INTERNATIONAL STANDARD

ISO 12772

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Laboratory glassware — Disposable microhaematocrit capillary tubes

Verrerie de laboratoire — Tubes capillaires microhématocrites à usage unique

Reference number
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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

This International Standard ISO 12772 has been prepared by Technical Committee ISO/TC 48, *Laboratory glassware and related apparatus*, Subcommittee SC 1, *Volumetric instruments*.

Annexes A, B and C form an integral part of this International Standard. Annexes D and E are for information only.

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Laboratory glassware — Disposable microhaematocrit capillary tubes

1 Scope

This International Standard provides details for two types of disposable glass capillary tubes, suitable for the microhaematocrit test and other analytical tests which include a separation of plasma and cells. The details specified are in conformity with ISO 8417, to the greatest possible extent.

WARNING — Capillary tubes can break during the analytical test procedure, resulting in broken sharp glass, blood spillage and aerosols. Appropriate precautions shall be taken to avoid dangerous infections.

2 Normative references

The following standards contain provisions which, through references in this text, constitute provisions of this International Standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this International Standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below. Members of IEC and ISO maintain registers of currently valid International Standards.

ISO 719:1985, *Glass - Hydrolytic resistance of glass grains at 98 °C - Method of test and classification.*

ISO 8417:—[1], *Laboratory volumetric instruments - Principles of design and construction of disposable volumetric articles.*

3 Definition

For the purposes of this International Standard, the following definition applies.

3.1 disposable: Adjective used to describe microhaematocrit capillary tubes which are intended to be used once only and then discarded.

NOTE — Such capillary tubes will only be expected to provide their specified performance during the original operation.

4 Classification

This International Standard describes two types of disposable glass capillary tubes as follows:

- Type I: coated with anti-coagulant
- Type II: uncoated

NOTE — Ammonium heparin, lithium heparin and sodium heparin are the preferred anti-coagulants for the microhaematocrit test. Salts of EDTA[2] and fluorides (usually sodium or potassium) may be used when capillary tubes are needed for special purposes.

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1) To be published.
2) EDTA is an abbreviation for ethylenediaminotetraacetic acid

5 Construction

5.1 Material

When tested in accordance with the procedure and classification given in ISO 719, the glass used for the capillary tubes shall at least comply with the requirements of class HGB 3.

The glass shall be free from visible defects and shall be free from internal stresses which would impair the performance of the capillary tube.

5.2 Design

The tubes shall be straight and open at both ends without lip or constriction. The tubes may be slightly fire-polished on one or both ends.

5.3 Dimensions

The dimensions of the tubes shall be as follows:

Length:	(75 ± 0,5) mm
Internal diameter:	(1,15 ± 0,08) mm
Wall thickness:	(0,2 ± 0,025) mm

The bore of the tubes shall be uniform and shall not vary by more than 4 % of the total over a distance of 75 mm.

NOTE — As the bore variation is critical for the analytical result, smaller bore variations than 4 % may be marked on the packaging of the capillary tubes.

5.4 Ring mark

The tubes may be provided with a ring mark to ease filling. Such a ring mark shall be at a distance of 60 mm max. from one end of the tube. The line thickness shall be between 0,5 mm and 1 mm.

In the case of colour-coded tubes (see 6.2), the colour of the ring mark should preferably be that of the colour code, or may be black.

5.5 Resistance to centrifugal force

When the tubes are tested as specified in annex A, not more than 0,5 % shall break.

5.6 Capillarity

The tube shall be capable of drawing plasma, serum or human whole blood to a level within 20 mm from the far end of the tube when tested as specified in annex B.

NOTE — In view of the possible infection risks, human blood should not be used.

5.7 Anti-coagulant (Type I only)

The inner surface of Type I tubes shall be evenly coated with an anti-coagulant (see clause 4). In the case of heparin, the coating shall show an activity of 2,13 IU to 7,45 IU (International Units) per capillary when tested as described in annex E. An airtight container should be used in order to prevent deterioration of the anti-coagulant caused by air moisture.

5.8 Efficacy of heparin coating (Type I only)

Coagulation of the sheep plasma shall not be evident when viewed under normal room lighting . This can be tested as described in annex D.

6 Markings

6.1 Labelling

The outer shipping carton shall be clearly marked with the following information:

a) manufacturer's or vendor's name and/or mark;

b) product description (e.g. disposable microhaematocrit capillary tubes) and the glass material (e.g. borosilicate glass 3.3 or soda-lime glass);

c) number of tubes in the package;

d) batch number or date of manufacture;

e) the number of this International Standard, i.e. ISO 12772;
and, if applicable (Type I only):

f) type of anti-coagulant (e.g. lithium heparin);

g) anti-coagulant activity and date of expiration.

