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Evacuated single-use containers for
human venous blood specimen
collection

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Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 3233** : 2011), which has been technically revised.

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Evacuated single-use containers for human venous blood specimen collection

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 6710** : 2017, Edition 2, with some modifications of the technical contents for only the parts relating to evacuated single-use containers for venous blood specimen collection in order to harmonize with the actual conditions in Japan.

The vertical lines on both sides and dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies requirements and test methods for sterile evacuated single-use containers for venous blood specimen collection (hereafter referred to as evacuated containers), ready to use by means of evacuation already induced by the manufacturer.

NOTE The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 6710 : 2017 *Single-use containers for human venous blood specimen collection* (MOD)

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and **JIS** are IDT (identical), MOD (modified), and NEQ (not equivalent) according to **ISO/IEC Guide 21-1**.

However, **JIS T 3233** : 2011 remains valid for three years from the date of public notice of the revision of this Standard.

2 Normative references

Part or all of the provisions of the following standards, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the editions of the indicated year shall be applied and the revisions (including amendments) made thereafter shall not be applied. For those without the indication of the year, the most recent editions (including amendments) shall be applied.

ISO 11137 (all parts) *Sterilization of health care products — Radiation*

ISO 17665-1 : 2006 *Sterilization of health care products — Moist heat — Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices*

ISO 80369-7 *Small-bore connectors for liquids and gases in healthcare applica-*

tions — Part 7: Connectors for intravascular or hypodermic applications

ISO/TS 17665-2 : 2009 Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ISO 17665-1

3 Terms and definitions

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

3.1

container

vessel intended to contain a blood specimen, together with additives, with closure in place

3.2

evacuated container

container intended for blood collection by means of evacuation already induced by the manufacturer

3.3

tube

part of the container, without the closure, that contains the specimen

3.4

closure

component by which the container is sealed, which may consist of several parts

3.5

primary pack

package intended to directly cover the containers

Note 1 to entry It usually refers to those containing multiple containers, e.g. 100 containers, which are used as the minimum sales unit.

Note 2 to entry When evacuated containers are packaged for the purpose of maintaining evacuation, moisture retention, light shielding, etc. before being packaged in a primary pack, this smallest package used for maintaining evacuation and other purposes is considered an inner bag, not a primary pack.

3.6

container interior

inner surface of the container

3.7

additive

substance that is placed in the container in order to allow the intended analysis to be performed

Note 1 to entry Inside surface treatments designed to be irremovable are excluded.

3.8

nominal capacity

volume of whole blood intended to be collected in the container, as specified by the manufacturer

3.9

free space

extra capacity, or head space, which is provided to allow adequate mixing of the contents of a container

Note 1 to entry It is determined by the minimum free space test specified in Annex A.

3.10

draw volume

volume of water that is aspirated into individual containers

3.11

expiry date

date after which the manufacturer does not claim that a container complies with the requirements of this Standard

3.12

visual inspection

inspection by an observer with normal or corrected-to-normal vision without magnification under a uniform illuminance between 500 lx and 1 000 lx

3.13

relative centrifugal force, RCF

force that is generated during the specimen centrifugation process, which is specified by the manufacturer for adequate separation

3.14

specimen

venous blood collected in a container

4 Configuration and names of parts

An evacuated container consists of tube and closure. It may include additives in accordance with the purpose of use.

Figure 1 illustrates a typical evacuated container.

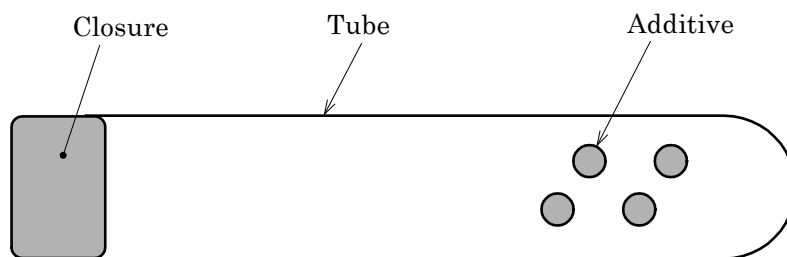


Figure 1 Configuration and examples of names of parts of container

5 Materials

5.1 The tube 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.

The interior of the glass tube intended to contain specimens for blood coagulation studies should not allow contact activation (see Bibliography [1]).

5.2 If a container is intended specifically for the determination of a certain element/substance, the maximum level of contamination with the element/substance inside the container and the analytical method employed shall be stated by the manufacturer in supporting literature or on the label or packaging (see 11.2).

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.

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

6 Draw volume

6.1 When tested in accordance with the methods specified in Annex A, the volume of water added or drawn from the burette or reservoir should be within the following with respect to the nominal capacity.

In the case where the volume of liquid additive affects the test result: $\pm 10\%$

In other cases: $\pm 20\%$

6.2 For containers with an additive, there shall be sufficient free space, when tested in accordance with the methods specified in Annex A, to allow adequate mixing by mechanical or manual means. The minimum free space shall be such as to allow sufficient mixing of the contents of the container even if it is filled with blood to the nominal capacity. Allowance shall be made between the underside of the closure and the liquid meniscus as free space useful for mixing the contents of a container.

7 Design

7.1 The closure shall not become loose during mixing when tested for leakage in accordance with the methods specified in Annex B 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 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, so that the part of the closure that could be in contact with the specimen is not touched.

NOTE 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.

8 Construction

8.1 The container holding the specimen 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 C.

NOTE $g = 9.806\ 65\ \text{m/s}^2$.

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 of the user.

9 Sterility assurance

The interior of the unopened and unused container shall be sterile. The container and any additive shall be subjected to a validated process designed in accordance with the criteria for validation of sterilization, or ISO 11137 (all parts) or ISO 17665-1 : 2006 and ISO/TS 17665-2 : 2009. The level of assurance of sterility shall be SAL 10^{-3} or lower.

NOTE The criteria for validation of sterilization include the Criteria for Validation of Sterilization specified by the Ministry of Health, Labour and Welfare.

10 Additives

10.1 The stated nominal amount of additive should be within the range specified in Annex D.

10.2 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.

11 Marking and labelling

11.1 Tube

11.1.1 Non-transparent labels, if used, shall not completely encircle the tubes.