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Laboratory glass and plastics ware — Tubes for the measurement of the erythrocyte sedimentation rate by the Westergren method

Matériel de laboratoire en verre et en plastique — Tubes pour le mesurage de la vitesse de sédimentation des érythrocytes par la méthode Westergren

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Foreword

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International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 13079 was prepared by Technical Committee ISO/TC 48, *Laboratory equipment*, Subcommittee SC 6, *Glass and plastics ware including volumetric instruments*.

Laboratory glass and plastics ware — Tubes for the measurement of the erythrocyte sedimentation rate by the Westergren method

1 Scope

This International Standard specifies requirements for single-use and re-usable glass and plastics tubes for measuring the erythrocyte sedimentation rate (ESR) by the Westergren method, and for a support to hold tubes during the performance of the test. These so-called “Westergren tubes” are also sometimes designated as “Westergren pipettes”. A procedure for measuring the erythrocyte sedimentation rate by the Westergren method is given in informative Annex D.

This International Standard does not apply to single-use containers for human venous blood specimen collection and their accessories for which other standards apply. It also does not apply for devices where the Westergren method has been used as basis to develop other, similar methods or equipment for the erythrocyte sedimentation rate determination.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 719, *Glass — Hydrolytic resistance of glass grains at 98 °C — Method of test and classification*

3 Material

3.1 General

3.1.1 Westergren tubes shall be made from rigid, transparent plastics or from glass of Class HGB 1, HGB 2 or HGB 3 in accordance with ISO 719 so that:

a) the rigidity, when tested according to Annex A, shall be such that the distortion does not exceed 1 mm for re-usable Westergren tubes and 1,5 mm for single-use Westergren tubes;

b) the transparency shall be sufficient to permit the top of the column of blood and the top of the red cell layer to be seen clearly in relation to the scale.

3.1.2 Westergren tubes shall be free from defects which impair observation of the top of the column of blood and of the top of the red cell layer.

3.2 Glass

The manufacturer of the glass tubes should ensure that the glass tubes are as free as possible from visible defects and reasonably free from internal stress.

3.3 Plastics

3.3.1 The material of which plastics tubes are made shall not affect the ESR value, when tested in accordance with the method described in Annex B, by more than 6 mm.

3.3.2 The manufacturer of the plastics tubes shall ensure the following:

a) they shall not show adhesive properties towards blood cells;

b) they shall not release plasticizers that might alter sedimentation;

c) if a mould-release agent is used in the manufacturing process, it shall not alter sedimentation.

3.3.3 The user should also check the validity of a batch of plastics tubes by comparing the ESR obtained when the test is performed using some of these with the results when glass reference tubes are used.

4 Single-use Westergren tubes

4.1 General design

The general design of the single-use Westergren tube shall be as shown in Figure 1.

4.2 Straightness

The tube shall be straight when tested in accordance with the method described in Annex C.

4.3 Finish

4.3.1 The glass tube shall be cut square (within 10°) with the axis of the tube, and shall be lightly fire polished at each end. The ends may be slightly narrowed within or close to the tolerance given in Table 1, due to the finishing process.

4.3.2 The plastics tube should be cut square (within 10°) with the axis of the tube. The ends should be smooth and may be slightly bevelled. Other ends are acceptable if they comply with the dimensional requirements as specified in Table 1.

4.3.3 The tube shall be supplied free from any contamination which would affect the ESR value when tested in accordance with the method described in Annex B.

4.3.4 The tube, by itself or in association with its support, shall have a mechanism which ensures that the tube remains filled with blood, from its lower end to the zero mark on the scale, during the 60 min required to determine the ESR.

4.4 Dimensions

The measuring part of the tube shall conform to the dimensions given in Table 1.

Table 1 — Essential dimensions of single-use Westergren tubes

Dimensions in millimetres

Internal diameter	2,55 ± 0,15
Length of measuring part	200 ± 2

4.5 Graduation and figuring

Graduation or figuring shall be in accordance with Clause 7.