NOTE — As the expiry date may strongly depend on storage conditions, that information should preferably be given in connection with storage requirements.

The smallest packaging unit shall be marked at least with the information stated in a), b), c) and f).

6.2 Colour code

6.2.1 Each Type I tube shall be colour coded to identify the type of anti-coagulant. The colour code for tubes coated with the following anti-coagulants shall be:

-orange	for lithium heparin
-red	for sodium heparin
-green	for ammonium heparin
-yellow	for sodium or potassium fluoride
-purple	for sodium or potassium EDTA

At the manufacturer's discretion, the tubes may be colour coded at the extreme tip of the tube (see also 5.4).

Anti-coagulants containing lithium should not be used if the sample is to be tested for lithium; the same constraints apply to sodium, potassium and ammonium compounds.

6.2.2 Type II tubes may be colour coded to identify that they are uncoated. If colour coded, the colour shall be blue.

Annex A
(normative)

Resistance to centrifugal force

A.1 Fill the tube to capacity with distilled water or a blood product as described in A.2, sealed or melted (see annex C for details) and place it in a microhaematocrit centrifuge. The centrifuge shall be accelerated until the bottoms of the tubes are subjected to an RCF of at least 11,000. Run the centrifuge at that speed for 4 min only, then shut it off and allow it to stop without using the brake.

A.2 Animal (e.g. bovine, equine) plasma, serum or whole or definibrated blood may be used for the above test. Human blood should not be used unless it has been tested and shown to be free of HIV and Hepatitis B and C.

Annex B
(normative)

Capillarity

B.1 The tubes shall be tested for capillarity when held at a horizontal level by immersing one end in a drop of a blood product as described in B.2. The tube shall fill within a 15 s time interval.

B.2 Animal (e.g. bovine, equine) plasma, serum or whole or definibrated blood may be used for the above test. Human blood should not be used unless it has been tested and shown to be free of HIV and Hepatitis B and C.

Annex C
(normative)

Closing the tube before centrifugation

In order to avoid spilling of blood, the tubes shall be closed at one end before placing them in the centrifuge. This can be done by sealing or melting. In either case, the tube shall not be filled completely to allow for dry space.

C.1 Sealing

The tube filled with blood, and still held horizontal, shall be pressed with its "dry" end into the sealant.

C.2 Melting

The "dry" end of the tube, which is filled with blood and still held horizontal, shall be slightly turned in the flame of a microburner. After a flat bottom has formed, a few seconds shall be allowed for cooling.

NOTE — This melting process can be facilitated by an optimization of dimensions of the tube and properties of the glass (e.g. internal diameter 1,15 mm, wall thickness 0,225 mm, softening point max. 700 °C).

To attain a rectangular, non-conical shape of the melted bottom, the melting should be performed preferably by turning the capillary with a small motor.

Sometimes anti-coagulants can cause remnants if the capillaries are closed by melting. As remnants effect the analytical result, these capillaries shall be closed by sealing. The manufacturer should mark on the packaging of the capillaries if they shall be closed by sealing.

Annex D
(informative)

Efficacy of anti-coagulant coating

The heparin-coated tubes may be tested by the following method.

D.1 Preparation

Carry out the test initially by preparing sheep plasma from whole sheep blood by using citrate, oxalate or EDTA as anti-coagulant. The sheep plasma is afterwards recalcified as follows: 10 ml sheep plasma are added to 2 ml of a 10 g/l calcium chloride solution. Mix the sheep plasma and calcium chloride solution well.

D.2 Procedure

Use as controls samples of both the plain sheep plasma and recalcified sheep plasma in accordance with the following:

a) positive control: a plain (i.e. non-coated) tube filled with recalcified sheep plasma;

b) negative control: a coated tube filled with plain sheep plasma.

Immediately after the preparation of the recalcified sheep plasma, fill the tubes by immersing the tips in the recalcified sheep plasma and in the plain sheep plasma, holding the tubes at such an angle as to facilitate quick filling. Fill the tubes to within 5 mm from the other end and immediately agitate them to bring the plasma into contact with the anti-coagulant, whereby avoiding premature coagulation. Then place them in a horizontal position.

At the end of 1 h, the tubes containing plasma shall be inspected for evidence of coagulation by carefully snapping off segments of tubing in approximately 25 mm lengths and placing them on a flat surface (use a black background to facilitate observation and comparison with the controls).

Coagulation has occurred if the sheep plasma becomes opaque or if a fine fibrin thread is noted.