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In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood

Dispositifs médicaux de diagnostic in vitro — Récipients à usage unique pour le prélèvement d'échantillons d'origine humaine autres que le sang

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Contents

Page

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 of 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 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*, in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 140, *In vitro diagnostic medical devices,* in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

In vitro diagnostic medical devices — Single-use containers for the collection of specimens from humans other than blood

1 Scope

This document specifies requirements and test methods for specialized single-use evacuated and non-evacuated containers, intended by their manufacturers, for the primary containment and preservation of specimens, other than blood specimens, derived from the human body, for the purposes of in vitro diagnostic examination. It is not intended to cover specimen containers for forensic investigations.

Examples of such specimens include, but are not limited to, cerebral spinal fluid (CSF), faeces, infected bodily fluids, saliva, ejaculate, sputum, urine, tissue samples.

Specimens and types of devices specifically excluded are specialized containers for cryo-preservation, samples for nucleic acid testing and swabs.

NOTE Requirements and test methods for evacuated and non-evacuated single-use human venous blood specimen collection containers are specified in ISO 6710.

This document does not specify requirements for auxiliary devices used in conjunction with specimen containers.

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 information to be supplied by the manufacturer — 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:

— ISO Online browsing platform: available at https://www.iso.org/obp

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

3.1
container
vessel, whether evacuated or not, intended to contain a *specimen* (3.17), together with any container *accessory* (3.5) and *additive* (3.9), with *closure* (3.4) in place

[SOURCE: ISO 6710:2017, 3.4]

3.2
evacuated container
container (3.1) intended for *specimen* (3.17) collection by means of evacuation, either already induced by the manufacturer (i.e. pre-evacuated containers), or induced by the user before or during specimen collection

[SOURCE: ISO 6710:2017, 3.7, modified — 'blood' has been replaced by 'specimen'.]

3.3
receptacle
part of the *container* (3.1), without the *closure* (3.4), that contains the *specimen* (3.17)

3.4
closure
component by which the *container* (3.1) is closed, which can consist of several parts

[SOURCE: ISO 6710:2017, 3.3, modified — 'sealed' has been replaced by 'closed' to reflect the different types of devices and their use covered by this document.]

3.5
accessory
component inside the *container* (3.1) that is intended by the manufacturer to assist in the collection, or mixing, or separation of the *specimen* (3.17)

[SOURCE: ISO 6710:2017, 3.1, modified — Note 1 to entry has been deleted.]

3.6
auxiliary device
device that is intended to be attached to a *container* (3.1) to enable sample collection to be performed

EXAMPLE Sampling spoons intended for the collection of solid specimens, or collection needles for liquid specimens.

3.7
primary pack
smallest package of *containers* (3.1)

[SOURCE: ISO 6710:2017, 3.13]

3.8
container interior
inner surface of the *container* (3.1) exposed to the *specimen* (3.17)

[SOURCE: ISO 6710:2017, 3.5]

3.9
additive
substance (other than surface treatments designed to be irremovable) that is placed in the *container* (3.1) in order to facilitate the preservation of the *specimen* (3.17), or is intended to react with the specimen, in order to allow the intended analysis to be performed

EXAMPLE Microbiological preservatives (boric acid).

[SOURCE: ISO 6710:2017, 3.2, modified — 'inner surface' has been reduced to 'surface' and 'facilitate the creation of the desired sample' has been replaced by 'allow the intended analysis to be performed', an example has been added.]

3.10
nominal liquid capacity
volume of *specimen* (3.17) with which the *container* (3.1) is intended to be filled plus the volume of any *additive* (3.9)

Note 1 to entry: The nominal liquid capacity is stated on the label and/or the instructions for use.

Note 2 to entry: The containers defined in this document are also used to collect solid specimens. For ease of use the capacity is defined in ml rather than cm^3 for solid specimens. These measures may be used interchangeably.

Note 3 to entry: For certain specimen types, a range of volume is applicable rather than a specific volume.

3.11
filling capacity
volume of a liquid *specimen* (3.17) needed to achieve the required *additive* (3.9)-to-specimen ratio

3.12
fill indicator
line marked on a *receptacle* (3.3) or its label to indicate the correct filling

[SOURCE: ISO 6710:2017, 3.9, modified — 'tube' has been replaced by 'receptacle'.]

3.13
graduation line
mark on a *receptacle* (3.3), or its label, to enable an estimate of the volume of a liquid *specimen* (3.17)

Note 1 to entry: A receptacle can be marked by more than one graduation line.

3.14
draw volume
quantity of liquid *specimen* (3.17) drawn into an *evacuated container* (3.2)

3.15
expiry date
date after which the product shall not be used

[SOURCE: ISO 6710:2017, 3.8]

3.16
closing torque
torque, specified by the manufacturer, that is needed to tighten a screw-threaded *closure* (3.4) sufficiently to affect the sealing of a *receptacle* (3.3)

3.17
specimen
discrete portion of a body fluid, breath, hair or tissue taken for examination, study or analysis of one or more quantities or properties assumed to apply for the whole

[SOURCE: ISO 15189:2012, 3.16, modified – the preferred term 'primary sample' has been deleted.]

