Designation: E734 – 80 (Reapproved 2021)

Standard Specification for Disposable Glass Blood Sample Capillary Tube (Microhematocrit)[1]

This standard is issued under the fixed designation E734; the number immediately following the designation indicates the year of original adoption or, in the case of revision, the year of last revision. A number in parentheses indicates the year of last reapproval. A superscript epsilon (ε) indicates an editorial change since the last revision or reapproval.

1. Scope

1.1 This specification covers disposable glass blood sample capillary tubes for use in microhematocrit procedures.

1.2 The values stated in SI units are to be regarded as standard. No other units of measurement are included in this standard.

1.3 *This international standard was developed in accordance with internationally recognized principles on standardization established in the Decision on Principles for the Development of International Standards, Guides and Recommendations issued by the World Trade Organization Technical Barriers to Trade (TBT) Committee.*

2. Referenced Documents

2.1 *ASTM Standards:*[2]

E438 Specification for Glasses in Laboratory Apparatus

2.2 *Other Standard:*

USP XIX United States Pharmacopeia

3. Terminology

3.1 *Definitions of Terms Specific to This Standard:*

3.1.1 *disposable capillary tubes, n*—in accordance with this specification and the expected product performance expressed in this standard, those capillary tubes which are to be used one time only. *Any institution or individual who reuses a disposable capillary tube must bear full responsibility for its safety and effectiveness.*

4. Classification

4.1 This specification covers two different disposable glass sample capillary tubes as follows:

Type I—Coated with heparin.

Type II—Uncoated.

5. Materials

5.1 *Glass*—The pipets made to this specification shall be fabricated from borosilicate glass, Type I, Class B, or soda-lime glass, Type II, in accordance with Specification E438.

5.2 *Heparin*—Heparin shall be of ammonium salt isolated from the lungs or intestinal mucosa of beef or pork origin. The heparin potency shall be 1 mg of ammonium heparin compound which shall be equal to at least 60 United States Pharmacopeia (USP) units. Dry or wet heparin may be applied to the tube.

6. Physical Requirements

6.1 *Design*—The capillary tubes shall be straight and open at both ends without lip or constriction. The capillary tube may be lightly firepolished on one end. The bore of the tube shall be uniform and not vary in excess of 0.025 mm in 75 mm.

6.2 *Dimensions*—Type I and Type II capillary tubes shall have a length of 75 ± 0.5 mm. Inside diameter shall be from 1.07 to 1.24 mm. Wall thickness shall be 0.20 + 0.03, – 0.02 mm, as specified in Fig. 1.

6.3 *Workmanship*—The capillary tubes shall be free of defects that noticeably detract from their appearance or impair their serviceability. The capillary tube shall be free of lint, or significant foreign matter, loose or embedded, when viewed under normal room lighting. The tube ends shall be cut approximately 90° to the tube axis and shall not be cracked or have jagged ends or chips that enter the bore of the tubing.

6.4 *Color Coding*—Each capillary tube shall be color coded to identify the tube as coated with heparin or uncoated. Type I, heparin coated, shall have a red band and Type II, uncoated, shall have a blue band. The location of the red or blue band shall be as specified in Fig. 1.

6.5 *Capillarity*—The capillary tube shall be capable of drawing sheep plasma or human whole blood to a level within 20 mm from the far end of the tube when tested as specified in 7.1.

[1] This specification is under the jurisdiction of ASTM Committee E41 on Laboratory Apparatus and is the direct responsibility of Subcommittee E41.01 on Laboratory Ware and Supplies.

