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Single-use containers for human venous blood specimen collection

[Revision of first edition (6710:1995)]

Récipients à usage unique pour prélèvements de sang veineux humain

ICS 11.040.20

ISO/CEN PARALLEL ENQUIRY

The CEN Secretary-General has advised the ISO Secretary-General that this ISO/DIS covers a subject of interest to European standardization. **In accordance with the ISO-lead mode of collaboration as defined in the Vienna Agreement, consultation on this ISO/DIS has the same effect for CEN members as would a CEN enquiry on a draft European Standard.** Should this draft be accepted, a final draft, established on the basis of comments received, will be submitted to a parallel two-month FDIS vote in ISO and formal vote in CEN.

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Pour accélérer la distribution, le présent document est distribué tel qu'il est parvenu du secrétariat du comité. Le travail de rédaction et de composition de texte sera effectué au Secrétariat central de l'ISO au stade de publication.

In accordance with the provisions of Council Resolution 15/1993 this document is circulated in the English language only.

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 3.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this International Standard may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 6710 was prepared by Technical Committee ISO/TC 76, *Transfusion, infusion and injection for medical and pharmaceutical use*, Subcommittee SC , .

This second edition cancels and replaces the first edition of 1995-08 which has been technically revised.

Introduction

This International Standard provides requirements relevant to specimen containers (receptacles) for venous blood. Revision of ISO 6710:1995 was proposed by a number of countries, mainly in Europe, due to technical changes made in the manufacture of these containers (receptacles). For their perceived safety of patients, a number of countries strongly require colour coding of containers (receptacles) for the identification of additives. Two well established colour codes are in common use without any known reports of incidents affecting patient safety arising from differences in colour code. Furthermore, it is suggested that bespoke colour coding of these products is an increasing trend. Any changes by manufacturers increase the cost of production and as a consequence the price of receptacles (containers) to users. It has not therefore been possible to make any agreed international recommendations on colour codes of receptacles (containers) and so this International Standard has been prepared without a recommended colour codes as the only possible means of obtaining consensus by Standards bodies.

Single-use containers for human venous blood specimen collection

1 Scope

This standard specifies requirements and test methods for single-use receptacles, intended by their manufacturer, for the collection of venous blood specimens from the human body, for the purposes of in vitro diagnostic examination. This standard also applies to receptacles containing media for blood culture.

This standard does not specify requirements for capillary blood specimen receptacles or arterial blood specimen receptacles. This standard does not specify requirements and test methods for single-use receptacles intended for the collection of specimens, other than blood.

2 Normative references

The following normative documents contain provisions which, through reference in this text, constitute provisions of this International Standard. For dated references, subsequent amendments to, or revisions of, any of these publications do not apply. However, parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the normative documents indicated below. For undated references, the latest edition of the normative document referred to applies. Members of ISO and IEC maintain registers of currently valid International Standards.

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

ISO 3696, *Water for analytical laboratory use — Specifications and test methods.*

3 Terms and definitions

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

3.1
additive
substance, other than surface treatments designed to be irremovable, that is placed inside the receptacle to facilitate the preservation of the specimen, or is intended to react with the specimen, in order to allow the intended analysis to be performed

3.2
closing torque
twisting force, specified by the manufacturer, that is required to tighten a screw threaded closure sufficiently, by means of a torque wrench, to effect the sealing of a receptacle

3.3
container
part of the receptacle without the closure, and without any accessory, that contains the specimen

NOTE Depending on the intended application, the part of the receptacle, without the closure, that contains a blood specimen may also be known as a "tube", "bottle", "vial" or similar name.