4 Materials

4.1 If the intended use requires visual inspection of the content in the receptacle, the receptacle shall be made of material that allows a clear view of the contents when subjected to visual inspection, unless exposure to ultraviolet light or visible light would degrade the contents.

If the receptacle 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 If a container is intended for the determination of a specific element/substance, e.g. trace elements, the maximum level of the element/substance in the container interior and the analytical method employed shall be stated by the manufacturer in the instructions for use or on the label or packaging (see also 11.4).

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 or specific examinations (for example those using fluorimetry) or little-used tests, limits of interference might not have been agreed on. In such cases, the laboratory should establish a blank value or determine the suitability of the container for the examination and/or consult the manufacturer.

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

5 Filling capacity/draw volume

5.1 For non-evacuated containers intended for collection of liquid specimens, the volume of water added shall be within ±10 % of the filling capacity when tested in accordance with the methods specified in Annex A.

5.2 For evacuated containers, the volume of water added shall be within ±10 % of the draw volume when tested as specified in Annex B. If ±10 % of draw volume is not met throughout the shelf life, the manufacturer shall ensure that correct results shall be obtained.

5.3 For containers with an additive or for containers intended for the collection of liquid suspensions that can settle out upon standing, provision shall be made for mixing.

NOTE This document does not specify a validation procedure.

6 Graduation lines

When non-evacuated containers of any capacity with graduation lines are tested in accordance with the methods specified in Annex A, the volume of water shall be between 90 % and 110 % of the volume indicated by the graduation lines.

7 Design

7.1 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.

7.2 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.

7.3 Consideration in the design shall be given to ensure compatibility with transportation systems, processes, pre-analytical and analytical automation.

7.4 The unused and dry label, if including a space for writing and/or marking, shall be suitable for marking with a writing implement which may be specified by the manufacturer.

7.5 If the manufacturer claims that the container 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 be 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 Containers intended for centrifugation shall not break, crack or leak, when centrifuged at a relative centrifugal force (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.

8.2 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 or gloves of the patient or user. Where a needle is integrated into the container to facilitate specimen collection, measures shall be taken to inform the user about the risk of unintentional contact with the needle (e.g. protective label with symbols).

9 Sterility and special microbiological states

9.1 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.

9.2 Sterility is mandatory when one or more of the following applies:

— the collection system is in contact with the patient's fluid pathway,

— the collection system is intended for the culture of the specimen,

— the container contains culture media.

NOTE A list of applicable sterilization standards is given in the Bibliography.

9.3 For non-evacuated containers with microbe-supporting additives, the solution shall be subjected to a validated process to remove or to render non-viable microbes in the additive and the container interior.

10 Additives

10.1 The manufacturer shall validate the choice of additive, its efficacy, its physical form and its specified concentration range for its intended purpose.

NOTE Additives can be present in several physical forms, for example as a solution, dried by heat from a solution, lyophilized, or as a powder.

10.2 The amount of additive shall be within the range specified by the manufacturer.

NOTE This document does not specify any test method.

10.3 For containers with an additive, provision shall be made for mixing.

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

11 Marking and labelling

11.1 Visibility of the specimen shall not be completely obscured by any label, print or mark unless exposure to ultraviolet light or visible light would degrade the contents.

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

11.3 Each primary pack shall be marked on the outside with, at least, 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;
- product name and/or a description of the contents;
- the word "STERILE" or the appropriate graphical symbol in accordance with 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 in accordance with ISO 15223-1;
- where required, special storage instructions.

11.4 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 instructions for use.

11.5 If a container has a liquid additive, its volume shall be stated on the label, the primary pack or in the instructions for use.

11.6 Containers shall have at least the following information marked directly onto the container or on the label:

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

b) product name and/or a description of the contents;

c) the batch number;

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

e) the nominal liquid capacity or filling capacity/draw volume, specified where appropriate on the receptacle;

f) the words "Single-use only" or the appropriate graphical symbol in accordance with 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 instructions for use;

h) the word "STERILE" or the appropriate graphical symbol in accordance with ISO 15223-1 if the manufacturer claims that the unopened and unused container interior and any contents of the container are sterile.

If the marking directly onto the container or on the label is not practicable or appropriate, some or all of the information may appear on the packaging for each unit. If individual full labelling of each unit is not practicable, the information shall be set out on the packaging of multiple devices.

11.7 If the container is intended to be used, under specific conditions, this shall be clearly stated on the container or on the label and/or on the instructions for use in the primary pack.

11.8 If the intended purpose of the container is not obvious to the user, the manufacturer shall clearly state the intended purpose in the instructions for use and, if appropriate, on the label.

11.9 If the container is designed to be stored at temperature extremes outside the range from 4 °C to 25 °C, this should be clearly stated on the container or on the label and/or in the instructions for use and/or on the primary pack.