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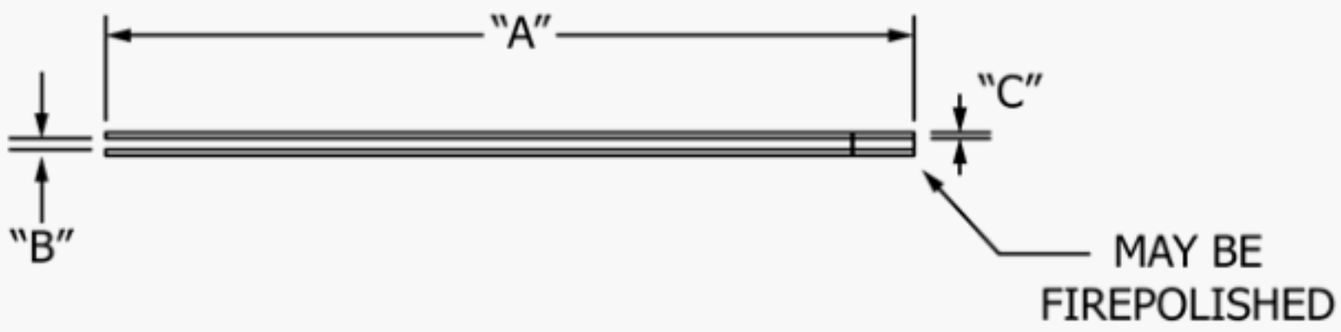
[2] For referenced ASTM standards, visit the ASTM website, www.astm.org, or contact ASTM Customer Service at service@astm.org. For *Annual Book of ASTM Standards* volume information, refer to the standard's Document Summary page on the ASTM website.



CODE	DESCRIPTION	SPECIFICATION	VARIANCE
A	LENGTH	75 mm	±0.5 mm
B	INSIDE DIMENSION	1.155 mm	±.085 mm
C	WALL WEIGHT	0.20 mm	+.03 mm −.02 mm

