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

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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 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*.

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, other than blood, from humans

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 are, but not limited to, cerebral spinal fluid (CSF), faeces, infected bodily fluids, saliva, sperm, sputum, urine, tissue samples.

Specimens and types of devices specifically excluded include 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 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 4788, *Laboratory glassware — Graduated measuring cylinders*

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:

— 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* (3.20), 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* (3.20) 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* (3.20) 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* (3.20)

3.4
closure
component by which the *container* (3.1) is closed, which may 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) which is intended by the manufacturer to assist in the collection, or mixing, or separation of the *specimen* (3.20)

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

3.6
auxiliary devices
device that is intended to be attached to a container to enable liquid sample collection to be performed

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

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

[SOURCE: ISO 6710:2017, 3.13]

3.8
container interior
any inner surface of the *container* (3.1) exposed to the *specimen* (3.20)

[SOURCE: ISO 6710:2017, 3.5]

3.9
additive
any 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* (3.20), or is intended to react with the *specimen* (3.20), in order to allow the intended analysis to be performed

EXAMPLE Microbiological preservatives (boric acid).

[SOURCE: ISO 6710:2017, 3.2, modified]

3.10
nominal liquid capacity
volume or *specimen* (3.20) with which the *container* (3.1) is intended to be filled plus the volume of any *additive* (3.9)

Note 1 to entry: This volume is stated on the label and/or the instructions for use.

Note 2 to entry: It is recognized that 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: It is recognized that for certain specimen types a range of volume is applicable rather than a specific volume.

3.11
free space
extra capacity, or headspace, above the *nominal liquid capacity* (3.10)

3.12
nominal fill line
mark on a *receptacle* (3.3), or its label, to indicate its *nominal liquid capacity* (3.10)

Note 1 to entry: A receptacle can be marked with more than one fill line.

3.13
filling capacity
volume of a liquid *specimen* (3.20) needed to achieve the required additive to *specimen* (3.20) ratio

3.14
fill indicator
line marked on a *receptacle* (3.3) or its label to indicate the correct filling

[SOURCE: ISO 6710:2017, 3.9, modified]

3.15
graduation line
mark on a *receptacle* (3.3), or its label, to enable an estimate of the volume of a liquid *specimen* (3.20)

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

3.16
draw volume
quantity of liquid *specimen* (3.20) drawn into an *evacuated container* (3.2)

3.17
expiry date
date after which the *container* (3.1) shall not be used

[SOURCE: ISO 6710:2017, 3.8, modified]

3.18
closing torque
twisting force, specified by the manufacturer, that is required to tighten a screw-threaded closure, sufficiently, to effect the sealing of a *receptacle* (3.3)

3.19
gravimetric analysis
method of determining the volume of a liquid by weighing and correcting for the mass density of the liquid

3.20
specimen
human biological material which is obtained in order to detect properties or to measure one or more quantities

4 Materials

4.1 If the intended use requires visual inspection of the content in the receptacle, the receptacle 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.

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/examination, 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 supporting literature 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 may 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, when tested in accordance with the methods specified in Annex A, the volume of water added shall be within ± 10 % of the filling capacity.

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 may 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 from 90 % to 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 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 $g = 9{,}806\ 65\ m/s^2$.

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 (i.e. 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 the collection system is in contact with the patient's fluid pathway, intended for the culture of the specimen, and when 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, lyophilised, 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.