3.4
closure
component by which the container is closed

3.5
draw volume
quantity of liquid specimen drawn into an evacuated receptacle

3.6
evacuated receptacle
receptacle intended for specimen collection by means of evacuation, either already induced by the manufacturer (i.e. pre-evacuated receptacle), or induced by the user immediately before a liquid specimen is taken

3.7
expiry date
date after which the receptacle shall not be used

3.8
fill line
mark on a container, or its label, to indicate the nominal liquid capacity of a container, or filling capacity of a receptacle

3.9
filling capacity
volume of liquid specimen needed to achieve the required additive to specimen ratio

3.10
free space
extra capacity, or headspace, which is provided to allow adequate mixing of the contents of a receptacle

3.11
graduation method
method of determining the volume of a liquid by weighing and correcting for the mass density of the liquid

NOTE For the purposes of this standard 1,000 ml of water is considered to have a mass equal to 1,000 g.

3.12
gravimetric analysis
method of determining the volume of a liquid by weighing and correcting for the mass density of the liquid

NOTE For the purposes of this standard 1,000 ml of water is considered to have a mass equal to 1,000 g

3.13
maximum fill line
mark on a container or its label, to indicate the maximum volume of specimen required to ensure that the in vitro diagnostic test for which the specimen is intended, can give accurate results

3.14
minimum fill line
mark on a container, or its label, to indicate the minimum volume of specimen required to ensure that the in vitro diagnostic test, for which the specimen is intended, can give accurate results

3.15
needle and holder assembly
device that is intended to be attached to an evacuated receptacle to enable venous puncture and subsequent blood collection to be performed

3.16
nominal liquid capacity
volume of specimen with which the receptacle is intended to be filled plus the volume of any additive

NOTE This volume is stated on the label and/or instructions for use

3.17
primary pack
smallest pack of receptacles

3.18
receptacle
vessel, whether evacuated or not, intended to contain a specimen, together with any receptacle accessory and additive, with closure in place

3.19
receptacle accessory
component inside the receptacle which is intended by the manufacturer to assist in the collection, or mixing, or separation, of the specimen

NOTE Examples of receptacle accessories are small plastic inert balls (or a separate gel), designed to agitate the blood specimen during mixing, or inert plastic beads used to form a layer between the serum or plasma and the cells after centrifugation

3.20
receptacle interior
inside surface of the receptacle or closure and the surface of any receptacle accessory exposed to the specimen

3.21
specimen
biological material which is obtained in order to detect properties or to measure one or more quantities

3.22
visual inspection
inspection by an observer with normal, or corrected-to-normal, vision without magnification, under a uniform illumination in the range from 300 lx to 750 lx

4 Materials

4.1 If a receptacle is intended to contain a specimen for a specific analysis, where the material of the closure, or container, or the interior coating, or the additive, or accessory, if present, may affect the final results of the test, then the maximum level of the contamination with that substance, and the analytical method employed, shall be stated by the manufacturer on the label, packaging or documentation (see also 11.4). Validation of the suitability of material with regard to a receptacle's specifically intended use is the responsibility of the manufacturer.

NOTE 1 This standard does not specify a validation procedure for material suitability.

NOTE 2 For certain infrequently performed analyses, limits of interference may not have been determined and the user is recommended to consult the manufacturer.

NOTE 3 A container should be manufactured from a material which allows a clear view of the contents when subjected to visual inspection by an observer with normal, or corrected to normal, vision without magnification, under uniform illumination between 300 lx and 750 lx unless exposure to UV or visible light would degrade the contents.

NOTE 4 If the container is not made of material that allows a clear view of the contents, the closure may be removed, to facilitate the examination of the contents.

4.2 When subjected to visual inspection the material of the receptacle shall be free from foreign matter.

4.3 Receptacles containing a microbe-supporting additive shall have been subjected to a validated process to eliminate microbial contamination from the additive and the receptacle interior. Validation of the process is the responsibility of the manufacturer.

NOTE For validation procedures and routine control of procedures for sterilisation methods see ISO 11134, ISO 11135 and ISO 11137.

5 Nominal liquid capacity

5.1 When tested in accordance with the methods specified in either annex A or B, the volume of water added from, or drawn from, the burette, plus the volume of any additive present, shall be between 90 % and 110 % of the nominal capacity.

