BRITISH STANDARD

BS EN
829 : 1997

In vitro diagnostic systems — Transport packages for medical and biological specimens — Requirements, tests

The European Standard EN 829 : 1996 has the status of a British Standard

ICS 11.100; 55.020

Committees responsible for this British Standard

The preparation of this British Standard was entrusted to Technical Committee PKW/1, Packaging generalities, upon which the following bodies were represented:

Association of Drum Manufacturers
British Adhesives and Sealants Association
British Association for Chemical Specialities
British Coatings Federation Ltd.
British Fibreboard Packaging Association
British Fruit and Vegetable Canners' Association
British Glass Manufacturers' Confederation
British Office Systems and Stationery Federation
British Plastics Federation
British Retail Consortium
British Rubber Manufacturers' Association Ltd.
Chemical Industries Association
China Clay Association
Environmental and Technical Association for the Paper Sack Industry
LP Gas Association
Metal Packaging Manufacturers' Association
Ministry of Defence
Pira International
Road Haulage Association Ltd.
Timber Packaging and Pallet Confederation

The following bodies were also represented in the drafting of the standard, through subcommittees and panels:

Association of British Health-care Industries
Association of Clinical Pathologists
Guild of Hospital Pharmacists
National Pharmaceutical Association
Pharmaceutical Services Negotiating Committee
Royal College of Ophthalmologists
Royal Pharmaceutical Society of Great Britain

This British Standard, having been prepared under the direction of the Consumer Products and Services Sector Board, was published under the authority of the Standards Board and comes into effect on 15 January 1997

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The following BSI references relate to the work on this standard:
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National foreword

This British Standard has been prepared by Technical Committee PKW/1 and is the English language version of EN 829 : 1996 *In vitro diagnostic systems — Transport packages for medical and biological specimens — Requirements, tests*, published by the European Committee for Standardization (CEN).

EN 829 : 1996 was published, despite a strong United Kingdom vote against the CEN enquiry draft, on the basis of an overall favourable vote in the CEN procedure leading to the publication of the European Standard.

Cross-references

Publication referred to	Corresponding British Standard
ISO 2859-1	BS 6001 *Sampling procedures for inspection by attributes* Part 1 : 1991 *Specification for sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*
ISO 6710	BS ISO 6710 : 1996 *Single use containers for venous blood specimen collection*

Compliance with a British Standard does not of itself confer immunity from legal obligations.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 829

May 1996

ICS 11.100; 55.020

Descriptors: Medicine, biology, samples, packing, transport packing, freight transport, specifications, tests, marking, graphic symbols

English version

In vitro diagnostic systems — Transport packages for medical and biological specimens — Requirements, tests

Systèmes d'analyses médicales in vitro — Emballages de transport pour échantillons médicaux et biologiques — Exigences, essais

In-vitro-Diagnostik/Diagnostika — Transportverpackungen für medizinisches und biologisches Untersuchungsgut — Anforderungen, Prüfung

This European Standard was approved by CEN on 1996-02-29. CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CEN member.

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CEN

European Committee for Standardization
Comité Européen de Normalisation
Europäisches Komitee für Normung

Central Secretariat: rue de Stassart 36, B-1050 Brussels

Ref. No. EN 829 : 1996 E

Foreword

This European Standard has been prepared by the Technical Committee CEN/TC 140, In vitro diagnostic systems, 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 November 1996, and conflicting national standards shall be withdrawn at the latest by November 1996.

The international agreements of the Universal Postal Union, the committee of experts of the United Nations, as well as of the World Health Organization (WHO) were taken into consideration when establishing graphical symbols.

According to the CEN/CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Luxembourg, Netherlands, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom.

1 Scope

This European Standard applies to packages for transport of medical and biological specimens, referred to in this European Standard as specimens, provided that

– the nominal volume of the specimen container(s) does not exceed 100 ml;

– in the case of multiple specimens, the total volume of specimens in the protecting container does not exceed 500 ml;

– no infectious substances are present in the specimen or a relatively low probability exists that infectious substances are present, e.g. medical and biological specimens to undergo routine screening tests or for the purpose of initial diagnosis.

NOTE 1. 'Transport' is defined as the movement of specimens outside the premises of either the sender or the receiver of the specimen.

NOTE 2. Transport packages used for specimens which contain or are likely to contain infectious substances of risk group II to IV as defined by WHO are subject to the provisions on the transport of dangerous goods. In this case the provisions of the agreements [1] to [5] quoted in annex A apply as appropriate.

This European Standard does not apply to packages for transport of disinfected microscopic slides or sterilized specimens for pathological examinations.

The purpose of this standard is to lay down standardized definitions, requirements and tests for transport packages for medical and biological specimens in order to minimize risk for man, animals and the environment.

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.

