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(JMED/JSA)

**Evacuated single-use containers for
venous blood specimen collection**

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Foreword

This translation has been made based on the original Japanese Industrial Standard 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 Japan Medical Devices Manufacturers Association (JMED)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 3233 : 2005** is replaced with this Standard.

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Evacuated single-use containers for venous blood specimen collection

Introduction

This Japanese Industrial Standard has been prepared based on the first edition of ISO 6710 published in 1995 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 portions with dotted underlines in this Standard are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies 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 : 1995 *Single-use containers for 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.

JIS T 3233 : 2005 may be applied until July 28 in 2014.

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the edition of the indicated year shall apply but the revisions (including amendments) made thereafter shall not apply.

JIS T 0307:2004 *Medical devices—Symbols to be used with medical device labels, labelling, and information to be supplied*

ISO 594-1:1986 *Conical fittings with a 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 1: General requirements*

ISO 3696:1987 *Water for analytical laboratory use—Specification and test methods*

ISO 11137:2006 (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/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 purposes of this Standard, the following terms and definitions apply.

3.1 container

vessel to contain a blood specimen, 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 closed

3.5 primary pack

package intended to cover directly the containers, which usually includes multiple containers, e.g. 100 containers and is used as the minimum sales unit package

When evacuated containers are packaged for the purpose of maintaining evacuation, moisture retention and light shielding, etc. before being packaged in primary pack, this smallest packaging intended to maintain evacuation is an inner pack, not a primary package.

3.6 container interior

inside surface of the container

3.7 additive

any substances (other than inside surface treatments designed to be irremovable) that is placed in the container in order to allow the intended analysis to be performed

3.8 nominal capacity

volume of whole blood with which the container is intended to be filled

3.9 free space

extra capacity, or head space, which is provided to allow adequate mixing of the contents of a container, as determined by the minimum free space tests laid down in Annex A

3.10 draw volume

nominal capacity of an evacuated container

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 300 lx and 750 lx

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.

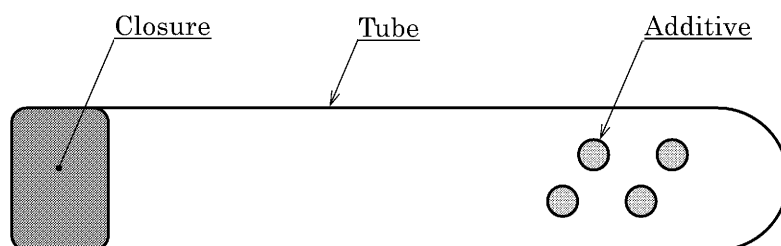


Figure 1 Configuration and names of parts of evacuated container

5 Materials

5.1 The tube shall be made of material which allows a clear view of the contents when subjected to visual inspection.

The inner surfaces of glass tubes intended to receive specimens for blood coagulation studies should not allow contact activation (see [1] in the bibliography).

5.2 If a container is intended specifically for the determination of a certain substance, the maximum level of container interior contamination with that substance and the analytical method employed shall be stated by the manufacturer in accompanying 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 shall be such as not to interfere with the determination thereby affecting the results.

5.3 There shall not be any evidence of foreign matters inside the container when inspected visually.

6 Capacity

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

In the case that the volume of liquid additive affects the test result within $\pm 10\%$

In other cases within $\pm 20\%$

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 adequate mixing of the contents of the container even if it is filled with blood to the nominal capacity. Allowance shall be made for the fact that the available free space for mixing the contents of a container is bounded by underside of the closure and the liquid meniscus.

7 Design

7.1 The closure shall not have any liquid leakage during mixing when tested for leakage in accordance with the methods specified in Annex B.

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 without using that part of the closure which may be contaminated by contact with the specimen being touched by the fingers.

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.

7.3 When the container is tested for leakage in accordance with the method specified in Annex B, no fluorescence shall be detectable in the water in which the container has been immersed.

8 Construction

8.1 The container holding the specimen, when centrifuged, shall withstand an acceleration of 3 000 *g* in a longitudinal axis 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 Assurance of sterility