International Standard 4822

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Single use blood specimen containers up to 25 ml capacity

Récipients non réutilisables pour échantillons de sang jusqu'à 25 ml de capacité

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Descriptors : containers, plastic products, glass packages, equipment for single use, blood, blood transfusion, specifications, capacity, coding, marking, labelling.

Foreword

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Draft International Standards adopted by the technical committees are circulated to the member bodies for approval before their acceptance as International Standards by the ISO Council.

International Standard ISO 4822 was developed by Technical Committee ISO/TC 76, *Transfusion equipment for medical use*, and was circulated to the member bodies in September 1979.

It has been approved by the member bodies of the following countries :

Australia	Ireland	South Africa, Rep. of
Austria	Italy	Switzerland
Chile	Libyan Arab Jamahiriya	USA
Denmark	Mexico	USSR
Germany, F.R.	Netherlands	
India	Romania	

The member bodies of the following countries expressed disapproval of the document on technical grounds :

France
United Kingdom

Printed in Switzerland

Single use blood specimen containers up to 25 ml capacity

1 Scope and field of application

This International Standard specifies requirements for single use blood specimen containers with closures for sizes from 0,5 to 25 ml nominal capacity inclusive intended primarily for use in collection of blood for haematological, biochemical and serological tests.

It also specifies a system of letter coding to identify any additive in the containers and a labelling system for the containers.

Blood collection devices in which the specimen is collected directly into the container are outside the scope of this International Standard.

2 Definitions

For the purpose of this International Standard the following definitions apply :

2.1 container : The vessel to contain the specimen.

2.2 closure : The component by which the container is closed.

2.3 liner : A wad inside the closure to ensure a leak-proof seal.

2.4 complete (specimen) container : The container closed with its closure and liner, if used.

2.5 sterile : Describes the condition of the interior of the complete container which has been subjected to an approved sterilizing process.

3 Material, sizes, design and construction

3.1 Material

3.1.1 The container shall be made from glass or plastics material and shall be sufficiently transparent to allow a clear view of the contents.

3.1.2 The complete container may be supplied sterile by the manufacturer, the method of sterilization being subject to approval by the relevant national regulatory authority.

3.1.3 Closures, if ferrous, shall have a corrosion-resistant finish and shall show no signs of corrosion after being subjected to the treatment described in annex C.

3.1.4 The complete container shall not influence, by contamination or other means, the results of the investigation for which the contents are intended.

3.2 Sizes

3.2.1 This International Standard refers to container sizes ranging from 0,5 to 25 ml nominal capacity inclusive.

3.2.2 In order to fit into commonly used centrifuge buckets, containers designed for use in the small bucket shall not exceed 17 mm external diameter and those designed for use in the large bucket shall not exceed 29 mm external diameter. These maximum external diameters apply to the body of the container excluding the thread.

NOTE — If the container and contents are to be centrifuged in an angle centrifuge, care should be taken that the volume of the specimen is such that it will not be forced against the cap during rotation. This precaution should be taken irrespective of the nominal size of the container.

3.2.3 The brimful capacity of a container shall be as given in table 1.

Table 1 — Brimful capacity

Nominal capacity	Minimum brimful capacity
ml	ml
0,5 to 5 ml	Nominal capacity + 25 %
Greater than 5 ml up to and including 10 ml	Nominal capacity + 20 %
Greater than 10 ml	Nominal capacity + 15 %

3.3 Design

3.3.1 When the closed container is tested in accordance with the method specified in annex A there shall be no trace of leakage as defined in annex A.

3.3.2 The closure shall have a minimum finger gripping surface of 9 mm in depth.

3.3.3 The liner, if used, shall remain in position in the closure during normal use, including centrifuging.

3.4 Fabrication

3.4.1 The complete container holding the specimen, when centrifuged, shall be capable of withstanding an acceleration of 3 000 g_n[1] in a longitudinal axis for 10 min without breakage or visible leakage.

NOTE — Care is required to ensure that the container is correctly supported and adequately balanced in the centrifuge bucket.

3.4.2 The container shall have a smooth internal surface.

3.4.3 Neither container nor closure shall have a sharp edge, projection or roughness on the surface capable of accidentally cutting, puncturing or abrading the skin of the user.

3.5 Limits of interfering substances

Where containers are provided for the estimation of specific substances i.e. sodium, potassium, etc. they may be labelled as being free from contamination if they give a concentration of that substance which is less than 1 % of the level of the mean of the reference range for that substance.

Testing for contaminants shall be carried out by means of a definitive or reference method where such a method is available. If there is no available definitive or reference method then a method in common usage may be used provided that the method is specified.