ISO 2758	*Paper — Determination of bursting strength*
ISO 2859-1	*Sampling procedures for inspection by attributes — Part 1: Sampling plans indexed by acceptable quality level (AQL) for lot-by-lot inspection*
ISO 6710	*Single-use containers for venous blood specimen collection*

Pharmacopoea Europaea

3 Definitions

For the purposes of this standard, the following definitions apply:

3.1 Medical and biological specimens

Materials derived from man, animal or plant, destined by the sender for examination.

NOTE. Infected living animals are not included.

3.2 Transport package for medical and biological specimens

An assembled package consisting of:

a) one or more specimen container(s);

b) absorbent material;

c) a protecting container;

d) a box or mailing bag.

4 Requirements

4.1 General

Ecological and waste disposal considerations should be observed when designing the transport package.

4.2 Assembled transport package

The assembled transport package shall be leakproof and resist mechanical stress, temperature change and a decrease in outer pressure.

The transport package, when tested in accordance with clause **5**, shall not show any evidence of leakage from either the specimen or the protecting container.

4.3 Specimen container

The specimen container shall be leakproof when tested in accordance with **5.3.2.1** a), b), d), f) and g) last dash, and should, where appropriate, conform to existing International Standards, e.g. ISO 6710.

4.4 Absorbent material

Absorbent material shall be sufficient to absorb any potential leakage. The maximum volume which can be absorbed shall be given in the product information.

4.5 Protecting container

4.5.1 If intended for multiple use, the protecting container shall be washable and able to withstand sterilization.

4.5.2 Unprotected accompanying papers should not be put in the protecting container.

4.6 Mailing bag

The box or mailing bag shall be sufficiently strong to withstand usual stress during transport.

These requirements are considered to be fulfilled if the mailing bag corresponds to the specifications of clauses **4.6.1** and **4.6.2**.

4.6.1 *Bursting strength*

When tested according to ISO 2758, the applied paper shall resist a bursting strength of 230 kPa.

4.6.2 *Breaking length*

The average breaking length of the applied paper shall be at least 4800 m.

NOTE. Testing procedures are given in ISO 1924-1 and ISO 1924-2.

4.7 Use of coolants

The use of coolant demands special features of the transport package as are for example given in the UN Recommendations on Transport of Dangerous Goods (see **6.13.2**) and in the Convention of the Universal Postal Union, article 120.

5 Test

5.1 Instruments and accessories

For a test according to this standard, the following instruments and accessories are needed:

a) thermostated freezer capable of maintaining a temperature at or below −20 °C;

b) steel cylinder (mass 500 g, diameter 30 mm);

c) device for a drop test from a height of 500 mm, carried out by means of a steel cylinder according to b);

d) vacuum pump, pressure gauge and chamber capable of maintaining an absolute pressure of 5 kPa;

e) UV lamp, e.g. a mercury lamp, emitting spectrum lines 365 nm and 405 nm;

f) spectro-fluorometer (optional).

5.2 Reagents

5.2.1 *Water*

The water shall meet the requirements in accordance with the monograph *Aqua purificata* of Pharmacopoea Europaea.

5.2.2 *Immersing alkaline buffer*

50 mmol·l^{-1} sodium phosphate buffer; pH = 8,5.

5.2.3 *Fluorescein solution*

25 g disodium salt of fluorescein ($C_{20}H_{10}O_5Na_2$)
9 g NaCl
60 g Dextran 70
Water ad 1000 ml

NOTE. The intense fluorescence of the dye is still visible when diluting the solution by adding 10^6 parts by volume of water to 1 part by volume of the solution.

5.3 Test method and test plan

5.3.1 *General*

A set of assembled transport packages including appropriate specimen container(s) shall be tested using sampling schemes in accordance with ISO 2859-1 to determine resistance to transport conditions, that is for:

– a change in temperature;
– a mechanical stress;
– a decrease in outer pressure.

Each transport package is tested in that order.

The test shall be performed in two stages; the first with the specimen container closed and the second with the specimen container intentionally allowed to leak.

5.3.2 *Performance of the test*

5.3.2.1 *Performance of the first stage of the test*

a) Fill the specimen container with fluorescein solution to the nominal volume specified by the manufacturer.

b) Immerse the specimen container in 100 ml of buffer according to **5.2.2** and inspect for contamination. If contaminated, wash container to eliminate contamination.

c) Assemble transport package with specimen container(s) enclosed according to the instruction of the manufacturer.

d) Heat the transport package to 50 °C, then cool to −18 °C and heat once more to 50 °C and cool to room temperature. Every step shall be monitored to ensure equilibrium of temperature in the specimen container.

e) Expose the transport package to mechanical stress by dropping a guided steel cylinder with a diameter of 30 mm and a mass of 500 g from a height of 500 mm onto the transport package. The height of the drop shall be measured from the underside of the cylinder to the upper side of the transport package. The transport package shall be placed on a rigid, non-elastic, plane and horizontal bearing surface made of steel. Each transport package shall be tested so that the weight impacts on the transport package in three different planes, ensuring that the specimen container is in the line of impact.

f) Place the transport package, with the closure of the specimen container oriented downwards, in a chamber and evacuate down to 5 kPa at room temperature for 4 h.

g) Examine the transport package as follows:

– visually inspect the protecting container for external contamination;
– open the protecting container;
– visually inspect the absorbent material;
– visually inspect the specimen container;
– immerse the specimen container in 100 ml buffer in accordance with **5.2.2** and inspect for contamination.