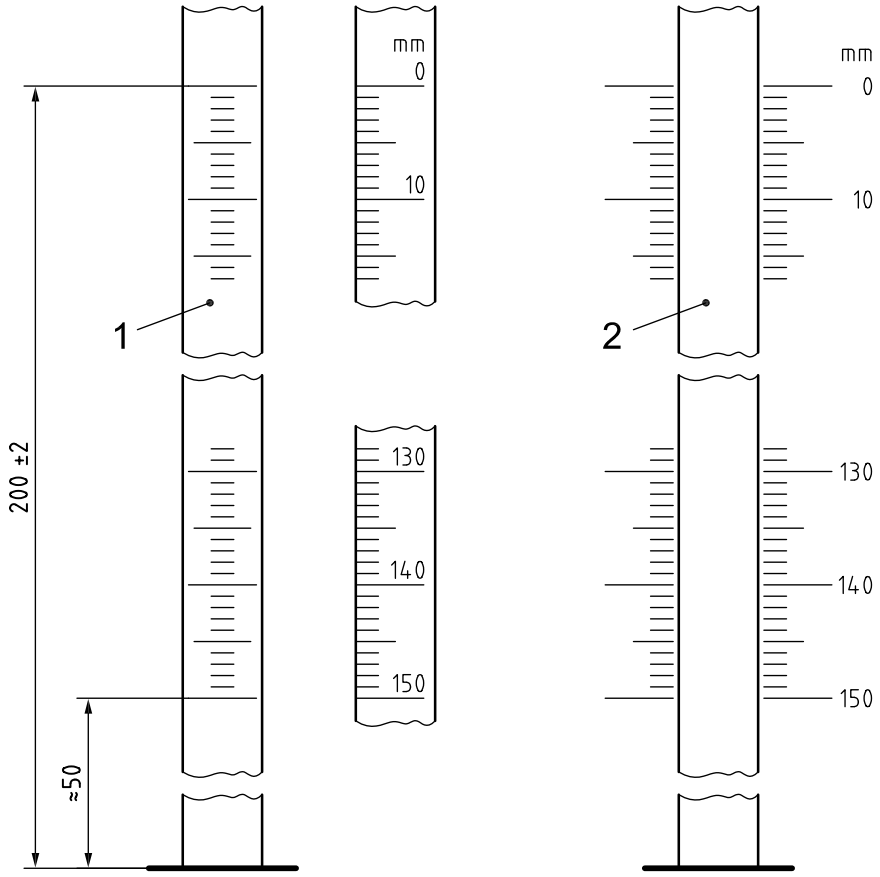
4.6 Inscriptions

Inscriptions on the Westergren tube shall be in accordance with Clause 8.

4.7 Labelling

Inscriptions on the packaging shall be in accordance with 9.1.

Dimensions in millimetres



Key

1 tube with scale

2 tube with scale on support

Figure 1 — Single-use Westergren tubes

5 Re-usable Westergren tubes

5.1 General design

The general design of a re-usable Westergren tube shall be as shown in Figure 2.

5.2 Straightness

The tube shall be straight when tested in accordance with the method described in Annex C.

5.3 Finish

5.3.1 The upper end of the tube shall be ground smooth and cut square with the axis of the tube, and shall be slightly bevelled, finely ground, polished or hot calendered.

5.3.2 The lower end of the tube shall be tapered as shown in Figure 2; the tapered portion shall be cut square with the axis of the tube and shall be finely ground, polished or hot calendered.

5.3.3 The specified bore of the tube shall be maintained throughout, and shall not be drawn down to form the jet. If jet and upper end of the tube are calendered, they may slightly narrow.

5.4 Dimensions

The tube shall conform to the dimensions given in Table 2.

Table 2 — Dimensions of re-usable Westergren tubes

Dimensions in millimetres

Overall length	300 ± 2
External diameter	6,5 ± 0,5
Internal diameter (bore)	2,55 ± 0,15
Length of measuring part	200 ± 2
Length of tapering portion	6 ± 2
Wall thickness of orifice	at least 0,5

5.5 Graduation and figuring

Graduation and figuring shall be in accordance with Clause 7. All graduation and markings on re-usable Westergren tubes shall be clean and permanent.

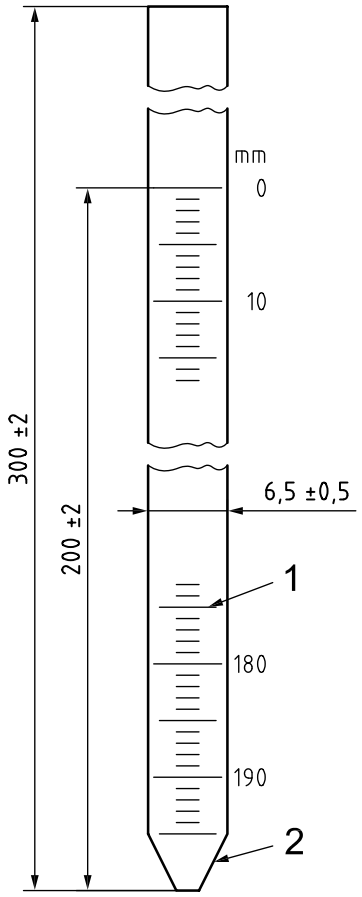
5.6 Inscriptions

Inscriptions on the re-usable Westergren tube shall be in accordance with Clause 8. Additionally, the inscription “re-usable Westergren ESR tube” may be inscribed.