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

5.3 Where free space is intended to facilitate mixing there shall be sufficient free space to allow mixing by mechanical or manual means.

5.4 The manufacturer shall validate that adequate mixing of the blood specimen, with any additive present, can be achieved.

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

6 Graduation and fill lines

6.1 Graduation line

When non-evacuated receptacles that have graduation marks are tested in accordance with methods specified in annex A, the volume of water shall be between 90 % and 110 % of the indicated volume.

NOTE This test is not suitable for non-evacuated receptacles that contain a liquid additive.

6.2 Maximum fill line

Evacuated receptacles that have a maximum fill line on the container, or container label, shall fill such that the meniscus of the liquid reaches, but does not exceed, the position of the line when tested in accordance with the method specified in annex B.

6.3 Minimum fill line

Evacuated receptacles that have a minimum fill line on the container, or container label, shall fill such that the meniscus of the liquid reaches, or exceeds, the position of the line when tested in accordance with the method specified in annex B.

7 Design

7.1 The closure shall not become loose when tested for leakage in accordance with the method specified in annex C. When the receptacle is tested for leakage in accordance with the method specified in Annex C, no fluorescence shall be detectable in the water in which the receptacle has been immersed.

7.2 Where a closure is intended to be removed, to gain access to the contents of the receptacle, it shall be designed, as far as is reasonable and practical to do, so that it can be removed by gripping with the fingers, and/or by mechanical means, without that part of the closure which may become contaminated by contact with the specimen, being touched by the fingers, or the mechanical removal device.

NOTE Specimen receptacles should be designed to avoid spontaneous discharge of the contents, when being opened. This standard does not specify a test procedure for this because it has not been possible to devise an objective and reproducible test

7.3 Visibility of the specimen and its liquid level shall not be completely obscured by any label, print or marking applied to the receptacle.

7.4 The unused and dry label shall be suitable for marking with a writing implement as specified by the manufacturer.

7.5 The marking and the label on the receptacle shall remain adherent and legible after exposure in air at (4 ± 1) °C for not less than 72 h.

7.6 If the manufacturer claims that the receptacle is suitable for storage at temperatures outside the normal ambient range, the label, the adhesive if used and marking shall remain in place, in a dry state, and legible at the extremes of the temperature range, specified by the manufacturer, for a minimum of 72 h at each stated extreme.

8 Construction

8.1 Receptacles shall withstand 4 cycles of removal and replacement of the closure in accordance with the manufacturers instructions, without breaks, collapse, cracks, or other visible damage, and when tested according to the annexes A, B, C and D. Where the initial opening of the receptacle destroys the closure, these requirements shall apply to the subsequent closure.

NOTE It has proved difficult to specify a single test procedure for robustness. The requirements specified above are intended to simulate the mechanical stress that occurs during the normal filling of the receptacle, storage, transportation and removal of the sample. Requirements for the transport of the specimen, in the receptacle, are given in UN 602 [10] and UN 650 [11].

8.2 Receptacles intended for centrifugation shall withstand a minimum acceleration of 3 000 g_n (or the acceleration specified by the manufacturer), in their longitudinal axis, without breaks, collapse, cracks, or other visible damage, and when tested according to annex D.

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

9 Sterility and special microbiological states

9.1 If a manufacturer claims that the interior of the unopened and unused receptacle, or the whole receptacle, 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.

NOTE Validation procedures for sterilisation methods are given in ISO 11134, ISO 11135 and ISO 11137.

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

9.3 Sterility or an aseptic process (e.g. a validated special microbiological state such as diphasic culture media) is mandatory when the blood collection system is intended for the culture of micro-organisms in blood and/or when the receptacle contains culture media.

10 Additives

10.1 The actual amount of additive, in each receptacle, shall be within the range specified by the manufacturer.

10.2 The maximum permitted tolerance interval on the specified volume of a liquid additive shall be from 90 % to 110 %.

10.3 Validation of the choice of additive (including culture medium), its efficacy and its specified concentration range shall be the responsibility of the manufacturer