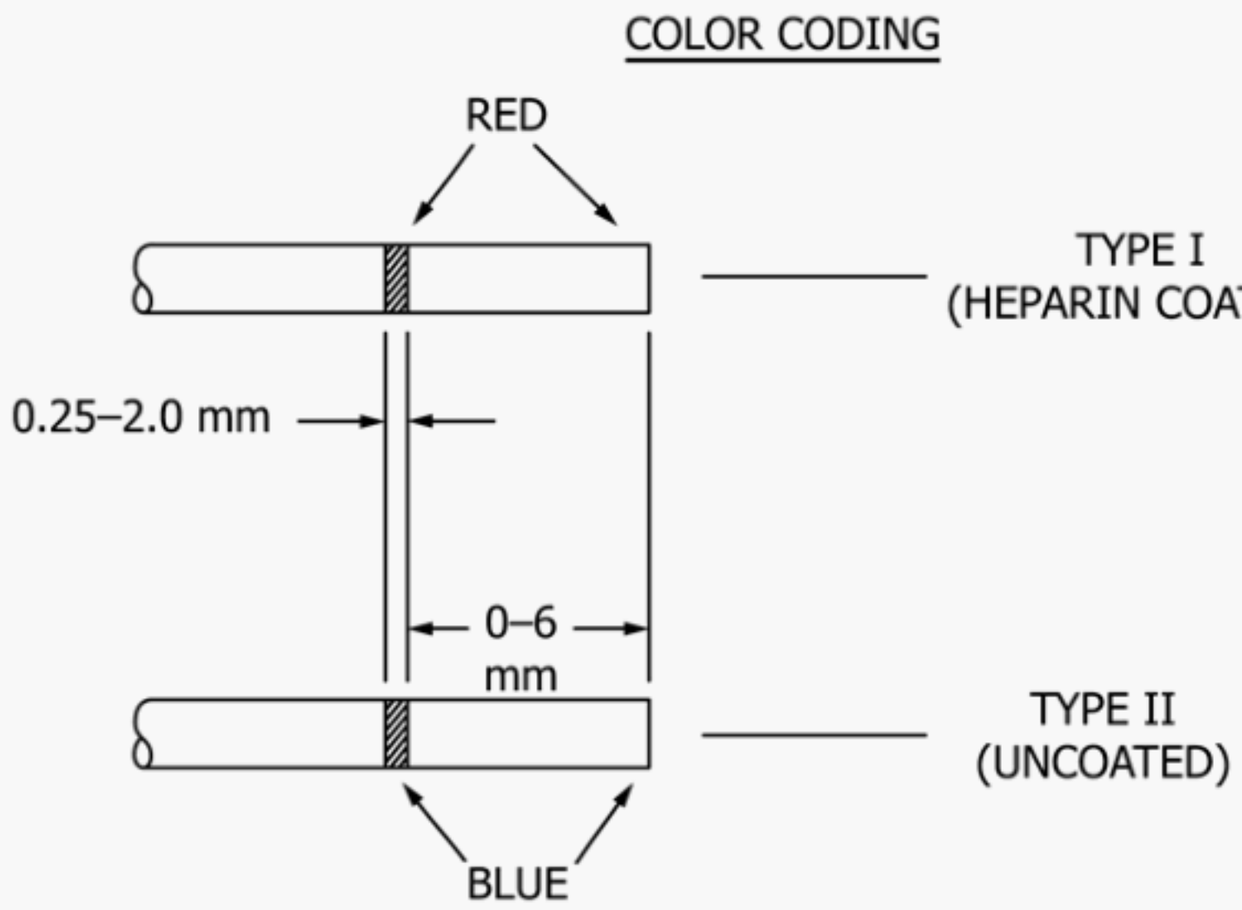


FIG. 1 Type I and Type II Capillary Tubes

6.6 *Fluidity* (Type I, Heparinized, only)—Coagulation of the sheep plasma or human whole blood shall not be evident when viewed under normal room lighting and tested as specified in 7.2.

6.7 *Lot or Control Number*—A lot or control number shall be indicated on the capillary tube unit container and on the intermediate package of containers. This lot or control number shall be traceable to the origin (raw material purchases) of the manufacturing record.

6.8 *Resistance to Centrifugal Force*—Resistance to capillary tube centrifugal force shall be such that no breakage results when the tubes are tested as specified in 7.4.

6.9 *Heparin Coating* (Type I, Heparinized, only)—The inner surface of Type I capillary tubes shall be evenly coated with ammonium heparin. A minimum of 2.0 units of heparin activity shall be present in the tube when tested as specified in 7.3. A statement on expected units of heparin and an expiration date may be claimed by the manufacturer. This option may be expressed on the label.

7. Test Methods

7.1 *Capillary Test*—Test sample capillary tubes for capillarity when held at a horizontal level. The tube shall fill with sheep plasma or human whole blood within a 15-s time interval.

7.1.1 When using a sealant, the tube may not be filled completely to allow for dry space to be occupied by the sealant and avoid leakage.

7.2 *Fluidity*—Test capillary tubes for fluidity by one of the following methods:

7.2.1 *Sheep Plasma Test*—Conduct the test initially by preparing recalcified sheep plasma by the following process:

7.2.1.1 Prepare sheep plasma in accordance with USP assay for sodium heparin.

7.2.1.2 Add 10 mL of the prepared sheep plasma to 2.0 mL of the 1.0 % calcium chloride solution used in the heparin assay. Mix the sheep plasma and calcium chloride solution well.

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

7.2.2.1 *Positive Control*—Fill a plain (that is, nonheparinized) capillary tube with recalcified sheep plasma.

7.2.2.2 *Negative Control*—Fill a heparinized capillary tube with plain sheep plasma. Immediately after the preparation of the recalcified sheep plasma, fill the capillary tubes by immersing the tips in the recalcified sheep plasma and holding the tubes at such an angle as to facilitate quick filling. Fill the capillary tubes to within 5 mm from the other end and place in a horizontal position. At the end of 1 h, inspect the tubes containing plasma for evidence of coagulation by carefully snapping off segments of tubing, in approximately 25 mm lengths, and place on a flat surface. (Use a black background to facilitate observation and comparing with the control sample.) Coagulation has occurred if the sheep plasma becomes opaque or if a fine fribin thread is noted.

7.2.3 *Human Whole Blood Test*—Human whole blood may be used instead of sheep plasma by following the steps outlined in 7.2.1. The testing laboratory shall use a known donor that does not have clotting mechanism deficiencies as a control.

7.3 *Heparin Potency Assay*—Determine heparin potency by the test procedure outlined in the latest edition of the United States Pharmacopeia (USP) or other acceptable methodology that will correlate and provide equivalent test results.

7.4 *Resistance to Centrifugal Force Test*—Fill the capillary to capacity with distilled water or whole human blood and seal and suspend in a centrifuge. Accelerate the centrifuge gradually to a speed of 12 000 rpm. Allow the centrifuge to run at 12 000 rpm for 4 min only; then shut off and allow to stop without using the brake.

7.5 *Heparin Content Test*—Determine the heparin content in the capillary tube by the method for assaying sodium heparin specified in the latest edition of the United States Pharmacopeia (USP), or other acceptable methodology that will correlate and provide equivalent test results. The results obtained shall represent the heparin content on the inner surfaces of the tubes. No heparin from the outside of the tubes surface shall enter the test sample.

8. Keywords

8.1 blood; capillary; disposable; glass; tubes