5.7 Labelling

Inscriptions on the packaging shall be in accordance with 9.2.

Dimensions in millimetres



Key

1 scale graduated every millimetre, numbered downwards every centimetre

2 length of taper 4 mm to 8 mm, wall at orifice minimum 0,5 mm

Figure 2 — Re-usable Westergren tubes

6 Support for Westergren tubes

6.1 Construction

6.1.1 The support shall be a rigid structure having clips or holes to hold rigidly one or several Westergren tubes in vertical position. The support shall stand on at least three feet, at the least two of which shall be adjustable.

NOTE The adjustable feet and an optional plumb-line or spirit-level permit adjustment that the tubes are held in vertical position. Vibration-free positioning of the support enables correct measurements.

6.1.2 When erythrocyte sedimentation rates are to be measured against scales marked on the support, the scales shall be marked on a surface fixed vertically behind the tubes and not more than 10 mm from each tube.

6.1.3 The support may be supplied with an automatic reading of the ESR value.

6.1.4 The support shall be constructed of such materials, and in such a way, that it is able to withstand repeated disinfection in the laboratory.

6.2 Graduation and figuring

6.2.1 Scales, figuring and inscriptions shall be provided on the support, if not marked on the tubes, and shall conform to Clause 7.

NOTE A re-usable tube is intended for use with an appropriate support forming a system. The distribution of markings between tube and support can differ between one system and another.

6.2.2 Markings on the support shall be permanent.

6.2.3 When scales are provided on a support, they shall be fixed behind every tube, within 10 mm of the tube, as shown in Figure 1.

6.3 Inscriptions

Inscriptions shall be permanent and shall conform to Clause 8. The following additional inscriptions shall be marked:

a) the recommended method for the disinfection of the support after use;

b) the inscription “Westergren ESR – ISO 13079”.

Alternatively, this information may be given in an accompanying product manual or product data sheet.

7 Graduation and figuring

7.1 Graduation

7.1.1 Graduation lines

Graduation lines shall be clean and of uniform thickness not greater than 0,4 mm.

Graduation lines shall lie in planes at right angles to the axis of each tube, and shall be without irregularity in their spacing.

7.1.2 Scale

A scale, graduated in millimetres, shall run downwards for at least 150 mm from a zero mark situated 200 mm above the lower end of each tube.

There shall be a distance of 1 mm between the centres of adjacent graduation lines.

The lengths of the graduation lines shall be varied so as to distinguish clearly every tenth line and every intermediate fifth line as follows.

a) The length of the short lines shall be not less than 10 % and not more than 20 % of the circumference of the tube.

b) The length of the medium lines shall be approximately 1,5 times the length of the short lines. They shall either extend symmetrically at each end beyond the ends of the short lines or they shall be right-aligned or left-aligned to the short lines.

c) The length of the long lines shall be approximately twice the length of the short lines. They shall either extend symmetrically at each end beyond the ends of the short and medium lines or they shall be right-aligned or left-aligned to the short and medium lines.

7.2 Figuring of graduation lines

Every tenth (long) graduation line shall be figured.

Figures shall be at least 2 mm high and shall be placed immediately above or next to the long lines.

8 Marking

8.1 The following inscription shall be marked on the tube or on the support, or both:

— the symbol “mm” above “0” on the scale.

8.2 The following inscriptions shall be labelled on the packaging and in the user information and can optionally be marked on the tube or on the support, or both:

a) the temperature “(20 ± 3) °C” or “(27 ± 2) °C” [1)];

b) the maker's and/or vendor's mark or name;

c) the number and date of this International Standard.

The inscriptions shall be positioned so that they are visible to the operator when the tube is put in the support for which it is intended.

9 Labelling

9.1 Single-use Westergren tubes

Each package of single-use Westergren tubes shall be clearly labelled with at least the following information:

a) the words “Single-use Westergren ESR tubes”;

b) the words “Ready for use”;

c) the temperature “(20 ± 3) °C” or “(27 ± 2) °C”;

d) the maker's and/or vendor's name or mark;

e) an identifying reference to the batch of manufacture;

f) the number of this International Standard.

