SLOVENSKI STANDARD

SIST EN 14254:2005

01-januar-2005

Diagnostiļ ni medicinski pripomoļ ki in vitro ï Posode za zbiranje vzorcev ļ loveġkega tkiva in drugih vzorcev, razen krvi, za enkratno uporabo

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

In-vitro-Diagnostika - Einmalgefäße für Untersuchungsgut vom Menschen mit Ausnahme von Blutproben

Dispositifs médicaux de diagnostic in vitro - Récipients a usage unique pour prélevement humains non sanguins

Ta slovenski standard je istoveten z: EN 14254:2004

ICS:

11.100.10	Diagnostiļ ni preskusni sistemi in vitro	In vitro diagnostic test systems

SIST EN 14254:2005 **en,fr,de**

EUROPEAN STANDARD

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English version

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

Dispositifs médicaux de diagnostic in vitro - Récipients à usage unique pour prélèvement humains non sanguins

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This European Standard was approved by CEN on 23 April 2004.

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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the Central Secretariat has the same status as the official versions.

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Contents

Foreword

This document (EN 14254:2004) has been prepared by Technical Committee CEN/TC 140 “In vitro diagnostic medical devices”, the secretariat of which is held by DIN.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by December 2004, and conflicting national standards shall be withdrawn at the latest by December 2004.

This document has been prepared under a mandate given to CEN by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive(s).

For relationship with EU Directive(s), see informative annex ZA, which is an integral part of this document.

Annexes A, B, C, D and E are normative.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, Switzerland and United Kingdom.

1 Scope

This standard specifies requirements and test methods for single-use evacuated and non-evacuated receptacles, 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.

NOTE 1 Requirements and test methods for evacuated and non-evacuated single-use venous blood specimen containers are specified in EN 14820.

NOTE 2 While it is desirable that 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.

This standard does not specify requirements for collection needles or needle holders or other accessories used in conjunction with specimen receptacles.

2 Normative references

This European Standard incorporates by dated or undated reference provisions from other publications. These normative references are cited at the appropriate places in the text and the publications are listed hereafter. For dated references, subsequent amendments to or revisions of any of these publications apply to this European Standard only when incorporated in it by amendment or revision. For undated references the latest edition of the publication referred to applies (including amendments).

EN ISO 3696, *Water for analytical laboratory use — Specification and test methods (ISO 3696:1987)*

ISO 4788, *Laboratory glassware — Graduated measuring cylinders*

3 Terms and definitions

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

3.1
receptacle
vessel, whether evacuated or not, intended to contain a specimen, together with any receptacle accessory and additive, with closure in place

3.2
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

3.3
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 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
receptacle accessory
component inside the receptacle which is intended by the manufacturer to assist in the collection or mixing, or separation, of the specimen

EXAMPLE Sampling spoons intended for the collection of solid specimens.

3.6
holder and suction tip assembly
device that is intended to be attached to an evacuated receptacle to enable liquid sample collection to be performed

3.7
primary pack
smallest pack of receptacles

3.8
receptacle interior
inside surface of the container receptacle or closure and the surface of any receptacle accessory exposed to the specimen

3.9
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

EXAMPLE Solid culture media.

3.10
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 the instructions for use.

3.11
free space
extra capacity, or headspace, which is provided to allow adequate mixing of the contents of a receptacle

NOTE This volume is determined by the minimum free space tests described in annexes A, B and C.

3.12
nominal fill line
mark on a container, or its label, to indicate the nominal liquid capacity of a container.

NOTE A container can be marked with more than one fill line.

3.13
filling capacity
volume of a liquid specimen needed to achieve the required additive to specimen ratio

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

3.16
graduation line
mark on a container, or its label, to enable an estimate of the volume of a liquid specimen

NOTE A container can be marked by more than one graduation line.

3.17
draw volume
quantity of liquid specimen drawn into an evacuated receptacle

3.18
expiry date
date after which the receptacle shall not be used

3.19
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

3.20
gravimetric analysis
method of determining the volume of a liquid by weighing and correcting for the mass density of the liquid

3.21
volumetric analysis
method of determining the volume of a liquid by using a burette

3.22
specimen
biological material which is obtained in order to detect properties or to measure one or more quantities

4 Materials

4.1 If a receptacle is intended to collect a specimen for a specific examination 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 examination, then the maximum level of the 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 also 11.7). 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 examinations, 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 a 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 the validation and routine control of sterilization procedures see EN 550, EN 552 and EN 554.

5 Nominal liquid capacity

5.1 For non-evacuated receptacles with a nominal liquid capacity up to and including 30 ml, and all evacuated receptacles, when tested in accordance with the methods specified in either annex A or C, the volume of water added plus the volume of any additive present shall be within ± 10 % of the nominal capacity.

5.2 For non-evacuated receptacles with a nominal liquid capacity greater than 30 ml, the volume of water added shall be within ± 10 % of the nominal capacity when tested as specified in annex B.

