, then close the tap.

A.3.3 Read off the volume of water delivered by the burette.

A.3.4 Continue running in water from the burette until it is level with the mouth of the tube and read off the volume delivered to an accuracy of ± 0,1 ml.

A.4 Test criteria

A.4.1 The container shall pass the nominal capacity test if the volume of water delivered is within ± 10 % of the nominal capacity.

A.4.2 The container shall pass the minimum free space test, if, after making allowance for the fact that the available free space for mixing the contents of a container is bounded by the underside of the closure and the liquid meniscus, the available free space is not less than that specified in table 1 for the type of container tested.

NOTE 12 Closures vary in design and in particular the blood contact side of plug-in types may extend appreciably beyond the mouth of the tube, be bifurcated or have a pronounced concave or convex profile. The effect of such features may influence the available free space for which allowance will have to be made when interpreting test results. Where necessary, the effect of closure geometry can be determined by measurement, for example of the length of the plug part of the closure, or of the extra volume provided by a concave feature.

Annex B
(normative)

Tests for draw volume and minimum free space for evacuated containers

B.1 Reagents and apparatus

B.1.1 Water, complying with ISO 3696, at 20 °C to 25 °C.

B.1.2 Burette, 50 ml capacity, graduated in 0,1 ml increments (accurate to ± 0,1 ml) with a tap at the bottom or side.

B.1.3 Clear silicone rubber tubing (short length) fitted with a **spring clip** at one end and attached to the burette tap at the other end.

B.1.4 Blood collection needles as recommended by the manufacturer of the specimen container.

B.1.5 Holder as recommended by the manufacturer of the specimen container.

B.2 Draw volume test

B.2.1 Test conditions

B.2.1.1 The tests shall be carried out in ambient conditions of 101 kPa and 20 °C; make corrections if other conditions are used.

B.2.1.2 The container to be tested shall be unused.

B.2.2 Test procedure

B.2.2.1 Assemble the product, if not supplied ready-assembled, and fit the blood collection needle into the holder in accordance with the manufacturer's instructions.

B.2.2.2 Fill the burette with the water, open the burette tap and bleed through the spring clip to fill the silicone rubber tubing; zero the burette.

B.2.2.3 Insert the outer needle of the blood collection needle/holder assembly through the wall of the silicone tubing until the needle is well inside the lumen of the silicone tubing.

B.2.2.4 Connect the container to the needle/holder assembly in accordance with the manufacturer's instructions.

B.2.2.5 Allow the container to fill for at least 1 min or fill as specified by the manufacturer.

B.2.2.6 Level the meniscus and read off the draw volume with an accuracy of ± 0,1 ml by reference to the meniscus height in the burette.

B.2.3 Test criteria

The container shall pass the test if the volume of water drawn is within ± 10 % of the nominal capacity.

B.3 Minimum free space test

B.3.1 Test conditions

B.3.1.1 Carry out the tests in ambient conditions of 101 kPa and 20 °C; make corrections if other conditions are used.

B.3.1.2 The containers to be tested shall be unused.

B.3.2 Test procedure

B.3.2.1 Remove the silicone tubing from the delivery jet of the burette with the tap closed and top up the burette with the water as necessary.

B.3.2.2 Position a tube with closure removed under the delivery jet of the burette.

B.3.2.3 Run in water until it is level with the mouth of the tube.

B.3.2.4 Read off the volume of water delivered to an accuracy of ± 0,1 ml.

Determine the minimum free space by subtracting the volume of water drawn in the draw volume test (see B.2) from the volume of water delivered from the burette.

B.3.3 Test criteria

The container shall pass the test if, after making allowance for the fact that the available free space for mixing the contents of a container is bounded by the underside of the closure and the liquid meniscus, the available free space is not less than that specified in table 1 for the type of container tested.

NOTE 13 Closures vary in design and in particular the blood contact side of plug-in types may extend appreciably beyond the mouth of the tube, be bifurcated or have a pronounced concave or convex profile. The effect of such features may influence the available free space for which allowance will have to be made when interpreting test results. Where necessary, the effect of closure geometry can be determined by measurement, for example of the length of the plug part of the closure, or of the extra volume provided by a concave feature.