4 Labelling marking and coding

4.1 Labelling

4.1.1 Containers may be supplied with or without labels. If labels are supplied, these may be plain or printed.

4.1.2 A printed label or container otherwise marked, shall meet the requirements of 4.1.3 and 4.2.

4.1.3 If a label is provided there shall be a gap of at least 5 mm on the circumference of the container and a gap of at least 4 mm at the top end of the container below the lower edge of the closure or of the shoulder, if any, of the container. The label shall be clear of the base of the container.

4.1.4 Sterile containers shall be marked accordingly.

4.2 Marking

4.2.1 If an anticoagulant is used the concentration as specified in annex B and an open date of manufacture or expiry date shall be marked on the label or tube.

4.2.2 If the container is intended for collection of blood into an anticoagulant, the required amount of blood shall be indicated by a distinct continuous or broken line on the label at right angles to the long axis of the container and extending to both edges of the label, or by a similar line marked directly on the container.

4.2.2.1 The top edge of the line indicating the level of the blood specimen shall be within ± 1 mm of the true position. (See 4.2.2.)

4.2.2.2 The calibration significance of this line shall be clearly marked on the label by adding after the letters for the anticoagulant code, an oblique stroke and a number indicating the volume of blood in millilitres.

4.3 Anticoagulant code

4.3.1 The following code indicates whether or not an anticoagulant has been used, and identifies the anticoagulant by the use of a letter coding :

Table 2 — Anticoagulant code

Anticoagulant	Code
EDTA Potassium salt Lithium salt Sodium salt	KE LE NE
Potassium oxalate	KX
Trisodium citrate (*figures denote ratio* between blood and anticoagulant)	9 NC 4 NC
Fluoride oxalate	FX
Ammonium and potassium oxalate	AKX
Lithium heparin Sodium heparin	LH NH
ACD	ACD
None	Z

NOTE — Because of the amount of printing required on the container labels, the anticoagulant identification letters have been kept to a minimum and for this reason the chemical formulae have not been used.

1) g_n = 9,806 65 m/s^2

Annex A

Test for leakage of a complete container

A.1 Reagent

Dissolve 2,5 g of *di*-sodium fluorescein (uranine) in 60 g/l dextran 70 in 0,15 mol/l saline solution, and make up to 100 ml.

A.2 Apparatus

A source of longwave ultra-violet light and a torque wrench or meter.

A.3 Procedure

Pipette carefully into the bottom of the container, taking care not to contaminate the rim or any of the external surfaces, sufficient reagent to cover the closured section of the complete container when it is inverted.

Close the container securely. In the case of a closure incorporating a screw thread, tighten to the torque value specified by the manufacturer.

Examine the outside of the container by ultra-violet light to ensure that there is no contamination.

Immerse the complete container upside down in a tube containing sufficient water, but using not more than 100 ml, to cover the closure completely, leave at a temperature of 37 ± 2 °C for 2 h and then at room temperature (20 ± 2 °C) for a further 2 h.

Remove the container from the water.

Examine the water by ultra-violet light for any fluorescence as an indication of leakage.

Annex B

Concentrations for anticoagulants

The following are concentrations for anticoagulants :

a) **EDTA** 1,19 ± 0,2 mg of anhydrous EDTA (acid) (≈ 4 nmol) per millilitre of blood[1].

b) **Fluoride oxalate** 1,0 ± 0,1 mg of sodium fluoride (≈ 24 nmol) and 3,0 ± 0,3 mg of potassium oxalate (≈ 18 nmol) per millilitre of blood.

c) **Ammonium and potassium oxalate** 1,2 ± 0,12 mg of ammonium oxalate (≈ 10 nmol) and 0,8 ± 0,08 mg of potassium oxalate (≈ 10 nmol) per millilitre of blood.

d) **Trisodium citrate**

1) trisodium citrate solution at a concentration of 0,109 ± 0,01 mol/l;

2) one volume of trisodium citrate solution to nine volumes of blood for coagulation studies;

3) one volume of trisodium citrate solution to four volumes of blood for measurement of erythrocyte sedimentation rate by the Westergren method.

e) **Heparin** 15 ± 2,5 international units per millilitre of blood.

f) **Acid citrate dextrose** 0,15 ± 0,015 ml of acid citrate dextrose N.I.H. solution A per millilitre of blood.

Dissolve 22 g of trisodium citrate dihydrate, 8 g of citric acid monohydrate, 25 g of dextrose with water to 1 litre.

1) EDTA is calculated as the anhydrous salt of sequestric acid. Appropriate alteration will have to be made to compensate for the actual salt used and its water of crystallization.

Annex C

Test for corrosion resistance of ferrous caps

C.1 Autoclave for 30 min in saturated steam at 121 ± 1 °C.

C.2 Immerse for 30 min in boiling water.

C.3 Immerse for 30 min in boiling aqueous saline 9 g/l sodium chloride solution (154 mmol/l).

C.4 Remove liner and inspect visually.