5.3 For receptacles with an additive or for receptacles intended for the collection of liquid suspensions that may settle out upon standing, provision shall be made for mixing. Where free space is intended to facilitate mixing there shall be sufficient free space to allow mixing by mechanical or manual means when tested in accordance with annexes A, B and C. Validation of claims for the adequacy of mixing is the responsibility of the manufacturer.

NOTE This standard does not specify a validation procedure.

6 Graduation and fill lines

6.1 Graduation lines

When non-evacuated receptacles, of any capacity, with graduation lines are tested in accordance with the methods specified in either annex A or B, the volume of water shall be from 90 % to 110 % of the volume indicated by the graduation lines.

6.2 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 C.

6.3 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 not exceeds the position of the line when tested in accordance with the method specified in annex C.

7 Design

7.1 The closure shall not become loose when tested for leakage in accordance with the method specified in annex D. The receptacle shall pass the test for leakage if no fluorescence is observed.

NOTE This standard does not specify a test procedure for receptacles intended by the manufacturer for storage in liquid nitrogen.

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 reasonably and practical to do, so that it can be removed by gripping with the fingers, and/or 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.

7.3 Visibility of the specimen shall not be completely obscured by any label, print or mark.

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 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 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 [11] and UN 650 [12].

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

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 patient or 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. Validation of the sterilization process is the responsibility of the manufacturer.

NOTE For the validation and routine control of sterilization procedures see EN 550, EN 552 and EN 554.

9.2 Sterility is mandatory when the collection system is intended for the culture of the specimen and 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 of the specified volume of a liquid additive shall be from 90 % to 110 %.

NOTE The quantity of an additive in a receptacle should be determined if appropriate, with a correction being made for the mass density of any liquid, by gravimetric analysis using a balance with an accuracy of 0,001 g.

10.3 Validation of the choice of additive including culture medium, its efficacy and its specified concentration range is the responsibility of the manufacturer.

NOTE This standard does not specify any test method.

10.4 The manufacturer shall ensure that the physical form for the specified additive is suitable for its purpose.

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

11 Information supplied by the manufacturer

11.1 Each receptacle shall be accompanied by the information needed to use it properly, taking account of the training and knowledge of the potential user and to identify the manufacturer. This information shall be set out on the receptacle itself, where space permits, and/or in the instructions for use and/or on the primary pack.

NOTE It is suggested that manufacturers may make use of electronic means, for example the Internet, as an additional means of communicating practical and functional information, concerning their product, to the end user.

11.2 As far as practical and appropriate the information needed to use the receptacle safely and properly shall be set out on the receptacle itself and/or, where appropriate, on the primary pack. If individual full labelling of each

receptacle is not practicable the information shall be set out on the packaging and/or on the instructions for use supplied with one or more receptacles.

NOTE By way of exception no instructions for use are required for receptacles whose purpose and method of use are obvious to the intended user, taking into account their technical knowledge, and where no specific warnings concerning storage or method of use are required.

Where appropriate, this information should take the form of graphical symbols as specified in EN 980 and colour codes. In areas where no such published symbols or colour codes exist, the meaning of the symbol and colour code used shall be described in the documentation supplied with the receptacle.

11.3 If a receptacle is supplied specifically for the determination, or detection, of a certain substance, the maximum level of contamination with the substance shall be stated directly onto the receptacle, or the label, if possible, and/or in the instructions for use and/or on the primary pack.

11.4 As appropriate, the label shall bear the following particulars, which may take the form of a symbol:

a) the name or trade name and address of the manufacturer. For receptacles imported into the European Community with a view to their distribution in the Community, the label, the outer packaging or the instructions for use shall contain the name and address of the authorised representative of the manufacturer;

b) the details strictly necessary for the user to uniquely identify the receptacle and the contents of the packaging;

c) where appropriate, the word 'STERILE' or a statement indicating any special microbiological state or state of cleanliness;

d) the batch code, preceded by the word 'LOT' or the serial number;

e) if necessary, an indication of the date by which the receptacle or part of it should be used, in safety, without degradation of performance, expressed as the year, the month and, where relevant, the day, in that order; in the format CCYY MM or CCYY MM DD;

f) in case of receptacles for performance evaluation, the words 'for performance evaluation only';

g) where appropriate, a statement indicating the *in vitro* use of the receptacle;

h) any particular storage and/or handling conditions;

i) where applicable, any particular operating instructions;

j) where applicable, the identity and concentration of any additive;

k) the nominal liquid capacity of the receptacle;

l) a fill line where necessary;

m) appropriate warnings and/or precautions to take.

11.5 If the intended purpose of the receptacle 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.

11.6 If the receptacle is suitable for storage at temperatures below 0 °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.

11.7 If the receptacle is suitable for storage in liquid nitrogen 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.