Symbols in accordance with ISO 15223-1 may be used.

9.2 Re-usable Westergren tubes

Each package of re-usable Westergren tubes shall provide the following information:

a) the words “Re-usable Westergren ESR tubes”;

b) the maker's and/or vendor's name or mark;

1) Some countries in tropical regions have adopted a standard reference temperature of 27 °C instead of 20 °C.

c) an identifying reference to the batch of manufacture;

d) the number of this International Standard;

e) the following instructions for washing:

   1) wash free of blood in running tepid water;

   2) soak in disinfectant for 1 hour;

   3) rinse out thoroughly in distilled or de-ionized water;

   4) dry completely in a warming or drying oven.

Symbols in accordance with ISO 15223-1 may be used.

Annex A
(normative)

Type test for rigidity of Westergren tubes

A.1 Principle

The distortion (in mm) of a Westergren tube supported at the 10 mm and 150 mm marks is determined when a load of 100 g is applied at the 80 mm point.

This type test is applied to all single-use Westergren tubes and to re-usable Westergren tubes manufactured from plastic. Re-usable Westergren tubes manufactured from glass comply with this test due to the wall thickness resulting from the specified external and internal diameters in Table 2.

A.2 Apparatus

A.2.1 Vertically working screw micrometer.

A.3 Procedure

A.3.1 Set up the apparatus as illustrated in Figure A.1.

Dimensions in millimetres

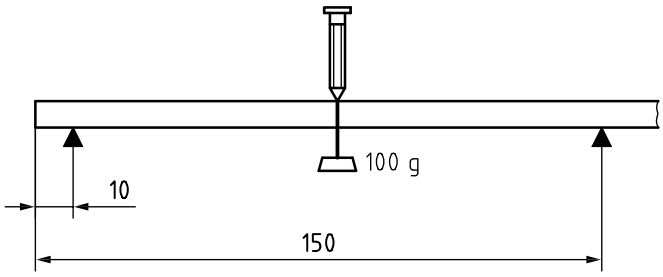


Figure A.1 — Apparatus for testing the rigidity of the Westergren tubes

A.3.2 Support a tube horizontally on knife-edges placed at 10 mm and 150 mm from the left end.

A.3.3 Mark the position of the upper surface of the tube at the 80 mm point using the vertically working screw micrometer.

A.3.4 Suspend a load of 100 g at the 80 mm point and measure the distortion of the tube at this point with the micrometer. Record this value.

A.4 Expression of results

Express the distortion in millimetres.

Annex B
(normative)

Type test for contamination and interfering substances

B.1 Principle

The difference in mean ESRs between a set of three Westergren tubes under test and three Westergren tubes manufactured from glass is determined by using aliquot portions of the same blood and under the same conditions.

This type test is applied to Westergren tubes manufactured from plastic.

B.2 Apparatus

B.2.1 Westergren tubes, new single-use Westergren tubes manufactured from glass or thoroughly cleaned re-usable Westergren tubes from glass.

B.3 Sample of tubes under test

Use a set of three plastics Westergren tubes, selected at random from a batch representative of the type under test.

B.4 Preparation of blood sample

Prepare 15 ml of diluted blood according to D.5, using blood of one group and an ESR between 50 mm/1st h and 120 mm/1st h.

B.5 Procedure

Perform the procedure described in D.5, but fill the three plastics tubes under test selected as described in B.3 and three tubes manufactured from glass with the diluted blood prepared as described in B.4.

B.6 Expression of results

Calculate the mean ESR value for each of the set of three tubes. Calculate the difference between the two mean results and report this as the result of the test.

Annex C
(normative)

Type test for straightness of Westergren tubes

C.1 Principle

The deviation from straightness of the tubes is assessed, using a straightness device.

This type test is applied to all single-use Westergren tubes and to re-usable Westergren tubes manufactured from plastics. Re-usable Westergren tubes manufactured from glass comply with this test due to the wall thickness resulting from the specified external and internal diameters in Table 2.

C.2 Apparatus

C.2.1 Straightness device, having two knife-edges 140 mm apart with a third knife-edge midway between the other two and recessed 1 mm behind the line joining them, as shown in Figure C.1.

C.3 Procedure

Support the tube under test in the vertical position. Apply the straightness device to the side of the tube, as shown in Figure C.1, and rotate the tube through 360°. Observe whether the middle knife-edge comes in contact with the surface of the tube.

C.4 Expression of results

If the middle knife-edge is not observed to make contact with the surface of the tube, then the tube shall be deemed to be “straight”. If the middle knife-edge is observed to make contact with the surface of the tube, then the tube shall be deemed to be “not straight”.