5.3.2.2 *Performance of the second stage of the test*

a) Fill the specimen container with fluorescein solution to nominal volume specified by the manufacturer and close in such a way as to ensure that contents will leak. The means of ensuring that the specimen container leaks shall be recorded.

b) Proceed as in **5.3.2.1**c.

c) Proceed as in **5.3.2.1**d.

d) Proceed as in **5.3.2.1**e.

e) Proceed as in **5.3.2.1**f.

f) Examine the transport package as follows:

– visually inspect the protecting container for external contamination;
– immerse the transport package in 1 l of buffer in accordance with **5.2.2** and inspect for contamination.

5.3.3 ***Test evaluation criteria***

The first stage of the test is considered passed if, after the testing procedure, the transport package shows no evidence of leakage from either the specimen container or the protecting container.

The second stage of the test is considered passed if, after the testing procedure, the transport package shows no evidence of leakage from the protecting container.

The fluorescein solution that has possibly leaked out is detected visually by the occurrence of a yellow-green fluorescence under UV light (see **5.1**e) or, better, measured by means of a spectro-fluorometer.

6 Marking

6.1 Marking of the specimen container

The marking of the specimen container shall, where appropriate, conform to existing International Standards. It is a minimum requirement that the specimen container shall carry the manufacturer's name or logo.

6.2 Marking of the protecting container

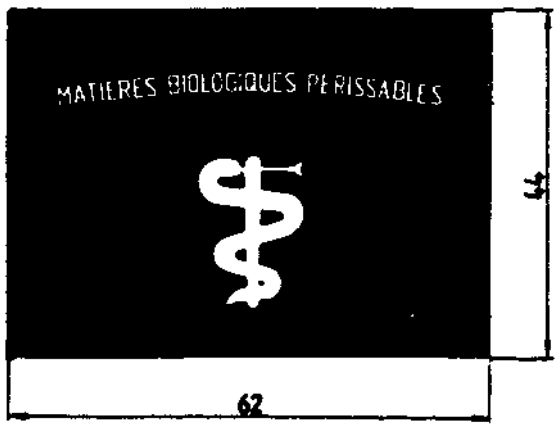
Protecting containers shall be provided with the year of manufacture and the manufacturer's name or logo.

Protecting containers shall be provided with the graphical symbol according to figure 1. Its size and colour need not meet the requirements specified under **6.3**; it shall be well recognizable, however.

6.3 Marking of the assembled transport package

The box or mailing bag mentioned in **3.2**d shall carry the symbol according to figure 1 on a violet background in the dimensions of 62 mm × 44 mm.

NOTE. For transport inside a country, the lettering should be in a language of the country. For international transport, according to the specifications of the Universal Postal Union regulations, the lettering in French applies: 'Matières Médicales Périssables' or 'Matières Biologiques Périssables'.



Dimensions in millimetres

Figure 1.

7 Instructions for use

A manufacturer shall supply instructions for use. These shall include details of compatibility between specimen containers and protecting containers.

Annex A (informative)
Bibliography

ISO 1924-1 *Paper and board — Determination of tensile properties — Part 1: Constant rate of loading method*

ISO 1924-2 *Paper and board — Determination of tensile properties — Part 2: Constant rate of elongation method*

[1] United Nations Recommendations on the Transport of Dangerous Goods (UN Recommendations), UN-ECOSOC, Geneva

[2] International Maritime Dangerous Goods-Code (IMDG-Code) of IMO, London

[3] Technical Instructions on the Safe Transport of Dangerous Goods by Air (ICAO-TI) of ICAO, Montreal

[4] European Agreement concerning the International Carriage of Dangerous Goods by Road (ADR) of UN-ECE, Geneva

[5] Regulations concerning the International Carriage of Dangerous Goods by Rail (RID) of OCTI, Bern

[6] Universal Postal Union Convention, revised by the 1989 Washington Congress and annotated by the International Bureau, Volume 2 of the annotated code, Bern 1991

[7] Laboratory Biosafety Manual, WHO, 1983

List of references

See national foreword.

BSI — British Standards Institution

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