Dimensions in millimetres

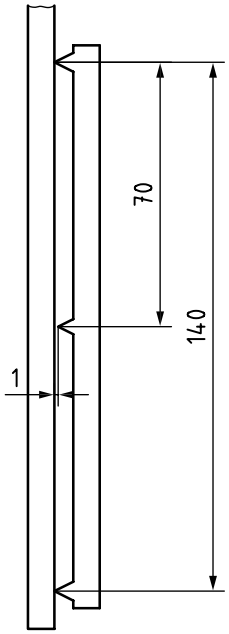


Figure C.1 — Apparatus for testing straightness of Westergren tubes

Annex D
(informative)

Measurement of the erythrocyte sedimentation rate by the Westergren reference method

D.1 Principle

The reference method is intended to provide a procedure for verifying the reliability of any modification of the test. It is carried out on EDTA blood not diluted in citrate or saline using Westergren tubes as described earlier and applying an experimentally derived formula for correction.

For the test, a 200 mm column of anticoagulated venous blood is allowed to stand undisturbed for 60 min at (20 ± 3) °C or at (27 ± 2) °C [see footnote to 8.2 a)] and the height of the sediment is determined.

D.2 Reagents

D.2.1 Dipotassium ethylenediaminetetraacetic acid (K_2EDTA), (1,50 ± 0,25) mg/ml blood.

D.2.2 Trisodium citrate solution ($Na_3C_6H_5O_7$), (0,11 ± 0,01) mol/l.

Dissolve 32,8 g of $Na_3C_6H_5O_7 \times 2H_2O$ in 1 l of distilled or de-ionized water.

D.2.3 Isotonic saline NaCl, 9 g to 1 l H_2O.

Filter through a sterile membrane of maximal pore diameter 0,22 µm into a sterile container and store at 4 °C. Before use, examine visually for freedom from particles and moulds.

D.3 Apparatus

D.3.1 Support, which shall hold the tube rigidly and in vertical position, and shall keep the tube filled with blood to the zero mark.

D.4 Conditions of test

The test shall not be performed in direct sunlight, near a heat source or in a draught.

The tube shall not be subjected to vibration during the test.

The test shall be performed in a stable environment at a temperature of (20 ± 3) °C or (27 ± 2) °C.

NOTE The performance of the test at a temperature outside this range, and variation in the temperature during the test, may cause considerable variation in results.

If tests are performed at a temperature other than (20 ± 3) °C, the corresponding normal range of erythrocyte sedimentation rate should be determined.

D.5 Procedure

WARNING — It is essential that mouth pipetting not be used because of the danger of infection, and that filling be done mechanically.

Follow the following procedure.

a) Select 10 specimens of EDTA anticoagulated blood, if possible with ESRs in a wide range between 15 mm and 150 mm. Adjust the PCV (packed cell volume) of part of each specimen, if necessary, to approximately 0,32 l/l by centrifuging the specimens, removing an appropriate amount of plasma or red cells, and then resuspending the cells by thorough mixing.

b) Immediately before filling the Westergren tube, mix the specimen by at least eight complete inversions. Measure the ESR on each specimen (undiluted) by the Westergren reference method as follows:

   1) Start the measurement of the erythrocyte sedimentation within 2 h of venepuncture.

   2) Fill the Westergren tube from the lower end to the zero mark with the blood [prepared as in a)] which has been well mixed immediately before use.

   3) Place the Westergren tube filled with the blood solution in the support.

   4) Allow the Westergren tube to remain undisturbed for (60 $\pm$ 1) min and then immediately read from the scale the upper limit of the red cell layer.

   Express results as millimetres in the first hour.

c) Adjust the reading for lack of dilution as follows:

   Corrected ESR (mm in 1 hour) = (undiluted ESR $\times$ 0,86) $-$ 12

d) At the same time, add 1 volume of trisodium citrate solution or isotonic saline to 4 volumes of samples from the same specimens or to 4 volumes of fresh blood from the same subjects and carry out the ESR by the method that is to be verified, in accordance with specified requirements.

e) Any new method may be considered to be satisfactory if the results between the two methods are identical or if there is a constant difference that can provide a correction factor or calculate correction ratios for different levels of ESR. However, because the ESR may be affected by several uncontrolled variables, the reference method cannot be used to adjust the measurements that are obtained. Thus, if the new method gives disparate readings, it will be necessary to establish a normal range specifically for that method.

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